ADDIS ABABA UNIVERSITY

SCHOOL OF GRADUATE STUDIES

ASSESSMENT OF HYPERTENSION TREATMENT PATTERN AT SELECTED HEALTH FACILITIES IN ADDIS ABABA AND CONSUMPTION OF ANTIHYPERTENSIVE DRUGS

By

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OCTOBER 2009

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Dedicated to my beloved friends: -

Samuel, Tekeba, Gebremedhin,

Solomon, Gizaw, Seifu, Kidu, Mengs

and Mussie.

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List of abbreviations

ACEI	Angiotensin Converting Enzyme Inhibitor
AIDS	Acquired Immuno Deficiency Virus
APF	Addis Pharmaceutical Factory
ATC	Anatomical Therapeutic Classification
BMI	Body Mass Index
BP	Blood Pressure
CCB	Calcium Channel Blocker
CSA	Central Statistical Agency
CVD	CardioVascular Disease
DACA	Drug Administration and Control Authority
DBP	Diastolic Blood Pressure
DDD	Defined Daily Dose
EC	Ethiopian Calendar
EPHARM	Ethiopian Pharmaceuticals Manufacturing
Eth. Birr	Ethiopian Birr
FMOH	Federal Ministry Of Health
HCT	Hydrochlorothiazide
INRUD	International Network for Rational Use of Drugs
NCD	Non Communicable Disease
QI	Quartile Index
RCT	Randomized Clinical Trial
SBP	Systolic Blood Pressure
SD	Standard Deviation
SPSS	Statistical Package for Social Science
SSA	Sub Saharan Africa
UN	United Nations
USA	United States of America
WHO	World Health Organization

Summary

Background: Hypertension along with other chronic diseases is on the rise in Ethiopia. In fact, the threats of non communicable diseases are not emerging rather they are well advanced and causing double burden to the society along with infectious diseases. Unhealthy life style is the determinant for this dilemma. Needless to say, it needs timely intervention to tackle the problem. Despite of this fact, studies on hypertension are very few. This study assesses the treatment pattern to hypertension and consumption of antihypertensive drugs.

Objective: To assess hypertension treatment pattern and consumption of antihypertensive drugs.

Methodology: An institution based cross sectional study involving retrospective data collection techniques (record review for the last five years and exit interview) was conducted between September and October 2008.

Results: The most commonly prescribed drugs either alone or in combination were methyldopa, nifedipine, hydrochlorothiazide, enalapril and atenolol. Treatment shift occurs frequently from therapeutic class to another on the basis of in effectiveness of the drug to adequately control blood pressure, reason not known and side effect. Monotherapy is favored regardless of sex. Furosemide is the most consumed antihypertensive drug and nifedipine ranks the first with regards to cost of sales of antihypertensive drugs.

Conclusion and recommendations: Methyldopa, nifedipine, hydrochlorothiazide, enalapril and atenolol are widely used drugs for the treatment of hypertension which is in accord with standard treatment guideline of the country. Future longitudinal research should be done to describe consumption trend of antihypertensive drugs.

1. INTRODUCTION

Epidemiologic surveys have demonstrated a continuous distribution of arterial pressure levels within the population and any point separating "normal" from "elevated" is therefore arbitrary. Absolute blood pressure levels vary with sex, age, race and numerous other factors. The higher the arterial pressure systolic or diastolic, the greater the cardiovascular morbidity and mortality. This has been found to be true in all countries studied in all age groups and in both sexes (WHO, 1978).

Hypertension is one of the major chronic diseases resulting in high mortality and morbidity in today's world. Socio-economic, behavioral, and nutritional and public health issues have also led to increase in cardiovascular disease (CVD) throughout the world (Collins et al., 1990).

Hypertension is the most common of the cardiovascular diseases and affects most of the populations is the world. Hypertension and associated disorders constitute some 60% of all cardiovascular diseases seen in adults in most developing countries (WHO, 1990).

The World Health Organization has estimated that high blood pressure causes one in every eight deaths, making hypertension the third leading killer in the world. Globally, there are one billion hypertensive and four million people die annually as a direct result of hypertension. Globally, 7.1 million deaths were attributed to high blood pressure in 2000, 4.4 million to high cholesterol and 2.6 million to high body mass index (BMI). This burden was shared approximately equally among the sexes (WHO, 2005).

Of the 10,006 deaths reported to the Federal Ministry of Health (FMOH) in 2000/01, 142 (1.4%) were due to hypertension, becoming the 7^{th} leading cause of death for the year. Of the 6591 deaths reported to FMOH in 2005/06, 199 (3%) for males and 72 (2.4%) for females, were due to hypertension. Some of the major risk factors in the increasing incidence of risks could be assumed to be socioeconomic development in segments of urban population, adoption of a western lifestyle in urban areas, consumption of food rich in calorie and fat, sedentary way of work and leisure, increasing cigarette smoking, improved life expectancy in urban Ethiopia and a greater stress (FMOH, 2001).

Several studies done in Ethiopia show complications of hypertension in one way or another (Fikreyesus and Bahta, 1989, Mamo and Oli, 2001, Melaku et al., 2006).

The choice of drug for the treatment of hypertension changes at short intervals. Efficacy, side effects, both short term and long term effects on other systems and cost are some of the factors responsible for the change. The market potential of these drugs causes the synthesis and release of newer drugs at a rapid rate which contributes in its own way to the choice of drugs made by physicians. At present the literature on the treatment pattern in Ethiopia is scanty, and studies on the problem are few. Thus the present study can serve in developing the literature on the subject, and it can also be used as a baseline data against which future consumption trends of the antihypertensive drugs can be assessed and it can give a clue for antihypertensive drug importers, manufacturers, policy makers, clinicians and the drug regulatory authority about hypertension treatment pattern and consumption of antihypertensive drugs.

2. LITERATURE REVIEW

2.1 What is hypertension?

Hypertension is a state of elevated blood pressure, which is commonly asymptomatic. It often leads to lethal complications like coronary artery disease, cerebrovascular accidents, heart and renal failures, and retinopathy. In 90-95% of cases, the cause is unknown; the rest are due to renal, endocrine, neurogenic and other abnormalities. Diagnosis is based on measurement of blood pressure on three separate occasions. Accordingly, a systolic blood pressure of 140 mm Hg or greater and /or a diastolic blood pressure of 90 mm Hg or greater, taken on two different occasions in an individual who is not acutely ill, establishes the diagnosis of hypertension. According to standard treatment guideline of district hospitals in Ethiopia, there are both non pharmacologic and pharmacologic treatment. The non pharmacologic treatment includes reduction of salt intake, losing weight if overweight, regular exercise, reduction in intake of saturated fat/cholesterol and quit smoking. The pharmacologic treatment includes drugs like hydrochlorothiazide, nifedipine, propranolol, enalapril, methyldopa and atenolol to be prescribed either alone or in combination (DACA, 2004).

Lifestyle interventions such as a healthy, low-calorie diet, aerobic exercise and a reduction in excess alcohol consumption can produce worthwhile reduction in blood pressure and should be discussed with the patient (Higgins and Williams, 2007).

Visceral obesity, insulin resistance, oxidative stress, endothelial dysfunction, activated renin-angiotensin system, increased inflammatory mediators, and obstructive sleep apnea have been proposed to be possible factors to develop hypertension in the metabolic syndrome. These factors may induce sympathetic overactivity, vasoconstriction, increased intravascular fluid, and decreased vasodilatation, leading to development of hypertension in the metabolic syndrome (Yanai et al., 2008).

2.2 Global burden of hypertension

The term cardiovascular refers to the circulatory system comprising the heart and blood vessels which carries nutrients and oxygen to the tissues of the body and removes carbon dioxide and other wastes from them. They are a class of diseases that include arteriosclerosis, coronary artery disease, heart valve disease, arrhythmia, heart failure, hypertension, orthostatic hypotension, shock, endocarditis, diseases of the aorta and its branches, disorders of the peripheral vascular system, and congenital heart disease (Adugna, 2009).

It is believed that cardiovascular diseases are now becoming prominent as a public health problem in developing countries as well as in industrialized ones. With progressive overall socioeconomic development as infection and malnutrition are steadily overcome in the developing world an increase in the toll of cardiovascular diseases is likely to follow (Pedol, 1982).

Cardiovascular disease (CVD) is the number one cause of death globally and is projected to remain the leading cause of death. An estimated 17.5 million people died from CVDs in 2005, representing 30% of all global deaths. Of these deaths, 7.6 million were due to coronary heart disease and 5.7 million were due to stroke. Around 80% of these deaths occurred in low and middle-income countries. If appropriate action is not taken, by 2015, an estimated 20 million people will die from CVDs annually, mainly from heart disease and stroke (Mendis et al., 2007).

Cardiovascular diseases (CVD), most of which are due to atherosclerosis (mainly heart attack and stroke) and often related to arterial hypertension, are responsible for nearly 20% of all deaths world-wide (nearly 10 million). They are the principal cause of death in all developed countries accounting for 50% of all deaths and are also emerging as a prominent public health problem in developing countries, ranking third with nearly 16% of all deaths. They have already become the first cause of death in such countries as Argentina, Chile, Cuba, Mauritius, Singapore, Sri Lanka, Trinidad and Tobago and Uruguay. Many developing countries are now in a phase of epidemiological transition and face the double burden of communicable and non-communicable diseases, with the severe repercussions this has on their very weak economies (Antezana, 1996).

Blood pressure is a well established determinant of cardiovascular disease. In global-health politics, cardiovascular disease is the elephant in the room—a massive problem that few want to acknowledge and even fewer wants to tackle (Lawes et al., 2006).

