A SURVEY OF HERBAL MEDICINE USE IN HYPERTENSIVE PATIENTS AT THE UNIVERSITY TEACHING HOSPITAL LUSAKA, ZAMBIA.

ANN MBULO

"THESIS SUBMITTED TO THE UNIVERSITY OF ZAMBIA IN PARTIAL FULFILLMENT OF THE REQUIREMENTS OFTHE MASTERS DEGREE IN CLINICAL PHARMACY"

THE UNIVERSITY OF ZAMBIA

2015

DECLARATION

I hereby declare that this dissertation represents my own work and that all the sources I have quoted have been indicated and acknowledged by means of complete references. I further declare that this dissertation has not been presented either wholly or in part for a degree at the University of Zambia or at any other University.

Signed………………………………   Date.....................................

Student: Ann Mbulo (0977 784435)

Signed……………………................   Date....................................

Supervisor: Dr. L.T.Muungo PhD
                 Head Lecturer
                 Pharmacy Department
                 University of Zambia
                 Lusaka, Zambia.

APPROVAL CERTIFICATE

The University of Zambia approves this dissertation of ANN MBULO in Partial Fulfilment of the requirement for the award of the Degree of Masters of Clinical Pharmacy.

Examiners

1. **Name:**..

   Signature:...

   Date:..

2. **Name:**..

   Signature:...

   Date:..

3. **Name:**..

   Signature..

   Date:..

DEDICATION

I dedicate this work to my daughters Lukundo, Zewelanji and Njavwa and my unreservedly supportive husband Emmanuel Silwimba. I would also like to dedicate this work to my parents and my late sister who always told me to believe in the almighty God in everything I do.

ABSTRACT

The safety and efficacy profiles of herbal medicines have not yet been established in treatment of hypertension. The study investigated the prevalence of herbal medicine use in hypertensive patients being managed at the University Teaching Hospital. It also determined control of blood pressure (systolic and diastolic) in hypertensive patients taking both herbal medicine and conventional medicine and those taking conventional medicine alone. To draw inference the study associated herbal medicine use with blood pressure control.

A cross sectional study at the University Teaching Hospital outpatient clinic 5 was conducted. Sample size of 255 was calculated using prevalence formula. Systematic sampling method with a sampling interval of 8 was used. Patients that met the eligibility criteria were included. Herbal medicine and conversional medicine were independent variables while hypertension was the dependent variable. Administered interviewer questionnaire was used. Their files were then checked for blood pressure readings (retrospectively for 6 months). SPSS version 22.0 was used to analyse the data.

Of 255 hypertensive patients interviewed, 24.7% combined herbal medicine with conventional medicine. The mean blood pressure for hypertensive patients that took both herbal medicine and conventional medicine was , 143.95 +/- 16.405 mmHg SD(systolic), 85.59 +/- 7.378 mmHg SD(diastolic) and hypertensive patient that took only conventional medicine was 143.10 +/- 17.201 mmHg SD(systolic) , 86.27 +/- -8.099 mmHg SD(diastolic). There was no significant difference in the mean blood pressure readings between patients that took herbal medicines together with conventional medicines and patients that took conventional medicines alone p=0.730 and p=0.556 systolic and diastolic respectively using t test. The commonly used herbal medicine was *Aloe barbadensis* (27.1%) followed by *Moringa oleifera* (20.8%).

The prevalence of herbal medicines use among hypertensive patients is high (24.7%). Herbal medicines were found to have no effect in controlling blood pressure in hypertensive patients taking both herbal medicines and conventional medicines.

ACKNOWLEDGEMENTS

TABLE OF CONTENTS

CONTENTS   **PAGE**

CHAPTER 1

CHAPTER 5

CHAPTER 6

List of Tables

LIST OF APPENDICES

ACRONYMS AND ABREVIATIONS

BP   Blood Pressure

WHO   World Health Organisation

CAM   Complementary and Alternative Medicines

NCD   Non-Communicable Diseases

UTH   University Teaching Hospital

TM   Traditional Medicines

THM   Traditional Herbal Medicine

PURE   Prospective Urban and Rural Epidemiological study

SPSS   Statistical Package for Social Sciences

SBP   Systolic Blood Pressure

DBP   Diastolic Blood Pressure

USEFUL TERMS AND DEFINITIONS

Traditional medicine

Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Complementary/alternative medicine (CAM)

The terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system. Types of complimentary therapies include aromatherapy, acupuncture, herbal medicine, massage therapy, visualization and yoga. This study will narrow down to herbal medicines alone. These will include herbs, herbal materials, herbal preparations and finished herbal products.

Herbal medicines

Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations.

- **Herbs:** Crude plant material such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.
- **Herbal materials:** In addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be

processed by various local procedures, such as steaming, roasting, or stir-baking with honey, alcoholic beverages or other materials.

- **Herbal preparations:** The basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.

- **Finished herbal products:** herbal preparations made from one or more herbs. If more than one herb is used, the term mixture herbal product can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal.

HYPERTENSION/ BLOOD PRESSURE

- Hypertension also known as high blood pressure is a measurement of the force against the walls of the arteries as the heart pumps blood through the body. Blood pressure readings are usually given as two numbers e.g. 120 over 80 written as 120/80 mmHg (Okubadejo *et al.*)

CHAPTER ONE

1.0   BACKGROUND

Hypertension is a common disease which presents with persistently elevated arterial blood pressure (BP). The World Health Organization (WHO) 2012 report estimates that 1 in 3 adults has raised blood pressure worldwide (Chaib,2012), while a Global burden of hypertension analysis estimates an increase by more than 29% by the year 2025 (Kearney *et al.,* 2005). The prevalence of hypertension in developed countries has been found to be relatively high for instance 44%, 28% in Western Europe and North America respectively (Ogah *et al., 2014*). According to a study in Southern African, about 20 million people in sub-Saharan Africa are hypertensive (Hughes *et al., 2013*). Goma *et al. (*2011) found 34.8% hypertension prevalence among adults in Lusaka urban, Zambia. Reports by WHO show a 24.3 % hypertension death rate per 100,000, in Zambia (WHO, 2011). Another report by WHO states that of the 57million deaths that occurred in 2008, 36million (63%) were due to non communicable diseases (NCDs); 80% of these were due to cardiovascular diseases among which is hypertension (Alwan *et al*., 2010). Improving BP control with treatment is considered a critical public health initiative to reduce cardiovascular morbidity and mortality.

However, the incidence of complementary and alternative medicines (CAM) use is increasing worldwide and is recognized in both Africa and global populations to be between 20-80% (Amira and Okubadejo, 2007). The terms *complementary* and *alternative* describe practices and products that people choose as adjuncts to or as alternatives to Western medical approaches. Increasingly, the terms *CAM* and Traditional medicine(*TM)* are being used interchangeably. According to studies that have been done in developed countries herbal medicine use is also on the increase for instance, in the United States over 15 million people use herbal medicines (Tachjian *et al.*, 2010). Reports show increased CAM use in African countries (Mwangelwa, 2013; Amira and Okubadejo, 2007; Shafiq *et al.,* 2003).

