OUTCOMES OF THE HEALTHY HEART AFRICA PROGRAM ON MANAGEMENT OF HYPERTENSIVE PATIENTS IN NAIROBI COUNTY, KENYA

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LIST OF ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reaction
AHT	Anti-hypertensive Therapy
ALLHAT	Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial
AMREF	African Medical and Research Foundation
ARBs	Angiotensin Receptor Blockers
ATM	Access to medications
BP	Blood pressure
BMI	Body mass index
CVD	Cardiovascular disease
CCBs	Calcium Channel Blockers
DBP	Diastolic Blood Pressure
DM2	Diabetes Mellitus Type 2
ESC	European Society of Cardiology
ESH	European Society of Hypertension
HCTZ	Hydrochlorothiazide
HHA	Healthy Heart Africa
ISH	International Society of Hypertension
JNC	Joint National Committee
LMIC	Low and medium income countries
NICE	National Institute for Health and Care Excellence
RAAS	Renin Angiotensin Aldosterone System
SAHS	South Africa Hypertension Society
SBP	Systolic blood pressure
SSA	Sub-Saharan Africa
WHO	World Health organization

DEFINITION OF TERMS

Adherence: Medication adherence is a ratio of the number of drug doses taken as prescribed to the number of doses prescribed over a given time period.

Adequate blood pressure control: Blood pressure levels maintained below those considered For a diagnosis of hypertension (<140/90 mmHg).

Blood pressure: The force exerted by blood against the walls of arteries as a Result of the pumping action of the heart

Diastolic blood pressure: The minimum arterial pressure during relaxation and dilatation of the ventricles of the heart when the ventricles fill with blood.

Essential medicines: Drugs that satisfy the health care needs of the majority of the population, and that should be of high quality, available at all times, in adequate amounts and in appropriate dosage forms and at a price the patients or their caregivers can afford.

Hypertension: Hypertension is defined as persistently elevated systolic and/or diastolic blood pressure (BP) of 140/90mmHg or more in subjects aged 18 years and above.

Systolic blood pressure: The maximum arterial pressure during contraction of the left ventricle of the heart.

ABSTRACT

Background: Hypertension is an independent risk factor for developing cardiovascular and renal diseases worldwide. Hypertensive patients in Sub-Saharan Africa have low hypertension awareness, treatment levels and control. In response to these problems, AstraZeneca, a British-Swedish Pharmaceutical Company, introduced the Healthy Heart Africa program which it implements in partnership with AMREF Health Africa in Nairobi.

Study objective: To compare the management and treatment outcomes of hypertensive patients enrolled into the Healthy Heart Africa (HHA) program and their unenrolled counterparts.

Method: The study was carried out at two HHA program implementation sites in Kibera slum i.e. Kibera Community Health Center and Karen Health Center. The comparison population was drawn from Dandora Phase 1 and 2 Health Centers. This study was conducted in two phases. The first phase that was quantitative adopted a retrospective cohort study approach whereby hypertensive patients who met the eligibility criteria were identified. A designed, pre-tested and modified Data Collection Form was used for collecting patient information including socio-demographic and clinical characteristics, BP readings and all prescribed medicines and the respective dosages. The primary outcome was adequacy of controlled blood pressure. The second phase was a qualitative research design that employed patient interviews that were used in assessing the level of adherence to treatment among the hypertensive patients. Prescribers and key informants were also interviewed to elicit information on aspects of management of patients as well as the challenges experienced in the adoption and implementation of the program. Quantitative data was analyzed descriptively using measures such as frequencies, percentages, mean and standard deviation. Two-sample t-test analysis were used to establish whether the mean and median BP of the patients at the two study groups were significantly different. The strength of association between adherence score and level of blood pressure was obtained using linear regression. Multiple logistic regression analysis was used to establish the independent relationship between adequacy of BP control and selected predictor variables of the study. The level of significance was set at 0.05. A descriptive thematic approach was used to analyze the qualitative data, whereby the data was examined; key and meaningful themes/patterns were identified and interpreted by triangulation of all the provided information. Approval to carry out the study was granted by Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (KNH/UoN-ERC).

Results: Of the 265 patients screened over a 6 months' period, 250 (91%) met the inclusion criteria and 205 were recruited; 58.5% were female; mean age was 54 years; mean duration of hypertension management was <2 years. Seventy-eight (72%) patients enrolled in HHA had adequate BP control compared to forty-two (43%) in the non-HHA sites after 6 months of treatment. Seventy (34.1%) of the patients were fully adherent to medication. Patients in the HHA (OR 2.6 95% CI 1.5, 4.6; p <0.001) had their BP better controlled compared to their unenrolled counterparts. Adherence to medication (OR 0.87 95% CI 0.8, 0.9; p<0.001) significantly contributed to BP control.

Conclusion: Patients managed at the HHA enrolled facilities had their Blood pressure levels adequately controlled compared to those in non-HHA health facilities. These patients were also observed to be highly adherent to their antihypertensive therapy. Adherence to antihypertensive

therapy and patient's level of education were predictors of adequate BP control. Programs similar to HHA should be designed and scaled up to cover numerous facilities so that large numbers of patients benefit. A prospective study on hypertension treatment outcomes and adherence should also be conducted.

CHAPTER ONE: INTRODUCTION

1.1 Background

Hypertension is described as a persistently elevated systolic and/or diastolic blood pressure (BP) of 140/90mmHg or more in subjects aged 18 years and above(1). One is considered hypertensive if after repeated examination the readings are over and above this cut-off. High blood pressure (hypertension) is one of the most common non-communicable diseases with a huge global burden. This is despite receiving much attention aimed at lowering both its incidence and prevalence.

The total number of people with high blood pressure worldwide grew from 600 million in 1980 to almost 1 billion in 2008. World Health Organization (WHO) estimates that approximately 40 percent of adults aged 25 and above had been diagnosed with hypertension. The prevalence of hypertension has been increasing at a rapid rate globally and according to the World Health Statistics 2012 report, one in three adults worldwide had raised blood pressure (2). It is estimated that there are 970 million people worldwide with elevated blood pressure. Of the above figures around 640 million are found in the developing world. The African region has the highest prevalence of hypertension with some regions having prevalence as high as 46%. The number of people with undiagnosed, untreated and uncontrolled hypertension are also high in developing countries compared to developed or high income countries (3).

Hypertension is one of the most important modifiable risk factors for the development of cerebrovascular and renal disease, as well as cardiovascular disease (CVD) which includes heart attacks and strokes. Effective management of hypertension is key to lowering morbidity and mortality from end stage organ damage associated with the above complications. It is well established that lowering of blood pressure in hypertensive patients is beneficial in reducing cardiovascular complications and in preventing premature mortality. The timing and intensity of interventions is determined by factors like the severity of hypertension, patient's absolute CVD risk and presence of other associated clinical conditions or end stage organ damage (4).
Hypertension control refers to the maintenance of blood pressure levels below 140/90 mmHg for the vast majority of hypertensive patients. For hypertensive patients with diabetes, adequate blood pressure control shall be defined as a blood pressure of less than 130/80mmHg (5).
The management and the subsequent control of hypertension involves the use of both pharmacological and non-pharmacological interventions. Non-pharmacological approaches

involve lifestyle modification like proper diet, weight control and regular physical exercises, low salt intake, smoking cessation and reduction of alcohol intake. Pharmacological interventions include the use of blood pressure lowering drugs and treatment of other modifiable CVD risk factors. The main classes of drugs used are the β- blockers, diuretics, calcium channel blockers (CCBs), angiotensin converting enzyme inhibitors (ACEIs), diuretics and angiotensin II receptor blockers (ARBs) (6).

According to WHO Essential Drugs and Medicines Policy 2007, anti-hypertensive medicines are priority/essential medicines which are vital to the success of any non-HHA health system. WHO further defines essential medicines as 'drugs that satisfy the health care needs of the majority of the population that are available at all times, in adequate amounts and in appropriate dosage forms and at a price the patients or their caregivers can afford. Accessibility of essential medicines is key to alleviation of disease and is a matter of great concern especially in the developing countries. Other estimates from WHO show that about 2 billion people do not have regular access to essential medicines. Due to resource limitation, nearly half the population sub-Saharan Africa (SSA) do not have regular access to healthcare services. Accessibility of essential medications has however been given a more fragmented approach where only issues of supply are considered. This approach fails to integrate other aspects of accessibility such as affordability, safety and efficacy (7).

In Africa, due to resource limitations hypertension has presented a great management challenge among patients who are diagnosed with an elevation in their blood pressure over and above the acceptable cutoff. The said challenges are multifactorial and include inaccessibility of medicines, poor compliance to medication and unidentified adverse drug reactions (ADRs) in the clinical setting. Hypertensive patients ultimately suffer serious debilitating effects of the complications and some eventually die (8).

Healthcare capitation in many developing countries is still below the Abuja Declaration where at least 15% of a countries budget should be set aside for provision of Healthcare services. With financial allocations as low as 4% like the case in Kenya, accessibility of essential medicines particularly anti-hypertensive medicines is likely to be poor due to both unavailability and unaffordability. Patients in sub Saharan Africa still encounter serious difficulties accessing medicines due to their poor economic status and inadequate supply of essential medicines to the governmental facilities closest to them and where they seek basic healthcare services (9).

Effective management of hypertension is only possible where medicines are not only available and affordable at all times but also supplied in adequate quantities and in appropriate dosage forms.

Adequate control of blood pressure also requires a strict treatment adherence. Non- adherence to antihypertensive therapy (AHT) involves the interplay of the healthcare- provider/health system, therapy, condition, client, and socioeconomic factors. Research on adherence to antihypertensive treatment has demonstrated that that at least 75% of patients are not adherent. A situation attributable to the combined demographic, organizational, psychological, disease- and medication- related factors. Upon initiation of therapy, clinicians' follow up on most patients haven't borne fulfilling results, with various patient factors contributing to poor or complete non-adherence to antihypertensive therapy (4,7).

In response to the increasing prevalence and poor control of hypertension and the increased burden of cardiovascular disease across Africa, AstraZeneca, a British-Swedish pharmaceutical company which manufactures and distributes a wide range of pharmaceutical products came up with an innovative program - the Healthy Heart Africa (HHA). HHA is aligned to AstraZeneca's sustainability goals and aims to improve access to hypertension management by raising awareness and educating patients around lifestyle choice and cardiovascular risk factors, train providers and drive care to lower levels of the healthcare system and facilitate access to low cost, high quality anti-hypertensive medications.

Similar community based interventional programs have been implemented in other countries. Findings from Brazil and the USA indicated that the HealthRise program had the potential to improve patient outcomes(10). Health promotion and interventions targeting various risk factors of hypertension and, salt consumption restriction interventions have been employed in Sub-Saharan Africa with varying levels of success(11). Two other studies one in South Africa and another in Uganda highlighted the need for health promotion programs but were quick to point out that poverty, illiteracy and shorter implementation were an impediment to the success of such programs(12,13).

The HHA program that was officially launched in Kenya in 2014 in collaboration with the Ministry of Health has had various implementing partners. African Medical Research Foundation (AMREF) Health Africa in Kenya is a key implementer of the program and has

since demonstrated the project is beneficial albeit with minimal data to support such a claim. This proposed research attempts to compare the management and treatment outcomes of adult hypertensive patients at selected HHA implementation sites versus non-HHA healthcare facilities in Nairobi County, Kenya.

1.2 Statement of Problem

The prevalence of poorly controlled hypertension has been on a steady rise globally and particularly in Africa. A rapid increase in the total number of people with hypertension was witnessed between 1980 and 2008. These numbers grew from 600 million to 1 billion within that period. According to the WHO, approximately 40 percent of adults aged 25 and above had been diagnosed with hypertension (14).

In most Africans, hypertension goes unrecognized, undiagnosed and in some cases even with treatment hypertension still remains uncontrolled (8). One specific research study conducted in four different sub-Saharan African countries singled out hypertension has the most prevalent risk for cardiovascular diseases in all the four populations. The crude prevalence of hypertension was highest in Namibia (32%) and lowest in Tanzania (19%) while the age adjusted prevalence was 38.0% in Namibia, 23.7% in Tanzania, 21.4% in Kenya and 19.3% in Nigeria (5). Another study conducted in Kibera slum in Nairobi to determine the prevalence of hypertension and associated risk factors found the age adjusted prevalence of hypertension to be 23% (15). This relatively high prevalence of hypertension in Kenya (and Africa at large) is a matter of great concern. To compound the issue even further, studies conducted in Kenya to assess the adequacy of BP control among diagnosed hypertensive patients have shown an overall poor control of BP with the proportion of patients with controlled BP ranging from7.4% to 48% (5,9). The poor BP control exposes these patients to cardiovascular, cerebrovascular and renal disease and mortality most of which are directly/indirectly attributable to hypertension.

The Healthy Heart Africa (HHA) program was introduced in Africa by AstraZeneca, a British-Swedish pharmaceutical company, in collaboration with Ministry of Health in response to the growing prevalence and increasing rates of uncontrolled hypertension. The program builds on existing health care systems through community education and awareness, provides training and treatment guideline development as well as provides access to affordable and high quality

anti- hypertensive medicines. The program was first piloted in four provinces in Kenya in October 2014: Central, Coast, Nairobi and Rift valley provinces. The impact (or lack thereof) of many interventional programs is often not assessed despite the great expense in launching and sustaining the programs. Therefore, this research intends to evaluate the success of adoption and implementation HHA program and its impact on Hypertension management among patients in Nairobi County.

1.3 Justification of the Study

Assessment of the adequacy of blood pressure control is an important step in preventing mortality and complications associated with hypertension. Uncontrolled BP is a major problem in the healthcare system because of its association with increased risk of cardiovascular, cerebrovascular and renal diseases as well as sudden death (1,2).

The adequacy of blood pressure control and ease of access to anti-hypertensive medicines among patients who are on the HHA program drugs compared to those accessing care in other hospitals but not enrolled into the HHA program has not been assessed before. Also, adherence to treatment by patients on the HHA program as well as the challenges that may have hindered effective implementation of this program are yet to be evaluated. This is the gap that the current study sought to address.

Knowledge of the contribution of the HHA program to the adequacy of BP control, improved access to medicines and increased adherence to medication will be used to provide feedback to the providers of the program especially on its success and areas that need improvement. A favorable BP control profile associated with the program would further be used to lobby for the complete adoption of the program's policies countrywide and its possible incorporation into the Kenyan hypertension treatment guidelines. The Kenyan Government through its Ministries of Health, Planning and Finance, County Government Health Department, AstraZeneca, Amref-Africa and other non-governmental institutions are likely beneficiaries of the outcomes of these research.

1.4 Study questions

i. Is there any difference in the adequacy of blood pressure control between patients enrolled into the HHA program and those receiving regular care at non-HHA health centers in Nairobi County?
ii. What is the difference in the average patient monthly cost of hypertensive medication for patients enrolled into the HHA program and those receiving regular care at non-HHA health centers in Nairobi County?
iii. What is the level of adherence to anti-hypertensive medication among patients enrolled into the HHA program and those receiving regular care at non-HHA health centers in Nairobi County?

1.5 Study Objectives

1.5.1 Main Objective

The main objective was to compare the management and treatment outcomes in adult hypertensive patients enrolled into the HHA program at two selected HHA implementation sites in Nairobi County with those of adult hypertensive patients not enrolled into the HHA program and receiving care at selected non-HHA healthcare facilities in Nairobi County.

Specific Objectives

i. To compare the proportions of hypertensive patients with controlled blood pressure between those enrolled into the HHA program and those receiving regular care at non-HHA health centers in Nairobi County.
ii. To estimate the difference in the average monthly cost of hypertensive medication to patients enrolled into the HHA program and those receiving regular care at non-HHA health centers in Nairobi County.
iii. To assess the level of adherence to anti-hypertensive medication among patients in the HHA program and those receiving care from non-HHA health centers in Nairobi County.

CHAPTER TWO: LITERATURE REVIEW

2.1 Hypertension definition and classification

Hypertension is a progressive cardiovascular (CV) syndrome arising from complex and interrelated etiologies. The hypertensive syndrome has certain early markers that often present before BP elevation is sustained; therefore, classifying hypertension solely by BP thresholds may not always give an accurate picture of the patient's hypertensive status. Its progression is strongly associated with functional and structural cardiac and vascular abnormalities that ultimately damage the heart, kidneys, brain, vasculature, and other organs resulting in premature morbidity and death. Reduction of BP when target organ damage is demonstrable or the functional precursor of target organ damage is present and still reversible generally reduces the risk for CV events. It is worthwhile separating elevated BP (one manifestation of the disease) from hypertension (the disease) (16,17).

Hypertension is defined as persistently elevated systolic and/or diastolic blood pressure (BP) of 140/90mmHg or more in subjects aged 18 years and above. A special threshold is set for all adult patients aged 80 years or older to whom a systolic blood pressure up to 150 mm Hg is currently regarded as acceptable (18). One is considered hypertensive if after repeated examination there is a repeated manifestation of disease with BP readings that are over and above this cut-off.

There has been contention globally in the mode of classification of hypertension. The seventh report of the Joint National Committee of the USA (JNC-7) published in 2003, classified BP levels in adults into 4 main classes as shown in Table 2.1 (19).

Table 2.1: Definitions and classification of BP levels - JNC-7

Category	Systolic (mmHg)		Diastolic (mmHg)
Normal	<120	and	<80
Prehypertension	120-139	And/or	80-89
Stage 1 hypertension	140-159	and/or	90-99
Stage 2 Hypertension	≥160	And/or	≥100

**Adapted from the seventh report of the Joint National Committee of the USA published in 2003*

This classification did not change in the JNC-8 report and as such this classification still finds application albeit with some refinements that led to the recognition and global acceptance of Blood pressure (BP) as a dependable biomarker for hypertension. From research initiatives a distinction was then made between the various stages of hypertension and global cardiovascular risk (16).