Globally, sub-optimal blood pressure (SBP>=115 mmHg) was estimated to account for 62% of cerebrovascular disease and 49% of ischemic heart disease (WHO, 2002).

Hypertension is a major health problem throughout the world because of its high prevalence and its association with increased risk of cardiovascular disease. Advances in the diagnosis and treatment of hypertension have played a major role in recent dramatic declines in coronary heart disease and stroke mortality in industrialized countries. However, in many of these countries, the control rates for high blood pressure have actually slowed in the last few years. It is estimated that by 2010, 1.2 billion people will be suffering from hypertension worldwide (WHO, 2005).

High blood pressure, including pre-hypertension, is a major global health economic issue, accounting for about half of the total cases of stroke and ischemic heart disease. It is responsible for about 7.6 million deaths each year and costs over 92 million disability-adjusted life years, both of which represent 13.5 and 6.0% of the respective global total in the year 2001. Low-income and middle-income countries, predominantly in eastern Europe, east and south Asia (China and India) and the Pacific regions, shoulder about 80% of the cardiovascular disease burden, half of which is in people of working age (Lawes et al.,2008).

2.3 Hypertension in Africa

Africa is in "epidemiological transition," due to a move by many people from a rural to an urban lifestyle, bringing with it "advances of civilization" such as an increased cardiovascular disease burden. Hypertension in Africa is a widespread problem of immense economic importance because of its high prevalence in urban areas, its frequent underdiagnosis, and the severity of its complications. For example, the INTERHEART Africa (a global study of risk factors for acute myocardial infarction) has shown that hypertension is the strongest risk factor for myocardial

infarction (MI) in black Africans, with an odds ratio of 6.99 compared with 2.3-3.9 in other ethnic groups. The latest estimate of the World Health Organization (WHO) is that more than 30 million people in Africa have hypertension. WHO predicts that if nothing is done about it, by 2020 three quarters of all deaths in Africa will be attributable to hypertension. The African Union has called hypertension "one of the continent's greatest health challenges after AIDS" (Anonymous, 2006).

Recent studies have described a growing prevalence of hypertension and other CVD in SSA, where they have long been considered rare. The prevalence of hypertension in many urban populations of SSA countries is comparable with that of developed countries in Europe, USA, and Canada. The rapidly growing burden of hypertension in SSA is of particular concern in light of the low level of detection, treatment and control, with increased morbidity and mortality from stroke and myocardial infarction. The level of detection of hypertension ranged between 11% in rural Cameroon and 47% in females in South Africa, and treatment varied between 10% in urban Cameroon and 32% in Ghana (Tesfaye, 2008).

There are varying responses to antihypertensive therapy in black hypertensive patients. Black patients respond well to thiazide diuretics, calcium channel blockers vasodilators like alpha-blockers, hydralazine, reserpine and poorly to beta-blockers, angiotensin-converting enzyme inhibitors and all receptor antagonists unless they are combined with a diuretic (Seedat ,2000).
For chronic disease patients in developing countries, the outlook is bleak; most countries do not have budget lines, essential medicines are not available in primary clinics, and donor and development agencies are largely neglectful and favor infectious diseases (Callow, 2006).

2.4 Hypertension in Ethiopia

The incidence of chronic disease risk factors such as high blood pressure, physical inactivity, overweight and obesity, is increasing in Ethiopia. However, efforts towards prevention are lacking, mostly because chronic diseases are regarded as "diseases of affluence" or "Western diseases" (Tesfaye et al., 2008).

National-level statistics on non-infectious adult diseases in Ethiopia are scarce. There is no doubt, however, that these illnesses are adding to the growing burden of the myriads of diseases responsible for morbidity and mortality among adults.

Among survey results reported in a recent literature survey by Frances Lester and Kebede Oli are the following:

A study employing the modified autopsy technique in Butajira showed that the category of non-infectious adult illnesses (NIAD) accounted for 24% of morbidity and 14.2% of mortality. These included cardiovascular diseases, malignancies, diabetes mellitus, chronic liver diseases, bronchial asthma, nephritis and nephrosis, and musculo-skeletal diseases (Lester and Oli,2006a).

A prospective study of patients in the 60+ age category found cardiovascular diseases, especially hypertension and its complications in 20% of patients, neurological diseases in 9%, liver diseases in 5%, and malignancies in 6%. These surveys indicate the importance among the Ethiopian elderly, of chronic diseases, which can be expected to increase as malnutrition and infectious diseases are controlled and life expectancy increases (Lester and Oli, 2006b).

Another study done on hypertension prevalence and age-related changes of blood pressure in semi-nomadic and urban Oromos of Ethiopia indicated that the prevalence of hypertension was 0.40% in the semi-nomadic and 3.15% in the urban population. In the latter, significant increases in BW and QI were found, which were significantly correlated to both SBP and DBP (Pauletto et al, 1994).

A study done about the prevalence of major non communicable diseases in south western Ethiopia revealed that the prevalence of hypertension among bank employees was 11.30%. It also concluded that the prevalence shows a considerable amount and stressed that NCDs are pandemics of the 21st century and finally suggested that most of them are difficult to treat and preventive measures like exercise, diet, life style adjustments and the like are better options (Gebreselassie, 2005).

2.5 Prevention, control and treatment

Declining mortality from infectious diseases is accompanied by increasing mortality from noncommunicable diseases in both developed and developing countries. The World Health Organization (WHO) has initiated the Integrated Program for Community Health in Noncommunicable Diseases (Interhealth). Interhealth is based on the concepts that noncommunicable diseases are related to a set of risk factors some of which can be controlled; the entire community must be involved; health promotion intervention strategies, such as population control, risk identification, screening and prevention strategies, must be integrated; different categories of intervention (e.g., lifestyle changes, health care reorganization) must be coordinated; social and environmental changes will be necessary; and noncommunicable disease prevention and control strategies will be implemented through existing primary health care systems (Shigan,1988).

A variety of life style modifications have been shown in clinical trials to lower BP and to reduce the incidence of hypertension. These include weight loss in the overweight, physical activity, moderation of alcohol intake, a diet with increased fresh fruit and vegetables and reduced saturated fat content, reduction of dietary sodium intake, and increased dietary potassium intake. Other life style changes have not been found in multiple clinical trials to have a significant or long lasting antihypertensive effect. These include calcium and magnesium supplements, reduction of caffeine intake, and a variety of techniques designed to reduce stress (Whitworth, 2003).

Hypertension, like most cardiovascular conditions, is a nutritional-hygienic disease. The seeds of hypertension are rooted in physical inactivity, obesity, high caloric intake, and excessive dietary sodium intake as well as alcohol consumption. Genetic susceptibility to hypertension remains ill-defined; however, environmental exposures of gene-environment interactions can be favorably influenced by manipulation of life style choices (Flack, 2007).

Each drug class is associated with its own set of adverse events that may reduce treatment compliance. In fact, lack of compliance is a common cause of inadequate control of hypertension.

Unsatisfactory treatment of hypertension has been reported in epidemiologic studies from different countries. Irrational use of antihypertensive drugs depends on several reasons such as the lack of proper training of physicians and pharmacists as well as patients' attitudes. Moreover, irrational use of drugs differs from country to country. Developed countries have taken some measures to solve these problems, but greater effort at national and international levels is needed for the developing countries. Undergraduate medical education focused on rational pharmacotherapy process is one of the solutions offered (Akici et al., 2007).

Recent analyses demonstrate that the cardiovascular effects of systolic versus diastolic blood pressure vary according to age. In the Framingham Heart Study, there is a gradual transition from diastolic to systolic blood pressure as the more important predictor of cardiovascular risk. In the Framingham Heart Study, for participants aged less than 50 years of age, diastolic blood pressure better predicts the development of coronary heart disease. However, between the ages of 50 and 59 years, there is a transition period with diastolic and systolic blood pressure assuming comparable risk. After the age of 60 years, the risk of coronary heart disease remains positively correlated with systolic blood pressure but is inversely related to diastolic blood pressure. That is, lower diastolic blood pressure levels in this age group are associated with a worsening of cardiovascular prognosis (Nishizaka and Calhoun, 2006).

Identifying deficiencies in prescribing is a prerequisite for planning interventions aimed at improving prescribing behavior of physicians. The relevance of health system research related to drug utilization is becoming important because it reflects the quality of care and has considerable implications for cost and resource management (Sequeira et al., 2002).

Inexpensive antihypertensive drugs are at least as effective and safe as more expensive drugs. Overuse of newer, more expensive antihypertensive drugs is a poor use of resources. The potential savings of resources are substantial, but vary across countries, in large part due to differences in prescribing patterns (Fretheim and Oxman, 2005).

Studies have shown that good blood pressure control, below 140mmHg (systolic) and 90mmHg (diastolic) is achieved in only a minority of patients on anti-hypertensive monotherapy. Majority

of patients will require combination of anti-hypertensive drugs to achieve good blood pressure control (Yusuff and Balogun, 2005).

Several studies have been done to assess antihypertensive drug utilization and the sales of antihypertensive drugs in the world. Some of them are mentioned below.

A study conducted in Punjab, India revealed that most of the male patients were on monotherapy (60 %). In the monotherapy category, four classes of drugs were used. These were calcium channel blockers (48.1 %), beta-blockers (46.2 %), ACEIs (3.9 %) and diuretics (1.9 %). Among monotherapy drugs, calcium channel blockers were prescribed most whereas diuretics were least used. Among those who were treated with drug combinations, 92.1% received two drugs and 7.9 % received three drugs. In combination therapy, a two-drug combination consisting of beta-blockers and calcium channel blockers was given to the majority of the patients. Overall, 57.8 % patients were treated with a single anti-hypertensive drug and 42.2 % were treated with anti-hypertensive drug combinations (Tiwari et al., 2004).