Conversely, in the effort to minimise the intake of medicines, people utilized non-pharmacological treatments to supplement their medicines (Pound *et al., 2008*). Though the prevalence of herbal medicine use is so significant in many countries, there is lack of scientific evidence for safety, efficacy and quality of traditional medicines to support their curative claims (Lotika *et al*., 2013; Marinac *et al*., 2007). Study done by Osamor *et al*. (2010), acknowledged the use of herbal medicine (63%) in hypertension in a Nigerian community and recommended further studies to be done in hypertension and other non- communicable diseases.

Though published studies done in Zambia are lacking, a newspaper article by Mwangelwa published in the Times of Zambia (2013) report showed that herbal medicines are being used a lot in Zambia. Commonly used herbs include*, Moringa oleifera*, *Aloe barbadensis*, *Allum sativum,Tianshi/Tiens, Zingiber officinale* root to treat conditions like hypertension, asthma, diabetes and for body well being and to boost appetite (Mwangelwa, 2013). Kahokola (2009 unpublished) reported a 45% general CAM use at the University Teaching Hospital but did not associate it with any other parameters.

This study therefore investigated the prevalence of herbal medicine use among hypertensive patients at the University Teaching Hospital, Lusaka Zambia and determined the association between herbal medicine use with blood pressure control.

1.1 Statement of the problem

The safety and efficacy profiles of Herbal medicines have not yet been established. Following the nature and sensitivity of hypertension, critical management using conventional medicines is important. Therefore knowing the prevalence of herbal medicine use among hypertensive patients is important as information is currently scanty.

However, media perception (The Times of Zambia, a public news publisher) and opinion on herbal medicine use in Zambia is that, herbal medicine use by the public has increased (Mwangelwa, 2013), though the prevalence in individual groups is not known.

It is important for clinicians and all healthcare providers to know other therapies the patient is taking to help manage them appropriately.

While most of such therapies are generally safe, they may not have the desired anti hypertensive properties, they may also interact with the prescription medicines thereby considerably elevating blood pressure (Calabro, 2009; Vora, 2005).

There is need to increase pharmaceutical care to the patients following the relatively high prevalence (34.8%) of hypertension in Lusaka, Zambia (Goma *et al.*, 2013).

A report by Tachjian *et al., (*2010) found that belief in the safety of CAM products remains unsubstantiated; even when data is available findings are often questionable because of lack of consistency in research methods.

This study therefore endeavored to determine the prevalence of herbal medicine use among hypertensive patients and the effect on blood pressure control when used concurrently with conventional medicine. In this study the prevalence of herbal medicine use was determined by way of a structured questionnaire and six months retrospective review of patient's files was done to obtain blood pressure readings and the means compared between those taking both herbal medicines and conventional and those taking conventional medicine alone.

1.2 RESEARCH QUESTION

What is the prevalence of herbal medicine use in hypertensive patients managed at UTH Lusaka Zambia clinic 5 and their effect on blood pressure control?

1.3 STUDY JUSTIFICATION

The study was done to determine the prevalence of herbal medicine use among hypertensive patients at UTH. Herbal medicines do not have consistent information following their safety and efficacy profiles. Therefore the levels of use of herbal medicines by hypertensive patients if known would motivate clinicians and healthcare

providers to find out from patients other therapies they are taking hence result in appropriate patient management.

In order to advise patients accordingly clinicians should have a good understanding of herbal medicines that are commonly used. Lotika *et al*. (2013) also affirms the general understanding of herbal medicines by clinicians in practice. Information concerning herbal medicine use should be made available in patient's files; this would be made possible if patients tell their doctors about their use of CAM, like reported by Cockayne *et al*. (2005) that most patients do not report CAM use to their physicians. The consequence of not reporting CAM use is that potential interactions between herbal medicines and prescription medicines may be missed. These interactions may result in poor blood pressure control. Lotika *et al*. (2013) attests to the fact that interactions between herbal medicines and prescription medicines can occur.

In a study by Tabassum *et al.* (2011), recommendations were made for more research to be done to confirm the effectiveness and to make clear the safety profile of herbal remedies. Therefore this study endeavored to determine the levels of herbal medicine use among hypertensive patients and blood pressure control in patients concurrently taking herbal medicine with prescription medicines.

This study will benefit hypertensive patients, clinicians, policy makers and researchers as it will provide a base for further research in herbal medicine use and also add to the body of knowledge.

1.4 AIM OF THE STUDY

The aim of the study was to determine the prevalence of herbal medicine use in hypertensive patients being managed at The University Teaching Hospital, Lusaka, Zambia.

1.4 SPECIFIC OBJECTIVES

1. To determine prevalence of herbal medicine use in hypertensive patients at UTH, Lusaka, Zambia.

2. To determine control of blood pressure (systolic and diastolic) in hypertensive patients that take both herbal medicines and conventional medicines and patients taking conventional medicines alone.

3. To determine the association between herbal medicine use and blood pressure control

CHAPTER TWO

2.0 LITERATURE REVIEW

The terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system. Types of complimentary therapies include aromatherapy, acupuncture, herbal medicine, massage therapy, visualization and yoga (Wilson, 2000). This study narrowed down to herbal medicines alone which were obtained from chemists, gardens, herbalists.

In a cross sectional descriptive study done in South Africa involving 443 participants to determine prevalence of Traditional Herbal Medicine (THM) use in hypertension, it was found that of 135 who used THM 21% used THM to treat hypertension, 82.1% were females, 96% were unemployed, 56% were aged between 55 and 64years. From the results obtained in this PURE study the participants could probably not afford the medicines for their condition because, of 135 THM users 96% were not employed. On the other hand over half of the participants were older adults (55-64yrs, p-value= 0.003) who are considered to be in the crucial stage of life with so many health related issues, they might have been the largest group in the 21% of THM use. A more even demographic distributed sample would have been more representative (Hughes *et al*., 2013).

Nuwaha *et al.* (2013), in a study to estimate the percentage of people that used alternative medicine and to identify factors leading to their use, found that 56.2% used alternative medicine at some point. At the time of the study 28.6% were using alternative medicines either alone or in combination with modern medicines. The predictors for the use of alternative medicines were the belief that they are effective for the treatment of hypertension and are safe to use. Safety of herbal medicines has not been scientifically established, however being herbs they are considered to possess some pharmacologically active components that have some risk of side effects and interactions

with conventional medicines. Some side effects encountered by participants in the study were diarrhea, darkening of stool and vomiting.

In Jamaica where natural treatment methods are highly reported, 80% of the participants reported combining natural products with prescription medicines in their treatments for hypertension, diabetes mellitus and gastro intestinal disorders with only 13% informing their doctors of the practice. The aim of the study was to have an insight of the prevalence of poly pharmacy practices. In the study, natural remedies' use was statistically prevalent in 47-57 age group, significant association of natural remedies use with residence was evident with (p<0.01) level of participants living in rural community was at 92 % (Delgoda *et al*., 2004). Association between residence and natural medicine use sends a message of affordability.

