DETERMINANTS OF NON-ADHERENCE TO LONG TERM THERAPY WITH PRESCRIPTION MEDICINES IN ADULT PATIENTS ATTENDING MEDICAL OUTPATIENT CLINIC AT MBAGATHI HOSPITAL

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UNIVERSITY OF NAIROBI DECLARATION OF ORIGINALITY

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Title of the work: Determinants of Non-Adherence to prescribed medicines in adult patients attending medical outpatient clinic at Mbagathi Hospital.

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SUPERVISORS' APPROVAL

This is to certify that this research proposal has been submitted for examination with our approval as the University supervisors.

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DEDICATION

To my family, you give me every reason to become better.

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LIST OF ABBREVIATIONS AND ACRONYMS

ER	Emergency room
MMAS	Morisky Medication Adherence Scale
WHO	World Health Organization
SES	Socioeconomic status
EM	Electronic monitoring
ARV	Antiretroviral
TB	Tuberculosis
HIV	Human Immunodeficiency Virus
MTM	Medication Therapy Management
MOPC	Medical Outpatient Clinic
PI	Principal Investigator

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OPERATIONAL DEFINITION OF TERMS

Adherence / compliance - extent to which a person's behaviour (taking medication, following a diet and/or executing lifestyle changes) coincides with medical or health advice.

Intentional non-adherence - is an active decision on the part of patients to forego prescribed therapy.

Unintentional non-adherence - is a passive process whereby patients fail to adhere to prescribing instructions through forgetfulness, carelessness, or circumstances out of their control (e.g., health literacy).

Pharmaceutical care - patient-centered, outcomes oriented pharmacy practice that requires the pharmacist to work together with the patient and the patient's other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective.

Drug therapy problem - an undesirable patient experience that involves drug therapy and that actually or potentially interferes with a desired patient outcome.

ABSTRACT

Background

Non-adherence is a drug therapy problem and can be due to economic factors, patient related factors among others. Studies have shown that non-adherence to prescribed medicines in general is as high as 20% to 60% irrespective of disease, setting or prognosis. This study is informed by there being minimal data on non-adherence among the study population in Kenya and Sub Saharan Africa in general.

Study objective

The aim of the study was to determine the magnitude and to identify the determinants of non-adherence to long term prescription medicines among adult outpatients attending medical outpatient clinic at Mbagathi Hospital.

Methodology

The study was hospital based, descriptive cross-sectional study to establish factors associated with non-adherence to prescribed medication for those patients attending the medical outpatient clinic of Mbagathi Hospital and on long term therapy. The study population was adult patients, on follow up. Data was collected over a period of one month. An adjusted sample size of 167 patients was used. Convenient sampling method was used to consecutively select every accessible patient who met the inclusion criteria. Data was collected using pretested questionnaires. Data collected was entered in a modified excel sheet and STATA version 13 used for analysis. Continuous variables were summarized to measures of central tendency. Categorical variables were summarized as percentages. Data was presented in the form of graphs, pie charts and tables. Inferential data analysis was carried out to look for association between the outcome variable (non-adherence to long term medicines) and the predictor variables for example patient related causes of non-adherence. Bivariate and multivariate logistic regression (backward stepwise) was done to identify the independent predictors of non-adherence to long term prescription medicines.

Results

A total of 167 respondents participated in the study with a mean age of 53.5±13.5 years. Majority were of the female gender (101, 60.5%).Overall, a third **(57, 34.1%)** of the participants were non-adherent to their long term therapy while 110 (64.9%) were adherent. Hypertension was the most prevalent (127, 76.1%) condition in the study population. Bivariate analysis showed statistically significant associations between non-adherence and patient understanding their disease(p=0.001),being aware of the need to take their drugs daily (p=<0.001),understanding dosage instructions (p=0.018),forgetting to take drugs, careless about taking their drugs, stopping to take after feeling better or worse all with (p=<0.001).Awareness of the need to take drugs daily was an independent predictor of non-adherence as indicated by bivariate analysis (COR =0.07; 95% CI 0.02-0.2; p<0.001) and on multivariate regression analysis (AOR=0.13; 95% CI 0.3-0.54 p=0.005),being bothered by the duration of treatment (COR = 2.13; 95% CI 1.1-4.11; p=0.024) together with patient understanding dosage instructions (COR=0.25; 95% CI 0.08-0.8;p=0.019). Headache as a side effect was an independent predictor of non-adherence as indicated by bivariate analysis (COR =5.31; 95% 2.5-11.3; p<0.001) and this prediction further affirmed on multivariate logistic regression (AOR=5.48; 95% CI 1.61-18.6 p=0.006).

Conclusion

Non adherence as a drug therapy problem is predominant on patients on long term therapy. This non adherence can in effect result to treatment failure and a bad medication experience and therefore there is an immediate need to curb this in our outpatient set ups.

CHAPTER ONE: INTRODUCTION

1.1 Background

In the health care system ,medication adherence is an important component and it is looked at as the extent to which there is observance of the treatment recommendations given to the patient as regards the timing of their medication, the dosage , how frequently the medication is given and for how long the medication will be taken ,also known as the duration of treatment (1) . This can further be looked at as to what extent the patient will act in accordance to the prescribed dosing regimen. Adherence is an important aspect in any success of a prescribed therapy and it plays a crucial role in the safety and effectiveness of any treatment regimen (2).Compliance or adherence will be used interchangeably throughout this study. The term adherence is what is commonly used by many health care providers. This is because compliance suggests that the patient is following the orders given to them by their health care provider, this is to suggest that the treatment being given to them is somewhat passive, there is no concordance or any form of contract by the health care provider to the patient with whom there is indeed an interaction (4).

Adherence to prescribed medicines is a widely studied subject that can be influenced by various factors. A huge number of studies have been carried out evaluating and enumerating these factors that influence medication adherence, and have been widely summarized as; demographic factors for example race, age, sex. Another component is the socio-economic status (SES) of the study patients such as education, income level. There are also factors pertaining the therapy itself for instance medication side effects. Knowledge possessed by the patient about their medicines, awareness of the treatment, beliefs and attitude and lastly factors highlighting aspects on the healthcare system and healthcare provider related factors (2,4).

Non- adherence is a drug therapy problem and can be due to any of these causes; unavailability of the drug product, unaffordability, and inability to swallow or administer the drug, lack of understanding on how to take the drug, patient's preference not to take and patient forgets to take the prescribed drug. Adherence rates for individual patients have been widely reported in the form of percentages. These percentages look at the actual doses of what has been prescribed and taken by the

patient over a period of time. Time is an important aspect in measurement of adherence. It can further be refined to capture the aspect of the actual dose taken and the timings of all the prescribed drugs (2).

This study will focus on medication non-compliance or non-adherence, the use of these two terms will be interchanged from time to time throughout the study. When you describe the aspect of non-adherence, you will include such aspects as failing to fill prescriptions, lack of proper timing when taking medications, having inappropriate dosing schedules and clear lack of diligence in following the given instructions for any given treatment. Non- adherence among the vulnerable groups with chronic conditions is high to a moderate level in comparison to those considered less vulnerable. The vulnerable groups will include elderly and young patients (3). Patient medication taking behaviour is a widely studied concept and in an effort to get to the detail of the matter, non- adherence has been differentiated into two distinct types and listed as either intentional or unintentional non-adherence (5).

In intentional non-adherence , the patient is seen to make an active decision to forego the prescribed therapy (2,6) whereas unintentional non-adherence is seen as a passive process where a patient will fail to adhere to the prescribed instructions due to such reasons such as being careless with taking their medication or forgetting to take their medication or other circumstances out of their locus of control such as the extent to which they can claim to have health literacy (2,6). More often than not, patients will exhibit both types of non-adherence (2,7,8). Patients who are not adhering intentionally will demonstrate this characteristic by failing to fulfill a new prescription or choosing to discontinue ongoing therapy without the advice of a healthcare provider. Studies have pegged those not full filling a new prescription at 15% (6); however even when they fulfill the new prescription, 50% will discontinue their therapy without any advice from their healthcare provider (2,9). A huge variation exists as to the extent of unintentional non-adherence with most studies giving a range from 20% to over 50%. Intentional non- adherence is also widely studied and researchers have shown that it is mostly patient driven with patient’s beliefs about their treatment, how they view their prognosis and how they objectively feel about their medicines taking center stage (7,8,10).

Research carried out earlier on unintentional non-adherence suggests that there is a stronger correlation to demographic characteristics as compared to medication knowledge or beliefs (11,12). However, recent research indicates that that there may be more to unintentional non-adherence than just being forgetful or careless (8). When patients report intentional or unintentional non-adherence, they have been found to be similar to one another in terms of their adherence-related knowledge and motivation(11). Patient medication beliefs are a strong indicator of unintentional non-adherence (8).

Non-adherence to prescribed medicines in general is as high as 20% to 60% irrespective of disease, setting or prognosis as obtained from several literature (13–15). Short term therapy has been shown to have a non-adherence rate of 20% whereas long term therapy has been shown to have a non-adherence rate of about 50% (6,11,14,16), similar to rates reported for other chronic conditions(7). There are challenges in coming up with fool proof methods that can be used in detecting non-adherence. A self-reported measure of non-adherence to medication, the Morisky Medication Adherence Scale (MMAS) has proved to be a reliable tool in the measure of non-adherence because it correlates well with other methods of measuring non-adherence such as pill counts, electronic monitoring, and pharmacy refill records. Also, other methods used in the assessment of Non-adherence may not overcome attempts at concealment by the study patients (14,17–19).

1.2 Problem statement

Poor adherence has been shown to have extremely serious consequences in reference to patient outcomes while on treatment. These are for example the development of resistance to the prescribed drugs, experiencing adverse drug reactions, and generally an increased morbidity and mortality, and reduced quality of life (14,20). Health care provider behaviour is also affected by poor adherence, who make decisions to increase dosages or discontinue medication believed to be ineffective (20). Clinical trials are able to demonstrate the therapeutic and economic benefits of one treatment over another in the controlled settings of such a clinical trial. These are benefits that cannot be demonstrated with much ease especially in patients who are partially compliant with their prescribed therapy. Adherence to therapy for some common

chronic conditions such as hypertension and diabetes is generally low at approximately 50% to 65%, on average (21).

Sub optimal treatment of conditions may worsen symptoms and increase complications that result to an increased use of hospital emergency room (ER) services, decreased man hours and overuse of medical resources (21). We can draw an inference to this and say adherence to prescribed medication has a positive economic value, leads to savings due to decreased medical expenditure (21).

The United States healthcare system is burdened by the underuse of prescription medicines especially when indicated to treat several chronic condition. This under use may be due under-treatment, missed diagnosis, misdiagnosis and this overall increases the burden of non-adherence to the healthcare system (22,23). This non-adherence contributes to greater morbidity and mortality and increases the healthcare cost to an estimated $170 billion annually. This has been the motivation of healthcare planners as they try to avert this enormous cost to try and measure the frequency of non-adherence and really go to the root causes and come up with interventions to address it (24,25).

It is clear that, there is little literature and studies carried out to try and enumerate the determinants of non-adherence in adult patients attending medical outpatient clinics in hospitals in Sub Saharan Africa. There is a myriad of studies on some cohorts such as those with malaria, human immunodeficiency virus (HIV), tuberculosis (TB) and their adherence or non-adherence to the prescribed medications (26–29). Furthermore, little is known about determinants of non-adherence among patients residing in Kenya. A systematic review carried out of patients' self-reported barriers of adherence to anti-hypertensive medication had its results as follows,76% of the studies reporting patient related factors, 27% reporting health system related factors, 29% reporting therapy related factors and 22% reporting socioeconomic factors (30). This systematic review had incorporated findings from mostly high income countries. Suffice to say these studies are many and vast, this will be clear as we look into the several literature written on these subjects.

When a systematic review and meta-analysis was carried out on studies including low and middle income countries , this gave a pooled percentage of non-adherence when using the eight-item Morisky Medication Adherence Scale (MMAS) as 63.35% and

25.45% when using the 80 and 90% cut-off scales (31). It is worthwhile to note these kind of studies are few and far between. The World Health Organization (WHO) has classified adherence/non-adherence factors into five dimensions which have been widely studies. These are:-socio-economic, health care provider related , condition related, therapy related and patient related factors (32). Looking at the systematic reviews above, specific cohort of patients have been looked into widely but there is no insight on a general population, say of adult patients or paediatric patients. Closer home , there are studies from such countries as Egypt, Ghana , Ethiopia all assessing non-adherence to hypertension medicines (31). In Kenya there are several studies too especially among HIV and TB patients. As stated, little is known about the patients attending medical outpatient clinics in general.

1.3 Study justification

Studies carried out from high resource settings suggest a high prevalence of non-adherence among different classes of patients (12,14,25). There is a lot of literature in high income countries concerning medication non-adherence, unlike in low and middle-income countries such as those in most Sub- Saharan Africa. Most of these studies have been carried out on specific cohort of patients such as hypertensive, diabetic and renal transplant patients among others in high income countries.

Human beings are generally different. These differences can easily play out in any kind of a research study. Differences like those seen in the genetic composition and in socio demographic characteristics among patients residing in different regions, implies findings of studies in other parts of the world may not reflect the true state of non-adherence to medications among patients within Kenya. Therefore, there is a need to have additional studies to investigate the determinants and clinical relevance of non-adherence to medication in patients residing in this region.