In 2013, the joint European Society of Hypertension (ESH) and European Society of Cardiology (ESC) produced guidelines that classified and defined the BP category by the highest level of BP, whether systolic or diastolic. These guidelines also recommend the classification of isolated systolic hypertension (ISH) into grades 1, 2, or 3 according to systolic BP values in the ranges indicated. Table 2.2 below lists all the ranges that should aid appropriate classification of hypertension in adults aged 18 years and above (16).

Table 2.2: Definitions and classification of BP levels

Category	**Systolic (mmHg)**		**Diastolic(mmHg)**
Optimal	<120	and	<80
Normal	120-129	And/or	80-84
High normal	130-139	and/or	85-89
Grade 1 Hypertension	140-159	And/or	90-99
Grade 2 Hypertension	160-179	And/or	100-109
Grade 3 Hypertension	≥180	And/or	≥110
Isolated Systolic Hypertension	≥140	And	<90

***Adapted from the Kenya national guidelines for the management of cardiovascular diseases published in 2018*

2.2 Epidemiology of hypertension

The prevalence of poorly controlled hypertension has been on a steady rise globally and particularly in Africa. A rapid increase in the total number of people with hypertension was witnessed between 1980 and 2008. These numbers grew from 600 million to a billion within that period. According to World Health Organization approximately 40 percent of adults aged

25 and above had been diagnosed with hypertension (14). The prevalence of hypertension has been increasing at a rapid rate globally and according to the World Health Statistics 2012 report, one in three adults worldwide have raised blood pressure. It is estimated that there are 970 million people worldwide with elevated blood pressure. Of the above figures around 640 million are found in the developing world.

In a study conducted United States (US) between 2011-2012 the adult-age adjusted prevalence of hypertension was found to be 29.1% (20). It was found from study conducted to determine the worldwide global prevalence of hypertension that the prevalence varied in different populations around the world. The reported prevalence was lowest in rural India (3.4% in men and 6.8% in women) and was highest in Poland (68.9% in men and 72.5% in women). Hypertension awareness varied from 25.2% in Korea to 75% in Barbados, treatment varied from 10.7% in Mexico to 66% in Barbados and BP control in patients on anti-hypertensive medicines varied from 5.4% in Korea to 58% in Barbados (21).

The African region has the highest prevalence of hypertension with some regions having prevalence as high as 46%. The number of people with undiagnosed, untreated and uncontrolled hypertension are also high in developing countries compared to developed or high income countries (2,3). A study conducted in in four different sub-Saharan African countries found hypertension to be the most prevalent risk for cardiovascular diseases in the studied four populations. The crude prevalence of hypertension was highest in Namibia (32%) and lowest in Tanzania (19%) while the age adjusted prevalence was 38.0% in Namibia, 23.7% in Tanzania, 21.4% in Kenya and 19.3% in Nigeria. The prevalence of hypertension was also found to increase with age and body mass index (BMI) (5). Another study conducted in Kibera slum in Nairobi to determine the prevalence of hypertension and associated risk factors found the age adjusted prevalence of hypertension to 23% (15).

Rural to urban migration has significant contribution to the non-communicable disease (NCD) burden globally. As populations move to urban centers across East Africa, lifestyle habits that affect cardiovascular disease have changed, affecting non-communicable disease risk. Lifestyle modification to a more sedentary way of life, inadequate exercise, poor dietary control and excessive salt intake have been found to be strongly associated with the non-communicable diseases (22).

2.3 Risk factors of Hypertension

Hypertension is a progressive cardiovascular syndrome arising from complex, interrelated and more often idiopathic etiologies. As such it is important to highlight the various risk factors that predispose individuals to this disease condition with serious debilitating effects and a poor prognosis globally. To adequately manage patients with hypertension their CV risk factor has to be determined. It is this determination that guides all treatment procedures and therefore an agreed upon algorithm needs to employed in classifying patients based on the CV risk factors. The Kenya National Guideline on Cardiovascular Disease Management 2018 which is an aggregate of several other guidelines uses an algorithm that classifies the major risk factors as either modifiable or non- modifiable. Modifiable risk factors are majorly environmental and individual related factors such as sedentary lifestyle, obesity and excess salt intake. Non-modifiable factors are genetically related factors are thought to include inappropriately high activity of the renin-angiotensin-aldosterone system (RAAS) and the sympathetic nervous system and susceptibility to the effects of dietary salt on blood pressure (23,24).

The prevalence of hypertension is age related, being the highest in those over 50 years (25). It is believed that essential hypertension could arise from the stiffening of the aorta with advancing age. Isolated or predominant systolic hypertension characterized by high systolic pressures (often with normal diastolic pressures) is thought to occur as a result of a stiffened aorta as an individual age (2,17). A 2013 Chinese study by Wang et al on the factors associated with prevalence, awareness, treatment and control of hypertension found out that old age is strongly associated with higher prevalence of hypertension; participants aged 45-59 years had 3.37 the odds of those aged 18-44 years of having hypertension and those aged 60 years and above had 8.1 times the odds of those aged 18-44 years of having hypertension (26). A longitudinal study of risk factors for hypertension and their relation to cardiovascular disease by Wenyu et al (2006) showed that for the same sex, there was a significant age difference in the incidence of hypertension, with participants 65 years and above having a 38% higher incidence than those aged 55 to 64 years and a 62% higher incidence than those aged 45 to 54 years (27).

2.4 Consequences and complications of uncontrolled Blood Pressure

Hypertension is one of the most important modifiable risk factors for the development of cerebrovascular and renal disease, as well as cardiovascular disease (CVD) which includes heart attacks and strokes. Effective management of hypertension is a key to lowering morbidity and mortality from end stage organ damage associated with the above complications (15). It is well established that lowering of blood pressure in hypertensive patients is beneficial in reducing cardiovascular complications and in preventing premature mortality. The timing and intensity of interventions is determined by factors like the severity of hypertension, patient's absolute CVD risk and presence of other associated clinical conditions or end stage organ damage (1,4).

The organ bearing greatest burden of uncontrolled hypertension is the heart. It undergoes a myriad of changes that apart from having a close relationship also arise from various etiologies and have varied manifestations. Dilatation, cardiosclerosis, congestive heart failure, hypertrophy, angina pectoris, disturbance of rhythm development of murmurs and coronary occlusion are among the various complications expressed by patients with uncontrolled hypertension. Cardiac complications constitute a large number of hospital visits by patients whose blood pressure is not adequately controlled (6).

Additional group of complications are those referable to the central nervous system include apoplectic seizures, tinnitus, cerebral crisis, transient ischemic attacks and severe vertigo. Others are changes in the vascular system as evidenced by the development of arteriosclerosis, dilatation of the aorta and sometimes aneurysm. The above are but links in a chain upon which most complications are anchored. Following the occurrence of some of the above complications renal impairment eventually occurs as a late complication in a number of individuals. Severe renal disease occurs in a small percentage of the patients (18).

2.5 Treatment targets and adequacy of Hypertension control

Hypertension can be easily diagnosed using BP readings as a biomarker of the disease. This is achieved through readily available diagnostic equipment and its control achieved using simple and well tolerated medication regimens to lower related morbidity and mortality even in resource- limited settings.

The amount of alcohol consumed by an individual could be both beneficial and harmful. Consumption of large amounts of alcohol leads to the development of hypertension while about two drinks of alcohol a day protects against cardiovascular events (18).

2.5.2 Pharmacological Management

Pharmacotherapy is initiated in patients whose BP remains high even after undergoing several non-pharmacologic treatment approaches. Pharmacologic treatment is initiated in patients with blood pressures >140/90 mm Hg in whom lifestyle treatments have not been effective. This is because it is recommended that drug treatment be delayed for some months in patients with stage 1 hypertension who do not have evidence of abnormal cardiovascular findings or other risk factors. In resource limited settings clinicians can consider an extension of the nondrug observation period in uncomplicated stage 1 hypertensive patients provided the patients have no signs or evidence of an increase in blood pressure or the appearance of cardiovascular or renal findings.

Anti-hypertensive combination therapy is currently encouraged as first-line treatment for lowering blood pressure levels (30). These combination therapies have been found to lower toxicity and improve patience adherence. However, the best combination for the black population is still a subject of debate because no large randomized controlled trials have been conducted in this group to compare the efficacy of different combination therapies to address this issue. This according to a studies on the rationale and design of the comparison of 3 combination therapies in lowering blood pressure in black Africans (CREOLE study) (31)

A 2-drug combination treatment is initiated immediately after diagnosis in patients with stage 2 hypertension (i.e. Blood pressure ≥160/100 mm Hg). There is also a possibility of immediately beginning treatment in all hypertensive patients provided it is the practitioner's considered opinion that there is an agent need to achieve more rapid control of blood pressure. One of the important factors that may accelerate initiation of treatment is the patients' cardiovascular risk factors. Such risk factors coupled with inadequately controlled BP often result in poor health outcomes for the patient.

Patients older than 80 years have their suggested threshold for starting treatment at levels ≥150/90 mmHg. The target of treatment for most of the patients should be <140/90 mmHg,

however, a special threshold of <150/90 mmHg is applied to patents older than 80 years (unless these patients have chronic kidney disease or diabetes, when <140/90 mm Hg can be considered). The treatment regimen for this group of patients comprises more than one drug to achieve control of their blood pressure. Dosage increase or addition of an extra drug to the regimen is mostly considered after 3 weeks of continuous monitoring. Initial dosages should be at least half the maximum dosage to allow for future adjustments (18,29). The choice of anti-hypertensive drugs is influenced by the age, ethnicity/race, and other clinical characteristics of the patient most importantly the patients cardiovascular risk profile. Pregnancy and lactation are also key considerations before initiating drug therapy. Long-acting fixed combination drugs that need to be taken only once daily are preferred to shorter-acting drugs that require administration as multiple doses as patients are more likely to follow a simple treatment regimen.

The choice of anti-hypertensive drugs will further be influenced by their availability and affordability. Access to medicines is a huge challenge in SSA where health budgetary allocations fall way below the Abuja declaration of at least 15%. Therefore, most patients are not optimally managed (32).

2.6 Access to anti-hypertensive medicines

Over the decades' African countries have witnessed a gradual rise in non-communicable diseases that coupled with resource limitation presented a huge management challenge. It is the multifactorial nature of these challenges and their interconnections that are barriers to policy formulation and implementation. Hypertension is one of the most common NCDs and both caregivers and patients face various obstacles in attempts towards its alleviation. Some of these obstacles include inaccessibility to medicines, poor adherence to medication and unidentified adverse drug reactions (ADRs) in clinical setting.

The ultimate effect is increased NCD burden, serious debilitating effects from its complications and eventual death (1,8). Healthcare capitation in developing countries is still below the Abuja Declaration where at least 15% of a countries budget should be set aside for provision of Healthcare services. With financial allocations as low as 4% like the case in Kenya, accessibility to essential medicines particularly anti- hypertensive medicines is likely to be poor due to both unavailability and unaffordability.

Access is defined as 'the timely use of services according to needs'. Barriers to access stem from both demand and supply sides. Demand side constraints influence individuals', households' and communities' ability to use services while supply-side constraints are aspects of health services and the health sector that hinder service uptake (33). Availability and affordability, supply of medicines in adequate quantities and in appropriate dosage forms are prerequisites to effective hypertension management. Widespread poverty in sub Saharan Africa hampers access to essential medicines by the population and additionally poses a huge challenge to good medicines supply chain practices (9).

Barriers to access arise from institutional, service provider and consumer factors. Proximity to service points, quality of care and availability of medicines at affordable prices are key determinants of service utilization. Various other issues have also been identified as possible hindrances to the uptake and utilization of health services. Some of them are perceived lack of skilled staff in non-HHA facilities, late referrals, health worker attitude, costs of care and lack of knowledge (33,34).

In a study conducted with the intention of embedding access to medicines (ATM) in the health system perspective, it was established that most health policy maker give ATM a more fragmented approach, usually a vertical one that only focus on supply which in itself is unrelated to the wider issue of access to health services and interventions, rather than a holistic one (35).

2.7 Adherence to anti-hypertensive medicine

Adequate control of blood pressure requires a strict treatment adherence. Non-adherence to antihypertensive therapy (AHT) involves the interplay of the healthcare-provider/health system, therapy, condition, client and socioeconomic factors. Research targeting all aspects of adherence to antihypertensive treatment has demonstrated that at least 75% of patients are not adherent because of the combination of factors i.e. demographic, organizational, psychological, disease- and medication-related factor. Upon initiation of therapy clinicians' follow up on most patients haven't borne fulfilling results, with various patient factors contributing to poor or complete non- adherence to antihypertensive therapy (4,7).

In study conducted in Italy, about 25% of patients taking antihypertensive drugs were found to be non-adherent to treatment; factors associated with poor adherence were younger age and female gender of patient, recent start of AHT, absence of diabetes, absence of chronic renal insufficiency and absence of concomitant drug treatments. Numerous clinical trials have demonstrated how correct antihypertensive drug treatment (AHT) significantly reduces cardiovascular diseases and mortality. In clinical practice, however, the use of antihypertensive drugs is often inadequate in terms of the numbers of patients treated and in terms of treatment adherence. This means that blood pressure (BP) values are not controlled sufficiently by drug treatment (36).

In studying adherence to anti-hypertensive medication several tools have been used in various settings. One such tool is the Hill-Bone Compliance with High Blood Pressure medication taking Tool/sub-scale. The Hill-Bone Scales were developed with funds from the National Institutes of Health (NIH); therefore, they are available for use at no cost. This tool has limited generalizability since it targets patients with antihypertensive medication only. It designed to test 3 subscales of adherence to medication; medication-taking behavior, ability to keep appointment and sodium intake. It is rated on a four- point Likert-type scale and the number of items available for testing varies among population types. This scale is customized to various categories of patients. A 14-item Scale is designed for urban dwelling black communities while a 9-item scale has been validated for community- dwelling populations (37).

This tool showed high internal consistency when it was first used (3), and so it did when used in a primary healthcare setting from a study in South Africa (38). Authors have also described Hill- Bone has having higher performance levels for black than non-black populations. Its internal consistency in outpatient settings was also proven by a study within the community dwelling population(37). Therefore, this scale has been suggested as suitable for use in studies specific for hypertension in a predominantly black population.

2.8 Healthy Heart Africa (HHA) Program

In response to the increasing prevalence and poor control of hypertension and the increased burden of cardiovascular disease across Africa, AstraZeneca a British-Swedish pharmaceutical company which manufactures and distributes a wide range of pharmaceutical products came up with an innovative program - the Healthy Heart Africa (HHA). HHA program builds on

existing health care systems through community education and awareness, provides training and treatment guideline development as well as provides access to affordable and high quality anti-hypertensive medicines.

This program was launched in Kenya in 2014 in collaboration with the Ministry of Health. It has had various implementing partners. African Medical Research Foundation (AMREF) Health Africa Kenya is a key implementer of the program and has since demonstrated the project is beneficial albeit with minimal data to support such a claim. This proposed research attempts to evaluate the impact of the Healthy Heart Africa program on hypertension management in selected clinics by reviewing the various strategies employed by the implementing partner (AMREF Health Africa Kenya) in ensuring accessibility of the medications and ultimate control of hypertension

2.9 Conceptual Framework

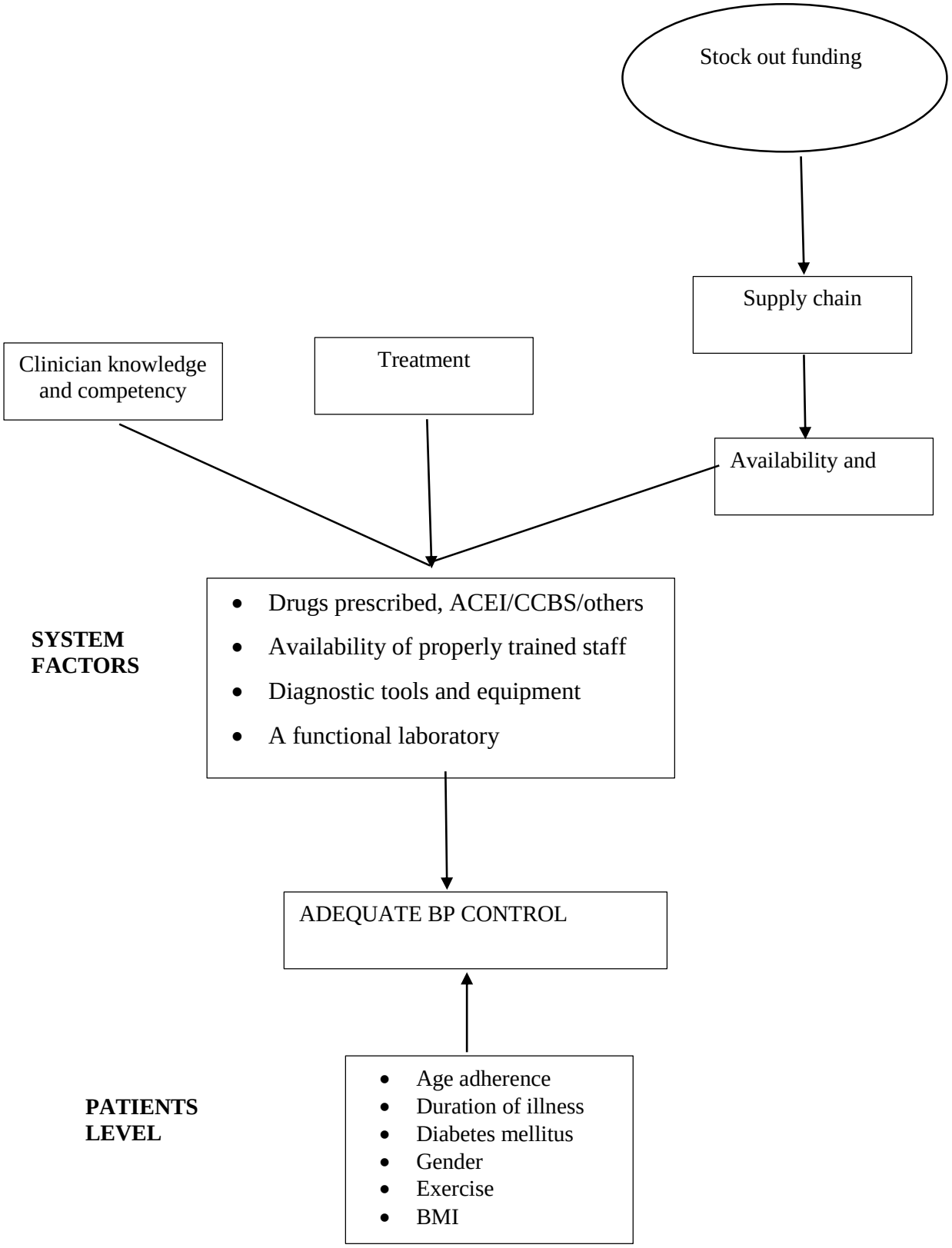

Figure 1 Conceptual framework

Adequate BP control is influenced by both system and patient factors. System factors include the availability of adequately trained staff, availability of diagnostic tools/equipment, a functional laboratory and the type of anti-hypertensive prescribed. The choice of drug is determined by clinician knowledge and competency, existing treatment guidelines and availability and access to the specific drug. Availability of the antihypertensive drugs is further influenced by supply chain factors such as funding and stock outs.