A study conducted in India to determine the prevalence of CAM in hypertensive patients of a tertiary care center, had 521 patients interviewed over a 6 month period where 63.7% were reported to have been using CAM for hypertension. The commonly used CAM was ayurveda and herbal medicines at (56.7%) and (14.4%) respectively. Conversely patients exceeding half ultimately disapproved using CAM. Only a few informed their doctor about CAM use (5.4%) (Shafiq *et al*., 2003). The high percentage (59%) of participants that was reported to have feared side effects of conventional medicines show that there was high level of misinformation. It is therefore worthwhile to communicate with the doctors and other health care providers to help in making an informed decision.

A study done in Malaysia reported a high prevalence of herbal medicine use by hypertensive patients, where results show about 33.9% respondents use herbal medicines (Aziz *et al.*, 2009).

Interactions between prescription and non-prescription medicines occur with severe outcomes sometimes. Dangerous interactions between herbs and medicines occur and are on the increase because of lack of communication between doctors and their patients. Studies show that about one half to two thirds of patients do not inform their doctors about their herbal medicine use (Howell *et al*., 2006). Herbal therapeutic products

7

considerably interact with other compounds and can also elevate blood pressure (Amira and Okubadejo, 2007; Cockayne *et al.,* 2005; Tebasam *et al*., 2011; Vora., 2005; Zhang *et al*., 2012) e.g. herbs like licorice, ephedra (Ma Huang) and yohimbine can increase blood pressure therefore should not be used together with anti-hypertensive medication (Klodas, 2012).

A retrospective study done by Mooi *et al*., (2013) to assess the prevalence and patterns of CAM use in Malaysia found that CAM use was at 64.6% and most CAM products used were bitter gourd 34.4% followed by garlic 17% and musai kucing 14.6%. It was also found that diastolic blood pressures were significantly higher with CAM use (Mooi *et al*., 2013).

Amira and Okubadejo, (2007), conducted a cross sectional retrospective study where 225 hypertensive patients attending the hypertension clinic of the Lagos University Teaching Hospital were interviewed. They found 88% CAM use, herbal products being the commonly used. The herbal medicines used were garlic, ginger, bitter leaf and aloe vera in the proportions 69.3%, 25%, 23.9% and 4.5% respectively. However, they did not find any difference in the clinical characteristics and blood pressure control of CAM users and non CAM users. Despite the high number of females than males in the study (60% and 40% respectively) which predisposes to bias, it addressed almost all the issues this study intends to look at. It is important therefore to see the prevailing situation in our setting.

A study done in Natalspruit Hospital South Africa reported poor blood pressure control and participants reported that they took traditional medicines as well (Lotika *et al.,* 2013).

Review Summary

The use of CAM to treat hypertension is being practiced at a considerably increased rate as shown by Hughes *et al.* (2013) 21% and Mooi *et al. (*2013) 64%. With respect to blood pressure control Mooi et al reported an increased diastolic blood pressure among CAM users but Amira and Okubadejo did not see any difference at all between the two

populations (CAM users and non CAM users), this can well be attributed to the fact that blood pressure control can be affected by a number of other behavioral factors such as diet, lack of exercise etc, which could have been the case with Mooi *et al*'s study.

Most studies reviewed conducted cross sectional surveys in an effort to determine CAM use among hypertensive patients. Cross sectional studies also known as prevalence studies are comparatively quick and easy to carry out. It is used where no suitable routinely collected data are available and it answers the question on prevalence. However sampling and data collection need great care (Stewart, 2002).The reviewed studies used a questionnaire as a tool for data collection (Hughes *et al*., 2013; Amira and Okubadejo, 2007; Nuwaha *et al*., 2013). Of the reviewed studies the methodology that was adopted and adjusted to our setting was that used by Amira and Okubadejo, (2007), because, the study also investigated blood pressure control which is relevant to this study, it took care of possible confounders in blood pressure control and was conducted at a tertiary institution similar to our study. Mooi investigated blood pressure control but the study was conducted at local clinic therefore was not preferred.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

A cross sectional study to determine herbal medicine use in hypertension was done.

3.2 Study Site

The study was conducted at the University Teaching Hospital Clinic 5, an Outpatient Department where patients with non communicable diseases are seen of which hypertension is one of them.

3.3 Study Population

Hypertensive patients on medication and managed at the University Teaching Hospital Clinic 5.

3.4 Study Sample

A study sample of 255 was arrived at; using the prevalence formula as follows:

$N = Z^2 \times P (1-P)/d^2$

$N = 1.96^2 \times 21(100-21)/5^2$

$N = 3.8416 \times 21 \times 79/25$

$N = 254.9$

$N = 255$

Where N- is sample required; p- herbal medicine use prevalence (21% was used from a PURE study done in South Africa, Hughes *et al*, 2013), d- acceptable accuracy range **+/-** 5 (according Naing *et al*, it is appropriate to have a precision of 5% if prevalence is

going to be between 10% and 90%) and z – z statistic at 1.96, z statistic for the level of confidence of 95% which is conventional z-1.96(Naing *et al*, 2006)

3.5 Sampling Techniques

Systematic random sampling method was used as it provides an equal chance for participants to be picked therefore avoiding biasness. Every eighth file of hypertensive patients was picked for recruitment. It was arrived at by proportions 255/2040 which is 1/ 8, where 255 was the sample size and 2040 was the population. Therefore; every eighth file was picked and the owners were included in the study (Health Information's Systems UTH, 2014, an average of 34 hypertensive patients are seen per day at clinic 5. Therefore 34 patients multiplied by 5 days in a week= 170 then, 170 multiplied by 4 weeks giving us 680 patients in a month, 680 was then multiplied by three, since the study was carried out in 3 months and thus the 2040).

3.6 Inclusion Criteria

Diagnosed hypertensive patients on conventional medication, managed at Clinic 5 an outpatient clinic at UTH for at least 6 months, should be 18 years to 75years, and willing to participate in the study

3.7 Exclusion Criteria

Under 18 years and above 75 years, not hypertensive, hypertensive patients not managed from Clinic 5, patients not willing to consent to the study, and hypertensive patients managed at clinic 5 UTH for less than six months.

3.8 Variables

Table 1: Table of variables

Specific objective	variable	Type of variable	Indicators
To determine prevalence of patients on herbal medicine	Herbal medicine use	➤ categorical	➤ Percentage of patients taking herbal medicines ➤ Percentage of those not taking herbal medicine
To determine blood pressure control in hypertensive patients taking herbal medicine with conventional medicine	Blood pressure	➤ Continuous	➤ Mean blood pressure in patients taking both herbal medicines and conventional medicine ➤ Mean blood pressure in patients taking conventional medicine alone.

3.9 Data Collection Instruments

The tool that was used to collect data was an interviewer administered questionnaire. It was divided in four parts where patient related information was collected in the first part, followed by herbal medicine use by the patients, doctor patient communication and blood pressure readings respectively.