There is a need therefore to establish this kind of data. To the best of our knowledge, this is the first study on the Kenyan population that has attempted to describe the determinants of non-adherence in a medical outpatient set up. The study findings will assist pharmacists and other healthcare professionals to identify the factors leading to non-adherence, establish the gaps, and make recommendations on ways to improve adherence and optimize therapeutic outcomes.

The study findings will also assist in policy formulation, to help curb non-adherence. For example, to curb non-adherence, a pharmacist offering medication therapy management (MTM) and in essence pharmaceutical care should be placed at all patient contact areas. Recent research on optimizing adherence to pharmaceutical care plans has led to the clear documentation of the value of a pharmacist-led patient care process in bringing about better adherence and acceptable treatment outcomes (33). In addition, it will help in stimulating further research in this area.

1.4 Purpose of the study

To provide a better understanding of non-adherence to prescribed medicines, especially on patients on long term therapy attending medical outpatient clinics of Mbagathi Hospital with the overarching goal of curbing the assessed outcomes of non-adherence.

1.5 Research questions

1. What is the prevalence of non-adherence to long term prescription medicines among adult outpatients attending the MOPC at Mbagathi Hospital?
2. What are the factors associated with non-adherence to long term prescription medicines among adult outpatients attending the MOPC at Mbagathi Hospital?

1.6 General objective

The study aimed at determining the magnitude and identifying the determinants of non-adherence to long term prescription medicines among adult outpatients attending medical outpatient clinic at Mbagathi Hospital.

1.6.1 Specific objectives

The specific objectives of this study were as follows:-

1. To assess the prevalence of non-adherence to long term prescription medicines among adult outpatients attending the MOPC at Mbagathi Hospital.
2. To determine the factors associated with non-adherence to long term prescription medicines among adult outpatients attending the MOPC at Mbagathi Hospital

1.7 Delimitations

The study was carried out in the medical outpatient set up only. In as much as non-adherence is a phenomena well established in all other set ups in the hospital, we focused on the medical outpatient only, thus the outcome could be narrow.

1.8 Limitations

This study was based on the following assumptions:-

1. That medication non-adherence is a random event that is evenly distributed throughout the study population.
2. That the sample selected will be representative of the target population.
3. That the respondents for the interview will give truthful and honest answers.

1.9 Conceptual framework

The factors associated with non-adherence to medication can be grouped into patient's social and economic factors, condition-related factors, therapy-related factors , patient-related and hospital-related factors (32).

Social and economic factors include such factors as lack of finances, culture and beliefs, family dysfunction. Condition-related factors include such factors as level of disability, severity of the disease, and availability of effective treatments. Therapy related factors include duration of treatment, complexity of medical regimen and side effects. Patient related factors include anxiety of possible side effects, misunderstanding of treatment instructions, and fear of dependence among others. Health care provider-related factors such as drug availability at pharmacy, drug affordability, concerns not addressed by clinician or other staff. The conceptual framework, **figure one (1),** shows how the above factors are interrelated with non-adherence.

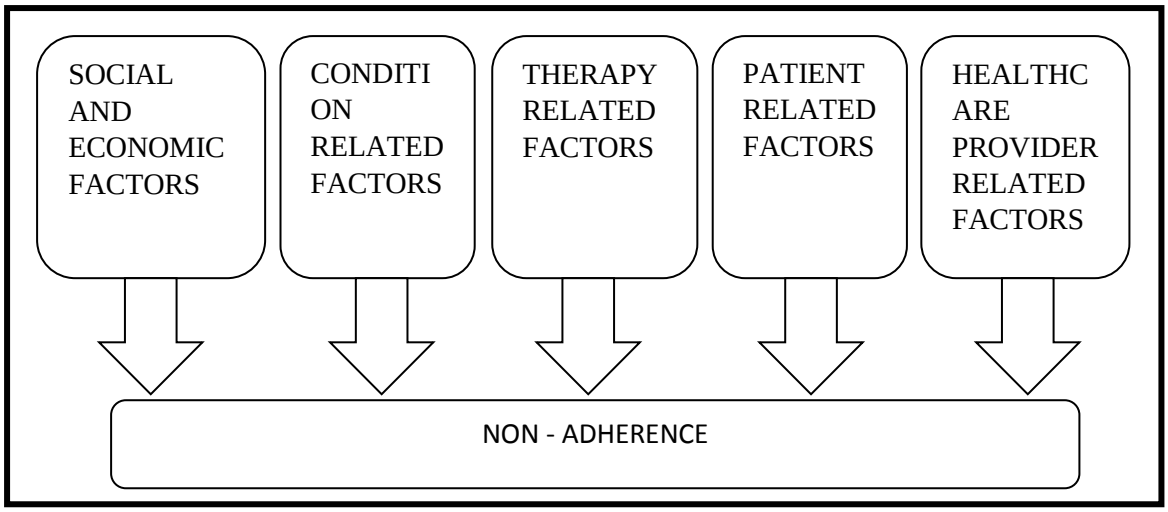

Figure 1: Conceptual framework (Source: Author)

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter provides information from publications on topics related to the research problem. It examines what various scholars and authors have said about the concept of non-adherence. It covers the five dimensions of adherence/non-adherence as classified by WHO. These dimensions are socio-economic factors, condition related factors, and therapy related factors, patient related factors and hospital/healthcare system related factors.

2.2 Factors associated with non-adherence

There are several factors associated with non-adherence to prescribed medicines. These are broadly classified as socio-economic, patient -related, condition-related and therapy-related among others.

2.2.1 Social and economic factors affecting non-adherence

2.2.1.1 Lack of finances

Lack of finances is associated with poor social economic status (SES). Lack of finances would emanate from the employment status of an individual and having an occupation deemed as low status , high travel costs to reach the treatment facility and generally a low annual income (32,34,35).

High cost of travel to reach the treatment facility, low annual income and unemployment or low status occupation have shown to have a significant association with non-adherence to anti-tuberculosis treatment. These medicines are provided free, but, cost to travel to the treatment facility still burdens the patients and can be a disabling factor in completing treatment. These factors together with a low status occupation and unemployment all play a big role in non-adherence to these drugs (34). Studies have been conducted in an attempt at trying to enumerate the relationship between socioeconomic status and adherence to inhaled corticosteroids and asthma control (36) and a significant relationship between poor asthma control and low social economic status has been established. Other studies conducted in patients taking statins either as continuation therapy or as preventive therapy for early onset stroke show a significant relationship again between the patients' socioeconomic status and adherence. Those with higher economic status, minimum

copay in their insurance showing a better adherence. Non-adherence to treatment is significantly associated with poor SES (17,37,38).

2.2.1.2 Culture and beliefs about illness

It is important to note that patients are known to hold various sets of beliefs and theories about health and illness even before they seek treatment. They try and deal with the illness even before trying to seek medical treatment and this is an important aspect in determining compliance (15).

A study carried out on the determinants of good compliance in adolescents with epilepsy highlighted that compliance was impaired by a feeling of being different from their friends, they lacked a sense of belonging and this impaired their adherence status. Provision of emotional support from friends and family was targeted at helping the adolescents feel accepted. Several studies carried out on epileptic patients emphasize psychological and social problems as factors influencing non-compliance. Patients who reported feelings of stigma showed poor compliance (39,40). Results from other studies show consistency with the fact that adherence to medication is influenced by culture and beliefs about illness (41).

A study carried out on schizophrenic patients' subjective reasons for adherence and non-adherence to their neuroleptic treatments showed that patients are more likely to rate relapse prevention as an important factor for their treatment adherence as opposed to the benefit they will get daily from their improved general well-being (42).

Compliance by a health professional is important, but even if this is the case, for the patient, especially one on treatment for a chronic condition, concerns such as there being adequate control of symptoms, preventing any form of medical crises, maintenance of financial comfort and enjoyment of a quality lifestyle takes precedence. A patient does not view all recommended treatments as necessary for their best interests and may become non- adherent as a result (15).

2.2.1.3 Family dysfunction

There have been several studies on factors promoting compliance with health regimens among adolescents with a chronic disease across several disciplines. Factors seen as psychosocial, for example attitudes, finding personal meaning, the significance of illness and treatment, and therapeutic motivation, have a major

influence on compliance. Being an adolescent is not a reason for non-compliance in itself. The compliance rates of adolescents with a chronic disease are similar to those of adults. Having family support can be regarded as a crucial factor in adolescents in chronic treatment. A positive family climate and open relationships between the family members have been related to good compliance (35,39,40).

A cross-sectional survey on beliefs about medicines among type 2 diabetic patients showed that marital status played a crucial role on adherence. The likelihood of married people not adhering is much lower than their unmarried counterparts (19). This shows that a good support system at the family level is an impetus to good adherence. An extensive literature review on children and adolescents who are HIV positive showed that if a caregiver believes in the treatment regimen this was a good pointer to adherence (43). Another study on patient identified barriers in asthma treatment had the respondents indicate that whenever there was deficiency in the social support system, it was indeed difficult to remain adherent to asthma medication while having good social support network of friends, family promoted adherence (44).

This shows that a good assessment of the importance and availability of a social support system can be used to assess the likelihood of adherence and readiness to take medication (43). This shows congruence with a study carried out on optimizing adherence to pharmaceutical care plans which drew an inference that there is need to include, a family member or caregiver in the educational sessions on long term therapy medication use counseling to help the patient follow instructions and stay on track over time. Social or group support can also help to boost the patient's confidence and sense of self-efficacy (33).

2.2.1.4 Inadequate knowledge of treatment

The ability to read, understand, and act on the health information provided to you is known as health literacy. Whenever there are poor skills or the lack of health literacy, this can result to medication errors, also it can lead to impairing of the patients' ability to remember and follow the recommended treatment guidelines, it can lead to a less effective interaction with the health care system, and overall result in an increased risk for hospitalization (43).

A study on patient identified barriers to asthma treatment indicated that patients had a belief that there was no real positive effect as regards their inhaled corticosteroids and

this can be related to the fact that the effects do not set in immediately. As a result the patients were reluctant to take their medicines thus resulting to non-adherence. On the same group of patients, poor inhaler use knowledge also resulted to non-adherence. Poor knowledge about treatment was also highlighted as a cause of non-adherence (44). With these, it can be concluded that inadequate knowledge of treatment contributes to non-adherence(45).

Poor clinics attendance, poor understanding of the consequences of compliance , poor knowledge and understanding of the disease lead to poor compliance (46) Some patients thinking that the need for medication was intermittent or for a short period, so they stopped the drug to see whether the medication is still needed (44). There is therefore a need of patient education in order to enhance compliance. Patient counseling on medication use is an important aspect in compliance and therefore healthcare providers should pay attention to their patients giving them education about their medication to ensure there is compliance (45).

2.2.2 Condition related factors

Level of disability and severity of disease are condition related factors that affect adherence. Several studies conducted in Hong Kong showed that having a number of comorbidities would in effect lead to a poor adherence to cardiovascular medications. One in every five patients showed non adherence to antihypertensive medication and there was a positive association established with mental co morbidity and negatively associated with cardiovascular risk factors. This study population showed a non-adherence rate of 20% which was within the 9-37% range established in other studies (47).

We can conclude that mental co-morbidity increased the risk of non-adherence to antihypertensive medicines by 8%. People who have a mental co-morbidity have been shown to have poor motivation towards their treatment, low attention, cognition and memory, increase self-harm an low self-care and these factors have been shown to affect adherence in this group of patients (48–50).

There are a number of studies conducted in those with advanced age. These studies showed that advanced age was associate with good adherence to antihypertensive agents. This can be seen as purely a perception issue where the number of co-morbidities makes them perceive themselves as being sicker and thus will adhere

better to their prescribed antihypertensive agents. This is not in congruence with some other research conducted that shows poor adherence having an association with increasing age. When patients suffer from disease fluctuations without symptoms at the initial stages, this may result in poor compliance. Diseases with such fluctuations are for example asthma and hypertension (14,51).

2.2.3 Therapy related factors

2.2.3.1 Duration of treatment

Treatment duration as a factor associated with poor adherence has been widely studied. Some studies have focused on finding out the alternatives to reducing the duration of treatment for example reduction in the number and prescribed dose of medicine or treatment stoppage for an unspecified amount of time once patients achieve blood pressure control. This was done on a cohort of hypertensive patients trying to find out why hypertensives do not comply with treatment. It has been established that treatments that have a longer length of time and seem to create a routine cause boredom and this may cause the patients to desire stopping treatment all together thus causing non-compliance (46).

2.2.3.2 Complexity of medical regimen

There is a wide array of data suggesting electronic monitoring (EM) for measurement of compliance. It is suggested that patients dosing schedules that are not very frequent are a strong indicator of compliance. The complexity of the regimen showed that there was an inversely related relationship to adherence in most therapeutic classes (52). Once daily dosing showed greater compliance to for example 4-times-daily thus reinforcing the fact that the simpler the regimen the higher the compliance. This reinforces the principle of simplicity. However, even with the once-daily dosing, poor compliance is possible. A study of once-daily dosing in antihypertensive showed compliance to be at 73% (31). This implies that there is a need for more resources to ensure proper compliance even with once-daily dosing. In view of this, there is a need for the patients to understand what is meant by duration of action of a drug and why the regular intervals in dosing are highly recommended in some therapeutic classes (52–54).