Patient's factors that influence the adequacy of BP control includes: age and sex of the patient, with advanced age and male sex being associated with a poor control. Patients with higher BMI have poor controlled BP compared to those with lower BMI. Healthy and low sodium diet and regular exercise leads to better BP control. Patients who have had hypertension for a long period and who have complications like kidney disease have poorly controlled BP. Smoking and alcohol consumption is also associated with poor BP control.

CHAPTER THREE: METHODS

3.1 Introduction

This chapter presents a detailed description of how the study was conducted. It entails research design, study site, study population and eligibility criteria. Sampling techniques, sample size, data collection tool, data management and analysis and limitations of the study as well as ethical considerations are also presented in this chapter.

3.2 Study Site

The study was carried out at two HHA program implementation sites in Kibera slum i.e. Kibera Community Health Center and Karen Health Center. The comparison population was drawn from Dandora Phase 1 and 2 Health Centers. Kibera slum and Dandora Estate are largely informal settlements located in Nairobi County. A majority of those residing in these informal settlements live on less than a dollar a day. Out-of-pocket financing of the healthcare, which in most instances is unreliable, is their only way of settling their medical bills. Chronic diseases like hypertension that are not only debilitating but also quite costly to manage are a huge economic burden to these residents whose economic status is likely to deteriorate from bad to worse as they attempt to service such healthcare needs. AMREF through the HHA program designed certain cost containment approaches and several strategies of improving adherence to medication in the management of hypertension that are currently being implemented in the study facilities within Kibera slum and hence their selection as study sites. The comparison sites from Dandora estate were suitable since the socio-demographic characteristics and the economic status of residents living here and accessing hypertension care in the two health centers were comparable to those living in Kibera slum. Furthermore, the HHA program has not been implemented in any of the two facilities.

3.3 Study Design

This study was conducted in two phases. The first phase that was quantitative adopted a retrospective cohort study approach whereby hypertensive patients who met the eligibility criteria were identified, followed by retrieval and review of these patients' records. Data on socio- demographic and clinical characteristics, the current BP readings and two other BP readings taken at least 4 weeks apart in the previous three months was obtained. These readings

were used to compare the adequacy of BP control among patients enrolled into the HHA program and those managed at equivalent non-HHA health facilities not having the HHA program. Part of the quantitative component of the study involved estimating the monthly cost of antihypertensive medications for each patient. This was achieved through extraction of data on all prescribed anti-hypertensive medicines, their respective dosages and estimation of their unit prices. These were used to calculate and compare the average monthly acquisition cost of medicines incurred by the patients enrolled in the HHA program and those accessing care at non-HHA health facilities.

The second phase was a cross-sectional survey. It involved a qualitative research design that employed patient interviews that were used in assessing the level of adherence to treatment among the hypertensive patients at the four study sites. Prescribers and key informants at the 4 sites were also interviewed. Those with the HHA program were interviewed to elicit information on aspects of management of patients diagnosed with hypertension at their facilities, the interventions initiated by the program, as well as the challenges experienced in the adoption and implementation of the program while those at non-HHA health facilities were interviewed about aspects of management of patients diagnosed with hypertension at their facilities.

3.4 Study Population

The study population was all adult hypertensive patients receiving their hypertension treatment from the four selected sites. Additionally, key informants including prescribers and nursing officers from the selected facilities were part of the study population.

3.5 Patient Eligibility Criteria

Patients who were eligible to take part in this study should have;

i. Been adults 18 years and older.
ii. Had a diagnosis of hypertension, defined as persistently elevated systolic and/or diastolic blood pressure (BP) of 140/90mmHg or more in subjects aged 18 years and above
iii. Been on hypertension treatment for at least 6 months at the time of the study.
iv. Been receiving their hypertension management from one of the 4 study sites

v. Had three independent BP readings at least 4 weeks apart during the last 6 months and at least three months after initiation of current therapy.

vi. Have basic understanding of either English or Swahili.

vii. Study participants who did not meet all of the above criteria were excluded from the study.

3.6 Sampling

3.6.1 Sample Size Estimation

To determine the appropriate sample size for this study the formula for a comparative study with equal sample size in each arm and the main outcome variable continuous was used (39).

$$n = \frac{2a2\ [\ (\alpha + \beta)2]}{(\mu 1 - \mu 2)2}$$

Where:

n= the sample size in each of the groups u1= population mean in treatment Group 1 u2= population mean in treatment Group 2

u1-u2 = the difference the investigator wishes to detect a2= population variance (SD2) α= 1.96. The conventional multiplier for alpha=0.05 β=0.842. The conventional multiplier for power=0.80

From a publication on BP control levels, the mean SBP of patients on standard hypertension treatment in Ruiru Sub-county hospital was 141.5 mmHg with a standard deviation of 20.5 mmHg (40). The researcher assumed that accessing care under the HHA program improves the mean SBP by 8 mmHg, the effect size (u1-u2) therefore was 8mmHg. We selected a small effect size of 8 because studies designed to find differences between interventions generally show a small difference.

$$n = \frac{2\ [(1.96 + 0.842)2\ 20.52]}{(8)2}$$

n=103.

Adjusting this sample size by 10% to cater for any loss of information, a total of 113 patients from the two HHA implementation sites and another 113 from the 2 selected non- HHA health centers were recruited into the study during routine clinic visits.

3.6.2 Sampling method and Participant recruitment

Convenience sampling was used to select the health facilities to include in this study. Two HHA implementation sites in Kibera sub counties (Kibera Community Health Center and Karen Health Center) were the primary data collection sites since they were the first locations in Nairobi where the HHA program was implemented, while Dandora Phase 1 and Dandora phase 2 Health Centers were used as comparison.

Convenient sampling method was employed to recruit patients from the medical outpatient clinics (MOPCs). We recruited equal number of patients from the four study sites. A list of all eligible patients was prepared from the records departments of the four study sites with the aid of an Eligibility Checklist (Appendix A). Patients were approached during routine clinic visits and those who are on this list (met the eligibility criteria) were requested to participate in the study after explanation of the study and its objectives with the aid of the Consent Form (Appendix E). Upon accepting to participate, each of their files was retrieved and reviewed to extract the required information, then recorded in the Patients Data Collection Sheet (Appendix B). Each of them was taken through a questionnaire-guided interview to ascertain their level of adherence to the prescribed antihypertensive medicine. We recruited equal number of patients from the four study sites.

In addition, universal sampling was used for the key informants, whereby all prescribers and nurses at the two study sites were eligible for interview. They were requested to participate in the study after explanation of the study and its objectives with the aid of the Consent Form (Appendix F).

3.7 Data Collection

3.7.1 Data Collection Instruments

The researcher was responsible for both quantitative and qualitative data collections. However, for practical reasons, two researcher assistants were requested from time to time to take up the role after having been adequately trained by the researcher on how to use the data collection tools in capturing timely and correct data.

A designed, pre-tested and modified Data Collection Form (Appendix B) was used for collecting patient information from the medical records. This information included patient's socio-demographic and clinical characteristics, BP readings and all prescribed medicines and the respective dosages.In order to determine the levels of adherence to prescribed medications, a semi-structured questionnaire adapted from the Hill-Bone Compliance with High Blood Pressure Therapy Medication Taking subscale was used (Appendix C). Recruited patients were required to fill in this questionnaire. The provided responses were used to classify the patients as either adherent or non-adherent depending on their respective scores (3).

Key informant interviews were conducted with the aid of the semi-structured interview guide (Appendix D). The semi-structured interview guide divided into two sections. The first section collected general data regarding management of hypertension. Data collected included approximate number of patients seen per clinic day (workload); awareness and adherence to treatment guidelines for hypertension; post-qualification training on the use of the guidelines; challenges encountered in their management of hypertensive patients; and barriers to their adherence to treatment guidelines. The second section explored the success of adoption and implementation of the HHA program, and the challenges and barriers associated with the implementation of the program. Additionally, these interviews assessed the consistent availability of antihypertensive medicines.

The researcher presented the patients and selected key informants with a Consent Form (Appendix E), which explained the purpose, methods and importance of the study, as well as the expected duration of the interview, voluntary participation and confidentiality. Upon provision of informed consent, the participants were required to sign the consent certificate.

3.7.2 Variables Primary Outcome Variable

The primary outcome variable in this was adequacy of controlled blood pressure. Patients with controlled blood pressure were those with the last three BP readings taken at least 4 weeks apart below 140/90 mmHg. Both the SBP and DBP had to be below these thresholds for BP to be considered controlled. For patients with diabetes, adequate control was defined as a blood pressure of less than 130/80mmHg. Patients older than 60 years were considered to have adequate BP control if the readings were below 150/100 mmHg. These cut-offs were according to the latest JNC-8 guidelines on management of hypertension (6).

Secondary Outcome Variables

Difference in monthly acquisition cost of anti-hypertensive medicines: This was the difference in the estimated average monthly cost (per patient) of acquiring anti- hypertensive medicines for patients in the HHA program and those in non-HHA health facilities. According to the WHO, cost is one of the key determinants of access to medicine. Level of adherence to medication: Adherence was defined as per the Hill-Bone Compliance with High Blood Pressure Therapy Scale. This adherence monitoring tool was designed to enable an evaluation of patient's self-reported adherence levels. It can be customized to a user friendly format and can either be self-administered or interviewer- assisted. It takes approximately five minutes to complete and has been validated in various communities including an African setting. It assessed three behavioral domains of high blood pressure treatment: medication taking, appointment keeping and reduced sodium intake (38).

However, the study focused on medication taking behavior and as such the adapted interview questionnaire is only customized to meet that objective. The scale had 8 items each with a four point response format: (4) all the time, (3) most of time, (2) some of time, and (1) none of the time (Appendix C). Items were assumed to be additive, and, when summed, the total score ranges from 8 (minimum) to 32 (maximum). Patients were classified as adherent or non-adherent depending on the total score. A patient was defined as fully adherent if they had a score of 8. A score ≥ 9 was considered representative of non- adherence. Non-adherence was graded from 9-32, with higher scores reflecting poorer levels of adherence (38).

For purposes of this study adherence and/or non-adherence was divided into four (4) categories. Category one comprised patients who were fully adherent with a Score of 8. Categories two (2) to four (4) were comprised of patients who were non-adherent to their medication. Patients with a score of 9-16 fell in category 2, those with scores of 17-24 fell in category 3 and those in category 4 had scores ≥24.

Predictor variables

Predictor variables included age, gender, duration of illness, employment status, occupation, alcohol consumption, smoking status, diet, exercise, BMI, study site among others.

3.8 Data Management and Quality Assurance

The data collection sheet was pretested using 10 patients' files at Mbagathi hospital to test its ability to adequately capture all the required information. Patient information was extracted from the records within the source area during working hours. Records were coded using unique patient numbers rather than their names to ensure confidentiality. Any document linking collected data to the patients' files was kept under lock and key and only accessed by the principal investigator. All raw data was entered the same day collected into Epi info version 7 and a database that was created. Data entry was double checked by the investigator to ensure accuracy and completeness. Backups were done on a weekly basis in an external hard Disk. Upon completion of the study the data collection form was shredded and the backup cleared.

3.9 Data Analysis Methods

Quantitative data was entered into Epi Info Version 7.15 and thereafter transferred to Stata® 10 (Stata Corp, USA) for analysis. Summary descriptive statistics were carried out for each of the demographic variables. Quantitative data was analyzed descriptively using measures such as frequencies, percentages, mean and standard deviation. Inferential analysis was used to establish any significant difference in the adequacy of BP control. Since the two samples were not normally distributed Mann-Whitney test was employed for the analysis. Two-sample t-test analysis were used to establish whether the mean and median BP of the patients at the two study groups were significantly different since the two samples were not normally distributed. Adherence score was analyzed as a categorical variable. The strength of association between adherence score and level of blood pressure was obtained using linear regression. Multiple logistic regression analysis was used to establish the independent relationship between adequacy of BP control and selected predictor variables of the study. The level of significance was set at 0.05. The results of the study were also presented as graphs, tables or pie-charts.

For purposes of this study adherence and/or non-adherence was divided into four (4) categories. Category one comprised patients who were fully adherent with a Score of 8. Categories two (2) to four (4) were comprised of patients who were non-adherent to their medication. Patients with a score of 9-16 fell in category 2, those with scores of 17-24 fell in category 3 and those in category 4 had scores $\geq$24. The estimated monthly acquisition cost of anti-hypertensive drugs for each patient was calculated based on the drugs and respective dosages prescribed, and the unit prices of each anti- hypertensive medicine as charged by the respective facility.

A descriptive thematic approach was used to analyze the qualitative data, whereby the data was examined; key and meaningful themes/patterns were identified and interpreted by triangulation of all the provided information.

3.10 Ethical Considerations

An approval to carry out the study was granted by Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (KNH/UoN-ERC) before commencement of the study. The KNH/UoN-ERC approval reference number was KNH-ERC/A/98. To ensure privacy and confidentiality, patients were identified using patients' record numbers (codes) instead of their names. Informed consent was sought from the patients and key informants and their names too were not to be used rather codes were used as identifiers.

CHAPTER FOUR: RESULTS

4.1 Recruitment of participants

A total of 265 files were sampled from the Medical Outpatient Clinic (MOPC) attendance lists from the four (4) study sites covering the period from August, 2018 to April, 2019 of which 250 were purposively sampled. Out of the 250 (94.3%) patients 30 (12%) patients had significant differences from the target population hence did not meet the inclusion criteria. Ten (10) 4% patients out of the remaining 220 (88%) patients declined to take part in the study, 3 (1.2%) of them were not on any antihypertensive medications while another 2(0.8%) had a language barrier. The remaining 205(82%) patients were recruited into the study. This is 91% of the calculated sample size of 226 patients. Among those enrolled in the HHA program, 59 were from Kibera Health Center while 49 were drawn from Karen Health Center. Dandora I Health Center had 51 patients while 46 sought care from Dandora II Health Center. The screening and recruitment of eligible patients is demonstrated in Figure 4.1

4.1.1 Demographic characteristics of the patients

The proportion of female patients enrolled into the study was 120(58.5%), while that of their male counterparts was 85(42.5%). The mean age of all the patients was 54 years with a standard deviation of 13 years. Their ages ranged from 20 to 90 years with 111(54.1%) of them belonging to the age group of 40-59 years while 61(29.8%) of them fell in the age category of 60- 79 years. Only 6(3%) of these patients were above 80 years and 27(13.2%) were between 20 – 39 years.