3.10 Data Collection Procedure

Participants were consented by way of a written consent and interviewed using an interviewer administered questionnaire for their response. After the questionnaire had been filled in the researcher checked their medical file for blood pressure readings in the last six months and documentation of herbal medicine use. Data collection was done in a period of three months.

3.11 Data Analysis

Data was coded and analysed using Statistical Package for Social Sciences (SPSS 22.0). **Descriptive analysis-** Descriptive statistics (percentage and frequencies) were used to describe demographic and other categorical variables.

Mean and standard deviation were used to describe blood pressure.

Inferential analysis- Independent t test was used to examine the differences in mean blood pressure between those taking both herbal medicines and conventional medicine and those taking conventional medicine alone with a confidence level being held at 95%, $p < 0.05$ was required for significance.

3.12 Ethical considerations

This study did not involve introducing any substance into the participant's body but their personal files were analysed for information. The study was presented to the ERES Converge IRB for approval before commencing the data collection. Permission from the UTH management was sought and so was the consent from patients for their participation. Participants were consented by way of written informed consent form. Participants were allowed to withdraw without any form of consequence, if they felt uncomfortable to go on. Codes were used as participants' identity to maintain confidentiality and questionnaires will be kept under lock and key by the researcher until the results are published.

CHAPTER FOUR

4.0 RESULTS

The study found that herbal medicine use at UTH is high (24.7%) as shown in table 2 below.

Table 2: Herbal medicine Use in Hypertension

	FREQUENCY	PER CENT
Herbal medicine users	63	24.7
Non herbal medicine users	193	75.3
Total	255	100

The prevalence of herbal medicine use in hypertensive patients on conventional medicine at UTH was found to be 24.7%

Of the total number of 255 participants 132 were females (51.8%) and 123 were males (48.2 %). Of these participants 105 (41.2 %) were more than 55 years, 52 (32.2%) were aged between 46-55 years while 32 (12.6 %) were less than 36 years old.

The percentage of participants that weighed over 80kg were 46 (18%) while those that had regular exercise at least three times a week were 66 (25%). Of the participants interviewed 41 (16 %) attained primary education, 65 (25.5%) attained tertiary education, 90(35.5%) attained secondary education and 59 (23.1%) did not go to school.

Of the people interviewed, the total number of herbal medicine users was 63 (24.7%) and they used different types of herbal medicines as shown in table 3 below. The commonly used herbal medicine was *Aloe barbadensis* (27.1%) and the least was *Allum sativum* (12.9%).

Table 3: Herbal medicines commonly used

	Frequency	Per cent
Moringa oleifera	53	20.8
Zingiber officinale	39	15.3
Allum sativum	33	12.9
Aloe barbadensis	69	27.1

The commonly used herbal medicine was *Aloe barbadensis* (27.1%) followed by *Moringa oleifera* (20.8%)

Of the participants that did not take herbal medicines 28% knew about someone who took herbal medicine for hypertension and 22.7% had heard of herbal medicine use by hypertensive patients. Duration of herbal medicine use by participants was between 7 months and 2 years. Of the herbal medicine users 18.4% talked to someone and 6.3% did not.

Recommendations for herbal medicine were mostly from family and friends 4.3%.

About 16% of herbal medicine users believed that herbal preparations helped relieve symptoms of the disease while 5.9% experienced side effects. Majority of the participants bought their herbal medicines from the market (14.5%) and shop (10.2%). Of the participants interviewed 98.4% thought it was important for the doctors to know the herbal medicines the patients were taking meanwhile only 41.6% practitioners enquired about the patients' herbal medicine use.

There was no statistically significant association seen between herbal medicines use and gender, age, residence (p= 0.127, p=0.416 p= 0.065) respectively, while education level showed a significant association (p=0.011) using pearsons' chi-square.

The mean blood pressure for hypertensive patients taking both herbal medicines and conventional medicines was , 143.95 +/- 16.405 mmHg SBP (systolic), 85.59 +/- 7.378 mmHg DBP (diastolic) and hypertensive patients taking only conventional medicine

was 143.10 +/- 17.201 mmHg SBD (systolic) , 86.27 +/- -8.099 mmHg DBP (diastolic) Table 4. There was no significant difference between patients taking both herbal medicines and conventional medicines and patients taking conversional medicine alone p=0.730 and p=0.556 systolic and diastolic respectively using t test (Table 5).

Table 4: Blood Pressure Control in Hypertensive Patients Taking Herbal Medicine

	Minimum	Maximum	Mean	Std. Deviation
Average sbp in herbal and conventional medicine users	115	191	143.56	16.570
Average dbp in herbal and conventional medicine users	68	107	85.45	7.398
Average sbp in conventional medicine only users	108	202	143.10	17.201
Average dbp in conventinal medicine only users	70	116	86.27	8.099

Data are means +/- SD for 63 hypertensive patients taking herbal medicines with conversional medicine and hypertensive patients taking herbal medicine alone
*P<0.05 Vs blood pressure control in hypertensive patients on both by t-test

Table 5: T test for Equality of means

	t	df	Sig (2 tailed)	Mean diff.
Average sbp equal variances assumed	0.346	253	0.730	0.853
Average dbp equal variances assumed	-0.589	253	0.556	-0.678

sbp- systolic blood pressure, dbp- diastolic blood pressure, sig- significance, diff- difference, df- degrees of freedom

CHAPTER FIVE

5.0 DISCUSSION

This study showed that there is a high prevalence of herbal medicine use among hypertensive patients at the University Teaching Hospital, Lusaka (24.7%).

These results are comparable with the ones by Hughes *et al*., 2013 (21%) and Nuwaha et al., 2013 (28.6%) However this estimate is lower than the ones observed in other countries like Malaysia 64.6%, 33.9% (Mooi et al., 2013 and Aziz et al., 2009) respectively and Jamaica 80% (Delgoda et al., 2004) but higher than that seen by Shafiq et al., 2003 (14.4%). This also shows that the practice of herbal medicine is everywhere world over and that its use is based on common belief that herbal medicines are effective in lowering blood pressure and alleviating symptoms of illnesses (Tachjian *et al*., 2010).

This study also found that using herbal medicines together with conventional medicines has no effect on blood pressure control as there was no difference in the means of the systolic and diastolic blood pressures of hypertensive patients taking both herbal and conventional medicines and the patients taking conventional medicines alone (143.56 +/- 16.57mmHg Vs 143.10 +/- 17.20 mmHg and 85.45 +/- 7.398 mmHg Vs 86.27 +/- -8.09 mmHg) respectively and the difference was not statistically significant p=0.556 (systolic) and p=0.730 (diastolic). However, there are confounding factors that could affect the control of blood pressure such as weight, diet, and exercise frequency. In this study about 18% participants weighed over 80Kg, while 25% exercised at least three times a week. It could have been that majority of patients that weighed over 80Kg were herbal medicine users thus affecting the outcome of the results.