It is established that a simple dose helps in adherence maximization especially in combination with other adherence enforcing behaviours such as reinforcement visits. When you have a dosing schedule of four times daily, the average adherence rate achieved was 50%. It was found that adherence was inversely proportional to frequency of dose (55).

Medications having a convenient way of administration for example oral medications are likely to make patients be more compliant. Studies conducted in a group of patients taking oral and inhaled medicines for management of their asthma showed better compliance with oral medications (33). It has been noted that, generally inhaler use technique is not easy and this contributes to non-compliance in patients with asthma (44).

2.2.3.3 Duration of treatment

Patients having acute illnesses are associated with better compliance as compared to those having chronic illnesses (46). This is to say a longer duration of a disease has a negative affect towards compliance and so does longer treatment period (15).

2.2.3.4 Side effects

Patient characteristics have been shown to have an association with unintentional non-adherence. On the other hand , intentional non adherence has been shown to reflect a rational decision making process on the side of the patient in which the individual will weigh the benefits to be achieved through treatment against adverse drug effects being experienced . it has also been shown that once a patient reports an adverse drug effect themselves, which is normally the case, this also contributes to non-adherence(6,15).

A qualitative study conducted amongst hypertensive patients cited experiencing side effects from the antihypertensive agents, being the biggest indicator of non-adherence (10). This is comparable to a study conducted amongst a group using lipid lowering agents. The study showed a strong association between non-compliance to medicines prescribed and side effects being experienced. This is in agreement with previous other studies (54,56).

2.2.4 Patient related factors

These are factors pointing at the patient directly. They entail a whole list of factors for example a patient's resources, their knowledge, their attitudes, their beliefs and

perceptions and expectations of the patients towards the therapy (42,44,57). Literature from studies conducted that were looking at these patient-related factors associated with non-adherence to immunosuppressive therapy after renal transplantation came up with several factors: patients were seen to have a low self-efficacy with medication intake, they were also experiencing high levels of anxiety and hostility. This particular group of patients also showed an external locus of control, this is when patients tend to think the evolution of their disease state is all due to chance. There was a belief amongst this patients that their immunosuppressive therapy was not needed to keep the kidney. They also believed that the drug therapy could be delayed and this could be related to their non-adherence state (58–60).

In these studies, the more knowledgeable the patients were about their drug therapy, the more likely they were not to adhere; knowledge about their medicines was positively related to non-adherence(58).

Similarly, a systematic review on patient self –reported barriers on adherence to antihypertensive medication using the WHO multidimensional model , showed that the most studied patient related barriers was the patient remembering to take their medication, patients' belief about their medication and patient self-efficacy (30).

2.2.5 Health care provider related factors

Healthcare provider related factors have not been studied extensively as compared to other factors. While looking at this category, of interest is the system and the healthcare team as a whole. This lack of evidence inadvertently puts the patient at the forefront of non-compliance. The importance of the healthcare system and the team as a whole cannot be overlooked while studying compliance. It is worthwhile to note that the lack of evidence in this category creates a missed opportunity for improvement of non-adherence, through the optimization of the healthcare system or healthcare worker through training. This is an area that needs to be exploited (30,61).

2.2.5.1 Concerns not addressed by clinician or other staff

It has been documented that a physician can contribute to a patients' poor adherence through the prescription of regimens deemed to be complex, when they fail to explain to the patient the benefits and side effects of the medicines prescribed at length. Some other factors contributing to non-adherence attributed to the physician are lack of

consideration of the patients' lifestyle or the cost of medication. Patients are likely to show poor compliance if they are not able to afford their medications (55).

Studies have documented that there is an association between adverse effects and treatment non-adherence. Health care providers may consider getting insights on adverse effects from the patient's perspective, especially those who perceive the side effects to be unpleasant. Dose adjustment would then be helpful with proper communication from the physician thus ensuring compliance. It would also be beneficial to communicate the expected side effects in advance (10).

Patients require healthy relationships with their prescribers, such relationships have been shown to improve compliance, patients wish for attentive and active listening and eye contact. They wish for respect and to be treated as equal partners in the management of their condition. When physicians spend too little time with the patient, and they lack active listening skills, patients' motivation for maintaining therapy is threatened (46,62–65). A study conducted on by Lim and Ngah on hypertensive patients showed that non-compliant patients felt that the prescribers did not show concern for their problem (62,63) whenever there are multiple physicians or healthcare providers attending to the patients, a patients confidence in the prescribed medicine is decreased (43).

2.2.5.2 Drug is unaffordable

Affordability and availability of medicines in a hospital are core to ensuring adherence. Healthcare systems have been shown to create barriers to adherence by having restricted formularies, switching formularies and having high costs that are prohibitive to the patient (55).

2.3 Literature gap

As established from the literature review, it is evident that non-adherence to prescribed medicines is a problem world over and especially in specific group of patients such as hypertensive, diabetic, HIV infected, TB infected and patients with chronic diseases. There is scarcity of data from African countries including Kenya regarding extent and types of non-adherence to prescribed medicines especially on adult medical outpatients in general. Moreover, the factors associated with non-adherence in the same group of patients in Kenya has not yet been established.

The study thus aims at establishing to what extent non-adherence to long term prescription medicines among adult patients attending the medical outpatient clinic at Mbagathi Hospital is spread. It also aims at establishing the association between the categories listed in the literature review; socio-economic factors, condition-related factors, therapy related factors, patient-related factors and hospital-related factors and non-adherence. The study findings will provide the much needed data on the extent and types of non-adherence among patients attending the outpatient clinics in Sub Saharan Africa. The study would also provide data on possible predictors of non-adherence among these patients

CHAPTER THREE: METHODOLOGY

3.1 Study Design

A hospital based cross-sectional design was used. This study design was used for this exploratory study because it is efficient and cost-effective. The study provided sufficient descriptive and analytic snapshots of the population phenomena under study at the time period in which the study was conducted.

Adult patients aged ≥18 years on long-term prescription medicines at the medical outpatient clinic of Mbagathi Hospital were recruited in the study.

3.2 Study site

The study was conducted at Mbagathi level IV hospital a ministry of health facility located in Nairobi County, within Dagoretti constituency. The hospital has a bed capacity of 450. The hospital boasts of several robust clinics such as the comprehensive care clinic, eye clinic, TB clinic, mother child health clinic and the medical outpatient clinic. The outpatient unit boasts of about 700 visits per day, these number is inclusive of the individual clinics such as diabetes clinic, surgical clinic which individually attend to a maximum of 60 patients in a day.

3.3 Study population

The study population consisted of adult (≥18 years) patients on long-term prescription medicines attending the medical outpatient clinic at Mbagathi Hospital.

3.4 Eligibility criteria

3.4.1 Inclusion criteria

1. Adult (age ≥18 years) attending Medical outpatient clinic
2. On long-term prescription medicines.
3. Patients who consented to participate in the study

3.4.2 Exclusion criteria

1. Patients who refused to give voluntary consent to participate in the study

3.5 Variables

3.5.1 Outcome Variable

The main outcome variable of interest in this study was non-adherence to long term prescription medicines. The four item Morisky Medication Adherence Scale (MMAS) was used to measure non-adherence, where patients were classified as either adherent or non-adherent after answering a series of questions

3.5.2 Predictor Variables

These were the factors under study, which may have influence adherence to prescribed medication.

These were grouped as below:-

1. Patient related factors: These include age, gender, marital status, level of education and income.
2. Hospital related factors: Including prescription patterns by clinicians, adherence counseling, ability to access health care and quality of healthcare in general.
3. Disease related factors: These include duration of the disease, co morbidity, disease associated complications and hospitalizations.
4. Medication related factors: For instance adverse effects from medication, complexity of the regimen and number of pills prescribed.
5. Social and economic factors: For instance lack of finances, culture and beliefs, family dysfunction

3.6 Sample Size

The study's sample size was based on the estimates of prevalence reported in several published literature (13–15).

Using Fisher's formula, the sample size was calculated as follows:- (66)

$$N = \frac{Z^2 \alpha/2 \times P(1 - P)}{\sigma^2}$$

N = Minimal sample size required.

P = Estimated prevalence of non-adherence = 50% (13–15) .

$\mathbf{Z^2\propto/2}$ = The standard normal deviate at 95 % confidence interval corresponding to 1.96.

σ = Absolute error between the estimated and the true population prevalence of non-adherence.

Therefore the sample size was expected to be:-

$$\mathbf{N = \frac{1.96^2\, \alpha/2\ \ 0.5\ (1\text{-}0.5)}{0.05^2}}$$

N = 384 patients.

The sample size was to be adjusted for 10 % non-response. Therefore, the number of patients that were to be recruited in the study would be 422. However, on conclusion of the study, only 180 patients were interviewed due to time constraints and of this 167 were included in the study as their data was complete (fully filled questionnaires). This was deemed to be a good enough sample size to bring out any expected associations.

3.7 Sampling Technique

Convenient sampling method was used to consecutively select patients who met the eligibility criteria. Only patients who met the eligibility criteria and gave voluntary informed consent were included in the study.

At Mbagathi hospital, the records office keeps a register of all patients on follow up at the medical outpatient clinic. A day prior to the clinic day, the Principal Investigator perused the register to identify patients that met the eligibility criteria using the eligibility screening form (Appendix 1. A) and a list of patients who met the eligibility criteria was made and this was the sampling frame.

On the day of the clinic, the patients are usually registered at the records office and queued up to see the attending clinician. Those patients that had been registered and formed part of the sampling frame were approached for possible inclusion in the study. The PI directed the patients to a private room for consenting and possible inclusion in the study. The patients were informed about the study by the PI and also emphasized on that participation was purely on voluntary basis. They were also informed if they refused to participate, this decision would not affect their right to get

services at the clinic. Only those patients who agreed to participate by giving voluntary consent were included in the study and taken through the study questionnaire (Appendix 5).

On average, the medical outpatient clinic attends to about 50-60 patients, most of whom are on long term prescription medicines. A daily target of 30 patients was set. This would have translated to about 120 patients every week, by our estimation. We however ended up interviewing about 20-25 patients on the clinic days. This meant that the target population could not be met within the stipulated study period. Data was collected over a period of six weeks and we ended up interviewing less patients than we had initially envisioned thus reducing the sample size. Of the 180 patient interviews conducted, only 167 had complete questionnaires thus this became our new sample size.

3.8 Patient Recruitment and Consenting process

On the day of the clinic, the patients were first registered and queued up to see the clinician. The patients who met the eligibility criteria were approached by the PI and directed to a private for possible inclusion in the study.

Once before the PI, a rapport was first established with the patient. The patient was quickly screened for eligibility using the eligibility screening form (Appendix 1). The patient was informed that participation in the study was absolutely voluntary and without any coercion. Further, the patient was informed that if they refused to participate in the study, this would not affect their right to receive care at the clinic. The PI was guided by the consent information forms (Appendix 2A) or the Kiswahili version (Appendix 3A). The patients who agreed to participate in the study were presented with the consent declaration form (Appendices 2B or 3B) on which they appended their signature. Copies of these forms were availed to the patient for their own reference.

Finally, the patient was taken through the interviewer administered questionnaire (Appendix 5) by the PI or the Research Assistants (RA).

3.9 Data Collection

One research assistant was recruited and trained on the objectives of the study as well as the data collection instruments. The research assistant was a pharmacist who was

available for the entire period of data collection. Pretesting of questionnaires was carried out at Mbagathi Hospital on 20 patients at MOPC.

Following recruitment of study participants and on obtaining informed consent to participate in the study, the data was collected through administering a structured questionnaire (Appendix 5). The data that was obtained from the face to face interviews with the patients included social and economic factors, demographic data, disease-related, medication-related and organization-related factors that may influence adherence to prescribed medication. Knowledge on treatment was assessed with the use of a self-reported tool on adherence to medication using a modified Morisky Medication Adherence Scale model (Appendix 4) which was also part of the questionnaire (Appendix 5), which helped in obtaining the main outcome of interest.

3.10 Research instruments

Eligibility screening form: This form was used to screen patients who met the eligibility criteria before the informed consent process was undertaken (Appendix 1).

Informed consent form: This was used to give the patients information they needed to know before agreeing to participate in the study (Appendices 2A and 3A)

Consent Declaration forms: This was signed by the patient after agreeing to participate in the study (Appendices 2B and 3B).

Morisky Medication Adherence Scale MMAS: This was the tool used to assess treatment non-adherence. Treatment non-adherence was assessed by the Morisky self-report scale, consisting of four statements describing non-adherence to drug therapy. Patients were asked to indicate the extent to which they agreed with each statement by rating their agreement on a 4-point scale (strongly agree, agree, disagree, strongly disagree). Statements corresponding to unintentional non-adherence include "I sometimes forget to take my prescribed medicine," and "I am sometimes careless about taking my prescribed medicine." Statements corresponding to intentional non-adherence included "When I feel better, I sometimes stop taking my prescribed medicine," and "If I feel worse when I take the prescribed medicine, sometimes I stop taking it." Patients were categorized as non-adherent if they indicate agreement (i.e., report either "strongly agree" or "agree") to either item of the subscale (7,19). (Section B of Appendix 5).

Study Questionnaire: A structured questionnaire was used to collect the information needed (Appendix 5).

3.11 Pilot Study

A pilot study was carried out with 20 (about 5% of the study sample) patients to test the relevance, completeness and ease of data collection. The pre-testing of the research instruments was carried out at the Medical outpatient clinic of Mbagathi hospital during clinic days. This was the exact place where the actual study was done.