Regarding marital status, 173(86.1%) of the patients were married. The others, 32(13.9%) comprised those who were single, divorced, separated or widowed individuals. A majority 147(71.7%) were small scale business people and about 34(16.6%) were unemployed. The other 11.7% were employed as civil servants, teachers and in the private sector. About half 111 (54.1%) of the sampled patients had completed their primary education with only 65(32%) having studied till secondary school level and just 3(2%) attaining tertiary education. The other 26(13%) had no formal education. Table 4.1 summarizes the demographic characteristics of the study population

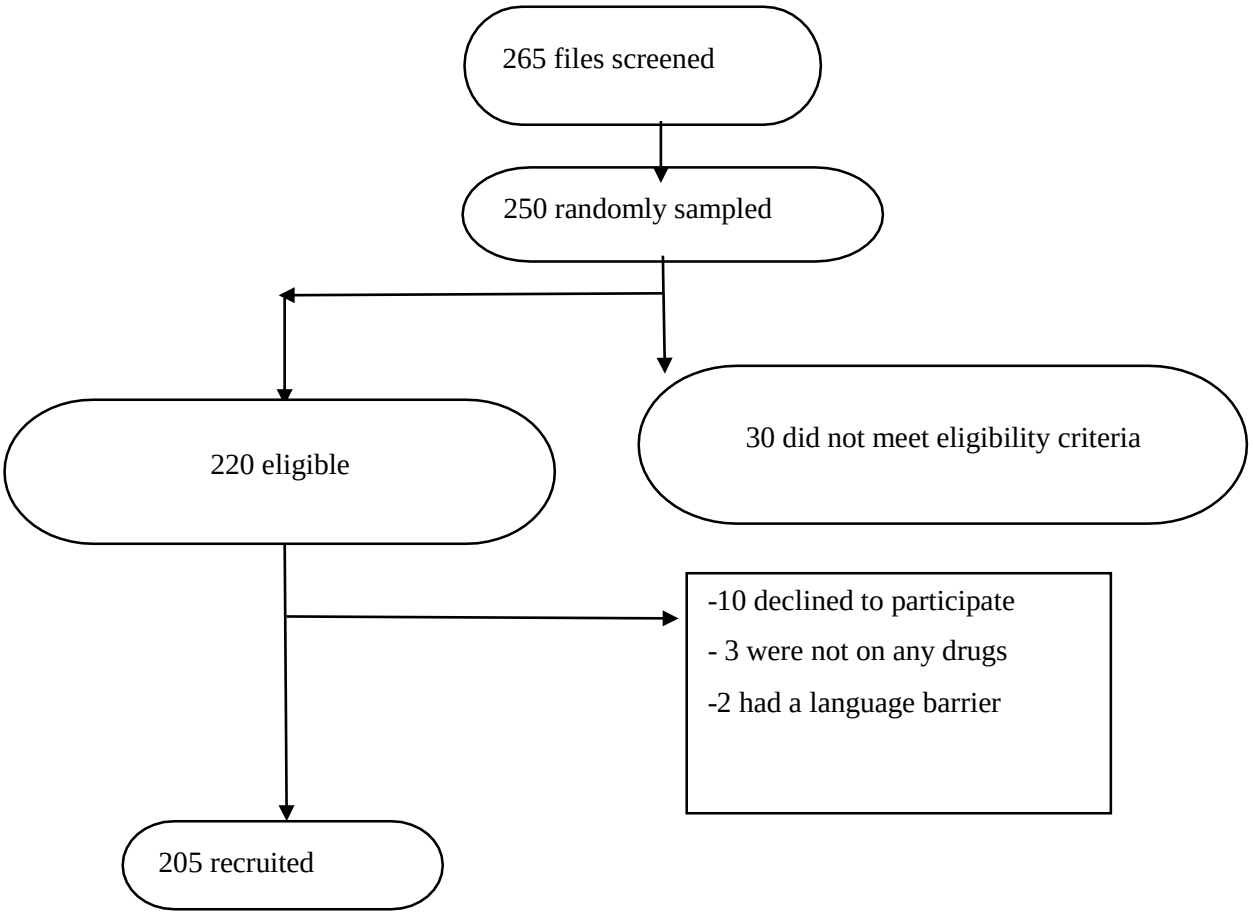

Figure 4.1 screening and recruitment of eligible patients

There were systematic differences between patients in the program and those receiving services in the non-HHA facilities. These differences were statistically significant. Those on the program were more likely to be female, single, employed or have more education. Therefore, marital status, occupation, level of education and gender are all potential confounders that need adjustment as analysis progresses. Interestingly Body Mass index (BMI) upon summary data analysis showed no statistically significant difference among the patients in the study.

Table 4.1: Demographic characteristics of the patients on Anti-hypertensives (n= 205)

Characteristic	Non-HHA (%)	nHHA Program (%)	nTotal n (%)	P value
Gender				
Male	47 (48.5%)	38 (35.2%)	85 (41.5%)	**0.054**
Female	50 (51.5%)	70 (64.8%)	120 (58.5%)	
Age (years)				
20-39	10 (10.3%)	17 (15.7%)	27 (13.2%)	0.913
40 – 59	54 (55.7%)	57 (52.8%)	111 (54.1%)	
60 – 79	31 (40%)	30 (27.8%)	61 (29.8%)	
>80	2 (2.1%)	4 (3.7%)	6 (2.9%)	
BMI				
<18.5 **(Underweight)**	7 (7%)	3 (3%)	10 (5%)	
18.5 – 24.9 **(Healthy)**	27 (28%)	35 (33%)	62 (30%)	0.986
25 – 29.9 **(Overweight)**	43 (44%)	50 (48%)	93 (45%)	
30 – 39.9 **(Obese)**	20 (21%)	17 (16%)	37 (18%)	
Marital Status				
Married	92 (96.8%)	81 (76.4%)	173 (86.1%)	**0.001***
Single	3 (3.1%)	11 (10.2%)	14 (6.83%)	
Widowed	0 (0.0%)	10 (9.3%)	10 (4.89%)	
Others	2 (2%)	6 (4,1%)	8 (3.90%)	
Occupation				
Business	78 (80.4%)	69 (63.9%)	147 (71.7%)	**<0.001***
Unemployed	10 (10.3%)	24 (22.2%)	34 (16.6%)	
Others	9 (9.3%)	15 (13.9%)	24 (11.7%)	
Level of Education				
No Education	15 (15.5%)	11(10.2%)	26(12.7%)	
Primary	50 (51.5%)	61 (56.5%)	111(54.1%)	
Secondary	32 (33%)	33(30.6%)	65 (31.7%)	**0.004**
Tertiary	0 (0.0%)	3 (2.7%)	3 (1.5%)	

4.1.2 Comorbidities amongst study participants

Diabetes was the most common comorbidity present in 51(24.9%) of all the patients. Five 5(2.4%) out of the sampled patient population had cardiovascular diseases and only one 1(0.5%) had chronic kidney disease (CKD). Patients enrolled in the HHA program had fewer comorbidities compared to the ones managed at the non-HHA health centers, an indicator of possible selection bias during recruitment into the program. More than half of the sampled patients had no coexisting comorbidity as shown in Table 4.2 below

Table 4.2: Comorbidities in patients on anti-hypertensive therapy

Comorbidity	Non-HHA n	HHA program n	Totals N (%)
Diabetes	41	10	51(24.9%)
Cardiovascular disease	4	1	5 (2.4%)
Peripheral neuropathy	2	3	5 (2.4%)
Arthritis	4	1	5 (2.4%)
Chronic Kidney Disease	1	0	1(0.5%)
Stroke	1	0	1(0.5%)
None	44	93	137 (66.8%)
Total			20500%)

Duration of current treatment

Figure 4.2 illustrates duration of current antihypertensive treatment in years. The largest proportion of the patients had been in treatment for a period of less than 2 years (95, 46.3%).

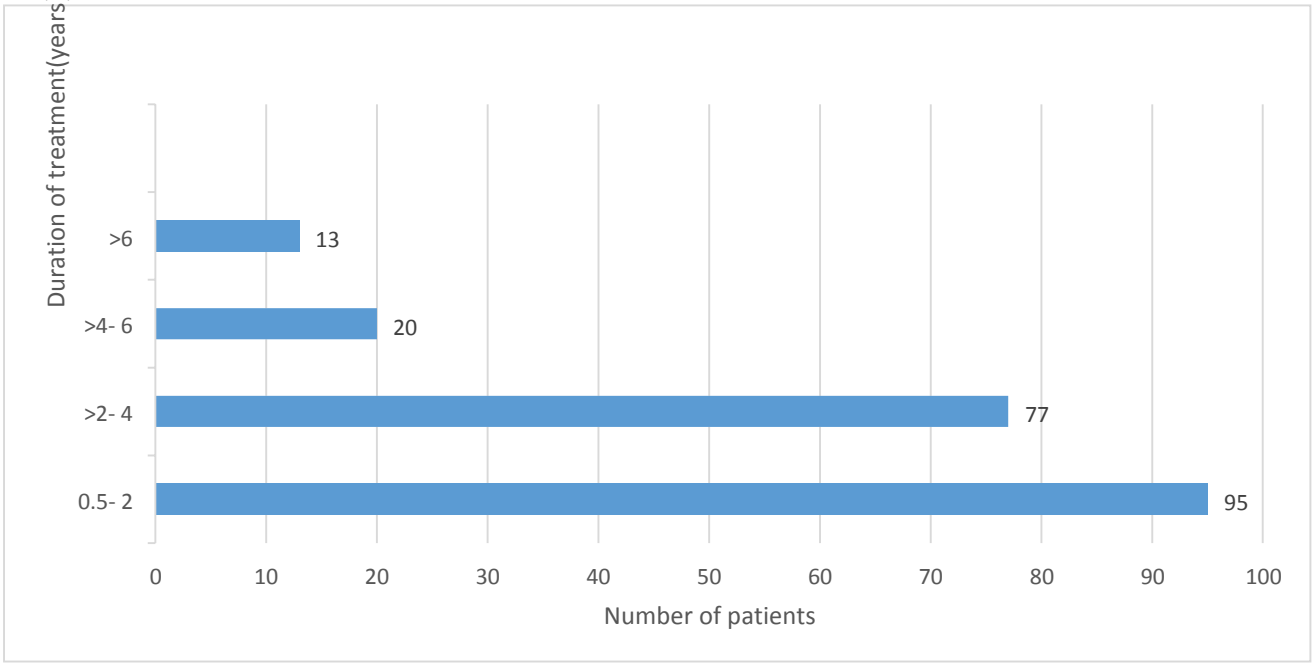

Figure 4.3: Current treatment duration of hypertensive patients

4.2.1 Change in mean blood pressure levels

The data set on blood pressure levels was not normally distributed. The mean SBP and DBP were statistically significant differences on commencement of the study. However significant differences were not observed after 3 and 6 months of treatment and monitoring.

The Median Systolic Blood pressure (SBP) at the beginning of the current treatment was 160mmHg for patients enrolled in the Healthy Heart Africa program and 147mmHg for those managed in the two non-HHA health centers. In addition, the median SBP after three 3 months was 139mmHg and 140mmHg for the two groups respectively. After 6 months, the median SBP readings were 134mmHg and 139mmHg for the two groups respectively. Similar reductions were reported for the diastolic blood pressure, albeit with significantly lower magnitudes.

Generally, there was no statistically significant difference in the medians of both the systolic and diastolic blood pressure between patients in the program and those managed in the non-HHA health centers at the beginning of their current treatment. However, statistically significant differences were noted between the two groups after management for three and 6 months. The distribution of both systolic and diastolic blood pressure levels from the time of diagnosis to 6 months are summarized in Table 4.3.

Table 4.3: Mean Distribution of blood pressure levels among hypertensive patients

	Treatment period (months)	**Non-HHA**	**HHA**	**P value**
Systolic Blood Pressure Mean(Range)	1 (Beginning of current treatment)	141 (138-143)	134 (131-137)	**<0.001**
	3	151 (147-154)	162 (159-166)	1.000
	6	144 (141-147)	140 (137-144)	**0.037**
Diastolic Blood Pressure Mean (Range)	1 (Beginning of current treatment)	83 (82-85)	81 (79-83)	**0.032**
	3	89 (87-92)	90 (88-93)	0.073
	6	86 (84-88)	84 (81-86)	0.067

Table 4.4: Median distribution of blood pressure levels among hypertensive patient

	Treatment period (months)	Non-HHA	HHA	P value
Systolic Blood Pressure Median (Range)	1 (Beginning of current treatment)	147(115-192)	160(110-211)	1.000
	3	140 (115-178)	139 (108-190)	**0.037**
	6	139 (117-170)	134 (105-197)	**<0.001**
Diastolic Blood Pressure Median (Range)	1 (Beginning of current treatment)	90 (60-113)	90 (64-129)	0.727
	3	84 (66-100)	83 (65-112)	**<0.001**
	6	84 (68-104)	80 (61-115)	**0.014**

4.2.2 Reduction in blood pressure

At the beginning of the current treatment, though those on the HHA program had higher SBP and DBP readings, there was no statistically significant differences in the levels. It was very clear that at 3 and 6 months, those patients attending facilities in the HHA had lower SBP and DBP and the difference in the median pressure was statistically significant.

The change in both median systolic and median diastolic pressures over the 6-month period is represented in Figure 4.2. The greatest magnitude of reduction was observed in the two facilities enrolled in the Healthy Heart Africa (HHA) program with patients at Kibera Health center showing greater reduction in median systolic pressure at -31mmHg compared to their counterparts at the Karen Health Center who a reduction of -22mmHg. Conversely patients managed at the non-HHA facilities showed very minimal reduction in their blood pressure levels over this same period. Dandora II Health Center reported the least reduction in blood pressure levels having only a reduction of -5mmHg of median SBP and -1mmHg in the median DBP after 6 months respectively.

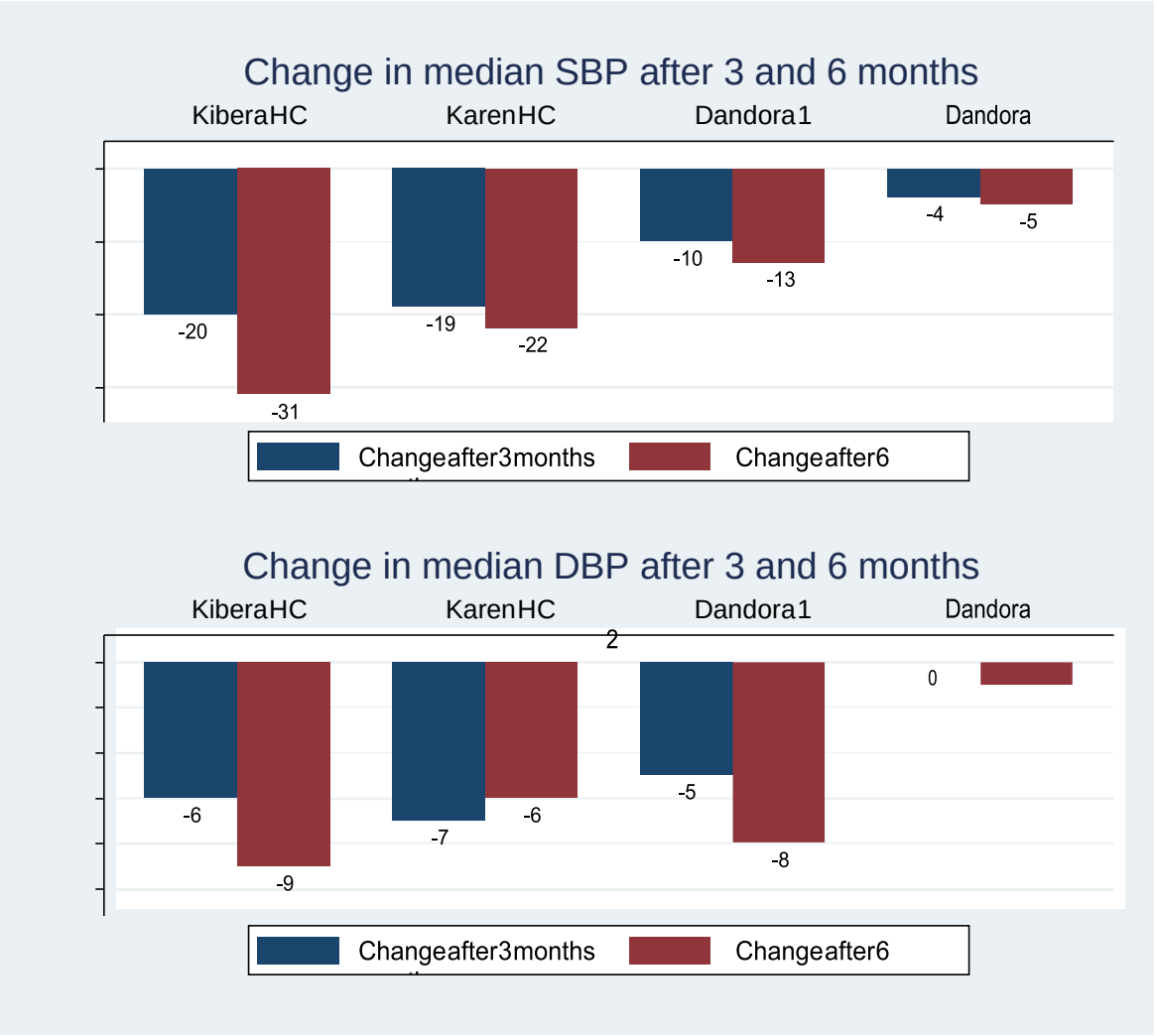

Figure 4.4: Changes in the median systolic and Diastolic pressure after 3 and 6 months

The graphs clearly depicted that there were clear inter facility differences in the reduction in the median blood pressure levels. The largest reduction was observed at Kibera Health Center while the least reduction was observed at Dandora II Health Center.

4.2.3 Severity of Hypertension at diagnosis/enrollment

The ESC/ESH guidelines were used to categorize the hypertension status of all the study patients at diagnosis or at the time of enrollment into the HHA. According to ESC/ESH guidelines, BP of 140/90mmHg and above is considered high (hypertension). Blood pressure of less than 140/90mmHg is categorized as “high normal” (130/85mmH and 139/89 mmHg) and “normal” (120/80mmHg and 129/84mmHg). On the other hand, hypertension is graded as either grade 1 hypertension (140/90mmHg to 159/99mmHg), grade 2 hypertension (160/100mmHg to 179/109mmHg) or grade 3 (≥180/110mmHg). Isolated systolic

hypertension is defined as elevated systolic BP (≥140mmHg) while the diastolic BP is normal (<90mmHg). At diagnosis 23(24%) of the patients managed in the non-HHA health centers had grade 1 hypertension, 17(17%) had grade 2 hypertension and 9(9%) were at grade 3. Twenty-one percent 20(21%) were diagnosed with isolated systolic hypertension, according to the ESC/ESH classification of hypertension.

At enrollment into the HHA program, 20(19%) of the patients had grade 1 hypertension, 20% had grade 2 hypertensions, 16(15%) had grade 3 hypertensions and 42(39%) had isolated systolic hypertension. A notable finding was the inaccurate diagnosis of hypertension. At least 28 patients managed at the non-HHA health facilities and who had either normal or high normal BP had been wrongly diagnosed as being hypertensive. Among those enrolled in the HHA program, eight 8) patients who had high normal BP were found to have been wrongly diagnosed and were on antihypertensive treatment despite not being hypertensive at the beginning of these treatment period. Table 4.4 presents the proportions of patients in the various BP categories from both groups.