Amira and Okubadejo also did not see any difference in the blood pressure control between hypertensive patients taking both herbal and conventional medicines and those taking herbal medicine alone. Though the two studies (Amira and colleague and this study) seem to have similar findings the commonly used herbal medicines were different and also the study locations are in two different parts of Africa therefore there could also be differences in the product species. This entails that there is need to conduct more studies on herbal medicines and their effect on blood pressure control. This information

would certainly be important for intervention programs to enhance patient medication adherence and health outcomes.

Contrary to our findings a study by Mooi and colleagues found an increase in diastolic blood pressure in hypertensive patients using CAM (Mooi *et al*., 2013). The difference in findings can be attributed to the variations in herbal medicines commonly used by the majority of participants and possible interactions between herbal and conventional medicines (Vora et al., 2005, Aziz et al., 2009)

The findings of this research following commonly used herbal medicine among hypertensive patients managed at UTH were that majority of participants used *Aloe barbadensis* (27.1%) followed by *Moringa oleifera* (20%) and only 12.9% use *Allum sativum* for their blood pressure control, different from Amira and Okubadejos study where majority of participants used garlic (69.3%) and *Aloe vera* (4.5%) (Amira and Okubadejo., 2013).

In this study it was shown that social demographic factors, age, employment status, residence were not significantly associated with herbal medicine use for hypertension, this is consistent with the study by Nuwaha (2013) but different from Hughes and Amira, on the other hand this study showed education level being statistically significant with herbal medicine use (p=0.011) consistent with Hughes and Amira. The study revealed that herbal medicine use was commonly used as adjunct therapy by unemployed, low income earners. Therefore lack of education among other factors such as social economic factors, accessibility of health facilities, could be the reason why the less educated and low income earners were majority in the use of herbal medicines (Tachjian *et al*., 2010). Another reason could be that the less income earners had difficulties in acquiring conventional anti-hypertensive medication in an event that they run out. Participants reported purchasing these readily available products from places such as the market, pharmacies and supermarkets.

Herbal medicine use can also be influenced by co-morbid situation as the patients strive to find a lasting solution to their condition. In this study, there was a statistically

significant association between herbal medicine use and hypertensive patients with co-morbid conditions. (p= 0.004) this is consistent with Ali-Shtayeh (p= 0.001).

This study showed that the main source of information about herbal medicine use was family and friends, media and articles, very few sought professional advice. This result is supported by other studies that also show that users of herbal medicines rarely seek professional advice in selecting herbal medicines but mainly depend on friends and relatives (Hughes et al., 2013, Ali-Shtayeh et al., 2013). Over half (58.4%) participants did not disclose their use of herbal medicines to their doctors, this is lower than the findings (70%) in a study that determined the patterns and determinants of CAM use in Ghana (Kretchy et al., 2014) and that found in a study by Ali-Shtayeh (68.1%). The high non disclosure rates of herbal medicine use can be due to fear by patients and non enquiry of the physicians as reported by Kretchy and colleagues. The difference in the results can be due to variations in how proactive physicians are in taking a detailed drug history. Such behaviors put patients in danger of being mismanaged as there is potential interaction between conventional and herbal medicines (Ali-Shtayeh et al., 2013) Over 80% were willing to tell the physicians about their use of herbal medicines only if they were asked (Tachjian *et al*., 2010). Such information on herbal medicine use is vital for health professionals as they need to asses patient needs in relation to treatment outcomes, medication adherence behaviors and possible drug interactions. Patients may develop complications resulting from poor blood pressure control if they lack such monitoring.

A study done in USA to determine the perception about CAM therapies relative to conventional therapies among adults who use both herbal and conventional medicines found that 79% perceived the combination to be superior to either one alone while in our study only 16.1% thought the combination was beneficial, when in essence herbal medicine used did not provide any benefits, this is according to the findings in this study (p=0.765 systolic and p=0.553 diastolic).

The frequency of herbal medicine use and length of time herbal medicines had been used by participants indicates how dependent participants were on herbal medicine in managing hypertension. This also indicates that there was little information flow between patients and the healthcare providers. Therefore there is need for healthcare providers to know about the increased herbal medicine use amongst their patients and be able to provide appropriate advice regarding potential adverse effects or possible herb drug interactions (Amira and Okubadejo, 2013, Hughes *et al*., 2013,).

CHAPTER SIX

6.0 SCOPE AND LIMITATIONS

The University Teaching Hospital was chosen considering that it serves as the country's specialist centre receiving referrals from all over the country.

This study had limitations that need to be acknowledged. To start with the study sample was not too representative therefore the results cannot be generalized to a broader population as it was done at one hospital only. The estimate of the prevalence of herbal medicine use was based on self-reported behavior (responder bias) and therefore some level of under reporting, a more possible occurrence in a survey of this nature could be hypothesized. Blood pressure management takes into consideration a number of factors such as Body Mass Index (BMI), diet, stress which were not factored in as the BP readings were recorded retrospectively.

6.1 RECOMMENDATIONS

1. Healthcare providers should probe the patients and document other therapies patients are using.
2. Herbal medicine information regarding their effect on blood pressure should be provided to the hypertensive patients. This can be done through media, journals and health talks at health facilities.

6.2 CONCLUSION

The prevalence of herbal medicine use among hypertensive patients is high (24.7%). Herbal medicine was found to have no effect in controlling blood pressure in hypertensive patients taking both herbal and conventional medicine as there was no statistically significant association as observed by T test for equality of means (systolic p=0.730, diastolic p=0.556).

REFERENCE

Alwam, A., Armstrong, T., Bettcher, D., Branca, F., Chisholm, D., Zzati, M., Garfield, R., Maclean, D., Mathers, C., Mendis, S., Poznyak, V., Riley, L., Cho Tang, K. and Wild, C; (2010) *Global status report of non-communicable diseases* (WHO), Pages 9-28

Ali-Shtayeh,M.S.,Jamous,R.M., Salameh,N.M.V ; (2013) 'Complementary and alternative medicine (CAM) use among hypertensive patients in Palestine', *Complementary Therapies in Clinical Practice,* **19**: 256-263

Amira, C.D and Okubadejo, U.N. (2007) 'Frequency of complementary and alternative medicine utilization in hypertensive patients attending an urban tertiary care centre in Nigeria,' *BMC Complementary and Alternative Medicine*, **7**(30):6882-7-30

Aziz, Z. and Tey, P (2009) 'Herbal Medicines: Prevalence and predictors of use among Malaysian adults,' *Complementary Therapies in Medicine*, **17**(1):44-50.

Chaib, F. (2012) *World Health Organization: New data highlights increases in hypertension, diabetes incidence*. Available from: http://www.who.int/mediacentre/news/releases/2012/world.........20120516/en/... (Accessed on 15 June 2014)

Calabro, S. (2009) *Herbs and Supplements for hypertension*. Available from :< http://www.everydayhealth.com/hypertension/herbs and supplements>. (Accessed on 6 April 2014)

Cockayne, N,L,.Daguid, M.,Shenfielf, G,M.,(2005) Health professionals rarely record history of complementary and alternative medicines. *British Journal of Clinical Pharmacology*: 59(20):254-258

Delgoda, R., Elington, C., Barrett, S., Gordon, N., Younger, N. (2004) 'The practice of poly pharmacy involving herbal and prescription medicines in the treatment of diabetes

mellitus, hypertension and gastrointestinal disorders in Jamaica,' *West Indian medical Journal*, **53**(6):400-405.