Another study done in Taiwan revealed that the most frequently prescribed antihypertensive medications were: calcium antagonists: 5,332,527 records (54.9% of enrolled visits); beta-blockers: 4,230,843 records (43.5%); angiotensin converting enzyme inhibitors (ACEIs): 3,057,009 records (31.5%); diuretics: 2,255,838 records (23.2%); and others (1,647,100 records, 16.9%). Regardless of gender, the top 2 groups of drugs prescribed as monotherapy were calcium antagonists and beta-blockers. Beta-blockers and calcium antagonists, ACEIs plus calcium antagonists were used as multiple therapies (Chou et al., 2004).

A study conducted in Turkey concluded that the rate of successful blood pressure control was low among hypertensive patients receiving treatment, and despite the inadequacy of monotherapy to control blood pressure, many of the patients continued this treatment regimen (Abaci et al., 2007).

Another study done in Mexico concluded that the top-selling antihypertensive drug classes are the CCB and ACEI. The most effective and least expensive drug-diuretics-had the smallest market shares of all antihypertensive agents (Altagracia et al., 2006).

A study also done in Iran revealed that the most prescribed drug class was β-blockers (46.2%) followed by calcium channel blockers (19.2%), angiotensin-converting enzyme (ACE) inhibitors (13.7%), diuretics (10.3%), angiotensin receptor blockers (9.2%) and other antihypertensive agents (1.5%). Most of the hypertensive patients (69.6%) were treated with a single drug, while 31.4% of the patients received more than one drug (Sepehri et al., 2008).

In Ethiopia, even though patchy, small scale studies confirm significant rise in NCDs-hypertension, diabetes mellitus, liver and cardiovascular diseases, mental problems, injuries and violence, carcinoma, asthma, dental problems to name a few. Lack of data is often mistaken for underestimation of the problem thus little or no attention is given. The good news is the FMOH is in the process of developing a national guideline concerning the major NCDs. The threats of NCDs are not emerging rather they are well advanced.

This study was justified by some emerging facts about hypertension in Ethiopia; because it is a growing health problem of all socio economic classes in Ethiopia as well in most developing countries. An increase in the prevalence of hypertension in Ethiopia is related with poor awareness, increase in sedentary life and ill feeding habits. Yet studies of hypertension treatment pattern and consumption of antihypertensive drugs have not been conducted.

Therefore; policy makers, importers, manufacturers, drug regulatory agency, nongovernmental organizations and various stakeholders interested in the politics of hypertension might be more willing to give emphasis on hypertension and as a result the whole society would get the benefit from collaborated efforts from all actors.

3. OBJECTIVES OF THE STUDY

General Objective

To assess hypertension treatment pattern and consumption of antihypertensive drugs.

Specific Objectives

- To identify commonly prescribed drugs (drug categories) for the treatment of hypertension in Addis Ababa from 2004-2008.
- To assess treatment shift in the treatment of hypertension in Addis Ababa from 2004-2008.
- To assess consumption of antihypertensive drugs using Defined Daily Dose (DDD) in Ethiopia from 1998-1999 E.C. and cost of sales in Addis Ababa from January 2006- October 2008.

4. METHODOLOGY

4.1 Study design

The study was an institution based, cross sectional study involving retrospective data collection which includes record review and exit interview, respectively. The two approaches were arranged to complement each other. It was conducted between September and October 2008.

4.2 Description of study area

Addis Ababa is the capital city of Ethiopia and also the largest city in Ethiopia, with a population of 2,738,248 (CSA, 2007). As a chartered city , Addis Ababa has the status of both a city and a state. It is often called the capital of Africa due to its historical, diplomatic and political significance for the continent. The city is populated by people from different regions of Ethiopia (the country has as many as 80 nationalities speaking over 80 languages and belonging to different religious communities including Christians, Muslims, and Jews).

During the time of the survey Addis Ababa had 34 hospitals; of which 5 are managed under the Health Bureau of the city administration, 4 are managed by the Federal Ministry of Health, one University Hospital (under Addis Ababa University) and the rest are either privately owned or owned by non governmental and other governmental organizations. It had also 28 health centers, 450 private clinics both for profit & not for profit and 37 health posts (FMOH, 2007).

4.3 Sampling and sample size determination

The health facilities were selected purposively based on the number of patients attending in the hypertension clinic of the hospitals. At least 600 patient cards are needed for review from each health institution. Accordingly, St.Paul's hospital, Bella defense hospital, Hayat hospital and Kazanches health center were selected. Two kenema retail pharmacies were chosen based on availability of sales data and these were kenema no. 2 (Piazza) and kenema no.3 (Stadium).
Two manufacturing plants that produce antihypertensive drugs in the country were chosen namely; Ethiopian Pharmaceutical Manufacturing and Addis Pharmaceutical Factory.

Cadila Pharmaceutical Manufacturing Company was not included because it has started to produce anti hypertensive drugs (Enalapril) as of January 2008 (Tir 2001 E.C.). Based on WHO recommendations on how to investigate drug use, 600 hypertensive patients' cards were selected for review and 30 exit interviews with patients were done per health institution (INRUD/WHO, 1993).

4.4 Data collection and management

4.4.1 Instrument

The instruments used to assess hypertension treatment pattern were data abstraction format and exit interview. The data abstraction format included sociodemographic characteristics, types of drugs prescribed initially and during survey, reasons given fore treatment shift, BP measurement during follow up and listing complications and concomitant medications if any. Pretest of the instruments was done before the actual data collection. These two instruments were used at the selected health facilities. Concerning consumption of antihypertensive drugs, data were obtained from manufacturing plants, the drug regulatory agency (DACA) and kenema retail pharmacies.

4.4.2 Data collectors

Data collectors were nurses working at hypertension clinics at each health institution. Training was given to the data collectors about the aim of the study and how to collect data from the patient cards on the data abstraction format. Once the data were collected, the principal investigator checked the completeness and accuracy of the data. Finally, the data abstraction formats were kept in the sequence in which they have been numbered. Exit interview was done by the principal investigator. Before the interview, verbal informed consent was obtained from each interviewee.

4.4.3 Data entry and analysis

Data were entered and cleaned using Epi Info 2002 and analyzed by SPSS version 15.0 statistical packages. Tables and figures were used for the presentation of the data.

4.5 Study variables

Independent Variables:

Sex, age and category of antihypertensive drugs.

Dependent Variables:

Monotherapy, multiple therapies, treatment shift and types of antihypertensive drugs.

4.6 Operational definitions

- Hypertensive: patients diagnosed with systolic blood pressure greater or equal to 140 mm Hg and / or diastolic blood pressure greater or equal to 90 mm Hg.
- Antihypertensive drugs: all drugs listed under List of Drugs for Ethiopia as antihypertensive drugs and drugs which have antihypertensive effect pharmacologically.
- DDD: assumed average maintenance dose per day for a drug used for its main indication in adults.

4.7 Ethical considerations

Ethical clearance was obtained from School of Pharmacy, Addis Ababa University. Permission was secured from each study site. The informed verbal consent process involved the data collector giving a verbal explanation to each potential participant on the nature of the study, its purpose, the expected duration, the potential risks and any discomfort it might entail. Each potential participant was also informed that participation in the study was voluntary and that he/she could withdraw at any time, and that withdrawal of consent would not affect his/her subsequent treatment or relationship with the facility staff or any other person. Code was used to identify each abstracted patients' information. This was to keep the anonymity of the patients' record.

5. RESULTS

5.1 Record review

5.1.1 Demographic characteristics

A total of 2,400 patient cards were reviewed from the selected four health institutions. The patients were 1,207 (50.3%) females and 1,193 (49.7%) males. They were aged between 18 and 98 years with a mean age of 50.8 (SD=12.07). Majority, 1,295 (53.9%) of the patients were in the age group of 45-64 (Table 1).

Table 1: Sociodemographic characteristics of hypertensive patients at the selected health facilities in Addis Ababa, Ethiopia, 2008 (N=2,400).

Variable	N	%
Sex		
Male	1,193	49.7
Female	1,207	50.3
Age group		
15-44	778	32.4
45-64	1,295	53.9
≥ 65	327	13.6

5.1.2 Monotherapy and multiple therapies

At the initiation of treatment, 1,645 (68.5%) of patients were on monotherapy, while the rest were on multiple therapies. Treatment pattern is associated with sex (X^2=9.853 and P<0.05). However, it is not associated with different age groups (X^2=2.109 and P>0.05) (Table 2).

Table 2: Study participants' gender and age with respect to mono and multiple therapies, Addis Ababa, Ethiopia, 2008.

Variable	Treatment pattern				X^{2*}	p-value
	1 drug		≥ 2 drugs			
	Frequency	Percentage	Frequency	Percentage		
Sex						
Male	782	65.5	411	34.5	9.853	0.002
Female	863	71.5	344	28.5		
Age group						
15-44	541	69.5	237	30.4	2.109	0.348
45-64	872	67.3	423	32.6		
≥ 65	232	70.9	95	29.0		

* Chi square

5.1.3 Commonly prescribed drugs (drug categories)

The most commonly prescribed drugs were in the order: methyldopa; 606 (36.8%), nifedipine; 434 (26%), hydrochlorothiazide; 334 (23.1%), Enalapril; 112 (6.8%) and Atenolol; 88 (5.3%). Among centrally acting agents, methyldopa was prescribed to all patients. With regards to calcium channel blockers, diuretics, angiotensin converting enzyme inhibitors and beta blockers, the majority of the patients were prescribed with nifedipine, hydrochlorothiazide, enalapril and atenolol respectively.