Table 4.5: Distribution and classification of Hypertension among the Patients

Blood pressure levels		**Normal (%)**	**nHigh normal (%)**	**Grade nn (%)**	**1Grade 2 (%)**	**nGrade 3 (%)**	**nIsolated Systolic (%)**	**n**
Treatment period (months)								
1 (Beginning of current treatment)	**Non-HHA**	6 (6.2%)	22 (22.7%)	23 (23.7%)	17 (17.5%)	9 (9.3%)	20 (20.6%)	
	HHA	0 (0.0%)	8 (7.4%)	20 (18.5%)	22 (20.4%)	16 (14.8%)	42 (38.9%)	
3	**Non-HHA**	5 (5.2%)	24 (24.7%)	23 (23.7%)	20 (20.6%)	10 (10.3%)	15 (15.5%)	
	HHA	31 (28.7%)	33 (30.6%)	14 (13%)	6 (5.6%)	2 (1.9%)	22 (20.4%)	
6	**Non-HHA**	16 (16.5%)	26 (26.8%)	30 (30.9%)	10 (10.3%)	0 (0.0%)	15 (15.5%)	
	HHA	45 (41.7%)	33 (30.6%)	11 (10.2%)	2 (1.6%)	2 (1.6%)	15 (13.9%)	

4.2.4 Adequacy of blood pressure control

Hypertension is considered adequately controlled in patients with diabetes mellitus Type 2 (DM2) when they consistently achieve BP readings of ≤ 130/80mmHg. On the other hand, patients without DM2 and other comorbidities, adequacy of BP control is achieved when the BP readings are less than 140/90 mmHg. For purposes of this study a patient was considered to have adequate BP control if after pharmacological management, their BP readings are <140mmHg for systolic blood pressure and < 90mmHg for diastolic pressure; if the BP readings were 'high normal' or 'normal' according to the ESC/ESH guidelines.

After 6 months of treatment only 42(43%) of patients managed at non-HHA health facilities had their BP controlled (i.e. were 'high normal' or 'normal' according to the ESC/ESH guidelines) compared to 78(72%) of those enrolled under the HHA program. There was a statistically significant difference in the adequacy of blood control between these two groups of patients ($p < 0.001$). The patients enrolled in the HHA program had better BP control than those in non-HHA facilities.

There were significant changes in the grades of hypertension too. Those with Isolated Systolic hypertension (ISH) and enrolled in the HHA program reduced by 20(47%) from the onset of the current treatment to the third month. A reduction of 7(32%) was also observed between the third and sixth month. On the contrary those with ISH in the non-HHA facilities only reduced by 5(25%) between the onset of current treatment and the third month with no reduction between the 3rd and 6th months of treatment (Table 4.4). Among patients falling between Grade 1 and Grade 3 hypertension, a 36(62%) reduction was observed between the 1st and 3rd months for those in the HHA program while those in non- HHA facilities had an increment of 3(6%). A further reduction of 7(32%) was observed between the 3rd and 6th months amongst patients in the HHA program while those in the non- HHA facilities reduced by 12(23%) (Table 4.4).

4.2.5 Prescribing patterns of Antihypertensive agents

4.2.6 Classes of antihypertensive agents prescribed

The most commonly prescribed classes of antihypertensives were thiazide diuretics at 164(44.3%) of the total prescription medicines, followed by CCBs at 122(33%) and ACE inhibitors at 79(21.4%) as shown in Table 4.5. In addition, among specific antihypertensive drugs, hydrochlorothiazide was the most commonly prescribed drug at 164(44.3%) with lisinopril at 64(17.3%). Atenolol, furosemide, methyldopa and losartan were the least prescribed.

Among those enrolled in the HHA program hydrochlorthiazide was the most prescribed at 93(45.1%), followed by lisinopril 64(31.1%) and Felodipine at 37(18%). A similar prescription pattern was observed among patients managed at the two non-HHA sites with hydrochlorthiazide remaining the most prescribed drug at 71(43.3%) followed by nifedipine at 49(30%). In addition, amlodipine 28(17.1%) and enalapril 12(7.3%) were also prescribed to patients in this group.

There was a statistically significant difference in prevalence in Hydrochlorthiazide use. Patients on HHA program drugs were more likely to be on HCTZ 93(86.1 %%) compared to 71(73.2%) of those managed in the non-HHA facilities ($p<0.005$). There were a statistically significant differences in the prevalence of use of these drugs. For calcium channel blockers, it was noted that patients in the HHA program were only prescribed for Felodipine while those in the non-HHA health centers had prescriptions of amlodipine and nifedipine ($p<0.001$). No significant differences were observed for other prescription medicines including those prescribed to manage other coexisting conditions ($p=0.542$).

Table 4.6: Comparison of antihypertensives used by patients in the HHA program and those not in the program

	Non HHA	HHA	Total	P values
Class	n	N	n (%)	
CCBs				
Nifedipine	49 (30%)	6 (2.9%)	54 (15%)	
Felodipine	0	37 (18%)	37 (10%)	<0.001
Amlodipine	28 (17.1%)	3 (1.5%)	31 (8.4%)	
ACE Inhibitors				
Lisinopril	0	64 (31.1%)	64 (17.3%)	<0.001
Enalapril	12 (7.3%)	3 (1.5%)	15 (4.1%)	
Thiazide Diuretics				
Hydrochlorthiazide	71 (43.3%)	93 (45.1%)	164 (44.3%)	0.005
BBs				0.108
Atenolol	0	1 (0.5%)	1 (0.3%)	
ARBs				0.689
Losartan	2 (1.2%)	0	2 (0.5%)	
Other Diuretics				\0.235
Furosemide	1 (0.6%)	0	1 (0.3%)	
Miscellaneous				0.942
Methyldopa	1 (0.6%)	0	1 (0.3%)	
TOTAL	164	206	370 (100%)	
Other Drugs				
Metformin	34	7	41 (44.1%)	
Glimepiride	28	3	31 (33.3%)	
Mixtard Insulin	8	4	12 (12.9%)	0.542
Atorvastatin	3	2	5 (5.4)	
Gliclazide	0	2	2 (2.2%)	
Aspirin	2	0	2 (2.2%)	
TOTAL			**93 (100%)**	

ACE*= Angiotensin converting enzyme,* ***ARBs****= Angiotensin receptor blockers,* ***BBs****= Beta blockers,* ***CCBs****= Calcium channel blockers*

4.2.7 Number of antihypertensive agents prescribed per patient

Most patients were on a 2 drug regimen 133(64.9%). Whereas one third 61(30%) were on a one drug antihypertensive regimen. A paltry number of 11 (5.3%) were on 3 drug regimen as shown in Figure 4.3 Majority of those on 2 antihypertensives were from the HHA program, while majority of those on 1 antihypertensive were from the non-HHA facilities.

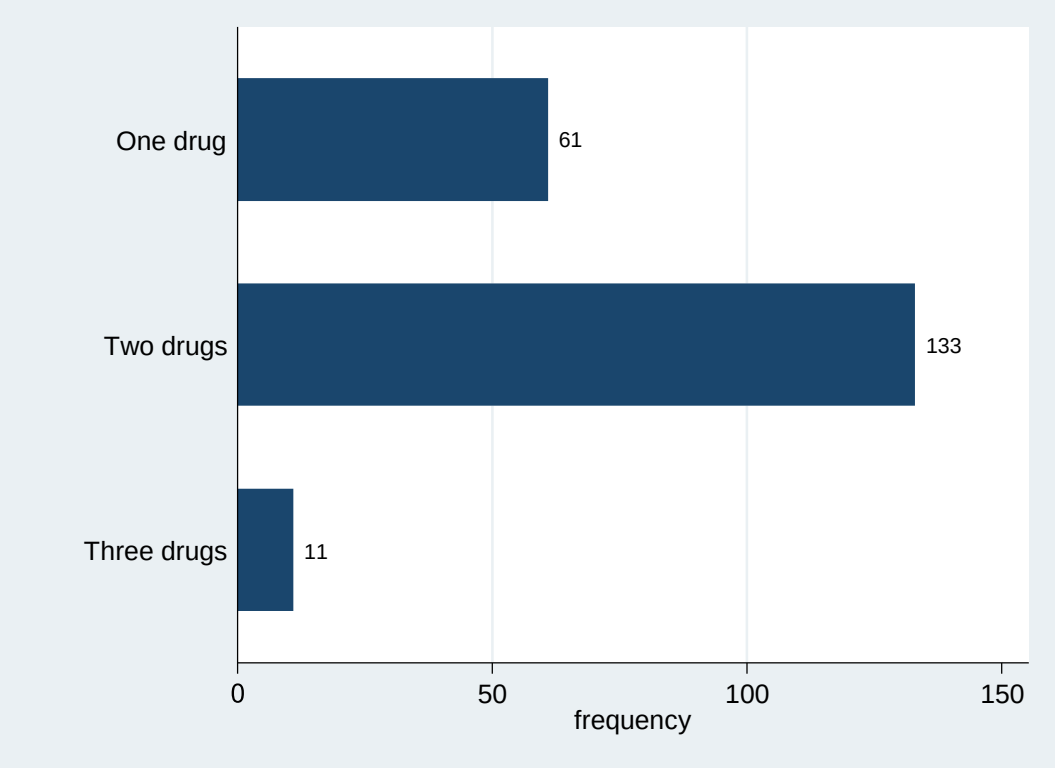

Figure 4.6: Number of antihypertensive per prescription

4.2.8 Antihypertensive regimens prescribed

The most commonly prescribed regimen was a 2-drug combination with an ACEI and a thiazide diuretic at 71(35.6%) followed a combination of a CCB and an ACEI at 38(18.6%). Table 4.6 shows the frequencies and percentages of the various regimens used. Among the1 drug regimens, thiazide diuretics were the most prescribed at 33(16.1%) while CCBs were the least prescribed at 10(4.9%). The only 3-drug regimen that was prescribed across these patient was a combination of CCB, ACEI and a thiazide diuretic at 11(5.3%).

Table 4.7 Specific regimens of antihypertensives prescribed for hypertensive patients

Regimen	Non-HHA	HHA	Total (%)
Monotherapy			**29.8%**
Thiazide Diuretic	33	0	33 (16.1%)
ACE Inhibitor	18	0	18(8.8%)
CCB	5	5	10 (4.9%)
ARB	0	0	0(0.0%)
2- Drug combination therapy			**64.9%**
Thiazide diuretic + ACEI	7	64	71 (35.6%)
CCB+ ACE Inhibitor	8	30	38 (18.6%)
CCB+ Thiazide Diuretic	18	0	18 (8.8%)
Thiazide diuretic + ARB	3	0	3 (1.9%)
CCB + ARB	0	0	0 (0.0%)
3- Drug Therapy			**5.3%**
CCB+ ACEI+ Thiazide diuretic	4	7	11(5.3%)
CCB+ ARB+ Thiazide diuretic	0	0	0
Totals	**97**	**108**	**205(100%)**

4.3 Cost of medications for Hypertension in Nairobi County

The average monthly cost of antihypertensives medications for the non-HHA patients was calculated. This figure was then compared to the monthly flat rate of Ksh 100 for the HHA patients. The unit price of each of the drugs was extrapolated from the average retail market rates and an average monthly acquisition cost per patient was found to be Ksh.190. HHA patients rarely missed their medications from the respective hospital Dispensaries. However, when they did the cost implications were catastrophic. On average they would spend up to Ksh. 3600 to purchase a month's supply of Felodipine 10mg (Plendil®) and another Ksh. 2200 for Lisinopril+ Hydrochlorthiazide 20/12.5mg (Zestoretic 20®).

The objective of this analysis was to estimate the difference in the average monthly cost of hypertensive medication to patients enrolled into the HHA program and those receiving regular care at non-HHA health centers in Nairobi County. Since patients enrolled in the HHA paid a flat fee of Ksh. 100 for their medications while those in the Level III hospitals like Dandora I and II were offered free health services a clear difference could not be determined. A summary of the average monthly acquisition cost per prescription for each individual drug was also obtained and used to answer this research question as summarized in Table 4.7.

Table 4.8 Average market price per prescription for hypertensive patients

Drug	Average cost per prescription (Ksh)
ACEIs	**2500**
Lisinopril	2200
Enalapril 5mg	150
Enalapril 10mg	150
CCBs	**3780**
Felodipine	3600
Nifedipine	30
Amlodipine	150
BBs	**150**
Atenolol	150
Diuretics	**130**
Hydrochlorthiazide	30
Furosemide	50
Spironolactone	50
ARBs	**280**
Losartan	280
Centrally acting Agents	**150**
Methyldopa	150

4.4 Adherence to anti-hypertensive medication

Adherence to medication was defined as per the Hill-Bone compliance with high blood pressure therapy scale. Using this scale, a patient was defined as fully adherent if their responses to the eight graded questions was 8. Those whose scores were ≥9 to 32 were considered non-adherent. Non-adherence was graded on a Likert scale with patients with higher scores representing very poor adherence to medication. The adherence scores were categorized as follows; category 1-fully adherent (scored 8), category 2 (scored 9-16), category 3 (scored 17-24) and category 4 (scored 25-32).

Consequently, out of the sampled patient population, only 70 (34.1%) from both arms were found to be fully adherent to their medication. The other 125 (65.9%) were found to be moderately non-adherent, 7(3.4%) had poor adherence while 3(1.5%) had very poor adherence to their medication. Figure 4.4 is a summary of the level of adherence to Antihypertensive therapy per category as described,

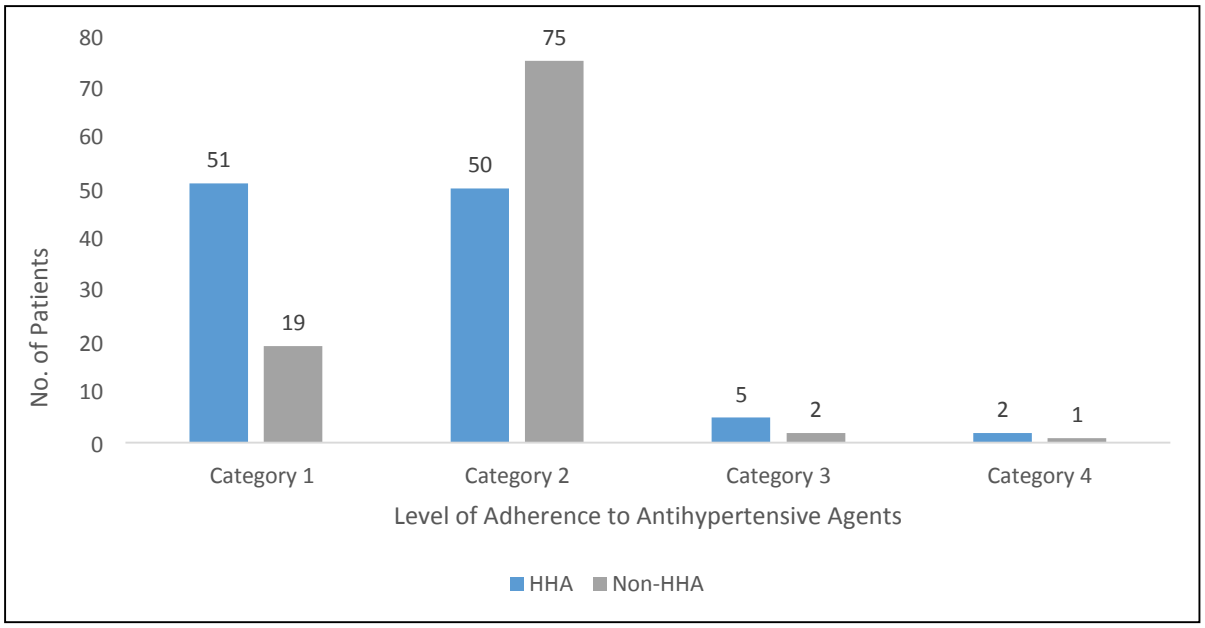

Figure 4.7 summary of the level of adherence to Antihypertensive therapy

4.5 Factors affecting adherence

Several demographic factors were observed to influence adherence to medication following Bivariable logistic regression analysis. Patient's level of education (p = 0.018) and marital status (p = 0.038) were the most significant socio demographic predictors of adherence. Majority of the patients who were adherent were married 52 (73.2%). Unexpectedly, the lower the levels of education the better the adherence, with 35(48.6%) of the adherent patients having attained only primary level education. The influence of gender, age and occupation was not statistically significant, though the larger proportion of adherent patients were involved in business 38 (45.2%).

It was noted that being in the HHA program and intra facility differences had a statistically significant influence on adherence both having p values <0. 001. Seventy-four percent 51 (74%) of the patients who were adherent were on the HHA program compared to only 19(26%) who were not the HHA. Hence a demonstration that the strategies employed in managing the patients in the HHA were not only different but also superior to those employed in the non-HHA health centers shown in Table 4.8.