Goma, F.M., Nzala, S.H., Babaniyi, O., Songolo, P., Zyaambo, C., Rudatsikira, E., Siziya, S.,[*] and Muula, A, S. (2011) 'Prevalence of hypertension and its correlates in Lusaka urban district of Zambia, a population based survey,' *International Archives of Medicine,* **4:34**.

Howell, L., Kochhar,J., Saywell,R., Zollinger,T.,Koehler,J.,Mandzuk,C.,Sutton, B.,Sevilla-Martir, J and Allen, D.(2006) 'Use of herbal remedies by hispanic patients: Do they inform their physician?,'*Journal of the American Board of Family Medicine*, **19**(6): 566-578.

Hughes, G.D., Aboyad, O.M., Clark, B.L., and Puoane, T.R. (2013) 'The prevalence of traditional herbal medicine use among hypertensives living in South African communities,' *BioMed Central complementary and Alternative Medicine*, doi: 10, 1186/1472-6882-13-38.

Kahokola, B. (2009) Complementary and Alternative Medicines use besides conversional medicines among hypertensive patients at University Teaching Hospital in Lusaka. Unpublished Bpharm Project. The University of Zambia.

Kearney, M, P., Whelton, M, B, S., Reynolds, K., Muntner, P., Whelton, P, K., Jiang, H. (2005) 'Global burden of hypertension: analysis of worldwide data,'*The Lancet*, **365** (9455): 217-223

Klodas, E. (2012) *Complementary and alternative treatments for high blood pressure*: Available from :< http://www.webmd.com/hypertension-high-blood-pressure/guide/hypertension-complementary-alt>. (Accessed on 8 April 2014)

Kretchy, I.A.,Owusu-Daaku, F., Danquah, (2014) 'Patterns and determinants of the use of complementary and alternative medicine: A cross sectional study of hypertensive patients in Ghana', *BioMed Central Complementary and Alternative medicine*; **14**: 44

Lotika, A. A. Mabuza, L .H., Okonta, H.I. (2013) 'Reasons given by hypertensive patients for concurrently using traditional and western medicines at Natalspruit Hospital in the Gauteng Province, South Africa,' *African Journal of Primary Health Care Family Medicine* **5** (1):458,7.

Marinac, S, J., Buchinger, L, C., Godfrey, A, L., Wooten, J, M., Sun, C., Willsie, K, S. (2007) 'Herbal Products and Dietary Supplements: A Survey of Use, Attitudes, and Knowledge Among Older Adults,' *Journal of the American Osteopathic Association (JAOA)* **107**(1):13-23.

Mwangelwa, E. (2013) *Zambia: Benefits of using herbal remedies.* Available from: <http://allafrica.com/stories/201310180781.html> . (Accessed on 9 April 2014)

Naing, L., Winn, T., Rusli, B. N. (2006) 'Medical Statistics: Practical issues in calculating the sample size for prevalence studies,' *Archives of Orafacial Science*, **1**: 9-14

Nuwaha, F. and Musinguzi, G. (2013) 'Use of alternative medicine for hypertension in Buikwe and Mukuno districts of Uganda: across sectional study,' *BioMed Central Complementary and alternative medicine,* 13:301 doi: 10, 1186/1472-6882-13-301

Ogah ,O. S., Okpechi, I., Chikwuonye, I.I., Akinyemi ,J.O., Onwubere ,B.J.C., Falase ,A.O., Stewart ,S. and Sliwa ,K. (2012) 'Blood pressure, prevalence of hypertension and hypertension related complications in Nigerian Africans,' A Review*; World Journal of Cardiology,***4**(12):327-340

Osamor, P. E., Owumi, B.E. (2010) 'Complementary and alternative medicine in the management of hypertension in an urban Nigerian community,' *BioMed Central Complementary and Alternative Medicine,* 10:36. Doi: 10.1186/1472-6882-10-36

Pound,P., Britten, N., Morgan,M., Yardley, L., Pope, C., White, G, D., Campell, R. (2005) 'Resisting Medicines: a synthesis of qualitative studies of medicine taking,' S*ocial Science and Medicine*, **61**(1):133-155

Shafiq, N., Gupta, M., Kumari , S., Pandhi, P.(2003) 'Prevalence and patterns of use of complementary and alternative medicine in hypertension patients of a tertiary care center in India,' *international Journal of Clinical Pharmacology The*, **41**(7):294-295

Mooi,S, C., Vasudevan, R., Zakaria, Z., Paimin,F.(2013) 'Frequency of complementary and alternative medicine usage among Malaysian hypertensive subjects*,' life science Journal,***10**(4):2526-2531

Stewart, A. (2002) *Basic Statistics and Epidemiology, a practical guide;* Abingdon: University of Wolverhampton page 91-92

Tabassum, N., Amad, F. (2011) 'Role of natural herbs in the treatment of hypertension,'*Pharmacognosy Reviews*, **5**(9): 30–40.

Tachjian, A. Maria, V. Jahangir, A (2010) 'Use of herbal products and potential interactions in patients with…,' *Journal of the American College of Cardiology*, **55**(6):515-525.

Vora, C. K., Mansoor, G.A (2005) 'Herbs and alternative therapies: Relavance to hypertension and cardiovascular diseases;Current hypertension reports,' *impact factor: 3. 74 ,* **7**(4):275-80.

Wilson,W.(2000) *World Health Organisation*, *General guidelines for methodologies on research and evaluation of traditional medicines.* (WHO/ EDM/ TRM/2000.1) Geneva page 1- 4

World Health Organization (2011) *Hypertension death rates by country*. Available from <http:// www.worldlifeexpectancy.com/cause-of-death/hypertension/by country> Accessed on 6 April 2014

Zhang, J. Wider, B. Shang, H., Xuemei Li, X. Ernst, E. (2012) 'Quality of herbal medicines;Challenges and solutions,complementary therapies in medicine,'**1**(20):100-106

APPENDICES

Appendix- A
Clearance letter from assistant dean post graduate studies

THE UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

Telephone : +260211252641

Telegram: UNZA, Lusaka

Telex: UNZALU ZA 44370

Email: assistantdeanpgmedicine@unza.zm

P.O Box 50110

Lusaka, Zambia

22nd   July, 2014

Ms. Ann Mbulo

Department of Pharmacy

School of Medicine

UNZA

LUSAKA

Dear Ms. Mbulo,

RE: GRADUATE PROPOSAL PRESENTATION FORUM

Having assessed your dissertation entitled **"A Survey of Herbal Medicine use in Hypertensive Patients at the University Teaching Hospital",** we are satisfied that all the corrections to your research proposal have been done. The proposal meets the standard as laid down by the Board of Graduate Studies.