On the day of the clinic, the patients were first registered and queued up to see the clinician. The patients who met the eligibility criteria were approached by the PI and directed to a private room for possible inclusion in the study. Once before the PI, a rapport was first established with the patient. The patient was quickly screened for eligibility using the eligibility screening form .The patient were informed that participation in the study was absolutely voluntary and without coercion. Patients who agreed to participate in the study were presented with the consent declaration form which they signed. Finally, the patient was taken through the study questionnaire.

3.12 Validity and Reliability of instruments

The following was done to ensure minimization of bias and confounding, thus an improvement on the quality of data collected and reliability of the study findings. The questionnaires were standardized to ensure uniformity. Questionnaires were written in English and also translated to a Kiswahili version so that the questions asked would be understood uniformly. The research assistant was well trained on the objectives of the study as well as the data collection tools. This ensured uniformity in the data collection process. The questionnaires were pretested before the actual study.

Study participants were sampled randomly to avoid selection bias. Participants were able to participate only once in this study as the researcher and assistant ensured a thorough confirmation with the records.

3.13 Data Collection Techniques

Once informed consent had been obtained, the study investigator interviewed the patient immediately using a structured questionnaire in the designated interview areas identified before the interviews begun.

3.13 Data Processing and Analysis

After each clinic day, data collected was entered into a password protected preformed excel (version 2010) database. Only the PI had access to the database. Data cleaning was done to remove inconsistencies and mistakes done during data entry. All data was backed up in two separate hard disks stored in locations accessible to only the PI.

After all data entry and cleaning had been done, data was then exported to STATA (version 13) for the purpose of analysis. Descriptive statistics, frequency distribution tables and graphs were used to present the collected data. Continuous variables were summarized to measures of central tendency (mean, mode, median). Categorical variables were summarized as percentages. Data was presented in the form of graphs, pie charts and tables.

Inferential data analysis was carried out to look for associations between the outcome variable (non-adherence to long term medicines) and the predictor variables of patient related causes of non-adherence, condition related factors among others. Further, bivariate and multivariate logistic regression (backward stepwise) was done to identify the most important predictor variables of non-adherence to long term prescription medicines.

The level of significance was set at 5% and P values <0.05 were considered to be statistically significant.

3.14 Ethical considerations

3.14.1 Ethical Approval to carry out the Study

The Principal Investigator oversaw the implementation of the research as per the protocol. All medical standards and research related ethical standards were observed at all times during this study. Ethical approval was sought from the Kenyatta National Hospital/ University of Nairobi Ethical and Research committee (KNH/UON-ERC) to carry out the study at the study site. Further, institutional administrative approval was sought from the Mbagathi Hospital management, through their training committee before the study was carried out.

3.14.2 Informed Consent

All eligible patients were taken through detailed consent explanation form (Appendices 2A/3A) and once they fully understood what the study was about and agreed to participate in it, then they were presented with a consent declaration form (Appendices 2B/3B) which they will signed.

Patients were informed that the study was voluntary and that they were free to withdraw from the study at any point without any loss of the usual benefits they receive from the hospital. Patients were free to ask any questions about the study in the course of the interview and were informed that if they had any concerns about their rights as patients they could contact the KNH/UoN-ERC.

3.14.3 Confidentiality

Study serial numbers were generated to act as the unique patient identifiers to safeguard their identity .All the data collection materials were kept under lock and key during the entire study period by the PI and they will be destroyed after a period of two years.

3.14.4 Risks involved

This study did not involve any intervention and therefore there was no risk to the patients. Patient's privacy and confidentiality was maintained at all times. Informed consent declaration forms were signed voluntarily without coercion.

3.14.5 Benefits from the Study

During patient interviews, the PI and RA were able to address any concerns the patient may have had in regards to their disease conditions and management. The PI will also share the findings of this study with the various concerned departments with the hope of bettering patient care.

CHAPTER FOUR: RESULTS

4.1 Introduction

This Chapter describes the data obtained from summary, inferential and logistic regression analyses. It contains socio-demographic characteristics of the study participant, condition-related, therapy-related, healthcare provider-related and patient-related factors as well as the non-adherence status of the study participants.

4.2 Socio-demographic and clinical characteristics of the study participants

The socio-demographic and clinical characteristics of the study participants are summarized in **Table 1**. A total of 167 respondents participated in the study with a mean age of 53.5±13.5 years. The youngest and oldest participants were 23 and 87 years, respectively. Majority were of the female gender (101, 60.5%) with a male to female ratio of 1:1.5. A large proportion (101, 60.5%) of the participants was married. Nearly half (82, 49.1%) of the participants had attained primary level education. Notably, large proportions of participants understood their disease condition and were aware of the need to take their medications daily. Further, 153 (91.6%) participants understood the instructions on how to take their medications. Notably, majority (102, 61.1%) of the participants had a monthly income of Ksh. ≤10000 (**Table 1**).

Table 1: Socio-demographic characteristics of the study participants

Socio-demographic and clinical characteristic	Participants (N=167)	Percentage (%)
Gender		
Female	101	60.5
Male	66	39.5
Age (years)		
≤50	73	43.7
>50	94	56.3
Mean±SD		53.5±13.5
Range		23, 87
Marital status		
Never married	15	9.0
Married	101	**60.5**
Divorced/separated	24	14.4
Widowed	27	16.1
Current residence		
Urban	142	**85.0**
Rural	25	15.0
Employment status		
Employed	43	25.8
Unemployed	9	5.4

Self-employed	67	40.1
Retired	48	28.7
Total monthly income (Ksh.)		
≤10000	**102**	**61.1**
10001-30000	36	33.5
30001-50000	7	4.2
>50000	2	1.2
Highest education level attained		
No formal education	15	9.0
Primary	82	**49.1**
Secondary	56	33.5
Post-secondary	14	8.4
Participant understands the disease	146	**87.4**
Aware of the need to take drugs daily	139	**93.2**
Understand instructions on how to take their medicines	153	**91.6**

Ksh=Kenya shillings; SD=Standard Deviation.

4.3 Prevalence of non-adherence in the study population

Overall, a third (**57, 34.1%**) of the participants were non-adherent to their long term therapy while 110 (64.9%) were adherent. Furthermore, 45 (27.0%) participants had unintentional non-adherence; 40 (24.0%) had intentional non-adherence whereas 28 (16.8%) patients were both intentionally and unintentionally non-adherent (**Figure 2**).

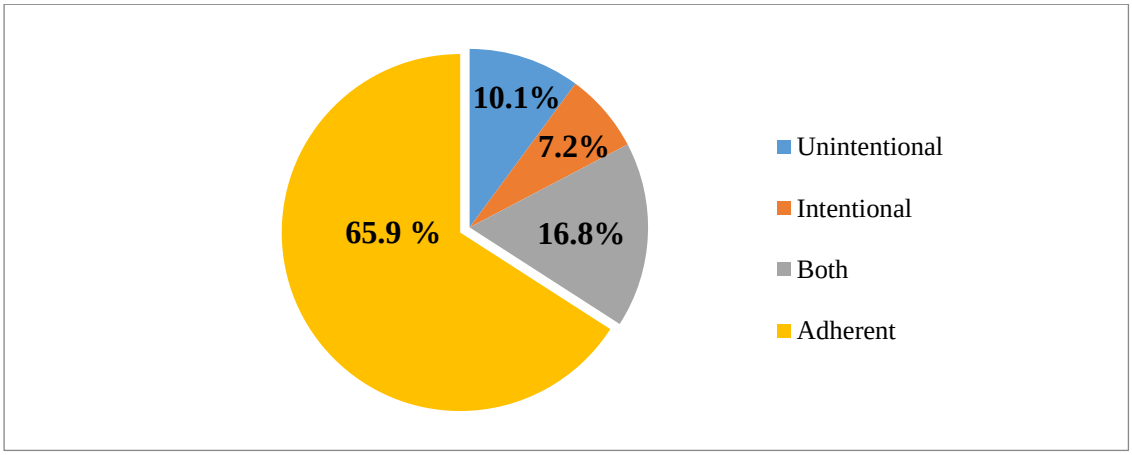

Figure 2: Pattern of non-adherence in the study population.

Self-reported non-adherence to medications was assessed using the Four-item Morisky Medication Adherence Scale (MMAS-4), and the responses to the four questions were summarized as shown in **Table 2.**

Table 2: Responses of the participants to the MMAS-4 questions

Question	Response n (%)			
	Strongly disagree	Disagree	Agree	Strongly Agree
Do you ever forget to take your medicines?	56 (33.5)	57 (34.1)	51 (30.5)	3 (1.8)
Are you ever careless at times about taking your medicines?	57 (34.1)	60 (35.9)	48 (28.7)	2 (1.2)
When you feel better do you sometimes stop taking your medicines?	45 (27.0)	75 (44.9)	47 (28.1)	0 (0)
Sometimes if you feel worse when you take your medicines do you stop taking them?	46 (27.5)	75 (44.9)	46 (27.5)	0 (0)

4.4 Reasons for non-adherence to prescribed long term medication therapy

The condition-related, therapy-related, and healthcare provider-related reasons for non-adherence are as shown in **Tables 3** and **Figure 3**.

4.4.1 Condition-related factors among the study participants

The disease factors that related to the non-adherence behaviour are as shown in **Figure 3** and **Table 3.** Hypertension was the most prevalent (127, 76.1%) condition in the study population while heart failure was the least (2, 1.2%). Other conditions included diabetes mellitus (71, 42.5%), asthma (9, 5.4%) and arthritis (18, 10.8%) **(Figure 3**).

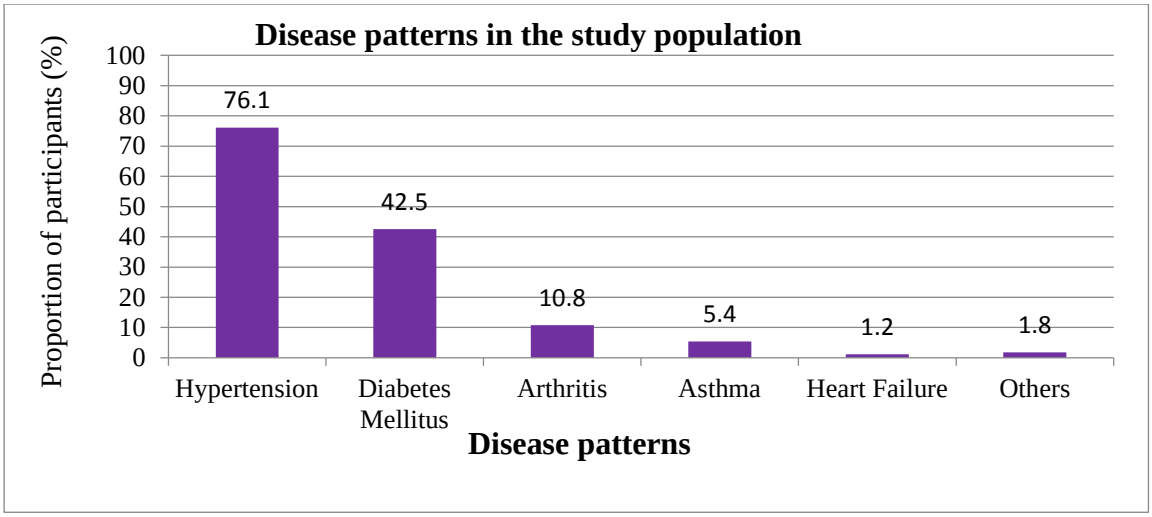

Figure 3: Disease patterns in the study population.

Table 3: Condition-related factors among study participants.

Variable	Participants (N=167)	Percentage (%)
Condition being treated		
Hypertension	127	**76.1**
Diabetes mellitus	71	42.5
Asthma	9	5.4
Arthritis	18	10.8
Heart failure	2	1.2
Others	3	1.8
Duration of treatment (years)		
≤5	118	70.7
>5	49	29.3
Mean±SD		4.4±3.9
Range		1, 25
Hospitalized in the last one year	8	4.8
Hospitalization related to the current disease	7	4.2
SD=Standard Deviation; Figure may not add up to 167 because of comorbidities		

4.4.2 Therapy-related factors

The therapy-related factors are as depicted in **Figure 4** and **Table 4.** More than a third (65, 38.9%) of the patients were using >3 (Mean 3.4±1.6; Range 1, 8) drugs for the management of the ailments. Most (85, 50.9%) patients were bothered with the long duration of their treatment.

One in every 10 participants stated that they had at one time experienced side effects of their medications. As shown in **Figure 4**, headache, dizziness and fatigue were the most prevalent (24.6%, 22.8% and 20.4%, respectively) medication side effects in the study population.

Table 4: Therapy related factors identified among study participants.