Table 4.9: Comparison of the sociodemographic traits of adherent and non- adherent patients

	Number of patients (n)	Adherent n (%)	Non-adherentn (%)	P value
Gender				
Male	85	29 (40.3%)	56 (42.1%)	0.800
Female	120	43 (59.7%)	77 (58%)	
Age (years)				
<60	139	47 (65.3%)	92 (69.2%)	
≥ 60	66	25 (34.7%)	41 (30.8%)	0.753
Marital status				
Single & others	32	19 (26.8%)	13 (9.7%)	**0.038**
Married	173	52 (73.2%)	121 (90.3)	
Occupation				
Formal Employment	12	7 (8.3%)	5(4.1%)	
Business	124	38 (45.2%)	86 (71.1%)	
Farmer	23	10(11.9%)	13 (10.7%)	0.082
Others	46	29(34.5%)	17 (14.1%)	
Education				
Tertiary	17	10(13.9)	7 (0.8%)	
Secondary	66	26 (36.1)	40 (30.1%)	**0.018**
Primary	111	35 (48.6)	76 (57.1%)	
None	10	1 (1.4)	9 (6.8%)	
HHA				
Yes	108	53 (68)	55 (41.7%)	**<0.001***
No	97	19 (32.1)	78 (58.3%)	
Facility				
Kibera HC	59	26 (44.1%)	33 (55.9%)	
Karen HC	49	27 (55.1%)	22 (44.9%)	**<0.001***
Dandora I HC	51	14 (27.4%)	37 (72.6%)	
Dandora II HC	45	5 (11.1%)	40 88.9%)	

4.6 Factors affecting blood pressure control

4.6.1 Bivariable logistic regression analysis of blood pressure control and other variables

Bivariable regression was conducted to identify various factors that contributed independently to the adequacy of blood pressure control. Based on this analysis the most important predictors of Blood pressure control were being in the HHA and adherence to medication. Patients in the HHA (OR 2.6 95% CI 1.5, 4.6; p <0.001) were almost three times as likely to have their BP controlled compared to those managed in the non-HHA facilities. Adherence to medication

(OR 0.87 95% CI 0.8, 0.9; p <0.001) was statistically significant. With regard to anti-hypertensive agents, being on enalapril (OR 1.5 95% CI 1.1,2.1; p = 0.021) and hydrochlorthiazide (OR 2.7 95% CI 1.4,5.4; p = 0.024) were key predictors of BP control. Patients on enalapril were one and a half times as likely to have their BP controlled compared to those on other drugs. Those on HCTZ were approximately three times as likely to have their BP controlled compared to those on other anti-hypertensive agents. A summary of Bivariable regression analysis findings are summarized in Table 4.9.

4.6.2 Multivariable logistic regression analysis of blood pressure control and other variables

In multivariable regression analysis, the effect of the HHA was investigated and we adjusted for confounding for all variables that had a p-value of <0.2 on bivariate logistic regression analysis. The facility (adjusted OR 2.8 95% CI 1.5, 5.3; p=0.002) of accessing care was found to be a positive confounder for the HHA (adjusted OR 16.6 95% CI 3.8, 73.1; p<0.001) effect. This implies that patients in the HHA facilities are more likely to have their BP controlled compared to those in the non – HHA facilities. The wide confidence interval was probably due to random and systematic errors that lead to the lack of precision.

Patient's adherence (adjusted OR 3.5 95% CI 1.7, 7.3; p <0.001) to anti-hypertensive medication was also found to positive predictor of BP control since its inclusion into the final BP control predictor model increased the odds ratio of the HHA fivefold. Patients who were more adherent to their medication were more likely to have their BP controlled compared to the non-adherent ones.

Table 4.10: Bivariable regression analysis of the association between BP control and other variables.

	Totals n	BP controlled n (%)	BP not controlled n (%)	Crude OR (95% CI)	P value
Gender					
Female Male	120	74 (58.8%)	46 (58.9%)	0.971	0.921
	85	53 (41.7%)	32 (41.3%)	(0.5, 1.7)	
Age(years)					
<60	127	82 (64.6%)	45 (35.4%)	1.00	0.888
≥60	78	55 (70.5%)	23 (29.5%)	(0.9, 1.0)	
Marital status					
Single	29	21 (72.4%)	8 (27.6%)	1.180	0.395
Married	176	107 (60.8%)	69 (39.2%)	(0.8, 1.7)	
Level of education					
College/University	17	14 (82.4%)	3 (17.6%)		
Secondary	66	39 (59.1%)	27(40.9%)	0.682	0.088
Primary	111	72 (64.9%)	39 (35.1%)	(0.4, 1.0)	
No formal education	10	2 (20%)	8 (80%)		
Number of Anti-hypertensive	61	36 (59%)	25 (41%)	1.440	0.218
1	133	81 (60.9%)	52 (39.1%)	(0.8, 2.6)	
2	11	10 (90.9%)	1 (9.1%)		
3					
On a Thiazide diuretic					
Yes	157	101 (64.3%)	56 (35.7%)	1.5	**0.021**
No		32 (66.7%)	16 (33.3%)	(1.1,2.1)	
On Enalapril					
Yes	161	101 (62.7%)	60 (37.3%)	2.7	**0.024**
No		25 (56.8%)	19 (43.2%)	(1.4,5.4)	
Facility					
Kibera HC	59	40 (67.8%)	19 (32.2%)	0.811	0.106
Karen HC	38	38 (77.6%)	11 (22.5%)	(0.6, 1.0)	
Dandora I HC	51	18 (35.3%)	33 (64.7%)		
Dandora II HC	45	30 (66.7%)	15 (33.3%)		
HHA					**<0.001**
Yes	108	78 (72.2%)	30 (22.8%)	2.6	
No	97	49 (50.5%)	48 (49.5%)	(1.5, 4.6)	
Adherent to medication	72	58 (80.6%)	14 (19.4%)	0.87	**0.001**
Yes	133	54 (40.6%)	79 (59.4%)	(0.8, 0.9)	
No					

Table 4.11 Multivariable regression analysis between BP control and variables. Other predictor

Variable	Totals (n)	Adjusted Odds Ratio	P value
Facility			
Kibera HC	59		
Karen HC	38	**2.8**	**0.002**
Dandora HC	51	(1.5, 5.3)	
Dandora II HC	45		
Program			
Yes	108	**16.6**	**<0.001**
No	97	(3.7,73.1)	
Adherent to medication			**0.001**
Yes	72	**3.6**	
No	133	(1.7, 7.3)	

4.7 Barriers and challenges to hypertension management as reported by prescribers

Of the 14 prescribers interviewed, 5 were clinical officers and 9 were nursing officers. Eight (8) of the prescribers were female with the other 6 being male. The average duration of practice of the prescribers was 2 years ranging from 1 to 3 years. The prescribers interviewed reported that they attended to about 20 to 100 patients per clinic day.

4.7.1 Knowledge and application of treatment guidelines

All prescribers noted that appropriate staging of hypertension is a prerequisite to its effective management. However, only 5 (35.7%) out the 14 prescribers were aware of at least one hypertension management guideline. It is worthwhile noting that 3 (60%) out of the 5 prescribers were aware of and were using guidelines in management were those working in the health facilities enrolled in the HHA program. The other 9 (64.3%) relied on their clinical knowledge and did not have access to any guidelines. Five 5 (55%) out of these 9 were aware of the existence of guidelines but did not know how to access them.

The 5 (55%) prescribers who used clinical guidelines knew about the Joint National Committee-7 (JNC-7), JNC-8 and the Kenya National Guidelines for Cardiovascular Disease Management which they used for management of hypertension. Three 3 (33%) of them used both JNC-8 and Kenya National Guidelines for Cardiovascular Disease Management, one used only the JNC-7 guideline and the last one used the JNC-7 guidelines.

Most of the prescribers who were not using guidelines had not undergone any formal trainings on the use of these guidelines except a few times when these guidelines are mentioned in Continuous Medical Education (CMEs) sessions conducted in the hospital.

4.7.2 Challenges of management of Hypertension and recommendations

The two most commonly reported challenges faced by the prescribers when managing hypertension is poor adherence to medication and unavailability of medicines. Other challenges include costly medications, high cost of laboratory tests, poor follow up mechanisms by both healthcare providers and the patients, stock outs and shortages of anti-hypertensive medicines. Prescribers suggested counselling patients on adherence to medication, ensuring an efficient supply chain system to avoid stock outs and shortages, and improving the laboratories in the various hospitals to enable conducting the relevant tests such as blood chemistry (potassium, sodium, creatinine, fasting glucose, total cholesterol and HDL cholesterol needed to effectively manage hypertension.

4.8 Perceived outcomes of the Healthy Heart Africa HHA as reported by prescribers

Eight (8) prescribers in the health facilities enrolled into the Healthy Heart Africa HHA were in consensus that the strategies employed by the HHA had significantly contributed to Blood pressure control among the patients. Continuous patient counselling on adherence to medication, patient education on lifestyle modification, constant BP monitoring and reduced medicine stock outs were the major attributes of the HHA program contributing to the adequately controlled BP among patients.

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

5.1.1 Characteristics of hypertensive patients

The male to female ratio in this study was about 2:3 which is consistent with findings from other studies on management of hypertension that have found more women than men on treatment (1,7,22,28,41). In a study carried out at Kenyatta National Hospital in 2009, 32.4% of men and 67.6% of women recruited were on treatment for hypertension. A similar study in Mombasa in 2010 found that only 16% of the sampled patients were men and the rest were female (22). In yet another study on hypertensive patients in a regional referral hospital in Central Kenya females were found to constitute 72.6% of the sampled population (28). This gender difference is attributable to the different health seeking behavior among men and women. Females are likely to take a more active sick role and seek remedies to their medical situation compared men (42) who still give "a traditional masculine behavior" as their reason for not seeking help in time when they experience illness (43).

The mean age was found to be 54.1 years for all the patients. This is consistent with a similar study on hypertensive patients conducted in Ruiru sub county in Kiambu where the mean age was 55.8 years (41). The most common comorbidity among the hypertensive patients was diabetes with a prevalence of 24.9%. This prevalence was quite high but still demonstrated that hypertension and diabetes frequently coexist due to similar range of risk factors (43).

5.1.2 Level of Blood pressure control

The detected levels of BP control of 126 (61.5%) falls above the WHO recommended 50% for community control (44). This high BP control levels are attributed to the HHA program effect as 78 (62%) out of the 126 patients with adequate BP control were those enrolled into the program. In clinical trial settings 60% and 90% respectively of Systolic and Diastolic Blood pressure are often controlled (45,46). The program effect is therefore large as it places the BP control levels within those in a clinical trial setting. This changes are attributable to constant BP monitoring, availability and affordability of medicine and adherence to prescribed medicines (1,7,47).

The HHA program applied strategies such as emphasizing continuous BP checks through roadside monitoring early in the morning/late evenings and a monthly medical review of the patients to monitor their treatment progress. Continuous patient education on dietary restriction and the role of exercise in managing hypertension were also emphasized. A revolving pharmacy fund was established that lowered the cost of acquisition of the medicines and significantly reduced anti-hypertensive agents stock-outs.

5.1.3 Predictors of adequate blood pressure control

In this study adequacy of BP control was observed in 62% of all the patients enrolled in the study. However, 62% of those with adequate BP control were enrolled in the HHA program and only 38% accessed care from the non-HHA sites. The prevalence of well controlled BP from other studies carried in Kenya was found to be lower. A study at KNH found the prevalence of adequate BP control at 26% while two other studies done in Mombasa and Ruiru-Kiambu established a prevalence of 25% and 46% respectively (22,41,48). The higher overall proportion of patients with adequately controlled BP observed in our study is attributed to the HHA effect as a result of the different approaches and strategies employed in managing the hypertensive patients.

On the other hand, the prevalence of poorly controlled BP in our study at 38% was consistent with those of other Kenyan studies conducted in Mombasa, KNH and Ruiru. This prevalence is first attributed to financial hardship as most patients (87.6%) relied on out of pocket payment as means of paying for all their healthcare needs. High cost of medication (94%) and medicine stock out periods (84%) lasting more than 6 months were also implicated as key contributors to this poor BP control. A study conducted in Nyeri in 2013 also had similar findings and attributed the low prevalence of BP control (33%) to factors similar to old age, having diabetes and being on three or more drugs as significant contributors too (28).

The most important predictors of adequate BP control in this study were being in the HHA program (adjusted, **OR 16.6** 95% CI 3.8, 73.1; $p<0.001$), intra facility differences (adjusted **OR 2.8** 95% CI 1.5,5.3; $p=0.002$) and patient's adherence to anti-hypertensive medication.
Adherence to medication was the most important predictor of adequate BP control. Although having a comorbidity like Diabetes and Chronic Kidney disease was not a significant predictor of well controlled BP on bivariate analysis it was included in the multivariable analysis since

none of the patients in the HHA had a chronic disorder and this variable was therefore a potential source of bias. In addition, duration of illness and treatment were also included as they are known risk factors for inadequately controlled blood pressure. However, they did not affect the association between being in the HHA program and adequately controlled BP.The facility of accessing care was found to be negative confounder for the HHA program effect. On adjusting for confounding by facility the measure of association of the HHA and adequately controlled BP increased threefold. It was observed that facilities where BP was poorly controlled, the NCD clinics were run by community health workers; implying if the HHA drugs are handled by an unskilled healthcare worker the effectiveness of the HHA would be diminished.

Married people

5.1.4 Class and number of antihypertensive medications prescribed

The most commonly prescribed class of antihypertensives was thiazide diuretics (44.3% of the total prescriptions) followed by ACE inhibitors at 21.4%. Such practice involving high prescription of thiazide diuretics and ACEIs could be attributed to prescribers applying recommendations by the JNC-8 and ESC/ESH Guidelines for the management of arterial hypertension that recommend use of thiazide diuretics in black populations and use of ACEIs for their reno-protective properties in diabetic hypertensive patients (24,49).In addition, most patients were on 2 and 1-drug therapies at 64.9% and 29.8% respectively. Only % of the patients were on 3 drug regimen. Combination therapies accounted for about 70% of all prescriptions. This finding was consistent with findings from other two studies one in Kenya and another in India that found 55% and 60% of the prescriptions being combined therapy respectively (41,50).

5.1.5 Adherence to antihypertensive medication therapy

One specific objective of the study the HHA effect on adherence to antihypertensive therapy. It was noted that being in the HHA (adjusted, OR 16.6 95% CI 3.8, 73.1; $p<0.001$) and intra facility differences (adjusted OR 2.8 95% CI 1.5,5.3; $p=0.002$) had a statistically significant influence on adherence both having p values less than 0.005. This is attributed to the improved approach and strategies of managing hypertension adopted by the HHA that included constant BP monitoring and availability and affordability of medicine.Other strategies that have been shown to improve adherence are a revolving fund pharmacy, adequate staff, adequate number

of BP monitoring machines and roadside BP monitoring. A study on Effectiveness of pharmacy interventions in improving availability of essential medicines at the primary healthcare level demonstrated improved availability of medicines when the revolving fund approached is used. There was a 91% improvement in availability of medicines in Nigerian health facilities and 85% in Ethiopia and Laos (51).

Patient education and counselling on medication use also contributed greatly to improved adherence to medication. Healthy Heart Africa adopted various approaches to promote patient education. Information booklets, one-on-one trainings on importance of adherence and lifestyle modification were the most preferred approaches. Patients were also organized into support groups from which an assigned healthcare would screen them and offer periodical trainings on effective ways of controlling their blood pressure including adherence to prescribed medicines (51,52).A systematic review and meta-analysis on interventions to improve adherence among hypertensive patients demonstrated that some of the most promising intervention components include educating patients on linking adherence behavior with daily habits, providing adherence feedback to patients, self-monitoring of blood pressure, special packaging of medications, and motivational interviewing (47). An unrelated randomized controlled study in 2019 on the effect of patient education on adherence to medication among patients with rheumatoid arthritis also demonstrated a significant improvement in adherence from baseline when patient education is included and emphasized upon as part of management of chronic conditions (53).

5.1.6 Cost implication on the access to antihypertensive therapy

A major challenge to accessing healthcare services in poor resource sub-Saharan African countries is the cost of prescription medicines as most of patients rely on out of pocket payment method as their only means of funding their healthcare needs (33,34). Average monthly acquisition costs of the anti-hypertensive medications was calculated in this study. Hydrochlorthiazide had lowest monthly cost at ksh.30 in the non-HHA hospitals and retail price of between Ksh. 30-90 in the community Pharmacies. Most patients found these prices affordable. Thiazide diuretics have generally been found to be the cheapest among various antihypertensive agents and most cost effective among the various antihypertensive drug classes. A cost minimization analysis conducted in the US, Canada and four other European countries on the potential savings of using thiazides as the first choice antihypertensive drug

found that millions of dollars could be saved if thiazide diuretics were prescribed more often in place of other expensive antihypertensive agents (54). Another study conducted in Nigeria also showed similar findings (55).

Among the other antihypertensive agents' losartan, felodipine, lisinopril and amlodipine were found to be the most expensive at over and above Ksh. 30 per tablet. Acquisition of such drugs puts the patients through serious financial hardships as most of them live below a dollar per day. The HHA program uses felodipine and lisinopril in managing 98% of the patients enrolled in the HHA. Monthly doses of these drugs are provided to the patients at a subsidized price of Ksh 100. The retail prices of each of the above is between Ksh. 2800- 3600 and Ksh. 2000-2800 respectively. This therefore means the cost of acquisition of these drugs is way higher than Ksh 100 and such raises a sustainability issue since the prices are more than tenfold the daily earnings of people living in poor resource settings.

5.1.7 Prescribers adherence to Treatment Guidelines

Knowledge and compliance to treatment guidelines was reported at 35.7% of all the prescribers interviewed. Prescribers from the hospitals enrolled into the HHA were the most compliant to the guidelines at 60%. Among the noncompliant prescribers, 70% reported unawareness and unavailability of the guidelines while the rest relied on their clinical judgement in managing hypertension. Other reasons for noncompliance were lack of training on current guidelines, their unavailability in print and a high workload; hence no time for continuous medical education (CME) and access to the online copies of these documents. This was contrary to previous findings in other studies like one at KNH that assessed rational prescribing of antihypertensives and clinician adherence to guidelines at 79% (48). A study in Malaysia also reported very high percentage of adherence to treatment guidelines by physicians which decreased significantly when managing patients with coexisting comorbidities (56).