You can proceed and present to the Research Ethics.

Yours faithfully,

Dr. S.H. Nzala

ASSISTANT DEAN, POSTGRADUATE

CC: HOD, Pharmacy
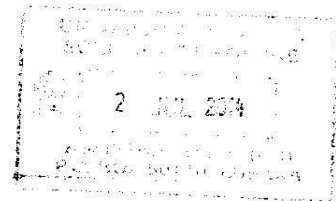
Appendix- B
Clearance from UTH management

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
PHARMACY DEPARTMENT

Telegram:	UNZA, Lusaka	Telephone:
Telex :	UNZALU ZA 44370	Deans Office: 252641
P.O. Box:	50110	Departmental Office: 257635

To,

The Head Clinical Care

UTH

28/7/14

Re: Mrs. Ann Mbulo; Computer No. 512806986

This is to inform you that the above named is a Masters' student presently in 3rd Year of her Masters in Clinical Pharmacy, UNZA.

Ann's research project is titled," A survey of Herbal medicine use in hypertensive patients at UTH."

As a department we seek your approval for the candidate to access, Clinic 5, UTH, to enable her to carry out the research.

We look forward to working together to improve patient safety and overall care.

Sincerely,

Dr Lavina Prashar

Head; department of Pharmacy

School of Medicine

APPENDIX-C

QUESTIONNAIRE

<u>Study No (   )</u>

<u>Location of interview</u>

Outpatient patient department clinic 5 University Teaching Hospital

INTRODUCTION

This questionnaire is for hypertensive patients that have accepted to participate in research on herbal medicine use in hypertension. Herbal medicines in this study refers to finished or unfinished products like ginger, garlic, moringa etc.

This survey instrument was adapted from the herbal product and dietary supplement survey by Morinac. S. J *et al* and modified to suit our setting.

PART A

PATIENT RELATED FACTORS

1. Social demographic factors

   Age :(years) (nearest birthday)

   18-25(   ) 1   26-35(   ) 2   36-45(   ) 3   46-55(   ) 4   above 55(   ) 5

   Sex: M (   ) 1   F (   ) 2

   Weight (Kg) last 6 months: 50-59 (   ) 1   60-69(   ) 2   70-79(   ) 3   above 80(   ) 4

   Exercise (last in last 6 months): 3 times a week (   ) 1   once a week (   ) 2
                  did not exercise at all (   ) 3

2. Level of education

   Primary (   ) 1 Secondary (   ) 2   Tertiary (   ) 3   Have not been to school (   ) 4

3. Residential address..

4. Are you employed? Yes (   ) 1   No (   ) 2

5. Income   (K500-K2,000) ( ) 1

                                 (K2, 000-K5, 000) ( ) 2

                                 (>K5, 000) ( ) 3

                                 (<2000) ( ) 4

PART B

TO ASSESS HERBAL MEDICINE USE WITH PRESCRIPTION MEDICINE

1. Are you currently taking any herbal medicines for hypertension?   Yes( )1
    No( )2
   If your answer in question 1 is **YES** proceed to question 4, if your answer is **NO** proceed
   to question 2.

2. Would you know anyone who takes herbal medicine for hypertension? Yes ( )1
    No ( )2
   If your answer is NO proceed to question 3 and if your answer is YES proceed to
   question 4

3. Have you ever heard of herbal medicine use in hypertension? Yes ( )1   No( )2

4. If so, what herbal medicine are you taking or the person you know is taking or the one
   you could have heard of that hypertensive patients are using.
   Ginger ( ) 1

   Moringa ( ) 2

   Garlic ( ) 3

   Aloe vera ( ) 4

   Other...................

If your answer in question 1 is NO then proceed to question 10
5. For how long have you been taking the herbal medicine?   7months( )1 2years( )2
    3years( )3   over 3 years( )4

6. Did you talk to anyone about herbal medicines before you started taking? Yes( )1
No( )2

7. How did you know about the herbal medicine? **Answer if your response in 6 is NO.**

8. Who prescribed the herbal medicine for you?   Medical doctor ( )1
   Traditional Doctor ( )2   Self( )3

9. In what form is the herbal medicine you are using and how much do you take each day?

   Liquid 1-3 tea spoons daily ( )   4-6 teaspoons daily ( ) 7-10 teaspoons daily ( )

   Powder 1 table spoon daily ( )   2-4 tablespoons daily ( )   more than 4
   table spoons daily ( )

   Tablet/capsules ( )   1 tabs/caps daily ( ) 2-4 tabs/ caps daily ( )   more than 4
   tabs/ caps daily ( )

   Other..

10. Are you taking any herbal medicine for any other condition apart from hypertension?
    Yes ( )   No ( )

    If the answer in question 10 is **NO** then proceed to part D

11. What condition are you taking it for? Diabetes( )1

    Anemia ( ) 2 Asthma ( ) 3 others....................................

12. What is the name of the herbal medicine you are taking?

PART C

ASSESSING THE EFFECTS OF HERBAL MEDICINE ON BLOOD PRESSURE

(Applicable to those taking herbal medicine)

1. Do you think herbal products have health benefits in relation to your blood pressure control? Yes ( ) 1   No ( ) 2

2. Do you experience any side effects due to herbal medicine?   Yes ( ) 1 No ( ) 2

3. Where do you buy your herbal medicines? Market( )1   Shop( )2

PART D

DOCTOR PATIENT COMMUNICATION

1. Is it important that your doctor know herbal products you are taking? Yes( )1 No( )2

2. Does your doctor ask you about the herbal medicines you take alongside the medication? Yes( )   No( )

3. If your doctor asked you of the herbal medicine would you tell him/her the truth? Yes ( )1 No( )2   Give reason to your answer...

PART E

BLOOD PRESSURE READINGS FOR THE LAST 6 MONTHS

MONTH	BLOOD PRESSURE READING

Alcohol consumption: Yes ( ) 1   No ( ) 2 (data from the file)

APPENDIX-D

INFORMATION SHEET

I am Ms Ann Mbulo a clinical pharmacy student at the University of Zambia. I am doing a research involving 255 participants on herbal medicine use in hypertensive patients at The University Teaching Hospital, Lusaka.

I am going to give you information and invite you to be part of this research. You can take your time to think about it or if you feel you need to consult you are free to talk to someone before you decide or ask me as we go through the information sheet.

PURPOSE OF THE RESEARCH

Hypertension as you may know is a common condition nowadays and may be dangerous if not managed well. The desire to control the blood pressure lead so many into taking other medicines (herbal) other than the ones the Doctors prescribe. This research wants to see if the other medications being taken together with medicines from the hospital really help control the blood pressure and the number of people using other medicines. We believe you can help us gather the necessary information required.

TYPE OF RESEARCH INTERVENTION

This research will not involve any kind of intervention.