Table 3: Commonly prescribed monotherapy drugs/drug categories, Addis Ababa,Ethiopia,2008 (N=1645).

Category of drugs	N(%)	Drugs (%)
Centrally acting agent	606 (36.8)	Methyldopa (100)
Calcium channel blockers	436 (26.5)	Nifedipine (99.5);Amlodipine, (0.5)
Diuretics	353 (21.5)	HCT (96.3); Furosemide (2.8); Spirinolactone (0.6)
ACEIs	139 (8.4)	Enalapril (80.5); Captopril (20.9); Lisinopril (1.4)
Beta blockers	117 (7.1)	Atenolol (75.2); Propranolol (25.6)

Multiple therapies

As shown in Table 4, the most common two drugs combination were in the order: centrally acting agents + diuretics; 326 (47%) followed by calcium channel blockers +diuretics; 132 (19%).

Table 4: Commonly prescribed two drug categories, Addis Ababa, Ethiopia, 2008 (N=693)

Category of drugs	N	%
Centrally acting agent + Diuretics	326	47.0
Calcium channel blockers + Diuretics	132	19.0
ACEIs + Diuretics	56	8.0
Beta blockers + Diuretics	55	7.9
Calcium channel blockers + ACEIs	34	4.9
Beta blockers + ACEIs	28	4.0
Calcium channel blockers + Beta blockers	27	3.9
Centrally acting agent + Calcium channel blockers	20	2.8
Centrally acting agent + Beta blockers	8	1.2
Centrally acting agent + ACEIs	7	1.0

The most common three drugs combination were calcium channel blockers plus two different kinds of diuretics; 29 (52.7%) followed by centrally acting agent plus two different kinds of diuretics; 10 (31%) (Table 5).

Table 5: Commonly prescribed three drug categories combination, Addis Ababa, Ethiopia, 2008(N=55).

Category of drugs	N	%
Calcium channel blockers + 2 Diuretics	29	52.7
Centrally acting agent + 2 Diuretics	10	31.0
Calcium channel blockers + Centrally acting agent + Diuretics	7	12.7
Calcium channel blockers + Beta blockers + Diuretics	6	11.0
Centrally acting agent + ACEIs + Diuretic	3	5.5

In few cases, 4 drugs were combined. The category of drugs prescribed in four drug combination were ACEIs + Calcium channel blockers + Diuretic + Beta blockers; 4 (57.1%) followed by Centrally acting agent + Diuretics + Beta blockers + Calcium channel blockers; 3 (42.9%).

5.1.4 Treatment shifts

Eight hundred and twenty nine (34.50%) of the patients had a treatment shift since the start of medication therapy. The common reasons claimed were failure to respond to drug: 424 (51.10%) and no reason (reason not known): 225 (27.10%) as shown in Figure 1 below.

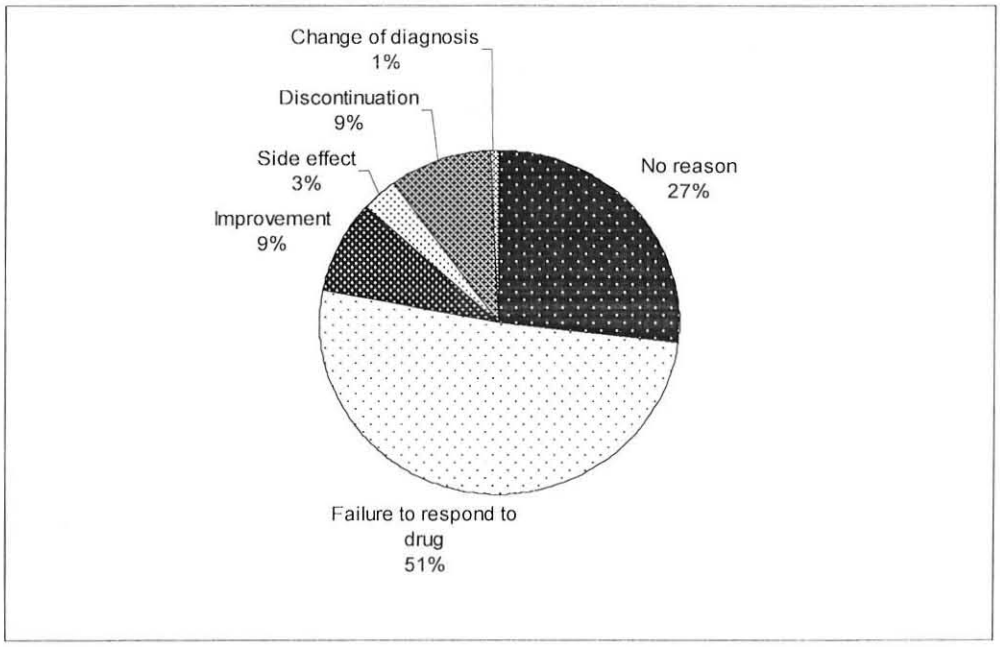

Figure 1: Reasons claimed for treatment shift from record review, Addis Ababa, Ethiopia, 2008.

As shown in Table 6 below, shifts are mostly from centrally acting agents to calcium channel blockers and calcium channel blockers to diuretics. From diuretics shift is mostly to centrally acting agents and from angiotensin converting enzyme inhibitors to calcium channel blockers and diuretics. Beta blockers are changed mostly to angiotensin converting enzyme inhibitors.

Table 6: Pattern of treatment shift for patients on monotherapy, Addis Ababa, Ethiopia, 2008.

First prescribed single category of drugs	Treatment shift :percentage and therapeutic category
Centrally acting agent	48.9% (calcium channel blocker) 21.3% (ACEIs) 17.0% (diuretic) 12.8% (beta blocker)
Calcium channel blocker	46.2% (diuretic) 25.6% (beta blocker) 15.4% (ACEIs) 12.8% (centrally acting agent)
Diuretic	53.9% (centrally acting agent) 28.9% (calcium channel blocker) 9.2% (ACEIs) 5.3% (beta blocker)
(ACEIs)*	53.3% (diuretic) 33.3% (calcium channel blocker) 6.7% (centrally acting agent)
Beta blocker	50.0% (diuretic) 25.0% (ACEIs) 8.3% (calcium channel blocker)

*: Angiotensin Converting Enzyme Inhibitors

5.1.5 Comorbidity from record review

Four hundred and seventy seven patients (19.9%) had comorbidity along with hypertension. The most common complications were diabetes mellitus, 311 (65.2%) and cardiovascular diseases, 129 (27 %) as shown in Figure 2 below.

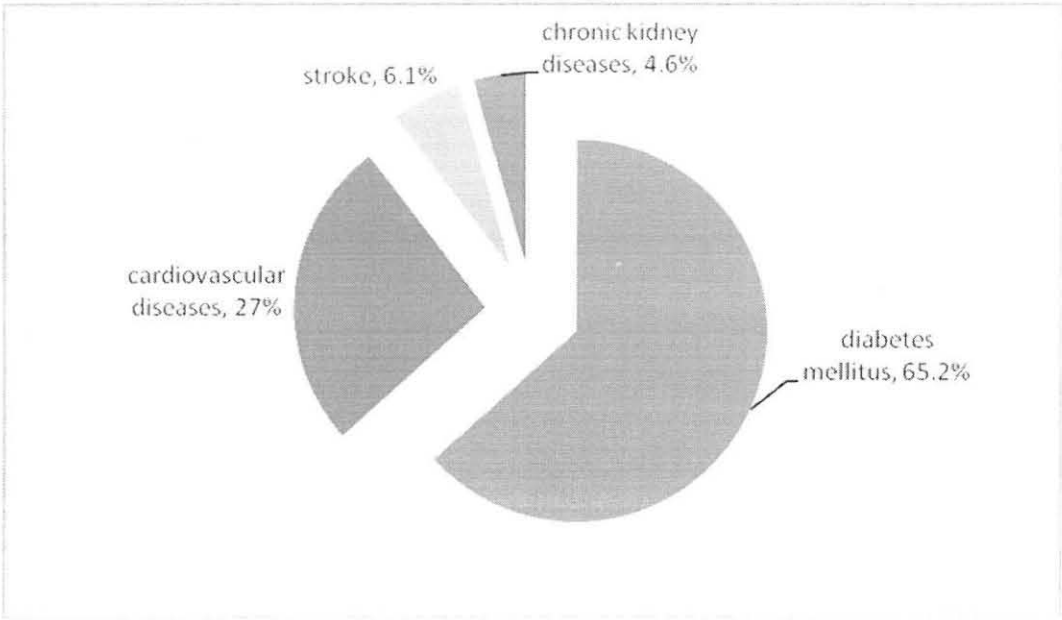

Figure 2: Comorbidity from record review, Addis Ababa, Ethiopia, 2008.

5.1.6 Concomitant medication

Seven hundred thirty eight (30.8%) of study participants were taking concomitant medication. The most common prescribed drugs were Glibenclamide (8.4%), Acetylsalicylic acid (3%), Insulin (2.2%), Metformin (2%), Digoxin (1.5%) and Paracetamol (1.3%).

5.1.7 BP measurement during follow up

Two thousand three hundred (95.8%) of the patients had a record of BP measurement more than once in their follow up of treatment at the hypertension clinics. Overall, the mean early systolic and diastolic blood pressure of the patients was 160 & 102 mm Hg and the mean recent systolic and diastolic measurement were 138 & 88 mm Hg respectively.