The differences in adherence to the guidelines can be explained by the levels of the hospitals. Kenyatta National Hospital being a level 6 hospital has highly specialized staff with proper training on hypertension management using the guidelines. Secondly, KNH has non communicable diseases (NCDs) clinics run by specialist in the area. On the contrary, the level 3 Hospitals are run mostly by Clinical Officers and nursing officers most of whom have no specialist training in NCDs management.

5.1.8: Inaccurate Diagnosis of Hypertension

A patient is considered to be hypertensive if the average of their BP readings after three or more consecutive readings taken at least 30 minutes apart is found to be above >140/90mmHg or above 150/100 mmHg for older patients above 60 years. At least 28 patients managed at the public health facilities had been wrongly diagnosed as being hypertensive. Among those enrolled in the program, eight (8) patients were found to have been wrongly diagnosed and were on treatment despite not being hypertensive at the beginning of these treatment period(24,31,49).

At diagnosis only 71% of patients seeking services in the non-HHA facilities were found to be hypertensive compared to 93% of those in the HHA an indication of misdiagnosis of hypertension. A study conducted to estimate the prevalence of pseudo-resistant hypertension due to inaccurate blood pressure measurement found the prevalence of inaccurate BP taking techniques to be around 33.1% for patients referred to a hypertension specialty clinic at the time of the initial visit attributable to poor BP reading technique (47).

There are currently no studies on BP misdiagnosis and classification but the findings above are inconsistent with the requirement of various guidelines including JNC-8 guidelines (49) and the European Society of Cardiology (ESC) and by the European Society of Hypertension (ESH) (24). This misdiagnosis is attributed to failure of healthcare workers to correctly take or interpret BP readings at triage due to lack of or failure to adhere to treatment guidelines.

5.19 Limitations of the study

This study used qualitative interviews from prescribers to authenticate the quality of quantitative data obtained from records and the patients' interview on adherence to medication. However, retrospective data from patient's records and survey responses from this study may not have been accurate and complete in certain circumstances. Furthermore, this study focused on four health centers and could not capture all aspects of hypertension management due to cost and time limitations.

5.2 Conclusion

Patients managed at the HHA enrolled facilities had their Blood pressure levels adequately controlled compared to those in non-HHA health facilities. These patients were also observed to be highly adherent to their antihypertensive therapy. Due to their inclusion into the program, they were least affected by high cost of medication and constant antihypertensive agents stock outs witnessed in non-HHA facilities. Adherence to antihypertensive therapy and patient's level of education had a better prediction of adequate BP control than many other variables. Additionally, intra facility differences in approach and management of hypertension also had significant influence on this outcome. These differences ranged from prescribers' knowledge of hypertension management to those touching on BP monitoring equipment and their handling techniques.

Overall the Healthy Heart Africa HHA had superior strategies of managing hypertension compared to those employed in some of the non-HHA health facilities. The HHA provided high quality medicine at affordable prices. In addition, it offered sufficient patient education on hypertension followed by counselling on the need and benefits of adherence to the prescribed medication. Furthermore, the HHA offered constant BP screening including roadside BP monitoring. Consequently, 72% patients enrolled in the HHA had their blood pressure adequately controlled compared to 50.5% in the unenrolled sites.

5.3 Recommendations

5.3.1 Policy changes and/or implementation

There is an urgent need to disseminate sufficient copies of the Kenya national guidelines on management of various cardiovascular disease 2018 to all healthcare workers. If possible the disseminated document should be in hardcopies.

Regular training of healthcare workers dealing with hypertensive patients is required to ensure that they keep up to date with changing trends with emerging new evidence for management of these patients.

Healthcare workers managing hypertensive patients should strongly adhere to proper BP measurement/taking procedure as articulated in the treatment guidelines; including allowing

adequate resting time before BP measurement and taking three (3) independent BP readings then determining an average.

Consistent supply of medicines to the hospital pharmacy at subsidized prices, support groups for hypertensive patients, free patient counselling, laboratory and imaging services and standardized forms for review are some of the interventions that can be considered for all healthcare facilities. These will enhance delivery of optimal care to hypertensive patients by the health workers.

Programs similar to HHA should be designed and scaled up to cover numerous facilities so that large numbers of patients benefit. The programs should have standardized way of reporting strategies, progress and achievements with a view of helping the government improve its healthcare delivery priorities and strategies.

5.3.2 Further research

A pharmacoeconomic evaluation comparing the cost of acquisition of anti-hypertensive medications and income level of the patients should be investigated as accessibility to medicines is a key factor in adherence to medication. A prospective study on hypertension treatment outcomes and adherence should also be conducted

Studies on why there exists a gender difference among hypertensive patients need to be carried by sampling larger populations. Other studies on the effect of prescriber knowledge on the outcomes of hypertension management should also be conducted.

Future research should also look into the Hypothesis that optimization of dosing thiazide diuretics and enalapril may the reason that they appear to be key determinants of adequacy of BP control.

In this study blood pressure control was only assessed based on certain parameters like periodical blood pressure readings, level of adherence to medication and the cost implication of drugs to patients. Ordinarily, data of this nature is vital to controlling hypertension but other specific studies should be undertaken to assess other factors that also affect hypertension management and control.

5.3.3 Disclosure of conflict of interest

The researcher is no way affiliated to and up until the time this report was compiled was not in any gainful employment with any of the HHA program implementing partners.

REFERENCES

Achieng' L, Joshi MD, Ogola EN, Karari E. Adequacy of blood pressure control and level of adherence with antihypertensive therapy. East Afr Med J [Internet]. 2009 Jan 1 [cited 2018 Oct 11];86(11):499-506–506.Availablefrom: https://www.ajol.info/index.php/eamj/article/view/55826

Kayima J, Wanyenze RK, Katamba A, Leontsini E, Nuwaha F. Hypertension awareness, treatment and control in Africa: a systematic review. BMC Cardiovasc Disord [Internet]. 2013 Aug 2 [cited 2018 Oct 15];13(1):54. Available from: https://doi.org/10.1186/1471-2261-13-54

Kim MT, Hill MN, Bone LR, Levine DM. Development and Testing of the Hill-Bone Compliance to High Blood Pressure Therapy Scale. Prog Cardiovasc Nurs [Internet]. 2000 Jun 1 [cited 2018 Oct 15];15(3):90–6. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1751-7117.2000.tb00211.x

Hashmi SK, Afridi MB, Abbas K, Sajwani RA, Saleheen D, Frossard PM, et al. Factors Associated with Adherence to Anti-Hypertensive Treatment in Pakistan. PLoS ONE [Internet]. 2007 Mar 14 [cited 2018 Oct 15];2(3). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1805684/

Hendriks ME, Wit FWNM, Roos MTL, Brewster LM, Akande TM, de Beer IH, et al. Hypertension in sub-Saharan Africa: cross-sectional surveys in four rural and urban communities. PloS One. 2012;7(3):e32638.

James PA, Oparil S, Carter BL, Cushman WC, Dennison-Himmelfarb C, Handler J, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). JAMA [Internet]. 2014 Feb 5 [cited 2018 Oct 12];311(5):507–20. Available from: https://jamanetwork.com/journals/jama/fullarticle/1791497

Muthuki EW, Nyamu DG, Karimi PN, Bosire KO. Predictors of non-adherence to antihypertensive therapy in a rural health facility in Kenya. Afr J Pharmacol Ther [Internet]. 2020 Jun 30 [cited 2020 Nov 27];9(2). Available from: http://journals.uonbi.ac.ke/ajpt/article/view/1913

Opie LH, Seedat YK. Hypertension in sub-Saharan African populations. Circulation. 2005 Dec 6;112(23):3562–8.

Law MR, Morris JK, Wald NJ. Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies. BMJ [Internet]. 2009 May 19

[cited 2018 Oct 15];338:b1665. Available from: https://www.bmj.com/content/338/bmj.b1665

Flor LS, Wilson S, Bhatt P, Bryant M, Burnett A, Camarda JN, et al. Community-based interventions for detection and management of diabetes and hypertension in underserved communities: a mixed-methods evaluation in Brazil, India, South Africa and the USA. BMJ Glob Health [Internet]. 2020 Jun 1 [cited 2020 Nov 25];5(6):e001959. Available from: https://gh.bmj.com/content/5/6/e001959

Wamba AA, Takah NF, Johnman C. The impact of interventions for the primary prevention of hypertension in Sub-Saharan Africa: A systematic review and meta-analysis. PLOS ONE [Internet]. 2019 Jul 19 [cited 2020 Nov 25];14(7):e0219623. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0219623

Jongen VW, Lalla-Edward ST, Vos AG, Godijk NG, Tempelman H, Grobbee DE, et al. Hypertension in a rural community in South Africa: what they know, what they think they know and what they recommend. BMC Public Health [Internet]. 2019 Mar 25 [cited 2020 Nov 25];19(1):341. Available from: https://doi.org/10.1186/s12889-019-6642-3

Katende G, Groves S, Becker K. Hypertension Education Intervention with Ugandan Nurses Working in Hospital Outpatient Clinic: A Pilot Study [Internet]. Vol. 2014, Nursing Research and Practice. Hindawi; 2014 [cited 2020 Nov 25]. p. e710702. Available from: https://www.hindawi.com/journals/nrp/2014/710702/

Organisation mondiale de la santé. Global status report on no communicable diseases 2014: attaining the nine global no communicable diseases targets; a shared responsibility. Geneva: World Health Organization; 2014.

Joshi MD, Ayah R, Njau EK, Wanjiru R, Kayima JK, Njeru EK, et al. Prevalence of hypertension and associated cardiovascular risk factors in an urban slum in Nairobi, Kenya: A population-based survey. BMC Public Health [Internet]. 2014 Nov 18 [cited 2018 Oct 11];14(1):1177. Available from: https://doi.org/10.1186/1471-2458-14-1177

Giles TD, Materson BJ, Cohn JN, Kostis JB. Definition and Classification of Hypertension: An Update. J Clin Hypertens [Internet]. 2009 Nov 1 [cited 2018 Nov 19];11(11):611–4. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1751-7176.2009.00179.x

Lloyd-Jones DM, Evans JC, Larson MG, O'Donnell CJ, Wilson PWF, Levy D. Cross-classification of JNC VI Blood Pressure Stages and Risk Groups in the Framingham Heart Study. Arch Intern Med [Internet]. 1999 Oct 11 [cited 2018 Nov 19];159(18):2206–12. Available from: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/485141

Weber MA, Schiffrin EL, White WB, Mann S, Lindholm LH, Kenerson JG, et al. Clinical Practice Guidelines for the Management of Hypertension in the Community. J Clin Hypertens [Internet]. 2014 Jan 1 [cited 2018 Nov 19];16(1):14–26. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/jch.12237

Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Joseph L. Izzo J, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: The JNC 7 Report. JAMA [Internet]. 2003 May 21 [cited 2018 Nov 19];289(19):2560–71. Available from: https://jamanetwork.com/journals/jama/fullarticle/196589

Nwankwo T, Yoon SS, Burt V, Gu Q. Hypertension among adults in the United States: National Health and Nutrition Examination Survey, 2011-2012. NCHS Data Brief [Internet]. 2013 Oct [cited 2018 Nov 20];(133):1–8. Available from: http://europepmc.org/abstract/med/24171916

Kearney PM, Whelton M, Reynolds K, Whelton PK, He J. Worldwide prevalence of hypertension: a systematic review. J Hypertens [Internet]. 2004 Jan [cited 2018 Nov 20];22(1):11. Available from: https://journals.lww.com/jhypertension/Abstract/2004/01000/Worldwide_prevalence_of_hypertension___a.3.aspx

Jenson A, Omar AL, Omar MA, Rishad AS, Khoshnood K. Assessment of hypertension control in a district of Mombasa, Kenya. Glob Public Health [Internet]. 2011 Apr 1 [cited 2018 Nov 20];6(3):293–306. Available from: https://doi.org/10.1080/17441692.2010.510478

Lurbe E, Agabiti-Rosei E, Cruickshank JK, Dominiczak A, Erdine S, Hirth A, et al. 2016 European Society of Hypertension guidelines for the management of high blood pressure in children and adolescents. J Hypertens [Internet]. 2016 Oct [cited 2018 Nov 19];34(10):1887. Available from: https://journals.lww.com/jhypertension/Abstract/2016/10000/2016_European_Society_of_Hypertension_guidelines.2.aspx

Mancia G, Fagard R, Narkiewicz K, Redon J, Zanchetti A, Böhm M, et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension. Blood Press [Internet]. 2013 Aug 1 [cited 2018 Nov 19];22(4):193–278. Available from: https://doi.org/10.3109/08037051.2013.812549

Shanthirani CS, Pradeepa R, Deepa R, Premalatha G, Saroja R, Mohan V. Prevalence and risk factors of hypertension in a selected South Indian population--the Chennai Urban Population Study. J Assoc Physicians India [Internet]. 2003 Jan 1 [cited 2018 Nov 28];51:20–7. Available from: http://www.japi.org

Wang H, Zhang X, Zhang J, He Q, Hu R, Wang L, et al. Factors Associated with Prevalence, Awareness, Treatment and Control of Hypertension among Adults in Southern China: A Community-Based, Cross-Sectional Survey. PLOS ONE [Internet]. 2013 May 9 [cited 2018 Nov 28];8(5):e62469. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0062469

Wang W, Lee ET, Fabsitz RR, Devereux R, Best L, Welty TK, et al. A Longitudinal Study of Hypertension Risk Factors and Their Relation to Cardiovascular Disease: The Strong Heart Study. Hypertension [Internet]. 2006 Mar 1 [cited 2018 Nov 28];47(3):403–9. Available from: https://insights.ovid.com/hype/200603000/00004268-200603000-00024

Mutua EM, Gitonga MM, Mbuthia B, Muiruri N, Cheptum JJ, Maingi T. Level of blood pressure control among hypertensive patients on follow-up in a Regional Referral Hospital in Central Kenya. Pan Afr Med J [Internet]. 2014 Aug 5 [cited 2018 Oct 15];18. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4258197/

Appel Lawrence J., Brands Michael W., Daniels Stephen R., Karanja Njeri, Elmer Patricia J., Sacks Frank M. Dietary Approaches to Prevent and Treat Hypertension. Hypertension [Internet]. 2006 Feb 1 [cited 2018 Nov 20];47(2):296–308. Available from: https://www.ahajournals.org/doi/abs/10.1161/01.hyp.0000202568.01167.b6

Ojji DB, Poulter N, Damasceno A, Sliwa K, Smythe W, Kramer N, et al. Rationale and design of the comparison of 3 combination therapies in lowering blood pressure in black Africans (CREOLE study): 2 × 3 factorial randomized single-blind multicenter trial. Am Heart J. 2018;202:5–12.

Ojji DB, Poulter N, Damasceno A, Sliwa K, Smythe W, Kramer N, et al. Rationale and design of the comparison of 3 combination therapies in lowering blood pressure in black Africans (CREOLE study): 2 × 3 factorial randomized single-blind multicenter trial. Am Heart J. 2018;202:5–12.

Solanki K, Mistry R, Singh A, Jadav S, Patel N, Trivedi H. Drug utilization study of anti-hypertensive drugs and their adverse effects in patients of a tertiary care hospital. J Clin Exp Res [Internet]. 2013 [cited 2018 Nov 20];1(3):58. Available from: http://www.scopemed.org/fulltextpdf.php?mno=49075

Kiwanuka SN, Ekirapa EK, Peterson S, Okui O, Rahman MH, Peters D, et al. Access to and utilisation of health services for the poor in Uganda: a systematic review of available evidence. Trans R Soc Trop Med Hyg [Internet]. 2008 Nov 1 [cited 2018 Nov 21];102(11):1067–74. Available from: https://academic.oup.com/trstmh/article/102/11/1067/1935286

Ensor T, Cooper S. Overcoming barriers to health service access: influencing the demand side. Health Policy Plan. 2004 Mar;19(2):69–79.

Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B, et al. Access to medicines from a health system perspective. Health Policy Plan [Internet]. 2013 Oct 1 [cited 2018 Oct 12];28(7):692–704. Available from: https://academic.oup.com/heapol/article/28/7/692/819804

Martino MD, Veronesi C, Esposti LD, Scarpa F, Buda S, Didoni G, et al. Adherence to antihypertensive drug treatment and blood pressure control: a real practice analysis in Italy. J Hum Hypertens [Internet]. 2008 Jan [cited 2018 Oct 12];22(1):51–3. Available from: https://www.nature.com/articles/1002253

Krousel-Wood M, Thomas S, Muntner P, Morisky D. Medication adherence: a key factor in achieving blood pressure control and good clinical outcomes in hypertensive patients. Curr Opin Cardiol [Internet]. 2004 Jul [cited 2018 Nov 21];19(4):357. Available from: https://journals.lww.com/co-cardiology/Abstract/2004/07000/Medication_adherence__a_key_factor_in_achieving.11.aspx

Lambert E. Cross-cultural validation of the Hill-Bone compliance to high blood pressure therapy scale in a South African, primary health care setting. Am J Hypertens [Internet]. 2002 Apr [cited 2018 Nov 19];15(4):A200. Available from: https://academic.oup.com/ajh/article-lookup/doi/10.1016/S0895-7061(02)02817-0

Mbui JM, Oluka MN, Guantai EM, Sinei KA, Achieng L, Baker A, et al. Prescription patterns and adequacy of blood pressure control among adult hypertensive patients in Kenya; findings and implications. Expert Rev Clin Pharmacol [Internet]. 2017 Nov 2 [cited 2018 Nov 20];10(11):1263–71. Available from: https://doi.org/10.1080/17512433.2017.1371590

Mufunda E, Albin B, Hjelm K. Differences in Health and Illness Beliefs in Zimbabwean Men and Women with Diabetes. Open Nurs J [Internet]. 2012 Sep 6 [cited 2019 Jul 24];6:117–25. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3439846/

Galdas PM, Cheater F, Marshall P. Men and health help-seeking behaviour: literature review. J Adv Nurs [Internet]. 2005 [cited 2019 Jul 24];49(6):616–23. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1365-2648.2004.03331.x

APPENDICES

Appendix A: Patient Eligibility Checklist Patient No. ……

Is the patient 18 years and above?	YES ( ) NO( )
Diagnosed with hypertension in the last 6 months or more?	YES ( ) NO( )
Has been on hypertension treatment in the last 6 months	YES ( ) NO ( )
Does the patient have their current BP reading and two other readings taken at least 4 weeks apart in the last 3 months	YES ( ) NO( )
Does the patient access care at one of the study sites	YES ( ) NO( )
Which study site does the patient access hypertension management?	