Variable	Participants (N=167)	Percentage (%)
Number of drugs currently taking		
≤3	102	61.1
>3	**65**	**38.9**
Mean		3.4±1.6
Range		1, 8
Patient bothered by the number of drugs	36	21.6
Stopped taking drugs due to number	11	6.6
Side effects	**74**	**44.3**
Dizziness	38	22.8
Fatigue	34	20.4
Headache	**41**	**24.6**
Cough	8	4.8
Leg edema	11	6.6
Blurred vision	2	1.2
Stomach upset	11	6.6
Epigastric pain	4	2.4
Abdominal tenderness	1	0.6
Others	6	3.6
Stopped taking drugs due to side effects	8	4.8
Bothered by duration of treatment	85	50.9
Patient understands their drugs	137	**82.0**

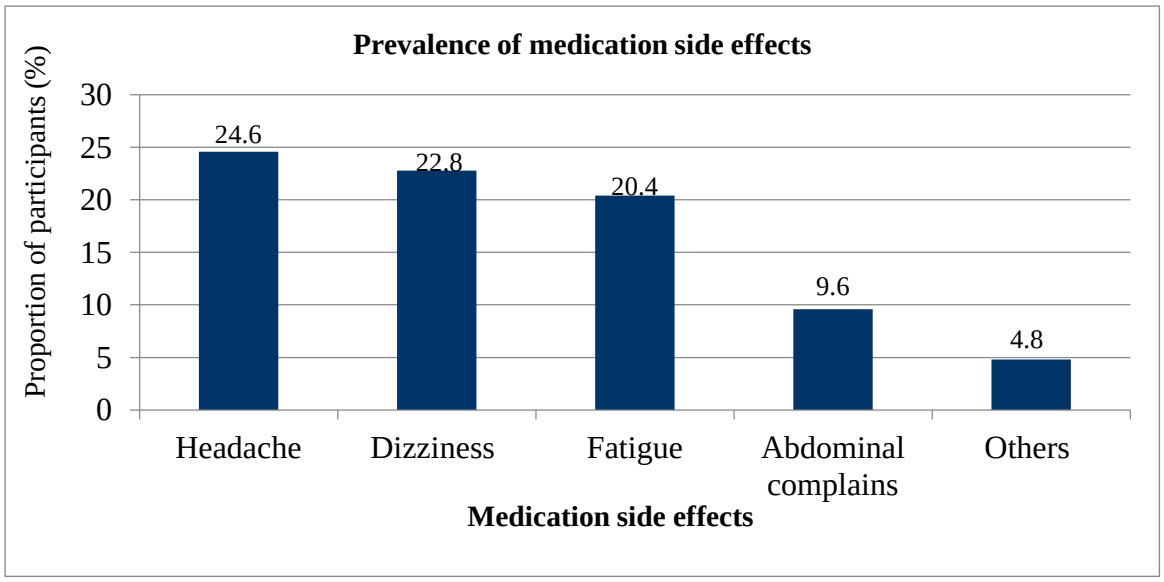

Figure 4: Prevalence of medication side effects in the study population

4.4.3 Healthcare provider related factors

The healthcare provider related factors are summarized in **Table 5**. Over three quarters (130, 77.8%) of the study participants paid Ksh. ≤200 as bus fare from their

homes to the hospital during every clinic visit. Further, nearly two thirds (110, 65.9%) of the participants spent Ksh. ≤2000 for the costs of their long term medications. Seventy, (41.9%) participants responded that their medications were not available at the hospital pharmacy when they needed to refill their medications.

Table 5: Healthcare provider related factors.

Variable	Participants (N=167)	Percentage (%)
Average bus fare to the hospital (Ksh)		
≤200	130	77.8
>200	37	22.2
Mean±SD		**222.5±170.2**
Range		**10, 990**
Average monthly cost of drugs (Ksh)		
≤2000	110	65.9
>2000	57	34.1
Mean±SD		**2195.9±2217**
Range		**50, 9990**
Drugs unavailable in the hospital	70	41.9
Stopped taking drugs due to unavailability	26	15.6
Adherence counseling by doctor	138	82.6
Ksh=Kenya shilling; SD=Standard Deviation.		

4.5 Relationship between non-adherence and other variables under study

We compared the non-adherence with other variables under study and the results are as tabulated in sections that follow.

4.5.1 Association between non-adherence and socio-demographic and clinical characteristics of the study participants

Bivariate analysis was done to compare between non-adherence and the various socio-demographic and clinical characteristics and the results are presented in **Table 6**. For logical data analysis and interpretation, the marital status of the participants was narrowed to two categories, that is, ‘married’ and ‘single’. The category ‘single’ encompassed the ‘never married’, ‘divorced/separated’ and ‘widowed.’ Similarly, participants who responded ‘strongly agree’ or agree to MMAS-4 questions were grouped ‘Yes’ whereas those who said ‘strongly disagree’ or ‘disagree’ made the ‘No’ category. Also, the monthly income was regrouped into Ksh. ≤10000 and >10000.

The participant's gender, age, marital status, area of residence, employment status, income level, and level of education were not statistically associated with non-adherence to medications. For instance, 36 (35.6%) males and 21 (31.8) males were non-adherent to medications and this relationship between non-adherence and gender was not significant (p=0.739). Nearly equal proportions of participants aged ≤50 years (34.4%) and > 50 years 34.3%) were non-adherent to their medications, although this association was not statistically significant (p=1.000).

Moreover, statistically significant associations were found between non-adherence to medications and participant's understanding of the disease and dosage instructions; awareness of the need to take drugs daily; and forgetting to take drugs, among others (**Table 6**). For instance 45 (83.3%) participants who forgot to take their medications were noted to be non-adherent compared to 111 (89.4%) who did not forget and consequently were adherent. This was a significant association (p<**0.001**).

Table 6: Association between non-adherence and socio-demographic characteristics.

Socio-demographic and clinical characteristics	Non-adherence (N=167)		P-value
	Yes n (%)	No n (%)	
Gender			
Female	**36 (35.6)**	65 (64.4)	0.739
Male	**21 (31.8)**	45 (68.2)	
Age (years)			
≤50	**32 (34.0)**	62 (66.0)	1.000
>50	**25 (34.3)**	48 (65.7)	
Marital status			
Single	32 (31.7)	69 (68.3)	0.505
Married	25 (37.9)	41 (62.1)	
Current residence			
Urban	50 (35.2)	92 (64.8)	0.472
Rural	7 (28.0)	18 (72.0)	
Employment status			
Employed	12 (27.9)	31 (72.1)	
Unemployed	4 (44.4)	6 (55.6)	0.704
Self-employed	24 (55.8)	43 (64.2)	
Retired	17 (35.4)	31 (64.6)	
Total monthly income (Ksh.)			
≤10000	37 (36.3)	65 (63.7)	0.506
>10000	20 (30.8)	45 (69.2)	
Highest education level attained			
No formal education	5 (33.3)	10 (66.7)	
Primary	24 (29.3)	58 (70.7)	0.539
Secondary	22 (39.3)	34 (60.7)	
Post-secondary	6 (42.9)	8 (57.1)	
Participant understands the disease			
Yes	43 (29.5)	103 (70.5)	**0.001***
No	**14 (66.7)**	7 (33.3)	
Aware of the need to take drugs daily			
Yes	34 (24.5)	105 (75.5)	**<0.001***
No	23 (82.1)	5 (17.9)	
Understands dosage instructions			
Yes	48 (31.4)	105 (68.6)	**0.018***
No	9 (64.3)	5 (35.7)	
Forgets to take drugs			
Yes	**45 (83.3)**	9 (16.7)	**<0.001***
No	12 (10.6)	**111 (89.4)**	
Careless about taking medications			
Yes	43 (86.0)	7 (14.0)	**<0.001***
No	14 (12.0)	103 (88.0)	
Stops taking drugs when feels better			
Yes	40 (85.1)	7 (14.9)	**<0.001***
No	17 (14.2)	103 (85.8)	
Stops taking when feels worse			
Yes	38 (82.6)	8 (17.4)	**<0.001***
No	19 (15.7)	102 (84.3)	

***=Statistically significant result**

4.5.2 Relationship between non-adherence and condition-related factors

Comparisons were made between the various condition-related factors versus the non-adherence as presented in **Table 7**. There was a statistically significant relationship between non-adherence and the duration of the treatment, as well as the hospitalization due to the severity of the participant's condition. Additionally, 23 (46.9%) participants who had been on treatment for ≤ 5 years were non-adherent compared to 34 (28.8%) who had been on treatment for > 5 years (p=**0.031**). Furthermore, nearly a third (52, 32.7) who had not been hospitalized due to the current disease was non-adherent whereas a larger proportion (5, 71.4%) who had been hospitalized was non-adherent. This was found to be statistically significant (=**0.048**).

Nevertheless, none of the disease conditions was statistically associated with poor adherence. For instance, over a third (46, 36.5%) hypertensive participants were non-adherent compared to 11 (27.5%) non-hypertensive participants. This association was not statistically significant (p=0.345). Similarly, nearly equal proportions of the diabetic (24, 33.8%) and non-diabetic (33, 34.4%) participants were non-adherent, and this was not statistically significant (p=1.000) (**Table 7)**.

Table 7: Relationship between non-adherence and condition-related factors.

Variable	**Non-adherent (N=167)**		**P-value**
	Yes n (%)	**No n (%)**	
Condition being treated			
Hypertension			
Yes	**46 (36.5)**	81 (63.8)	0.345
No	**11 (27.5)**	29 (72.5)	
Diabetes mellitus			
Yes	**24 (33.8)**	47 (66.2)	1.000
No	**33 (34.4)**	63 (65.6)	
Asthma			
Yes	2 (22.2)	7 (77.8)	0.720
No	55 (34.8)	103 (65.2)	
Arthritis			
Yes	7 (38.9)	11 (61.1)	0.793
No	50 (33.6)	99 (66.4)	
Heart failure			
Yes	0 (0)	2 (100)	0.548
No	57 (34.6)	108 (65.4)	
Others			
Yes	1 (33.3)	2 (66.7)	1.000
No	56 (34.2)	108 (65.8)	

Duration of treatment (years)			
≤5	**23 (46.9)**	26 (53.1)	**0.031***
>5	**34 (28.8)**	84 (71.2)	
Hospitalized in the last one year			
Yes	5 (62.5)	3 (37.5)	0.123
No	52 (32.7)	107 (67.3)	
Hospitalization related to the current disease			
Yes	**5 (71.4)**	2 (28.6)	**0.048***
No	**52 (32.7)**	107 (67.3)	

***=Statistically significant result.**

4.5.3 Relationship between non-adherence versus therapy-related factors

Therapy-related factors were compared with non-adherence and results are as tabulated in **Table 8**. Statistically significant associations were found between non-adherence and participants who were bothered with the duration of their treatment; those who had stopped taking their medications due to the side effects; and those who experienced specific side effects of dizziness and headache. Half (20, 52.6%) of the participants who experienced dizziness after taking their medications were non-adherent compared to 92 (71.3%) participants who did not experience dizziness and consequently were adherent. This was a statistically significant relationship (p=0.**011**). Twenty six (63.4%) participants who experienced headache as a side effect from their drugs were also non-adherent compared to 95 (75.4%) who did not experience and were adherent. This was also statistically significant (p<**0.001**). Moreover, 4 in every 10 participants (36, 42.4%) who were bothered by the duration of treatment were non-adherent to their medication and this association was statistically significant (p=**0.020**) (**Table 8**).

Table 8: Relationship between non-adherence versus therapy-related factors.

Variable	**Non-adherent (N=167)**		**P-value**
	Yes n (%)	**No n (%)**	
Number of drugs currently taking			
≤3	20 (30.8)	45 (69.2)	0.506
>3	37 (36.3)	65 (63.7)	
Participant bothered by the number of drugs			
Yes	16 (44.4)	20 (55.6)	0.166
No	41 (31.3)	90 (68.7)	
Stopped taking drugs due to number			
Yes	5 (45.5)	6 (54.5)	0.513
No	52 (33.3)	104 (66.7)	

Noted side effects			
Yes	29 (39.2)	45 (60.8)	0.252
No	28 (30.1)	65 (69.9)	
Dizziness			
Yes	**20 (52.6)**	18 (47.4)	**0.011***
No	37 (28.7)	**92 (71.3)**	
Fatigue			
Yes	14 (41.2)	20 (58.8)	0.418
No	43 (32.3)	90 (67.7)	
Headache			
Yes	**26 (63.4)**	15 (36.6)	**<0.001***
No	31 (24.6)	**95 (75.4)**	
Cough			
Yes	4 (50.0)	4 (50.0)	0.447
No	53 (33.3)	106 (66.7)	
Leg edema			
Yes	6 (54.5)	5 (45.5)	0.191
No	51 (33.1)	103 (66.7)	
Blurred vision			
Yes	0 (0)	2 (100)	0.548
No	57 (34.5)	108 (65.5)	
Stomach upset			
Yes	1 (9.1)	10 (90.9)	0.100
No	56 (35.9)	100 (64.1)	
Epigastric pain			
Yes	0 (0)	4 (100)	0.299
No	57 (35.4)	104 (64.6)	
Abdominal tenderness			
Yes	0 (0)	1 (100)	1.000
No	56 (35.0)	104 (65.0)	
Others			
Yes	3 (50.0)	3 (50.0)	0.412
No	54 (33.5)	107 (66.5)	
Stopped taking drugs due to side effects			
Yes	6 (75.0)	2 (25.0)	**0.020***
No	51 (32.3)	107 (67.7)	
Bothered by duration of treatment			
Yes	**36 (42.4)**	49 (57.6)	**0.033***
No	21 (25.6)	61 (74.4)	
Participant understands their drugs			
Yes	42 (30.7)	95 (69.3)	0.056
No	15 (50.0)	15 (50.0)	
***=Statistically significant result**			

As indicated in **Table 8**, many therapy-related factors were not statistically related to non-adherence. These factors included participant's understanding of their drugs; side

effect such as fatigue, cough, leg edema, blurred vision, stomach upset and abdominal tenderness.