5.2 Exit interview

5.2.1 Sociodemographic characteristics

Of the 120 study participants interviewed, 79 (65.8%) were females and the rest 41 (34.2%) were males. The average age of the patients was 51.91 (SD=12.12) years and they were aged between 26 and 78. With regards to educational background, 35 (29.2%) were secondary and 29 (24.2%) were illiterate. Concerning their marital status, 66 (55%) were married and 25 (20.8%) were widowed. With regards to occupation, 28 (23.3%) were housewives and 27 (22.5%) were government employees.

Table 7: Demographics of exit interview respondents, Addis Ababa, Ethiopia, 2008 (N=120)

Characteristics	N	%
Sex		
Male	41	34.2
Female	79	65.8
Age group		
15-44	31	25.8
45-64	65	54.1
≥65	24	20.0
Educational status		
Illiterate	29	24.2
Read & write	6	5.0
Primary(1-8)	23	19.2
Secondary(9-12)	35	29.2
College/University	27	22.5
Marital status		
Married	66	55.0
Widowed	25	20.8
Single	11	9.2
Divorced	9	7.5
Separated	9	7.5
Occupation		
House wife	28	23.3
Government employee	27	22.5
Private sec. employee	18	15.0
Retiree	17	14.2
Unemployed	15	12.5
Self employee	11	9.2
Military	4	3.3

5.2.2 Treatment duration

Seventy (58.3%) of the patients replied that they were taking medication for the last five years while 27 (22.5%) of them were on therapy from five years to ten years. The rest 23 (19.2%) were taking drugs for more than ten years.

5.2.3 Average payment per month

Seventy one (59.2%) of respondents revealed that they were taking medication freely and the rest 49 (40.8%) were paying at the start of treatment. The average payment per month was approximately 39 Ethiopian Birr (SD=43.17).Whereas during interview, 49 (40.5 %) of the respondents claimed they were paying for medication and the rest replied they were not paying. The average payment was 46.5 Ethiopian Birr per month (SD=41.55).

5.2.4 Comorbidity claimed during exit interview

Half of the respondents, 60 (50%) replied that they had co morbidity in addition to hypertension. Chronic kidney diseases, 24 (20%) was on the top of the list followed by diabetes mellitus, 20 (16%) (Table 8).

Table 8: Comorbidity claimed by hypertensive respondents, Addis Ababa, Ethiopia, 2008.

Comorbidity	N	%
Chronic kidney diseases	24	20.0
Diabetes mellitus	20	16.7
Cardiovascular diseases	13	10.8
Eye disease	10	8.3
Stroke	5	4.2
Gout	4	3.3
Arthritis	4	3.3
Asthma	2	1.7
Others*	4	3.3

* includes breast cancer, prostate cancer and gastritis.

5.2.5 Non pharmacological treatment (advices)

Non pharmacological treatment plays a vital role in the prevention/control of various diseases including hypertension. It is applied before first line drugs and/or as a supplement with medication therapy. Almost all, 119 (99.2%) of the respondents claimed that they were given advices as to how to control their blood pressure in addition to taking medications. The most frequent advices were to reduce salt intake, 116 (96.7%) followed by restriction of coffee consumption, 73 (60.8%) (Table 9).

Table 9: Advices given to respondents by prescribers, Addis Ababa,Ethiopia,2008.

Advices	N	%
Reduce salt intake	116	96.7
Restriction of coffee consumption	73	60.8
Reduce alcohol	45	37.5
Restrict from fatty meals	44	36.7
Exercise	43	35.8
Avoid stress	14	11.7
Lose weight	13	10.8
Restrict from sweet meals	9	7.5
Quit smoking	7	5.8
Others*	9	7.5

*includes checking BP regularly, refrain from khat, sweetie meal, bread, tea intake and restricting from drinking a lot of water.

5.3 Consumption of antihypertensive drugs

The consumption of drugs was described using DDD and cost of sales. The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults. For chronically used drugs, DDDs per 1000 population per day gives a better estimate on the consumption of drugs.

It is also important to note that appropriate age group for the population should be selected since some drugs are not used in all age groups. In our study, we encountered patients who are hypertensive as young as 18 years old. In addition, since the drugs were imported and get distributed to the whole country, the Ethiopian population excluding those under the age of 15 was used as a population in the denominator which stands at 40,649,074 according to population and housing census in 2007. Recent DDD of each antihypertensive drug was used from ATC/DDD Index 2009 developed by WHO (WHO, 2009).

The formula used to calculate DDD/1000 population/day was used as per the recommendation of WHO's manual introduction to drug utilization research (WHO, 2003):

$$\text{DDD/1000 population/day} = \frac{\text{Amount used in 1 year (mg)} * 1000}{\text{DDD (mg)} * \text{population} * 365 \text{ (days)}}$$

5.3.1 Imported antihypertensive drugs

Drug Administration and Control Authority is a drug regulatory agency in Ethiopia under the Federal Ministry of Health. All pharmaceuticals that are imported in to the country are reported to the authority office. Hence, all available data on the list of imported antihypertensive drugs was obtained for two years (1998 and 1999 E.C.) and hence, the consumption of the drugs was quantified using DDD.

5.3.2 Volume of locally manufactured antihypertensive drugs

Ethiopian Pharmaceutical Manufacturing

Ethiopian Pharmaceutical Manufacturing is a pharmaceutical company located in Addis Ababa. It manufactures a wide range of pharmaceuticals and hence, the quantity of manufactured Furosemide in 1998 and 1999 E.C was calculated and hence DDD/1000 inhabitants/day was quantified.

Addis Pharmaceutical Factory

Addis Pharmaceutical Factory is a pharmaceutical company located in Adi-grat. Amlodipine, furosemide and methyldopa are antihypertensive drugs manufactured by APF. The amount of Amlodipine, Furosemide and Methyldopa manufactured from 1998 to 1999 E.C was obtained and the respective DDD/1000 inhabitants/day was calculated.

Table 10: DDD/1000 population/day for each antihypertensive drugs imported as well as manufactured, Ethiopia, 2008.

Description	Quantity (in mg)		DDD/1000 population/day	
	1998 E.C	1999 E.C	1998 E.C	1999 E.C
Furosemide	260,104,000	382,024,000	0.438	0.643
Methyldopa	3,743,775,000	5,173,275,000	0.252	0.348
Enalapril	34,994,500	44,785,000	0.235	0.301
Nifedipine	54,205,000	141,696,000	0.121	0.318
Atenolol	106,073,000	165,060,000	0.095	0.148
Propranolol	83,330,000	65,615,000	0.035	0.027
Captopril	71,927,500	17,194,500	0.096	0.023
Lisinopril	2,562,000	2,117,600	0.017	0.014
Amlodipine	1,973,670	237,670	0.026	0.003
HCT	3,290,000	3,810,000	0.008	0.01
Felodipine	219,300	775,000	0.002	0.01
Verapamil	None	57,600	None	0.00001
Spirinolactone	25,000,000	None	0.022	None

5.3.3 Data compiled from KENEMA retail pharmacies

KENEMA pharmacies are retail outlets which are run by the government with a profit margin range of 18% to 20 % with the objective of ensuring affordable prices of medicines to the society. They were selected for this study because of the fact that they hold the biggest market share and they have organized sales data. The sales figure of all antihypertensive drugs in two kenema branches was added up over the years.

Kenema no. 2 (Piassa)

Data on the sales of antihypertensive drug were obtained for the period between January 2006 and October 2008. As it can be seen in the table 11 below, nifedipine stands at the top followed by atenolol and hydrochlorothiazide.

Table 11 : Cost of sales of each antihypertensive drug from Jan'06-Oct'08 for Piassa Kenema Pharmacy, Addis Ababa, Ethiopia, 2008.

Description	Cost of sales (in Eth. Birr)
Nifedipine	415,508.97
Atenolol	193,371.00
Hydrochlorothiazide	182,390.90
Spirinolactone	146,657.20
Enalapril	134,516.34
Methyldopa	116,110.28
Furosemide	103,609.42
Felodipine	79,271.13
Carvedilol	72,815.25
Lisinopril	55,643.63
Propranolol	46,682.94
Captopril	32,286.90
Amlodipine	24,362.70
Verapamil	1,555.00

Kenema no. 3 (Stadium)

Data on the sales of antihypertensive drugs was obtained for the period between July 2007 and October 2008.Just like the above pharmacy branch (Piassa), nifedipine ranks at the top followed by atenolol and hydrochlorothiazide.

Table 12: Cost of sales of each antihypertensive drug from Jul'07-Oct'08 for Stadium Kenema Pharmacy, Addis Ababa, 2008.

Description	Cost of sales(in Eth. Birr)
Nifedipine	339,152.33
Atenolol	230,202.50
Hydrochlorothiazide	172,889.70
Lisinopril	141,829.01
Enalapril	128,630.30
Felodipine	115,189.87
Spirinolactone	93,829.60
Carvedilol	78,380.95
Furosemide	75,248.73
Amlodipine	56,410.03
Methyldopa	46,076.53
Propranolol	40,526.24
Captopril	13,500.80
Verapamil	3,754.35

6. DISCUSSION

This study revealed that hypertensive patients with regards to sex are almost equal in proportions from the record review. With regards to age group, majority of the study particpatns were between 45 and 64 years.

The present study also found out that there is significant association between treatment pattern (monotherapy and multiple therapies) with sex, where; both males and females tend to get treated with monotherapy. However, there is no significant association between different age groups and treatment pattern (monotherapy and multiple therapies).

Control of BP to levels persistently below target levels will require multiple antihypertensive agents in the majority of patients with hypertension (Flack, 2007). In most, if not all, hypertensive patients, therapy should be started gradually and target blood pressure values achieved progressively through several weeks. To reach target blood pressure, it is likely that a large proportion of patients will require combination therapy with more than one agent. According to the baseline blood pressure and the presence or absence of complications, it appears reasonable to initiate therapy either with a low dose of a single agent or with a low-dose combination of two agents (Erdine *et al.*, 2006).