APPENDIX B: DATA COLLECTION SHEET 1.7

Patient's Demographics	
Age	
Sex	
Education level	
Marital Status	
Occupation	
Patient's Characteristics	
Weight	
Height	
Date of diagnosis	
BP at diagnosis	
Duration of treatment	
BP reading	
Current reading (3rd Month)	
2nd month's reading	
1st month's reading	
Comorbidities	Diabetes Cardiovascular diseases Renal problems Others (Specify) …… ……
Anti- hypertensive medications and Dosages	
Other drugs prescribed during the last visit	
Additional comments/information	

APPENDIX C: QUESTIONNAIRE FOR THE PATIENTS

Adapted from Hill-Bone compliance with high blood pressure therapy medication taking subscale

No	Item	Responses None of the time Some of the time Most of the time All of the time
1	How often do you forget to take your HBP medicines?	
2	How often do you decide NOT to take your HBP medicines?	
3	How often do you miss to take your medicines because you feel better?	
4	How often do you do you decide to take less of your prescribed medicine?	
5	How often do you stop taking your medicine because you feel sick due to effects of the medicine?	
6	How often do you forget to bring along your medicine when you travel away from home?	
7	How often do you NOT take you medicine because you run out of them at home?	
8	How often do you miss your HBP pills when you are feeling sick?	

What are some of the challenges you have regarding your anti-hypertensive medication?

……

……

……

……

……

……

APPENDIX D: KISWAHILI TRANSLATION OF THE QUESTIONNAIRE FOR PATIENTS

Nambari	**Kipengee**	**Majibu** **Hakuna wakati** **Nyakati zingine** **Nyakati mingi** **Nyakati zote**
1.	Mara ngapi unasahau kumeza madawa yako ya kudhibiti shinikizo la damu?	
2.	Ni mara ngapi unapoamua kuacha kutumia madawa hayo?	
3.	Ni mara ngapi unakosa kumeza madawa hayo kwa sababu unajihisi vema mwilini?	
4.	Ni mara ngapi unaamua kutumia madawa chini ya kiwango kilichopendekezwa na mhudumu wako wa afya?	
5.	Ni mara ngapi unaacha kumeza madawa yako kwa sababu unajihisi mgonjwa kutokana na madhara ya madawa yenyewe?	
6.	Ni mara ngapi unasahau kubeba madawa yako wakati unapokuja kliniki?	
7.	Ni mara ngapi wewe hukosa kumeza madawa yako kwa sababu madawa yenyewe yameisha?	
8.	Ni mara ngapi unakosa madawa yako ya kudhibiti shinikizo la damu wakati unajihisi mgonjwa?	

Je, ni changamoto zipi unazo kuhusu dawa yako ya kudhibiti na shinikizo la damu?

.....

.....

.....

.....

APPENDIX E: INTERVIEW SCHEDULE

Section A: Background Information

1. 1. Gender Male () Female ()
2. Highest Education level…….
3. Years of experience ……...

4. What is the approximate number of patients seen per clinic day (workload)?.....
5. Are you aware of any Hypertension treatment guidelines? (YES/NO)
   …… (If Yes, List any 2)
   i.……
   ii. ……
6. In a scale of 1-10, what is your level of adherence to this guidelines?
   (1-poorly adherent, 10- Very adherent)
   ……
7. What are some of the barriers to adherence to treatment guidelines?
   i. ……..
   ii. ……..
   iii. ……..
   iv. …….
   v. ……
8. What are some of the challenges faced in the management of hypertensive patients?
   i. ……
   ii. ……
   iii. ……
   iv. ……
   v. ……
9. Approximately how long is a stock out period for this facility? (in months)

10. Do these stock out periods affect the supply of anti-hypertensive medicines?
    (YES/NO)

Section B: Impact of the Healthy Heart Africa (HHA) on adequate blood pressure control

1. Do you think HHA has managed to adequately control BP of the patients? Support your answer.

   ……
   ……

2. Do you think the patients strictly adhere to their medication? Why do you think so?

   ……
   ……

3. What are the factors that influence adhere to hypertensive medication?

   ……
   ……

4. What are the successes of HHA?

   ……
   ……

5. What are the challenges facing the adoption and implementation of HHA?

   ……
   ……

6. How best can the above challenges be averted?

   ……
   ……

APPENDIX F: COST OF SELECTED DRUGS USED IN THE STUDY

Generic name	Dosage form	Price per unit(Ksh)
Amlodipine 5mg	Tablets	2.20
Atenolol 50mg	Tablets	1.00
Enalapril 5mg	Tablets	2.45
Enalapril 10mg	Tablets	0.65
Furosemide 40mg	Tablets	0.90
Hydrochlorthiazide 50mg	Tablets	0.40
Losartan 50mg	Tablets	2,20
Methyldopa 250mg	Tablets	2.95
Nifedipine retard 20mg	Tablets	0.35
Spironolactone 50mg	Tablets	3.80
Felodipine	Tablets	120
Lisinopril	Tablets	79

APPENDIX G: CONSENT FORM FOR INTERVIEW WITH KEY INFORMANTS AND PATIENTS

To be read in a language that the respondent is fluent in.

Title of the study: Outcomes of the Healthy Heart Africa HHA on management of hypertensive patients in Nairobi County, Kenya.

Institution: Department of Pharmacology and Pharmacognosy, School of Pharmacy,

University of Nairobi, P.O BOX 30197-00400, Nairobi.

Investigator: Dr. Otieno P. Ochieng, P.O BOX, 30197-00400, Nairobi.

Supervisors: Prof Faith Okalebo, Dr. M.O. Oluka, and Dr. Eric Guantai - Department of Pharmacology and Pharmacognosy;

Ethical Approval: Kenyatta National Hospital/ University of Nairobi Ethical and Research

Committee, P.O BOX 20723-00100, Nairobi. Tel 2726300/2716450 Ext 44102

Permission is requested from you to enroll in this medical research study. You should understand the following general principles, which apply to all participants in a medical research:

i. Your agreement to participate in this study is voluntary.

ii. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.

iii. After you have read the explanation, please feel free to ask any questions that will enable you to understand clearly the nature of the study.

iv. The interview is anticipated to last 15-30 minutes

Introduction: In this study, I am assessing **Outcomes of the Healthy Heart Africa HHA on management of hypertensive patients in Nairobi County, Kenya**.

Purpose of the study: The purpose of this study is to broadly identify and characterize current practices in the management of Hypertension and specifically ascertain to what extent the interventions made under the HHA have helped in lowering the prevalence of hypertension by investigating the adequacy of blood pressure control.

Procedure: With your permission, Iwill engage you in a discussion that will allow me collect data on various aspects of management of hypertension. I will also retrieve your treatment record for the purposes of extracting data on your current BP reading and two other BP readings taken at least two weeks apart. I will extract from these records all your prescribed anti-hypertensive medication and the doses plus any other diseases you may be suffering from concurrently. I will record all your responses in the data collection sheets. I will also take some notes on pen and paper where necessary. All information obtained will be handled with confidentiality. This procedure will be repeated in all four different study sites and the data obtained will be compared during analysis.

Risks: There will be no risks involved in this study.

Benefits: There will be no direct benefits to you but the findings will be useful in improving the quality care among patients diagnosed with elevated blood pressure, through identification and implementation of any superior practices that shall be identified from the HHA HHA.

Assurance of confidentiality: All information obtained from you will be kept in confidence. At no point will your name be mentioned or used during data handling or in any resulting non-HHAtions. Codes will be used instead.

Who can you talk to if I have further questions?

If you have any further questions or concerns about participating in this study, please call or send a text message to the researcherthrough the number provided at the bottom of the last page.

For more information about your rights as a research participant you may contact the **Chairperson, Kenya National Hospital- University of Nairobi Ethics and Research Committee Prof. Anastasia Guantai** on Telephone no. **2726300** Ext**. 44102** Email: **uonknh_erc@uonbi.ac.ke**

APPENDIX H: CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study staff. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study:	**Yes**	**No**
I agree to provide contact information for follow-up:	Yes	No

Participant name: _____

Participant signature/Thumb stamp_____ Date _____

Researcher's Agreement

I confirm that the participant has been given an opportunity to ask questions about the study, and all the questions have been answered correctly and to the best of my ability. I confirm that the participant has understood and knowingly given consent.

Researcher's signature _____

Date_____

You can contact the following researcher at;

Otieno Preston Ochieng
School of Pharmacy,
University of Nairobi
otienopreston01@gmail.com
+254773140622

APPENDIX I: KISWAHILI TRANSLATION OF CONSENT FORM FOR INTERVIEW WITH KEY INFORMANTS AND PATIENTS

HATI HII IMEKUSUDIWA KUSOMWA KWA LUGHA AMBAYO MHOJIWA ANAIELEWA FIKA.

Mada ya utafiti: Matokeo ya Mpango wa Afya ya moyo barani Afrika (HealthyHeart Africa) kuhusu matibabu wanaopewa wagonjwa wa shinikizo la damu katika kata ya Nairobi, nchini Kenya.

Taasisi: Idara ya Famakolojia na Famakognisia, Shule ya Famasia, Chuo Kikuu cha Nairobi, Sanduku la Posta 30197-00400, Nairobi.

Mtafiti: Dkt. Otieno P. Ochieng, Sanduku la Posta, 30197-00400, Nairobi.

Wasimamizi: Profesa Faith Okalebo, Dkt. M.O. Oluka, na Dkt. Eric Guantai – Wote kutoka Idara ya Famakolojia na Famakognosia, Chuo kikuu cha Nairobi.

Idhini ya Kimaadili: Utafiti huu umeidhinishwa na kamati ya Maadili na Utafiti ya Hospitali Kuu ya Kenyatta-Chuo Kikuu cha Nairobi. Nambari ya usajili ni…….

Sanduku la Posta 20723-00100, Nairobi. Nambari za simu (44102)-2726300/2716450.

Utangulizi: Ningependa kukualika kushiriki katika utafiti huu. Kabla ya kufanya uamuzi wako, nitakupa maelezo yote kuhusu utafiti huu itakayokusaidia kuamua iwapo utashiriki au la. Jisikie huru kunikatiza wakati wowote kwa ajili ya kuuliza maswali kuhusu madhumuni ya utafiti huu, madhara au faida yoyote inayowezatokea kutokana na kushiriki katika utafiti huu au jambo lingine lolote linalohusiana na utafiti huu. Ikiwa utahisi umeridhika na maelezo kuhusu utafiti huu na baada ya maswali yako yote kujibiwa, utahitajika kutia sahihi yako kwenye fomu ya ridhaa iwapo utaamua kushiriki. Pia ni vema kuelewa kwamba uamuzi wa kushiriki katika utafiti huu ni kwa hiari yako na uko huru kujiondoa kwenye utafiti wakati wowote bila ya kutoa sababu . Kukataa kushiriki haitaathiri kwa njia yoyote huduma ambayo una haki ya kupata katika hospitali hii. Nitakupa nakala ya fomu hii kwa rekodi yako.

Naweza kuendelea? NDIO LA

Kusudi la utafiti: Kusudi la utafiti huu ni kutambua na kufafanua mbinu za kisasa katika matibabu ya shinikizo la damu na hasa kujua jinsi hatua zilizochukuliwa chini ya mpango wa HHA zimesaidia kupunguza makali na kiwango cha kuenea kwa shinikizo hili la damu miongoni mwa wanaougua.

Utaratibu: Kwa idhini yako, nitakuhusisha kwenye majadiliano ambayo yataniwezesha kukusanya na kupata maelezo mwafaka kuhusu vipengele mbalimbali vya matibabu ya shinikizo la damu. Mimi kama matafiti nitachimbua rekodi yako ya matibabu kwa makusudi ya kudondoa data kuhusu vipimo vyako vya shinikizo la damu kwa muda wa miezi tatu zilizopita. Nitachukua kipimo chako cha shinikizo la damu la leo na kuchimbua vipimo vingine viwili kutoka kwenye rekodi yako ambavyo vilichukulia kadri miezi mitatu zilizopita. Nitadondoa kwenye rekodi hizi madawa yako yote yaliyopendekezwa na mhudumu wa afya kwa makusudi ya kudhibiti shinikizo lako la damu. Juu ya hayo nitadondoa data kuhusu magonjwa mengine yoyote ambayo unaweza kuwa unakabiliwa nayo kwa nyakati zilizopita na hata kwa wakati huu. Nitaandika rekodi zako zote katika karatasi za kukusanya data. Taarifa zote utakazonipa zitashughulikiwa kwa siri.

Hatari: Hakuna hatari zozote zinazohusika na utafiti huu lakini mimi kama mtafiti nitahakiksha mazingira tunayofanya majadiliano haya yana usalama wa kutosha.

Kuna faida yoyote kwangu ikiwa nitaamua kushiriki katika utafiti huu?

Manufaa kuu utakayopata kutoka kwa utafiti huu ni kupewa mawaidha ya namna ya kufuatilia shinikizo lako la damu. Isitoshe utapata mawaidha kuhusu mlo ambazo ni hatari na zinazowezakupa changamoto kadha za kudhibiti shinikizo lako la damu. Maelezo mengine utakayopata ni yale kuhusu mbinu mwafaka ya matumizi ya madawa yote uliyopendekezewa na mhudumu wako wa afya.

Je, kuna gharama au malipo itakayotokana na kushiriki katika utafiti huu?

Hakutakuwa na gharama kwako kwa kushiriki katika utafiti huu. Hutapata fedha au aina yoyote ya fidia kwa kushiriki katika utafiti huu.

Je, haki zangu kama mshiriki katika utafiti huu ni zipi?

Kushiriki kwako katika utafiti huu ni kwa hiari. Kujiondoa au kukataa kushiriki katika utafiti hautaathiri kwa namna yoyote matibabu unayopokea katika hospitali hii sasa na siku za usoni.

Ninaweza kuwasiliana na nani ikiwa nina maswali?

Ikiwa una maswali zaidi au mahangaiko juu ya kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi wa simu kwa wafanyakazi wa utafiti huu kwa namba iliyotolewa mwishoni mwa maelezo haya.

Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu / Mwenyekiti, Kamati ya Maadili na Utafiti ya **Hospitali Kuu ya Kenyatta-Chuo Kikuu cha Nairobi;** Nambari ya simu 2726300 Ext. 44102 Barua pepe**: uonknh_erc@uonbi.ac.ke** .

FOMU YA RIDHAA (TAARIFA YA RIDHAA)

Taarifa ya Mshiriki

Nimesoma au nimesomewa maelezo yaliyoko katika fomu hii ya ridhaa. Nimekuwa na fursa ya kujadili utafiti huu na mfanyikazi wa utafiti. Maswali yangu yote yamejibiwa kwa lugha ninayoelewa. Nimeelezewa kuhusu hatari na faida za utafiti huu. Ninaelewa kuwa kushiriki kwangu katika utafiti huu ni kwa hiari na kwamba ninaweza kujiondoa wakati wowote. Ninakubali kwa hiari kushiriki katika utafiti huu.

Ninaelewa kwamba jitihada zote zitafanywa kuweka taarifa kuhusu utambulisho wangu siri.

Kwa kutia sahihi fomu hii ya ridhaa, sijasalimisha haki yangu yoyote ya kisheria kama mshiriki katika utafiti.

Nakubali kushiriki katika utafiti huu:	**Ndiyo**	**Hapana**
Nakubali kutoa maelezo ya mawasiliano kwa ufuatiliaji:	Ndiyo	Hapana

Jina la mshiriki : _____

Sahihi / Alama ya kidole_____Tarehe _____

Mkataba wa Mtafiti

Ninathibitisha kuwa mshiriki amepewa fursa ya kuuliza maswali kuhusu utafiti, na maswali yote yamejibiwa kwa usahihi kadri ya uwezo wangu. Ninathibitisha kuwa mshiriki ameelewa na kutoa idhini yake kwa kusudi.

Sahihi ya Mtafiti ……

Tarehe…….

Unaweza kuwasiliana na

mtafiti afuatayo ; Otieno

Preston otieno

Shule ya Famasia ya Chuo

Kikuu cha Nairobi

otienopreston01@gmail.com

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Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/98

21st March, 2019

Otieno Preston Ochieng
Reg. No.U51/7421/2017
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL * APPROVED 21 MAR 2019 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI *

Dear Preston

RESEARCH PROPOSAL: OUTCOMES OF THE HEALTHY HEART AFRICA PROGRAM ON MANAGEMENT OF HYPERTENSIVE PATIENTS IN NAIROBI COUNTY, KENYA (P885/12/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 21st March 2019 – 20th March 2020.

This approval is subject to compliance with the following requirements:

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

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
The Chair, Dept. of Pharmacology and Pharmacognosy, UON
Supervisors: Dr.Eric M. Guantai, Dr. Margaret N. Oluka, Prof.Faith A. Okalebo

Thesis - OUTCOMES OF THE HEALTHY HEARTAFRICA PROGRAM ON MANAGEMENT OF HYPERTENSIVE PATIENTS IN NAIROBI COUNTY, KENYA

ORIGINALITY REPORT

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