4.5.4 Association between non-adherence and healthcare provider-related factors

A comparison was made between non-adherence versus the healthcare provider related factors as shown in **Table 9**. A statistically significant association was found between the availability of drugs in the hospital pharmacy and non-adherence. For instance, 33 (47.1%) participants who agreed that sometimes the prescribed medications was not available in the hospital pharmacy were non-adherent as compared to three quarters (73, 75.3%) who denied that the drugs were unavailable in the hospital pharmacy and consequently were adherent to their medications. The association between non-adherence and availability of drugs in the hospital pharmacy was statistically significant (p=**0.003**). Nevertheless, other factors such as bus fare; cost of drugs; and counseling by the doctor on adherence were not statistically associated with non-adherence. For instance, two thirds (94, 68.1%) participants who had received adherence counseling from the clinician were adherent compared to 44 (31.9%) who were non-adherent. However, this association was not statistically significant (p=0.200).

Table 9: Comparison between non-adherence and healthcare provider related factors.

Variable	Non-adherent (N=167)		P-value
	Yes n (%)	No n (%)	
Average bus fare to the hospital (Ksh)			
≤200	11 (29.7)	26 (70.3)	0.562
>200	39 (30.0)	84 (64.6)	
Average monthly cost of drugs (Ksh)			
≤2000	21 (36.8)	36 (63.2)	0.609
>2000	36 (32.7)	82 (67.3)	
Drugs available in the hospital pharmacy			
Yes	**33 (47.1)**	37 (52.9)	**0.003***
No	17 (17.5)	**73 (75.3)**	
Stopped taking drugs due to unavailability			
Yes	11 (42.3)	15 (57.7)	0.372
No	46 (32.6)	95 (67.4)	
Adherence counseling by doctor			
Yes	**44 (31.9)**	**94 (68.1)**	0.200
No	13 (44.8)	16 (55.2)	

***=Statistically significant result**

4.5.5 Independent predictors of non-adherence to long term prescription medicines

Forward stepwise logistic regression was done in order to identify the independent predictors of non-adherence as summarized in **Table 10.** Participant's awareness of the need to take drugs daily; being on treatment for >5 years; as well as experiencing headache as a side effect were found to be independent predictors of non-adherence. Furthermore, after bivariate logistic regression participants who were aware of the need to take their drugs daily had 0.07 times the odds of being non-adherent as compared to those who were not aware (COR=0.07; 95% CI: 0.02-0.2; **p<0.001**). This relationship became more apparent after multivariate regression analysis as shown in **Table 10**. Nevertheless, other associations were lost after multivariate regression analysis. For instance, participants who understood dosage instructions had 0.25 times the likelihood of being non-adherent (COR=0.25; 95% CI: 0.08-0.8; **p=0.019**). However, the statistical significance of this association was lost after multivariate analysis (AOR=0.64; 95% CI: 0.01-3.8; p=0.625).

Table 10: Independent predictors of non-adherence among study participants.

Variable	Bivariate Analysis		Multivariate Analysis	
	COR (95% CI)	**P-value**	**AOR (95% CI)**	**P-value**
Aware of the need to take drugs daily	0.07 (0.02-0.2)	**<0.001***	0.13 (0.3-0.54)	**0.005***
Understands dosage instructions	0.25 (0.08-0.8)	**0.019***	0.64 (0.01-3.8)	0.625
Treatment duration >5 years	2.19 (1.1-4.35)	**0.026***	2.44 (1.05-5.67)	**0.039***
Dizziness	2.76 (1.32-5.8)	**0.007***	0.55 (0.15-2.0)	0.365
Headache	5.31 (2.5-11.3)	**<0.001***	5.48 (1.61-18.6)	**0.006***
Bothered by duration of treatment	2.13 (1.1-4.11)	**0.024***	1.72 (0.75-3.92)	0.200
Drugs available in the pharmacy	2.71 (1.4-5.24)	**0.003***	2.17 (0.97-4.86)	0.061

COR=Crude Odd Ratio; CI=Confidence Interval; AOR=Adjusted Odds Ratio; *=Statistically significant result.

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses the research findings as seen in Chapter 4 within the perspective of previous research literature. Conclusion and recommendations have been highlighted based on the research findings.

5.2 Discussion.

A total of 167 respondents participated in the study with a mean age of 53.5±13.5 years. These findings are consistent with closely related studies done in other set ups (67–69). The majority were of the female gender (101, 60.5%) with a male to female ratio of 1:1.5.This study showed a female predominance as well and closely matches related studies done in the same setting and somewhat related participant profiles (70,71). The majority of participants had obtained at least primary level of education. This is expected since the study area was urban. Hypertension was the most prevalent (127, 76.1%) condition in the study population. Studies carried out in other set ups trying to correlate co morbidities and non-adherence showed a predominance of hypertension among the study population (70,72,73).

Our study found that overall, a third **(57, 34.1%)** of the participants were non-adherent to their long term therapy which is consistent with other studies on non-adherence which give a range of 20-60% irrespective of the condition and set up (13–15). Furthermore, 45 (27.0%) participants had unintentional non-adherence which tallies with other studies stated at 20-40% (7,8,10); 40 (24.0%) had intentional non-adherence which is consistent with other studies with ranges of 20-60%. Twenty eight,16.8% participants were both intentionally and unintentionally non-adherent all similar to studies carried out in different set ups which give ranges of 20-60% (7,8,55). The high adherence levels seen in this study may be related to the self-reported data collection method used. This is a common method of assessment in adherence research, and it is very prone to self-presentational and recall biases(74).

Bivariate analysis showed that there were statistically significant associations between non-adherence and participant understanding of their disease condition (p=0.001), participant being aware of the need to take their drugs daily (p=<0.001), participant

understanding dosage instructions (p=0.018), participant forgetting to take drugs, careless about taking their drugs, stopping to take drugs after feeling better or worse, all with (p=<0.001). Awareness of the need to take drugs daily was an independent predictor of non-adherence as indicated by bivariate analysis, participants who were aware of the need to take their drugs daily had 0.07 times the odds of being non-adherent as compared to those who were not aware (COR =0.07; 95% CI 0.02-0.2; p<0.001) and this prediction further affirmed on multivariate regression analysis (AOR=0.13; 95% CI 0.3-0.54 p=0.005). This means that patients who are aware of the need to take drugs daily are less likely to be non-adherent. This is an avenue that can be exploited to strengthen adherence by empowering the patient through adherence counseling.

These participant related results are especially well elaborated in studies on beliefs, experiences and behaviours about the patient in relation to non-adherence. A study carried out in a sheltered housing on prescription medication's beliefs, experiences, behavior, showed statistical significance on all the above aspects (75). Further, this kind of associations shows the role and the relevance of patient education in achieving adherence. Individualized patient education is therefore key in our clinical set ups (11). Further, this goes to show the more a patient is aware of the need to take their drugs daily, the more they will be less non-adherent. This study highlighted being bothered by the duration of treatment as an independent predictor of non-adherence on bivariate analysis (COR = 2.13; 95% CI 1.1-4.11; p=0.024) together with patient understanding dosage instructions (COR=0.25; 95% CI 0.08-0.8; p=0.019) but these relationships were lost in multivariate logistic regression analysis. These two findings lay emphasis on the role of patient education in adherence. Studies have shown that a patient who can read and understand their drug labels are more adherent (30). Health literacy means that the patients are able to read , understand, remember medication instructions and act on health information provided to them(43). Patients with low health literacy were reported to be less adherent to their therapy(33).

There was a statistically significant association between non-adherence and duration of treatment with those patients who were on treatment for a period of >5 years having a (COR= 2.19; 95% CI 1.1-4.35; P=0.026 and (AOR=2.44; 95%CI 1.05-5.67 P=0.039. This implies that those on treatment for a longer period of time are more likely to be adherent. This can be explained by assuming that as patients gain more

experience with their disease condition, they become more knowledgeable and hence more adherent. A study carried out on factors affecting adherence to anti hypertensives and lipid lowering agents showed similar results(56,76). In this particular study, patients who have been on treatment for a longer duration(over 5 years)reported better adherence than patients with a shorter duration(5 years or less).This finding was consistent with a previous study conducted using the MMAS-8 where poor antihypertensive drug adherence was more commonly found among those first diagnosed with hypertension for less than 10 years(56).

The explanation that can be given for these kind of results could be that patients having taken their drugs for a longer duration gain more experience with their condition, establish a better physician-patient relationship and had greater faith on physician's advice. They might also become more knowledgeable about their own health condition and the appropriate management for a better disease control (51).However, studies carried out in other cohorts show a contrast with those on treatment for a longer time deemed to be non-adherent (56,70). This kind of difference may emanate from the fact that the studies were carried out in different cohorts of patients, one group in particular had hyperlipidemia and their non-adherence was due to the perceived long term side effects of the medicine being a factor influencing non-adherence. An additional explanation to this would be these studies have been carried out in developing countries where patient counseling is more established. As a result, patients are more aware of the expected outcomes of their treatment including side effects and once they develop these side effects, they stop taking their drugs thus making them non-adherent.

A common reason for medication non adherence in most settings is medication side effects(77). A good example is the kind of side effects developed while using antihypertensive medication such as a dry cough, dizziness, nausea, headache, and sexual dysfunction depending on the drug administered (14). This study was carried out in a medical outpatient set up and the most prevalent condition was hypertension. In this study (127, 76.1%) of the study participants had hypertension. It is difficult to compare side effects between studies, this is because the medications prescribed, the dosages of the prescribed medication and the characteristics of the enrolled patients vary. Looking at hypertension, the side effects well studied and documented are listed above. In this particular study carried out at the Mbagathi Hospital Medical outpatient

clinic, headache was the most prevalent side effect (41, 24.6%) followed by dizziness (38, 22.8%) all well documented side effects of anti hypertensives. It can be extrapolated that the majority of the side effects experienced are in effect due to hypertension as a condition on its own. We are of the view that these results could be interpreted in different perspectives to inform the current situation of medication non-adherence among adult outpatients attending the medical outpatient clinic of Mbagathi hospital.

There was a statistically significant association between non-adherence and headache as a side effect $p<0.001$. Headache as a side effect was an independent predictor of non-adherence as indicated by bivariate analysis (COR =5.31; 95% 2.5-11.3; $p<0.001$) and this prediction further affirmed on multivariate logistic regression (AOR=5.48; 95% CI 1.61-18.6 $p=0.006$). These results imply that the likelihood of non-adherence increased with a patient experiencing headache as a side effect. Headaches can be debilitating and affect ones quality of life. There is also a need for close monitoring of hypertensive patients because development of headache can be linked to poor treatment and also the drug side effects. These results are affirmed by studies carried out in a cohort of hypertensive patients and headache was found to be a statistically significant association to non-adherence (14). Bivariate analysis showed a statistically significant association between non adherence and stoppage of taking medicines due side effects $p=0.020$. These results are in agreement with most previous studies concerning other group of patients and drug classes. The effect of side effects on adherence may be explained in terms of physical discomfort, skepticism about the efficacy of the medicines once side effects set in, and decreasing the trust in physicians. This ultimately makes the patient non-adherent(54,56,78).

Hospitalization due to current condition showed a statistically significant outcome in relation to non-adherence $p= 0.048$. This result gives more weight to the fact that being hospitalized while on long term therapy could be due to complications emanating from non-adherence, complications develop when there is treatment failure as a result of not taking drugs as prescribed. This is a paradox because a study among hospitalized Japanese patients showed that they were more adherent to their medication. The study concluded that non-adherence is most likely to occur among non-hospitalized patients who are prescribed long-term preventive medications(79).

5.3 Study limitations

Having taken our sample from a single out-patient clinic in Kenya, and there being a possibility that patient characteristics may differ from other areas in the country, a problem of external validity may be raised from this study.

There is a lot of generalization in the study because we have looked at different conditions in the study population yet we are not able to highlight our study findings per condition.

When involving self-reported measures in any research, such as the ones used in our research, the responses depend largely on individuals' memory and this may introduce recall bias. Few studies on non-adherence to long term prescription medicines have been conducted in Kenya and Africa at large in this particular set up, therefore we lack data that can be used for cross referencing. Thus, more studies are needed in this area.

Lastly, lack of associations between the Morisky scores and objective measures such as blood pressure, blood glucose cannot give us results that are fool proof.

5.4 Summary

5.4.1 Key findings

In this study, a third (57, 34.1%) of the patients were non adherent to their long term therapy. Hypertension was the most prevalent (127, 76.1%) condition in the study population followed by diabetes mellitus whereas heart failure was the least (2, 1.2%).

There was a statistically significant association between non-adherence and the patients' awareness of the need to take drugs daily , treatment duration and development of side effects especially headache. Therapy-related factors and patient-related factors seemed to give the most significant results in relation to non-adherence which was our main outcome of interest.

5.4.2 Implications of the findings

Non-adherence as a drug therapy problem is predominant in patients on long term therapy. Non-adherence can in effect result to poor outcomes with safety and effectiveness of drugs being compromised, bad medication experiences and thus there's an immediate need to curb this in our outpatient set ups.