This study also found out that the use of two and more drugs (multiple therapies) in almost one third of the patients. This can be explained probably by physician's attempt to control blood pressure adequately with multiple drugs instead of a single drug at later times of the disease.

The present study found out that the most commonly prescribed antihypertensive drugs in the health institutions either alone or in combination were methyldopa, nifedipine, hydrochlorothiazide, enalapril and atenolol from each category of drugs during the initiation of medication therapy. This gives a clue that physician's prescription pattern is in accord with the standard treatment guideline (be it zonal hospital, district hospital or health center) of the country.

This finding is almost consistent with other studies done in Nigeria where methyldopa, nifedipine, hydrochlorothiazide or their combination are commonly prescribed antihypertensive drugs (Amira and Okubadejo; 2006, Yusuff and Balogun, 2005).

Methyldopa's usage, alone or in combinations, has been considerably reduced in the developed world due to their side effects (WHO, 1999). The negative impact of patients' experience of adverse effects on level of adherence and subsequent outcome of therapy are well documented (Eraker *et al.*, 1984).

The finding of this present study also revealed that there is tremendous treatment shift among different antihypertensive drug therapeutic category. The possible reasons for treatment shift are commonly failure to respond to drug, reason not known (not documented in the patient cards) and side effect to mention few.

Patient noncompliance with prescribed antihypertensive drug regimens are very common. High medication adherence ($\geq$ 80%) compared with intermediate (50%-79%) and low ($<$ 50%) medication adherence to a single-pill antihypertensive drug regimen was recently linked to greater BP control—43% for high, 34% for intermediate, and 33% for low medication adherence, respectively, over a 4-year period in 13 USA health plans (Bramley *et al.*, 2006)

This finding is in accord with a study done in USA where the continued shift from calcium antagonists to beta blockers and diuretics plus the large use of angiotensin converting enzyme inhibitors would indicate greater adherence to treatment guidelines (Lopez *et al.*, 2004).

Despite the widespread perception that the new agents are better tolerated, randomized clinical trials had failed to document any significant differences in rates of compliance or adverse events among the different classes of antihypertensive drugs (Mcalister *et al.*, 1997).

In addition, data from more than 20 RCTs have been published since 1967, comparing diuretics, beta blockers, and calcium channel blockers against placebo hypertensive patients. The data conclusively demonstrated reductions in both morbidity and mortality with these three drug

classes. A meta analysis of data from RCTs comparing two newer classes, i.e. angiotensin converting enzyme inhibitors and calcium channel blockers, against older classes, i.e. diuretics and beta blockers, in almost 75,000 hypertensive patients was published in 2000. For the end points of total cardiovascular mortality, the meta analysis showed no significant convincing differences between drug classes or between groups of old and new drugs (Whitworth, 2003).

Since the clinical trials document no significant difference among the different classes of antihypertensive drugs, cost effectiveness should be the vantage point for treatment shifts if there are no other confounding factors.

With regards to consumption, furosemide has the highest DDD/1000 inhabitants/day value. This is possibly due to self medication by a large number of the population. Another reason that could be cited is its availability at the market (imported and manufactured) in a tremendous amount has led to increased consumption of the drug by the society. Its consumption might have been exaggerated because it is also used for other clinical indications other than hypertension (for example; edema due to cardiac and renal disorders).

It is not surprising methyldopa to be the most common prescribed drug for the treatment of hypertension in a resource limited country like Ethiopia and the DDD/1000 inhabitants/day value is amongst the top because it is a generic drug. Its high prescription rate is in agreement with its high DDD/1000 population/day value.

Nifedipine, enalapril and atenolol have also high DDD/1000 population/day value which agrees with their high prescription rates at the selected health instutions. However, hydrochlorothiazide has low DDD/1000 population/day despite of their high prescription rates. This possibly could be due to frequent stock out of the drugs at the market or patient noncompliance.

Verapamil and spirinolactone had a gap when they were being imported to the country. This possibly happened due to decision of the respective importer companies to quit importing the drugs. The time between decision of the previous importer to stop importing and the registration of another importer to re continue its import might have been the cause for the gap.

The rest of the antihypertensive drugs have low consumption and this is possibly due to very low prescription rates of the drugs by physicians.

Cost figures are suitable for an overall analysis of expenditure on drugs. Long-term studies are difficult due to fluctuations in currency and changes in prices. When cost data are used, an increase in the use of cheaper drugs may have little influence on the total level of expenditure on drugs, while a shift to more expensive drugs is more readily noticed (WHO, 1993).

Based on cost of sales of antihypertensive from the selected two kenema pharmacies; nifedipine, atenolol, hydrochlorothiazide and enalapril stand at the top which is in agreement with the most commonly prescribed antihypertensives at the health institutions except for methyldopa. The possible reason could be self medication being practiced by the patients to control their blood pressure adequately as a result of peer influence or difference in price amongst antihypertensive drugs. Hydrochlorothiazide is at the top based on the cost of sales but low at consumption; this could be possibly due to the fact that a large number of populations purchase drugs from Kenema pharmacies because they have low profit margin as compared to private retail pharmacy outlets. The picture would have been different if the cost of sales was seen from private pharmacy retail outlets.

Lifestyle measures should be instituted whenever appropriate in all patients, including subjects with high normal blood pressure and patients who require drug treatment. The purpose is to lower blood pressure and to control other risk factors and clinical conditions present. The lifestyle measures that are widely agreed to lower blood pressure or cardiovascular risk and that should be considered are: smoking cessation, weight reduction, reduction of excessive alcohol intake, physical exercise, reduction of salt intake, increase in fruit and vegetable intake, and decrease in saturated and total fat intake (Erdine *et al.*, 2006).

Substance use such as cigarette smoking, binge drinking, and khat chewing could increase risk for CVD among adults because of their widespread prevalence among adult men and their significant association with increased diastolic BP (Tesfaye *et al.*, 2008). This indicates that the nonpharmacologic treatment should be continued in a strong manner.

Our finding also revealed that the most common complications and comorbidity were diabetes mellitus, chronic kidney diseases and cardiovascular diseases.

This is in agreement with a study done in South Africa where cardiovascular diseases, chronic kidney diseases, diabetes mellitus, asthma and arthritis are the most frequent underlying comorbid states. (Rayner *et al.*, 2007).

Recent data suggest that individuals who are normotensive at age 55 years have a 90% lifetime risk for developing hypertension. The relationship between blood pressure and risk of cerebrovascular disease events is continuous, consistent and independent of other risk factors. The higher the blood pressure, the greater the chance of myocardial infarction, heart failure, stroke and kidney disease. For individuals aged 40–70 years, each increment of 20 mmHg in systolic blood pressure or 10 mmHg in diastolic blood pressure doubles the risk of cardiovascular disease. These alarming data support a need for greater emphasis on public awareness of the problem of high blood pressure and for an aggressive approach to antihypertensive treatment. The presence of cardiovascular risk factors, particularly diabetes mellitus, target organ damage and associated cardiovascular and renal disease, substantially increases the risk of hypertension. The level of risk is used to determine the threshold and type of therapeutic intervention (WHO, 2005).

7. STRENGTHS AND LIMITATIONS OF THE STUDY

Even though the study is informative, it has many limitations. Recall bias during exit interview by respondents is evident. Another limitation that could be cited is, as we know, there are antihypertensive drugs which are also used for other clinical indications (for example, ACEIs for congestive heart failure and beta blockers for cardiac arrhythmias) and might have exaggerated the prescription pattern and consumption. Consumption trend of drugs for at least five years could not be assessed due to lack of available data.

Despite the above limitations, the present study provides useful information to assess hypertension treatment pattern and consumption of antihypertensive drugs. Furthermore, the large sample size and the use of several methodologies to complement different methods with each other can be taken as the strength of the present study.

8. CONCLUSION AND RECOMMENDATIONS

From the present study it can be concluded that methyldopa, nifedipine, hydrochlorothiazide, enalapril and atenolol are widely used drugs either alone or in combination for the treatment of hypertension which is in line with standard treatment guideline of the country and the guideline of international society of hypertension with the exception of methyldopa. There is tremendous treatment shift amongst different therapeutic class of antihypertensive drugs mainly based on failure of the drug to adequately control blood pressure. Furosemide followed by methyldopa, enalapril, nifedipine and atenolol are the most consumed drugs for two consecutive years based on the data obtained by drug regulatory authority and manufacturing plants. Nifedipine ranks at the top based on cost of sales of the two selected kenema pharmacies followed by atenolol, hydrochlorothiazide and enalapril.

Based on the findings the following recommendations can be made:

- Policy makers, clinicians, drug regulatory agency and other concerned stakeholders should assess and reconsider the benefits and risks of using methyldopa in the treatment of hypertension except for pregnant patients.
- Cost effectiveness should be a priority during treatment shift among the different category of antihypertensive drugs.
- Manufacturers should try to produce at least one drug from each therapeutic class, namely; nifedipine, hydrochlorothiazide, enalapril and atenolol locally and importers should prioritize on these drugs to be imported in to the country so that stock out will be avoided.
- Health education should be given to the public at large about the risk factors for hypertension and how to avoid unhealthy life style and ill feeding habits.
- Future longitudinal research should be done to describe consumption trend of antihypertensive drugs.