PARTICIPANT SELECTION

Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

PROCEDURE

To gather information you will be requested to respond to questions provided to you by the interviewer through a questionnaire which would not take more than 20 minutes and a review of your treatment file will follow to check for blood pressure readings in the last 6 months.

CONFIDENTIALITY

The information recorded is confidential, your name will not be included on the forms, a code will be assigned for identification. No one will have access to your filled in questionnaire except my supervisors and I.

APPROVED

0 4 NOV 2014

ERES CONVERGE
P/BAG 125, LUSAKA.

RISKS

There will be no risks involved in participating in this research

BENEFITS

There will be no direct benefits to you but knowing the levels of blood pressure control in people taking herbal medicines and the prevalence of herbal medicine use in hypertensive patients will help the clinicians discuss with you in detail with regard to the medicines you are taking and advise accordingly.

Contact detail of researcher: Ms Ann Mbulo

(Master of Clinical Pharmacy Student)

Pharmacy Department, University Teaching Hospital,

P/Bag RW 1X, Ridgeway, Lusaka.

Contact details of Ethics Committee: The Chairperson, ERES CONVERGE IRB
33 Joseph Mwilwa Road
Rhodes Park
LUSAKA
Tel: 0955 155633/4

APPENDIX E

CONSENT FOR PARTICIPATION IN INTERVIEW RESEARCH

I volunteer to participate in a research project conducted by Ms Ann Mbulo from The University of Zambia. I understand that the project is designed to gather information about Herbal medicine use in hypertensive patients at the University Teaching Hospital. I will be one of the 255 people being interviewed for this research.

1. My participation in this project is voluntary. I understand that I will not be paid for my participation.

2. If I feel uncomfortable in any way during the interview session, I may withdraw and discontinue participation at any time without penalty.

3. Participation involves being interviewed by researcher from The University of Zambia. The interview will last approximately 20 minutes and my file will be reviewed for blood pressure readings. A questionnaire will be filled in during the interview.

4. I understand that the researcher will not identify me by name and assured me of confidentiality.

5. I have read and understood the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study.

6. I have been given a copy of this consent form.

_____   _____

My Signature   Date

_____   _____

My Printed Name   Signature of the Investigator

For further information, please contact:

Ms Ann Mbulo **(0977784435)**

APPROVED
0.4 NOV 2014
ERES CONVERGE
P/BAG 125, LUSAKA.

APPENDIX- F

Ethical approval

33 Joseph Mwilwa Road
Rhodes Park, Lusaka
Tel: +260 955 155 633
+260 955 155 634
Cell: +260 966 765 503
Email: eresconverge@yahoo.co.uk

I.R.B. No. 00005948
F.W.A. No. 00011697

4ᵗʰ November, 2014

Ref. No. 2014-Sept-005

The Principal Investigator
Ms. Ann Mbulo
University Teaching Hospital
Dept. of Pharmacy
P/Bag RW 1X,
LUSAKA

Dear Ms. Mbulo,

RE: A SURVEY OF HERBAL MEDICINE USE IN HYPERTENSIVE PATIENTS AT THE UNIVESRITY TEACHING HOSPITAL LUSAKA ZAMBIA.

Reference is made to your corrections dated 30ᵗʰ October, 2014. The IRB resolved to approve this study and your participation as principal investigator for a period of one year.

Review Type	Ordinary	Approval No. 2014-Sept-005
Approval and Expiry Date	Approval Date: 4ᵗʰ November, 2014	Expiry Date: 3ʳᵈ November, 2015
Protocol Version and Date	Version-Nil	3ʳᵈ November, 2015
Information Sheet, Consent Forms and Dates	• English.	3ʳᵈ November, 2015
Consent form ID and Date	Version-Nil	3ʳᵈ November, 2015
Recruitment Materials	Nil	3ʳᵈ November, 2015
Other Study Documents	Questionnaire.	3ʳᵈ November, 2015
Number of participants approved for study	225	3ʳᵈ November, 2015

Where Research Ethics and Science Converge

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.
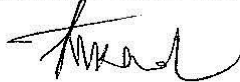
Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- ERES Converge IRB does not "stamp" approval letters, consent forms or study documents unless requested for in writing. This is because the approval letter clearly indicates the documents approved by the IRB as well as other elements and conditions of approval.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB

Dr. E. Munalula-Nkandu
BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD
CHAIRPERSON

APPENDIX – G
EXTRACTS OF SPSS ANALYSIS

User of herbal medicine (Refer to table 2 page 14)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	63	24.7	24.7	24.7
	no	192	75.3	75.3	100.0
	Total	255	100.0	100.0	

Control of blood pressure in hypertensive patients taking

herbal medicines (Refer to table 4 page 16)

Report

user of herbal medicine		average sbp	average dbp
yes	Mean	143.95	85.59
	N	63	63
	Std. Deviation	16.405	7.378
no	Mean	143.10	86.27
	N	192	192
	Std. Deviation	17.201	8.099
Total	Mean	143.31	86.10
	N	255	255
	Std. Deviation	16.979	7.918

Type of Herbal Medicine (Refer to table 3 page 15)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		61	23.9	23.9	23.9
	ginger	39	15.3	15.3	39.2
	moringa	53	20.8	20.8	60.0
	garlic	33	12.9	12.9	72.9
	aloe vera	69	27.1	27.1	100.0
	Total	255	100.0	100.0	

Benefits of herbal medicine on blood pressure control

		Frequency	Percent
Valid		192	75.3
	yes	41	16.1
	no	22	8.6
	Total	**255**	**100.0**

Age of participants in years

		Frequency	Percent
Valid	18-25	2	.8
	26-35	30	11.8
	36-45	36	14.1
	46-55	82	32.2
	above 55	105	41.2
	Total	**255**	**100.0**

Sex of participants * user of herbal medicine cross tabulation

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.451[a]	1	.117		
Continuity Correction[b]	2.017	1	.155		
Likelihood Ratio	2.468	1	.116		
Fisher's Exact Test				.146	.077
N of Valid Cases	255				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 30.39.

b. Computed only for a 2x2 table

Income * herbal medicine use

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	6.314[a]	4	.177
Likelihood Ratio	7.676	4	.104
N of Valid Cases	255		

a. 2 cells (20.0%) have expected count less than 5. The minimum
expected count is .49.

Employment status * herbal medicine use

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.072[a]	1	.789		
Continuity Correction[b]	.015	1	.903		
Likelihood Ratio	.072	1	.788		
Fisher's Exact Test				.884	.453
N of Valid Cases	255				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 27.92.

b. Computed only for a 2x2 table

Age of participant * user of herbal medicine Cross tabulation

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	3.926[a]	4	.416
Likelihood Ratio	4.669	4	.323
N of Valid Cases	255		

a. 2 cells (20.0%) have expected count less than 5. The minimum
expected count is .49.

education level * user of herbal medicine cross tabulation
Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	11.090[a]	3	.011
Likelihood Ratio	12.131	3	.007
N of Valid Cases	255		

a. 0 cells (.0%) have expected count less than 5. The minimum
expected count is 10.13.