5.5 Conclusion

In this study, a third (57, 34.1%) of the patients were non adherent to their long term therapy. Hypertension was the most prevalent (127, 76.1%) condition in the study population followed by diabetes mellitus whereas heart failure was the least (2, 1.2%).

Non-adherence was significantly associated with the patients' aweness of the need to take drugs daily , treatment duration and development of side effects especially headache. Therapy-related factors and patient-related factors seemed to give the most significant results in relation to non-adherence our outcome variable.

The lack of an association among commonly observe correlates when studying non-adherence may have to do with the measurement of the variables chosen in this study. There is reason to believe there are no fool proof methods of detecting non-adherent behaviours after conducting this study. This study used a measure of self-reported non-adherence to medication because it correlates well with pill counts, electronic monitoring, and pharmacy refill records and because less practical methods of assessing non-adherence may not overcome attempts at concealment. Even with correlation, the tool does not give room for objective measures of non-adherence to be incorporated (80).

Overall, our study objectives were met. We were able to establish the prevalence of non-adherence in this particular study population and determine the main factors causing non-adherence in this group of participants.

5.6 Recommendations

5.6.1 Policy and practice

There is need to include a pharmacist at the medical outpatient clinics to educate the patients on the most highlighted factors leading to non-adherence and how to manage them to get better outcomes. Patient education could be in the form of pamphlets originating from the hospital pharmacy.

Efforts to improve follow up care within the patients attending this medical outpatient clinics is encouraged as a way of reducing non adherence.

5.6.2 Recommendations for research

Healthcare provider related factors did not come out clearly as a correlate of non-adherence in this particular study and thus further research on the same is suggested. Future research should therefore focus on issues such as communication styles of the healthcare provider, knowledge and skills of the healthcare worker, time constraints during clinical consultations and how the organization carries out its follow-up care. These insights will help in correlating non-adherence and healthcare provider related factors.

WORK PLAN

Research Activity	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sept**	**Oct**	**Nov**
Proposal Development and Writing									
Ethical Review									
Pilot study and Data Collection									
Data Analysis									
Report Writing Submission and Defense									

BUDGET

ITEM	DESCRIPTION	UNITS	UNIT COST	COST(Ksh)
Proposal Development	Internet bundles	100 GB	50	5000
	Typesetting, printing, photocopying, binding	20Copies	250	5000
Stationery	Questionnaire, informed consent forms, eligibility screening forms	500 copies each 10 pages	50	25000
Ethical Approval	Fees	-	2000	7000
Data Collection	Research Assistants	2	20000	40000
Data Analysis	Biostatistician's fees	1	40000	40000
Final Dissertation	Printing, binding, burning	-	-	5000
Publication fees	-	1	20000	20000
Other logistics	-	-	-	8000
			TOTAL	**150000**

Funding: Principal Investigator

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APPENDICES

APPENDIX 1: ELIBILITY SCREENING FORM

Medical Outpatient clinic

Unique Identifier: ☐☐☐

MOPC Number:_____

Criteria	Remark	
Adult aged ≥18 years	YES ☐	NO ☐
On long-term prescription medicines	YES ☐	NO ☐
Given Consent	YES ☐	NO ☐

If all **YES** please proceed to the study Questionnaire

APPENDIX 2A: PATIENT INFORMATION FORM

Study Title

DETERMINANTS OF NON-ADHERENCE TO LONG TERM THERAPY WITH PRESCRIPTION MEDICINES IN ADULT PATIENTS ATTENDING MEDICAL OUTPATIENT CLINIC AT MBAGATHI HOSPITAL

INSTITUTION	Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi. P.O Box 30197-00400, Nairobi.
PRINCIPAL INVESTIGATOR	Dr. Leah Njeri Njenga P.O Box 76439-00508, Nairobi, Kenya. Phone number: 0720872197 Email: *njeriln@yahoo.com*
SUPERVISORS	Prof. Francis Ndemo Phone No:0792190924 Email:*fandemra@gmail.com* Dr. Sylvia Opanga Phone No. 0204915026 Email: *sylvia.adisa@uonbi.ac.ke*
ETHICAL APPROVAL	Kenyatta National Hospital/University of Nairobi Ethical and Research Committee P.O Box 20723-00100, Nairobi. Tel. 2726300/2716450 Ext 44102 Email: *uonknh_erc@uonbi.ac.ke*.

Introduction

My name is Dr. Leah Njeri Njenga. I would like to tell you about a study being conducted by the above-listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a patient in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all patients in a medical research) Your decision to participate is entirely voluntary; ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal; and iii) Refusal to participate in the research will not affect the services you are entitled to in

this health facility or other facilities. We will give you a copy of this form for your records. This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No.: **P312/05/2018.**

What is this study about?

The researchers listed above are interviewing individuals who are on long – term treatment. The purpose of the interview is to find out whether the patient is taking the medication as required and identify things the patient is doing (or not doing) that may be making them not to take the medicines as required. You will be asked questions about the management of your condition. There will be approximately 424 patients in this study. We are asking for your consent to consider participating in this study.

What will happen if you decide to participate in this research study?

If you agree to participate in this study, you will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 15 minutes. The interview will cover topics such as bio data, the disease being treated, drugs being used among others.

Are there any risks, harms or discomforts associated with this study?

Although any medical research has the potential to introduce psychological, social, emotional and physical risks, efforts will be made to minimize the risks. One potential risk of being in the study is the loss of privacy. However, we will safeguard your privacy by keeping everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out that you were in this study and could access information about you. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these interviews. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

Benefits

Patients in this study will benefit through advice from the Principle Investigator or Research Assistants on ways to improve their medication adherence. The results from this study will be shared with the patient's regular clinician so as to improve on the care of the particular patient. Also, the findings of this research will provide more scientific information for practice as well as build on the existing body of knowledge on human health and science.

Will being in this study cost you anything?
This study will cost you about fifteen minutes of your time.

Will you get refund for any money spent as part of this study?
This study will not cost you money.

What if you have questions in future?

If you have further questions or concerns about participating in this study, please call or send a text message or email to the study staff via the contact details provided in this document provided at the bottom of this page.

For more information about your rights as a research patient you may contact the Principal Investigator, my Supervisors or the KNH-UoN Ethics and Research Committee using the contacts provided.

If in agreement, please sign the attached consent declaration form.

APPENDIX 2B: CONSENT DECLARATION FORM

Patient's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with the researcher. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw anytime. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a patient in a research study.

I agree to participate in this research study: **YES** ☐ **NO** ☐

I agree to provide contact information for follow-up: **YES** ☐ **NO** ☐

Patient printed name: _____

Patient signature / Thumb stamp _____

Date _____

Witness_____Date_____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the patient named above. The patient has understood and has freely given his/her consent.

Researcher's Name: _____ **Signature**

_____

Date: _____ Role in the research: _____

In case of any questions or concerns, feel free to contact any of the following:

Principal Investigator:	Dr. Leah Njeri Njenga 0720805643.
Lead supervisor:	Dr. Francis Ndemo 0792190924.
Ethics Committee:	KNH-UoN ERC on 2726300 Ext 44102.

APPENDIX 3A: MAELEZO KUHUSU KUSHIRIKI KATIKA UTAFITI

Kichwa cha Utafiti

KUCHUNGUZA UADILIFU WA WAGONJWA WANAOTUMIA DAWA KWA MUDA MREFU KATIKA MATUMIZI YA DAWA HIZO NA VIGEZO VINAVYO HUSIKA KATIKA UADILIFU HUU KATIKA KLINIKI YA MATIBABU YA BILA KULAZWA

CHUO KIKUU	Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi. S.L.P. 30197-00400, Nairobi.
MTAFITI MKUU	Dkt. Leah Njeri Njenga S.L.P. 76439-00508, Nairobi, Kenya. Simu: 0720805643 Tovuti: *njeriln@ahoo.com*
WAHADHIRI	Profesa. Francis Ndemo Simu: 0792190924 Tovuti:*fndamera@gmail.com* Dkt. Sylvia Opanga Simu. 0721296448 Tovuti: *sylvia.adisa@gmail.com*
KAMATI YA MAADILI	Kenyatta National Hospital/University of Nairobi Ethical and Research Committee S.L.P. 20723-00100, Nairobi. Simu: 2726300/2716450 Ext 44102 Tovuti: *uonknh_erc@uonbi.ac.ke*.

Utangulizi:

Jina langu ni Dkt. Leah Njeri Njenga. Ningependa kuzungumza nawe kuhusu utafiti huu utakaofanywa na waliotajwa hapo juu. Umuhimu wa mazungumzo haya ni kukufahamisha zaidi ili ufanye uamuzi wa busara kushiriki au kutoshiriki katika utafiti huu. Kuwa huru kuuliza maswali yoyote kuhusu kitakachofanyika utakapokubali kushiriki, madhara yanayoweza kutokea, manufaa ya utafiti huu, haki zako kama mshiriki na maswali yoyote kuhusu lolote ambalo hulielewi. Tutakapo jibu maswali yako yote, basi utaamua kushiriki au la. Utakapokubali, nitakuuliza tafadhali utie sahihi na majina yako kwa ukurasa hapa chini. Unafaa uelewe kwa ujumla nguzo muhimu ambazo zinalinda washiriki katiaka ufatiti wa sayansi ya afya: i) Kushiriki kwako ni kwa hiari; ii) Unaweza kujiondoa wakati wowote bila kushurutishwa kutoa maelezo ya kufanya hivyo; na iii) Kutoshiriki kwako katika utafiti huu hakutaathiri huduma unazopaswa kuzipata kwa hosipitali hii. Tutakupa nakala yako ili ujiwekee kwa manufaa yako binafsi.

Utafiti huu umeidhiniswha na kitengo cha maadili na utafiti cha hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi nambari: **P312/05/2018.**

Utafiti huu unahusu nini?

Watafiti waliondikwa hapo juu wanawahoji washiriki ambao wanatumia madawa kwa muda mrefu. Mahojiano haya yana madhumuni ya kuchunguza mambo yanayohusika na uadilifu katika matumizi ya dawa hizo. Washiriki wataulizwa maswali kuhusu matibabu yao. Kutakuwa na washiriki 424 ambao wamechaguliwa kwa njia ya kisayansi. Tunaomba idhini yako uwe mshiriki kwa utafiti huu.

Ni nini kitakachofanyika ukikubali kushiriki?

Yafuatayo yatafanyika: Utahojiwa na mtafiti aliyehitimu kwa sehemu ya tulivu na ya kisiri ambapo utakuwa huru kwa muda wa dakita kumi na tano hivi. Mahojiano yatahusu historia ya ugonjwa wako, matibabu yako na kadhalika.

Utafiti huu una madhara yoyote?

Ijapokuwa utafiti wa kiafya una madhara yake kama ya kisaikolojia, tutajitahidi kabisa kupunguza madhara yoyote kwako. Kwa mfano, dhara moja ni uwezekano wa kupoteza usiri wako. Hata hivyo, mambo yote utatueleza tutayaweka kwa siri. Tutakupa nambari ya siri kwa compyuta ambayo imelindwa. Stakabadhi zote zitawekwa kwenye kabati lilifungwa kwa kufuli. Lakini, kama unavyojua, bado kunao uwezekano wa kuvunjwa kabati na kuiba stakabadhi zako za siri. Pia kuyajibu maswali katika mahojiano huenda kusikuridhishe. Kama kutakuwa na maswali ambayo hungetaka kuyajibu, utaruhusiwa kutoyajibu. Uko na haki ya kutojibu swali lolote katika mahojiano. Tutajaribu kuhakikisha mahojiano yamefanyika kwa njia ya siri. Pia, watafiti wetu wote wamehitimu kufanya mahojiano haya. Kama kutakuwa na kuumia, ugonjwa au shida zingine zozote kwa ajili ya utafiti huu, tafadhali wasiliana nasi kupitia nambari iliyo chini ya kurasa hizi. Watafiti wetu wanaweza kutibu magonjwa kidogo na pia wanao uwezo wa kukuelekeza ifaavyo kwa usaidizi zaidi.

Ufatiti huu una manufaa yoyote?

Utafaidika kwa kupata wosia mwafaka kuhusu matumizi ya dawa zako kupitia kwa Mtafiti mkuu au wasaidizi wake. Tunaweza kukuhimiza kutembelea kituo maalum cha afya kadiri inavyofaa. Matokeo ya utafiti huu yataelezwa daktari wako anayekuhudumia ili kuimarisha matibabu kwa manufaa yako. Aidha, utafiti huu utatuwezesha kuelewa magonjwa haya zaidi and jinsi ya kukabiliano nayo. Pia, tutaongeza ufahamu zaidi kwa sayansi ya afya na binadamu.

Kuna gharama ya kushiriki?

Utafiti huu utahitaji dakika kidogo tu za muda wako.

Utarejeshewa pesa zako?

Utafiti huu hautakugharimu pesa.

Na kama utakuwa na maswali baadaye?

Kama una maswali zaidi au lolote ambalo hulielewi kuhusu utafiti huu, tafadhali usisite kuwasiliana na yeyote kati yetu kupitia nambari za simu, sanduku la posta au tovuti zilizowekwa kwa kurasa hizi.
Kama unayakubali haya na ungependa kushiriki katika utafiti huu, tafadhali tia sahihi yako kwa cheti kifuatacho.