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Annex 1: Data abstraction format

Assessment of hypertension treatment pattern at selected health facilities in Addis Ababa and consumption of antihypertensive drugs

Data abstraction format

Name of the health institution: _____

Code No _____

1. Sex ☐ Male ☐ Female
2. Age _____
3. Date of initial diagnosis of hypertension _____
4. At initial diagnosis name of the antihypertensive medication/s prescribed _____

   Number of medication/s prescribed _____

   Category of medication/s _____

   Date of prescription _____
5. Is there a change of medication/s prescribed (treatment shift)? ☐ Yes ☐ No If No, Skip to Qn 8
6. Reason given for treatment shift

   ☐ No reason given

   ☐ Failure to respond to drug

   ☐ Improvement

   ☐ Side effect

   ☐ Change of diagnosis

   ☐ Others, please specify _____
7. Name of the current antihypertensive medication/s prescribed _____

   Number of medication/s prescribed _____

   Category of medication/s _____

   Date of prescription _____

8. BP measurement

Early BP	
2nd Visit BP	
3rd Visit BP	
4th Visit BP	
Recent BP	

9. Was there any complication/s due to hypertension?

☐ Yes ☐ No If No, skip to Qn. 11

10. What was/were the complication/s?

☐ Diabetes mellitus

☐ Cardiovascular diseases

☐ Chronic kidney diseases

☐ Stroke

☐ Others, please specify _____

11. Was there concomitant mediation? ☐ Yes ☐ No

12. If yes to the above question, name of the medication/s

A. _____

B. _____

C. _____

D. _____

E. _____

Annex 2: Informed consent (Amharic)

በአዲስ አበባ ከተማ በተመረጡ የጤና ማእከላት ስለ ከፍተኛ የደም ግፊት በሽታና ተያያዥ ጉዳዮች በተመለከተ ጥናት

በጥናቱ ላይ ለመሳተፍ የቀረበ የፈቃደኝነት መጠየቂያ ቅጽ

ጤና ይስጥልኝ ስሜ መዋዕል ተሻለ እባላለሁኝ። የምሰራው ከአዲስ አበባ ዩንቨርሲቲ የጥናት ቡድን ጋር‹‹ ስለ የከፍተኛ ደም ግፊት በሽታና ተያያዥ ጉዳዮች›› ላይ ነው። የዚህ ጥናት ዓላማው በበሽታው ላይ ያተኮረ ተግባራዊ ለውጥ በግለሰቡ፣ በቤተሰቡ እና በጤና ማዕከሉ ከፍተኛ አስተዋጾኦ ለማምጣት ነው። ስለዚህ ጥናት ይረዳ ዘንድ 20 ደቂቃ ገደማ የሚወስዱ ጥያቄዎችን ልጠይቅዎት እፈልጋለሁ። የሚሰጡት መልስ በሚስጥር የሚጠበቅ ሲሆን ስምዎንም ሆነ አድራሻዎን በመጠየቁ ላይ አይጠቀስም። በዚህ ጥናት ላይ መሳተፍ በእርስዎ ሙሉ ፍቃድ ላይ የተመሰረተ ሲሆን የተወሰኑትን ወይም ሁሉንም ጥያቄዎች አለመመለስም ይቻላል። ነገር ግን የእርስዎ አስተያየት ወይም መልስ በጣም ጠቃሚ ስለሆነ በጥናቱ ላይ ይሳተፉሉ ብለን ተስፋ እናደርጋለን።

በቃለ መጠይቁ ለመሳተፍ ፈቃደኛ ነዎት?

አዎ _____ አይደለሁም _____

የመረጃ ሰብሳቢ ስም <u>መዋዕል ተሻለ</u> ፊርማ _____

የተቆጣጣሪ ስም <u>መዋዕል ተሻለ</u> ፊርማ _____

Annex 3: Questionnaire for exit interview (Amharic)

የቃለ መጠይቅ ቅፅ

የጤና ማዕከሉ ስም _____

የመጠይቁ መለያ ቁጥር _____

ቃለመጠይቁ የተደረገበት ቀን _____

ሀ.

1. ጸታ 1. ☐ ወንድ 2. ሴት ☐
2. እድሜ _____
3. የትምህርት ደረጃ
    1. ☐ ማንበብና መፃፍ የማይችል
    2. ☐ ማንበብና መጻፍ የሚችል
    3. ☐ አንደኛ ደረጃ
    4. ☐ ሁለተኛ ደረጃ
    5. ☐ ኮሌጅ/ዩኒቨርሲቲ
4. የጋብቻ ሁኔታ
    1. ☐ ያላገባ (ች)
    2. ☐ ያገባ (ች)ና ከትዳር ጓደኛው (ዋ) ጋር አብሮ (ራ) የሚኖር (የምትኖር)
    3. ☐ ያገባ (ች)ና ከትዳር ጓደኛው (ዋ) ጋር አብሮ (ራ) የማይኖር(የማትኖር)
    4. ☐ በህጋዊ መንገድ የፈታ (ች)
    5. ☐ የትዳር ጓደኛው (ዋ) የሞተበ(ባ)ት
5. የሥራ ዓይነት
    1. ☐ የመንግሥት ሠራተኛ (ሲቪል)
    2. ☐ መንግስታዊ ያልሆነ ድርጅት ሠራተኛ
    3. ☐ የግል ሥራ ተዳዳሪ
    4. ☐ ተማሪ
    5. ☐ የቤት እመቤት
    6. ☐ ወታደር
    7. ☐ ጡረተኛ
    8. ☐ ሥራ የለኝም
    9. ☐ ሌላ ካለ ይግለጹ _____

ለ.

1. የከፍተኛ ደም ግፊት ታማሚ ከሆኑ ምን ያህል ጊዜ ይሆንዎታል? _____

2. የከፍተኛ ደም ግፊት መድኃኒት (ቶች) መውሰድ ከጀመሩ ምን ያህል ጊዜ ይሆንዎታል?

_____

3. ለመጀመሪያ ጊዜ የከፍተኛ ደም ግፊት ተመርምረው ታማሚ ሲሆኑ የታዘዘልዎት መድኃኒት (ቶች) ምንድን ነው (ናቸው)?

3.1. ☐ ሜትይል ዶፓ
3.2. ☐ ካርቨዲሎል
3.3. ☐ አቴኖሎል
3.4. ☐ ኘሮኘራኖሎል
3.5. ☐ ስፓይሪኖላክቶን
3.6. ☐ ሃይድሮክሎርቲያዛይድ
3.7. ☐ አሚሎዲፒን
3.8. ☐ ፊሎዲፒን
3.9. ☐ ቬራፓሚል
3.10. ☐ ፋሮሰማይድ
3.11. ☐ ሊሲኖኘሪል
3.12. ☐ ኢናላኘሪል
3.13. ☐ ካፕቶኘሪል
3.14. ☐ ኒፊዲፒን
3.15. ☐ ሌላ ካለ ይግለፁ _____

4. እነዚህ ከላይ የተጠቀሱት የከፍተኛ ደም ግፊት መድኃኒት (ቶች) ለምን ያህል ወሰዱ? ____

5. ለመድኃኒቱ (ቶቹ) ይከፍሉ ነበር?

1. ☐ ነፃ 2. ☐ እከፍላለሁ

5.1. የሚከፍሉ ከሆነ በወር ምን ያህል ብር ነበር? _____

6. በአሁን ሰዓት ለሚወስዱት የከፍተኛ ደም ግፊት መድኃኒት (ቶች) ምንድን ነው (ናቸው)?

6.1. ☐ ሜትይል ዶፓ
6.2. ☐ ካርቨዲሎል
6.3. ☐ አቴኖሎል
6.4. ☐ ኘሮኘራኖሎል
6.5. ☐ ስፓይሪኖላክቶን
6.6. ☐ ሃይድሮክሎርቲያዛይድ
6.7. ☐ አሚሎዲፒን
6.8. ☐ ፊሎዲፒን
6.9. ☐ ቬራፓሚል
6.10. ☐ ፋሮሰማይድ
6.11. ☐ ሊሲኖኘሪል
6.12. ☐ ኢናላኘሪል
6.13. ☐ ካፕቶኘሪል
6.14. ☐ ኒፊዲፒን
6.15. ☐ ሌላ ካለ ይግለፁ ____

7. እነዚህ ከላይ የተጠቀሱት መድኃኒት (መድኃኒቶች) ለምን ያህል ጊዜ ወሰዱ? _____

8. ለመድኃኒቱ (ቶቹ) ይከፍላሉ ወይ?

1. ☐ ነዓ 2. ☐ አይደለም

8.1. የሚከፍሉ ከሆነ በወር ምን ያህል ብር ነው? _____

9. መጀመሪያ ላይ ሲወስዱ በነበረው የከፍተኛ ደም ግፊት መድሀኒት (ቶች) እና አሁን በመጠቀም ላይ ባሉት የከፍተኛ ደም ግፊት መድሀኒት (ቶች) መሀል ሌላ የታዘዘልዎት የከፍተኛ ደም ግፊት መድሀኒት (ቶች) ነበር ወይ?

1. ☐ አዎ 2. ☐ አይደለም

9.1. አዎ ከሆነ የከፍተኛ የደም ግፊት መድሀኒት (ቶች) ምንድን ነው (ናቸው)? ለምን ያህል ጊዜ?