APPENDIX 3B: RIDHAA (CHETI CHA KUKUBALI KUSHIRIKI KATIKA UTAFITI)

Taarifa ya Mshiriki

Nimesoma au nimesomewa nakala hili. Nimepata kuzungumza kuhusu utafiti huu na mtafiti mwenyewe. Maswali yangu yamejibiwa kwa lugha ninayoielewa vizuri. Madhara na manufaa yameelezwa wazi. Ninaelewa kushiriki kwangu ni kwa hiari na kwamba ninao uhuru wa kutoshiriki wakati wowote. Ninakubali bila kushurutishwa kushiriki katika utafiti huu. Ninaelewa kwamba bidii itatiwa kuhakikisha habari zangu zimewekwa siri. Kwa kutia sahihi kwa daftari hili, sijapeana haki zangu za kisheria ambazo ninazo kama mshiriki katika utafiti huu.

Nimekubali kushiriki katika utafiti huu: NDIO ☐ **LA** ☐

Nimekubali kupeana nambari ya mawasilianao baadaye: **NDIO** ☐ **LA** ☐

Jina la Mshiriki:
_____

Sahihi / Kidole _____

Tarehe _____

Taarifa ya Mtafiti

Mimi, ninayetia sahihi hapo chini, nimeelezewa maswala muhimu ya utafiti huu kwa mshiriki aliyetaja hapo juu na ninaamini ya kwamba ameyaelewa vilivyo na kwamba ameamua bila kushurutishwa kukubali kushiriki.

Jina la Mtafiti: _____ **Sahihi** _____

Tarehe: _____

Kazi yangu kwa utafiti huu: _____

Kwa maelezo zaidi au tashwishi lolote, tafadhali wasiliana na yeyote kati ya wafuatao:

Mtafiti Mkuu:	Dkt. Leah Njeri Njenga 0720805643
Mhadhiri:	Prof. Francis Ndemo 0792190924.
Kamati ya Maadili:	KNH-UoN ERC on 2726300 Ext 44102.

APPENDIX 4: MORIKY MEDICATION ADHERENCE SCALE

The Four Item Morisky Medication Adherence Scale(14,18,81)

	Morisky Questionnaire Item
Item 1	**Do you ever forget to take your prescribed medicines?**
Item 2	**Are you ever careless at times about taking your prescribed medicines?**
Item 3	**When you feel better, do you sometimes stop taking your prescribed medicines?**
Item 4	**Sometimes, if you feel worse when you take your prescribed medicines do you stop taking them?**

APPENDIX 5: RESEARCH QUESTIONNAIRE

DETERMINANTS OF NON-ADHERENCE TO LONG TERM THERAPY WITH PRESCRIPTION MEDICINES IN ADULT PATIENTS ATTENDING MEDICAL OUTPATIENT CLINIC AT MBAGATHI HOSPITAL

Questionnaire ID No: _____

Name of Interviewer:_____

SECTION A: TO FIND OUT FACTORS ASSOCIATED WITH NON ADHERENCE TO LONG TERM MEDICATION

Part 1: Socio-demographic Characteristics

1. Gender (0) Female ☐ (1) Male ☐
2. Age (in completed years) _____.
3. Age category (0) ≤50 (1) >50
4. What is your current marital status?
   - (0) Never married
   - (1) Married
   - (2) Divorced/Separated
   - (3) Widowed
5. Where do you currently live?
   - (0) Urban
   - (1) Rural
6. What is your employment status?
   - (0) Employed
   - (1) Unemployed
   - (2) Self employed
   - (3) Retired
7. What is your total monthly income (Ksh) _____?
   - (0) Up to 10,000
   - (1) 10,001-30,000
   - (2) 30,001-50,000
   - (3) Above 50,000

8. What is the highest level of education you attained?
   (0) No formal education
   (1) Primary Level
   (2) Secondary level
   (3) Post-secondary

Part 2: Condition related factors

Which condition are you being treated for?

9. Hypertension (1) Yes (0) No
10. Diabetes mellitus (1) Yes (0) No
11. Asthma (1) Yes (0) No
12. Arthritis (1) Yes (0) No
13. Heart failure (1) Yes (0) No
14. Other (1) Yes (0) No
15. For how long have you been on treatment? _____ Years
16. Treatment duration (1) >5 years (0) ≤ 5years
17. Have you been hospitalized in the last one year? (1) Yes (0) No
18. Was the hospitalization related to the current condition you are being treated for? (1) Yes (0) No

Part 3: Therapy related factors

19. How many drugs are you on?
    (0) ≤3
    (1) >3
20. Does the number of drugs bother you? (1) Yes (0) No
21. Does this stop you from taking you medication (1) Yes (0) No
22. Have you ever noted any side effects on the drugs you are taking? (1) Yes (0) No

    If yes, which ones?
23. Dizziness (1) Yes (0) No
24. Fatigue (1) Yes (0) No
25. Headache (1) Yes (0) No
26. Cough (1) Yes (0) No
27. Leg oedema (1) Yes (0) No

28. Blurred vision (1) Yes (0) No
29. Stomach upset (1) Yes (0) No
30. Epigastric pain (1) Yes (0) No
31. Abdominal tenderness (1) Yes (0) No
32. Other (1) Yes (0) No
33. Does this stop you from taking your medication? (1) Yes (0) No
34. Does the duration of treatment bother you? (1) Yes (0) No
35. Do you understand what your medicines are for? (1) Yes (0) No

Part 4: Healthcare provider related factors

36. What is the average bus fare in Ksh. from your residence to the hospital?____
37. Average bus fare category (0) ≤200 (1) >200
38. What is the average cost of your medication per month (Ksh)?_____
39. Medication cost category (0) ≤2000 (1)>2000
40. Are those drugs readily available in the hospital pharmacy? (1) Yes (0) No
41. If NO, Does this stop you from taking your medication? (1) Yes (0) No N/A(2)
42. Have you ever been told by your doctor the importance of taking your medication? (1) Yes (0) No

Part 5: Assessment of the respondent's patient related factors

43. Do you understand your current condition? (1) Yes (0) No
44. Do you know you have to take your medicines daily? (1) Yes (0) No
45. Do you understand the instructions on how to take your medicines? (1) Yes (0) No

SECTION B: ASSESSMENT OF RESPONDENT'S NON-ADHERENCE STATUS (INTENTIONAL AND UNINTENTIONAL NON ADHERENCE)

For each of the statements below, circle the statement that best characterizes how you feel about each statement.

1=Strongly Disagree 2=Disagree 3=Agree 4=Strongly Agree

The Four item Morisky Medication Adherence Scale (35,51,81)				
	Strongly Disagree	Disagree	Agree	Strongly Agree
46. Do you ever forget to take your medicines?	1	2	3	4
47. Are you ever careless at times about taking your medicines?	1	2	3	4
48. When you feel better do you sometimes stop taking your medicines?	1	2	3	4
49. Sometimes ,if you feel worse when you take your medicines do you stop taking them	1	2	3	4

50. Patient is (1) Adherent (0) Non-adherent for 39 & 40(Unintentional)
51. Patient is (1) Adherent (0) Non-adherent for 41 & 42(Intentional)

KISWAHILI GUIDED QUESTIONS

KUCHUNGUZA UADILIFU WA WAGONJWA WANAOTUMIA DAWA KWA MUDA MREFU KATIKA MATUMIZI YA DAWA HIZO NA VIGEZO VINAVYO HUSIKA KATIKA UADILIFU HUU KATIKA KLINIKI YA MATIBABU YA BILA KULAZWA

NAMBARI YA DODOSO: _____

Jina la muhoji:_____

SEHEMU A: VIGEZO VINAVYOHUSIKA KATIKA UADILIFU

Chama 1: Tabia za kijamii

1. Jinsia (0) Kike ☐ (1) Mume ☐
2. Umri (kwenye miaka) _____.
3. Hali ya kuolewa kwako?
   (0) Sijawahi Olewa
   (1) Nimeolewa
   (2) Talaka/kuwachana
   (3) Nimefiwa
4. Unaishi wapi?
   (0) Mjini
   (1) Bara
5. Hali yako ya kikazi?
   (0) Nimeandikwa
   (1) Sijaandikwa
   (2) Nimejiandika
   (3) Nimestaafu
6. Kwa mwezi unapata mshahara kiwango kipi (Ksh) _____?
   (0) Up to 10,000
   (1) 10,001-30,000
   (2) 30,001-50,000
   (3) Above 50,000
7. Umefika kiwango kipi kwenye masomo?
   (0) Sijwahi kusoma kwenye shule
   (1) Shule ya msingi

(2) Shule ya sekondari

(3) Zaidi ya shule ya sekondari

Chama 2: Maelezo kuhusu ugonjwa wako sasa

8. Unatibiwa ugonjwa upi?

   _____

   _____

   _____

9. Umekuwa kwenye matibabu kwa muda upi? _____ miezi.
10. Umewahi kulazwa hospitalini kwa muda huu? (1) Ndio (0) La
11. Kulazwa kwako kulilingana na ugonjwa unao ugua kwa sasa? (1) Ndio (0) La

Chama 3: Maelezo kuhusu dawa unazotumia

12. Unatumia dawa aina ngapi sasa hivi?

    (0) 1

    (1) 2

    (2) 3

    (3) 4

    (4) 5

    (5) ≥5

13. Umewahi kuwa na shida zozote katika matumizi ya dawa hizi? (1) Ndio (0) La
14. Kama ni ndio, dawa zipi?

    _____

    _____

    _____

15. Je, muda mrefu wa matumizi ya dawa hizi unakusumbua? (1) Ndio (0) La
16. Je, Unazielewa dawa zako ? (1) Ndio (0) La

Chama 4: Maelezo kuhusu muuguzi wako na hospitali yako

17. Kwa jumla, unatumia nauli kiasi kipi kuja hospitalini (Ksh)?

    _____

18. Kwa jumla , dawa zako zinakugharimu kiwango kipi cha pesa (Ksh)?

    _____

19. Je, dawa amabazo unatumia hupatikana kwenye duka la dawa la hospitali ? (1) Ndio (0) La
20. Je, muuguzi wako amewahi kueleza umuhimu wa kutumia dawa zako kwa makini ? (1) Ndio (0) La

Chama 5: Maelezo kuhusu jinsia ya mgonjwa

21. Unauelewa ugonjwa wako sasa hivi? (1) Ndio (0) La
22. Je, unafahamu kwamba unahitaji kutumia dawa zako kila siku? (1) Ndio (0) La
23. Je, unaelewa maelezo ambayo umepatiwa kuhusu utumizi wa dawa zako? (1) Ndio (0) La

SEHEMU B: TAHIMINI YA MHOJIWA KATIKA MASHIRIKA KUZINGATIA (KWA KUSUDIA AU BILA KUKUSUSIA)

Weka alama kwenye sentensi unayokubaliana nayo

1=Unapinga vikali 2=Unapinga 3=Unakubali 4=Unasisitiza

The Four item Morisky Medication Adherence Scale (35,51,81)				
	Unapinga vikali	Unapinga	Unakubali	Unasisistiza
Je , wewe husahau kutumia dawa zako?	1	2	3	4
Je, wewe hutojali kutumia dawa zako?	1	2	3	4
Je, wakati umehisi umepata nafuu wewe huwacha kutumia dawa zako?	1	2	3	4
Kwa wakati mwingine unapohisi umezidiwa na ugojwa unapotumia dawa zako,wewe huwacha kuzitumia?	1	2	3	4

APPENDIX 6: KNH-UON ERC APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

16 AUG 2018

Ref: KNH-ERC/A/316

August 16, 2018

Leah Njeri Njenga
Reg. No.U56/87495/2016
School of Pharmacy
Dept. of Pharmaceutics and Pharmacy Practice
College of Health Sciences
University of Nairobi

Dear Leah

RESEARCH PROPOSAL – DETERMINANTS OF NON-ADHERENCE TO LONG-TERM THERAPY WITH PRESCRIBED MEDICINES IN ADULT PATIENTS ATTENDING MEDICAL OUTPATIENT CLINIC AT MBAGATHI HOSPITAL (P312/05/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 16th August 2018 – 15th August 2019.

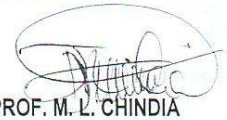
This approval is subject to compliance with the following requirements:

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

Protect to discover

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

Yours sincerely,



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

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UON
The Chair, Dept. of Pharmaceutics and Pharmacy Practice, UON
Supervisors: Prof. Francis Ndemo, Dr. Sylvia Opanga

APPENDIX 7: MBAGATHI HOSPITAL RESEARCH AUTHORIZATION

NAIROBI CITY COUNTY

Tel: 2724712, 2725791, 0721 311 808
Email: mbagathihosp@gmail.com

Mbagathi Hospital
P.O. Box 20725- 00202
Nairobi

COUNTY HEALTH SERVICES

Ref: MDH/RS/1/VOL.1

2nd October 2018

Leah NJeri Njenga
University of Nairobi

RE: RESEARCH AUTHORIZATION

This is in reference to your application for authority to carry out a research on ***"Determinants of non-adherence to long -term therapy with prescribed medicines in adult patients attending medical outpatient clinic at Mbagathi Hospital"***

I am pleased to inform you that your request to undertake the research in the hospital has been granted.

On completion of the research you are expected to submit one hard copy and one soft copy of the research report / thesis to this office.

02 OCT 2018

Dr. Marion Ong'ayo
For: Chairman – Research Committee
Mbagathi Hospital