	የተጠቀሙበት ጊዜ		የተጠቀሙበት ጊዜ
9.1.1. ☐	ሜትይል ዶፓ	☐ 9.1.8.	ፊሎዲፒን .....
9.1.2. ☐	ካርቨዲሎል	☐ 9.1.9	ቬራፓሚል .....
9.1.3. ☐	አቴኖሎል	☐ 9.1.10	ፋሮሰማይድ .....
9.1.4. ☐	ኘሮኘራኖሎል	☐ 9.1.11.	ሊሲኖፕሪል .....
9.1.5. ☐	ስፓይሪኖላክቶን	☐ 9.1.12	ኢናላፕሪል .....
9.1.6. ☐	ሃይድሮክሎሮቲያዛይድ	☐ 9.1.13.	ካፕቶፕሪል .....
9.1.7. ☐	አሚሎዲፒን	☐ 9.1.14.	ኒፊዲፒን .....
		☐ 9.1.15.	ሌላ ካለ ይግለፁ_____

9.2. ሲወስዱት የነበረውን የከፍተኛ ደም ግፊት መድኃኒት (ቶች) ሲቀየሩ የተነገርዎት ምክንያት ምንድን ነበር?

9.2.1. ☐ የጐንዮሽ ውጤት

9.2.2. ☐ መሻሻል ስለታየብኝ

9.2.3. ☐ መድኃኒት በማቋረጥ

9.2.4. ☐ መድኃኒቱ ስላልሰራ

9.2.5. ☐ የምርመራ ለውጥ

9.2.6. ☐ ምክንያት አልተነገረኝም

9.2.7. ☐ የታዘዘው መድኒት በመጥፋቱ

9.2.8. ☐ የመድሃኒት ዋጋ

9.2.9. ☐ ሌላ ካለ ይግለፁ _____

10. ከከፍተኛ ደም ግፊት ህመም ውጪ ሌላ ህመም (ህመሞች) ታመዋል ወይ?

1. ☐ አዎ 2. ☐ አይደለም

10.1. አዎ ከሆነ ህመሙ (ህመሞቹ) ምንድን ነው (ናቸው)?

10.1.1. ☐ የስኳር በሽታ

10.1.2. ☐ የልብና ተያያዥ ህመም

10.1.3. ☐ የኩላሊት ህመም

10.1.4. ☐ ስትሮክ

10.1.5. ☐ አስም

10.1.6. ☐ አርትራይተስ

10.1.7. ☐ ሌላ ካለ ይግለፁ _____

11. የከፍተኛ ደም ግፊት መድኃኒት (ቶች) ከመጠቀም በተጨማሪ ሊያደርጉ ስለሚገባዎት ጥንቃቄ ፡ ምክር ተሰጥዎት ያውቃሉ ወይ?

1. ☐ አዎ ☐ 2. አይደለም

11.1. አዎ ከሆነ ምክሮቹ ምንድን ነው (ናቸው)?

11.1.1. ☐ የጨው መጠን መቀነስ

11.1.2. ☐ የአካል ክብደት መቀነስ

11.1.3. ☐ የአካል እንቅስቃሴ ማድረግ

11.1.4. ☐ ሲጋራ ማጨስ ማቆም

11.1.5. ☐ የአልኮል መጠጥ መጠን መቀነስ

11.1.6. ☐ ቡና ከመጠጣት መቆጠብ

11.1.7. ☐ የቅባት ምግቦችን አለመውሰድ

11.1.8. ☐ ሌላ ካለ ይግለፁ _____

ጥያቄዎችን ጨርሻለሁ፡- ለትብብርዎ እና ለጊዜዎ በድጋሚ አመሠግናለሁ፡፡

Annex 4: Informed consent (English)

Assessment of hypertension treatment pattern at selected health facilities in Addis Ababa and consumption of antihypertensive drugs

Hello! My name is _____ and I am part of a team of people who are carrying out a study on "Assessment of hypertension treatment pattern at selected health of facilities in Addis Ababa and consumption of antihypertensive drugs". The purpose of this study is to bring tangible changes to the individual, family and the health facility thus contributing a great positive role towards the treatment of hypertension. I would like to ask you some questions about hypertension and related issues and it will take about 20 minutes. Your response will be anonymous. All questions are based on your full consent and you have a full right not to answer any question. All answers are based on your full consent and you have a full right not to answer any question that you feel stressful. However, we hope that you will participate in this study since your views are very important.

As you willing to participate in the study?

Yes _____ No _____

Name of Data collector: _____ Signature _____

Name of supervisor: _____ Signature _____

Annex 5: Questionnaire for exit interview (English)

Name of the health facility _____

Code No _____

Date of interview _____

A.

1. Sex 1. ☐ Male ☐ 2. Female
2. Age _____
3. Education
   1. ☐ Illiterate
   2. ☐ Can read & Write
   3. ☐ Primary
   4. ☐ Secondary
   5. ☐ College/University
4. Marital status
   1. ☐ Single
   2. ☐ Married
   3. ☐ Separated
   4. ☐ Divorced
   5. ☐ Widowed
5. Occupation
   1. ☐ Government Employee
   2. ☐ Private sector employee
   3. ☐ Self Employee
   4. ☐ Student
   5. ☐ House Wife
   6. ☐ Military
   7. ☐ Retired
   8. ☐ Unemployed
   9. ☐ Other, specify .....

B.

1. How long have you been diagnosed as hypertensive?

_____

2. How long have been taking antihypertensive medications?

_____

3. What was/were the antihypertensive medication/s prescribed for you initially at the start of you diagnosis?

3.1. ☐	Methyldopa	☐ 10.	Furosemide
3.2. ☐	Carvedilol	☐ 11.	Lisinopril
3.3. ☐	Atenolol	☐ 12.	Enalapril
3.4. ☐	Propranolol	☐ 13.	Captopril
3.5. ☐	Spirinolactone	☐ 14.	Nifedipine
3.6. ☐	Hydrochlorothiazide	☐ 15.	Others, Please specify ___
3.7. ☐	Amilodipine		
3.8. ☐	Felodipine		
3.9. ☐	Verapamil		

4. For how long have you taken these antihypertensive medication/s listed above?

_____

5. Were you paying for these antihypertensive medication/s?

1. ☐ Free 2. ☐ I was Paying

5.1. If you were paying, how much per month? _____ Eth Birr

6. What is/are the antihypertensive medication/s you are currently taking?

6.1. ☐	Methyldopa	☐ 10.	Furosemide
6.2. ☐	Carvedilol	☐ 1.	Lisinopril
6.3. ☐	Atenolol	6.12. ☐	Enalapril
6.4. ☐	Propranolol	6.13. ☐	Captopril
6.5. ☐	Spirinolactone	6.14. ☐	Nifedipine
6.6. ☐	Hydrochlorothiazide	6.15. ☐	Others, Please specify _____
6.7. ☐	Amilodipine		
6.8. ☐	Felodipine		
6.9. ☐	Verapamil		

7. For how long have you taken these antihypertensive medication/s listed above?

_____

8. Are you paying now for these antihypertensive medication/s?

1. ☐ Free 2. ☐ I am paying

5.1. If you are paying, how much per month?

_____ Eth Birr

9. In between from the initiation of antihypertensive medication/s up to present ones, were there any other typed of antihypertensive medication/s prescribed for you?

1. ☐ Yes 2. ☐ No

9.1. If yes to the above question, what was/were the antihypertensive medication/s prescribed? For how long?

		Duration			Duration
9.1.1. ☐	Methyldopa	_____	9.1.10 ☐	Furosemide	_____
9.1.2. ☐	Carvedilol	_____	9.2.11. ☐	Lisinopril	_____
9.1.3. ☐	Atenolol	_____	9.1.12. ☐	Enalapril	_____
9.1.4. ☐	Propranolol	_____	9.1.13. ☐	Captopril	_____
9.1.5. ☐	Spirinolactone	_____	9.1.14. ☐	Nifedipine	_____
9.1.6. ☐	Hydrochlorothizide	_____	9.1.15. ☐	Others, Please Specify	____
9.1.7. ☐	Amilodipine	_____			
9.1.8. ☐	Felodipine	_____			
9.1.9. ☐	Verpamill	_____			

9.2. What was/ware the reason/s given for switching the previous antihypertensive medication/s to the current one?

9.2.1. ☐	Side effect	9.2.5. ☐	Change of diagnosis
9.2.2. ☐	Improvement	9.2.6. ☐	No reason given
9.2.3. ☐	Discontinuation	9.2.7. ☐	Unavailability of prescribed drug
9.2.4. ☐	Failure to respond to drug	9.2.8. ☐	Cost of drug
		9.2.9. ☐	Others, please specify _____

10. Do you have co morbidity/co morbidities other than hypertension?

1. Yes ☐ 2. ☐ No

10.1. If yes to the above question, what is/are the co morbidity/co morbidities?

10.1.1. ☐ Diabetes mellitus
10.1.2. ☐ Cardiovascular diseases
10.1.3. ☐ Kidney disease
10.1.4. ☐ Stroke
10.1.5. ☐ Asthma
10.1.6. ☐ Arthritis
10.1.7. ☐ Others, please specify _____

11. Was advice given in addition to antihypertensive medication/s?

1. ☐ Yes 2. ☐ No

11.1. If yes to the above question what was/were the advices given to you?

11.1.1. ☐ Reduce salt intake
11.1.2. ☐ Lose weight
11.1.3. ☐ Increase aerobic exercise
11.1.4. ☐ Quit smoking
11.1.5. ☐ Limit alcohol consumption
11.1.6. ☐ Restrict coffee consumption
11.1.7. ☐ Restrict fatty meals
11.1.8. ☐ Other, please specify _____

I have finished my interview. Thank you very much again for your time and cooperation.

DECLERATION

I, the undersigned declare that this thesis is my original work and has not been presented for a degree in any other university.

Name : Mewael Teshale Arefayne

Signature: _____

This thesis has been submitted for examination with our approval as university advisors.

Name : Teferi Gedif(PhD)

Signature: _____

Name : Fikru Tesfaye (PhD)

Signature: _____

Place and date of submission: Addis Ababa, Ethiopia

October, 2009.