EFFECTS OF COST ON PHARMACEUTICAL AVAILABILITY OF NON-COMMUNICABLE DISEASES (NCDs) DRUGS

A Research Paper Submitted in Partial Fulfilment of the Requirements for the Award of the Degree of Masters of Science in Health Economics and Policy at the School of Economics, University of Nairobi.

DECEMBER 16, 2019.

DECLARATION

I hereby declare that this research paper is my original work and has never been presented either in part or in whole to any other examining body for the award of certificate, diploma or degree.

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SUPERVISOR'S APPROVAL

I declare that this research paper has been presented with my approval as the university supervisor.

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DEDICATION

I devote this academic work to my family members; my dear wife Mary and daughters Lera and Rieko and mother Margaret whom have been my cheerleaders in this academic journey.

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I pass my undying gratitude to my supervisor Dr. Japheth Awiti for his immense support in actualizing this work. I am also indebted to all my lectures whom I interacted with during my period of study particular Dr. T. Kamanu for his insightful inputs.

Many thanks to the Almighty Father for He is the Alpha and Omega in this life and its beginnings so I hail Him for my being and insurmountable blessings.

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ABBREVIATIONS

BOD:	Burden of Disease
CVD:	Cardiovascular Disease
CAD:	Coronary Artery Disease
CHD:	Congenital Heart Disease
CHF:	Congestive Heart Failure
COI:	Cost of Illness
COPD:	Chronic Obstructed Pulmonary Disease
GDP:	Gross Domestic Product
GBD:	Global Burden of Disease
HAI:	Health Action International
IRP:	International Reference Price
KHSSP II:	Kenya Health Sector Strategic Plan II
KDHS :	Kenya Demographic Health Survey
KNBS:	Kenya National Bureau of Standards
LMICs:	Low and Middle Income Countries'
MLR:	Multinomial Logistic Regression
MOH:	Ministry of Health
MSDAC:	Metabolic Syndrome Diabetes type II and Atherosclerosis Congress
NCD:	Non Communicable Disease
OECD:	Organization of Economic Cooperation and Development
OOP:	Out of Pocket
QoL:	Quality of Life
SDGs:	Sustainable Development Goals
SSA:	Sub Saharan Africa
THE:	Total Health Expenditure
TPE:	Total Pharmaceutical Expenditure
UHS:	University Health Services
UHC:	Universal Health Care
UNGA:	United Nations General Assembly
WHO:	World Health Organization

DEFINITIONS OF TERMS

Cardiovascular Diseases (CDVs): Are clustered disorders of the heart and blood vessels that is associated with stroke, heart attack, atherosclerosis, heart failure, arrhythmias and heart valve problems.

Communicable Disease (CDs): Are clustered illnesses that are transmissible or infectious whose causative agents are majorly microbes such as fungi, parasites, bacteria and viruses get transmitted from one person to another either directly or indirectly. Other transmission modes are by insect bites and consumption of contaminated foods and water.

Non Communicable Disease (NCDs): These are degenerative disease that has slow progression and chronic in nature that are not transmittable from one person to another.

Diabetes Disease/ Diabetes Mellitus: Is a degenerative disease majorly caused by insufficient blood glucose regulation in the body that is associated with endocrine insufficiency to produce enough insulin or the body cells is incapacitated to respond to excess glucose or when both cases are impaired to regulate blood glucose levels.

Pharmaceutical Cost: Is the entire cost of a prescribed drug or health aide which can be financed by either out of pocket spending, health insurance or paid by a third party.

Pharmaceutical Drug: Is a medicinal product that is holistically used in healthcare in the aid of diagnosis, palliative, treatment, curing and or prevention of maladies. It is that drug that legally requires a prescription to be dispensed by qualified pharmacist in contrast to over the counter medications which can be obtained minus a prescription

ABSTRACT

Purpose of the study: Pharmaceuticals are essential in addressing the increasing burden of Non Communicable Diseases which are the leading cause of mortalities in low and middle income countries (LMIC's). Pharmaceuticals account for a significant part of the economic costs of treatment budget of NCDs that have reduced the productivity of many individuals and increased poverty index particularly in LMIC's who do not have an inclusive feasible health financial medical scheme. Few studies have been done which focused on the availability of essential medicines across African countries. This study therefore aimed to establish the effects of cost on pharmaceutical drug availability for the treatment and management of chronic patients in particular cardiovascular and diabetes conditions.

Method: A descriptive survey design was adopted to capture satisfaction level and opinions of chronic on the NCD drugs availability at the University Health Services. The study utilized primary data from a cross-sectional survey using structured questionnaires from a sample of (N=89) patients. Questionnaires were self-administered to patients receiving treatment and care on cardiovascular and diabetes conditions to collect information on their satisfaction level of pharmaceutical availability at the University Health Services.

Analysis: The dependent variable was pharmaceutical availability and had a multinomial response category that was coded in three levels (i.e never available =1, sometimes available =2, and always available =3). Multinomial Logistic Regression (MLR) using IBM SPSS ver.20 was used to determine the effects of the two predictor variables; type of drugs which was nominal in measure (i.e low priced generic drugs = coded 1 and high priced originator drugs =coded 2) and the drug dosing formulation which was also nominal in measure (i.e fixed dose combination therapy =coded 1 and single dose therapy =coded 2) on the pharmaceutical availability and "never available" used as a reference category.

Results: Results of the study show that the type of drug prescribed as generic was significant ($p<0.000$) and had a stronger impact on pharmaceutical availability. The type of drug dosing formulation as fixed dose combination with a ($p<0.051$) had a slight impact on the availability of pharmaceuticals. The originator drugs and single dose therapy were redundant and did not have any significant impact pharmaceutical availability. Most patients preferred generic drugs which were sometimes and always available at the time of visiting the clinic.

Conclusion: Pharmaceutical availability is imperative in the continuity of care and treatment of chronic patients. Making available of quality and low priced generic drugs will ease the cost burden associated with treatment and management of chronic conditions in our health facilities and significantly reduce disabilities and deaths in the country. . The results of this study can be used by the government, health planners and administrators to create a policy plan that will help in ensuring sufficient supply of NCD drugs used in the management and treatment of chronic patients.

CHAPTER ONE

INTRODUCTION

1.1 Background

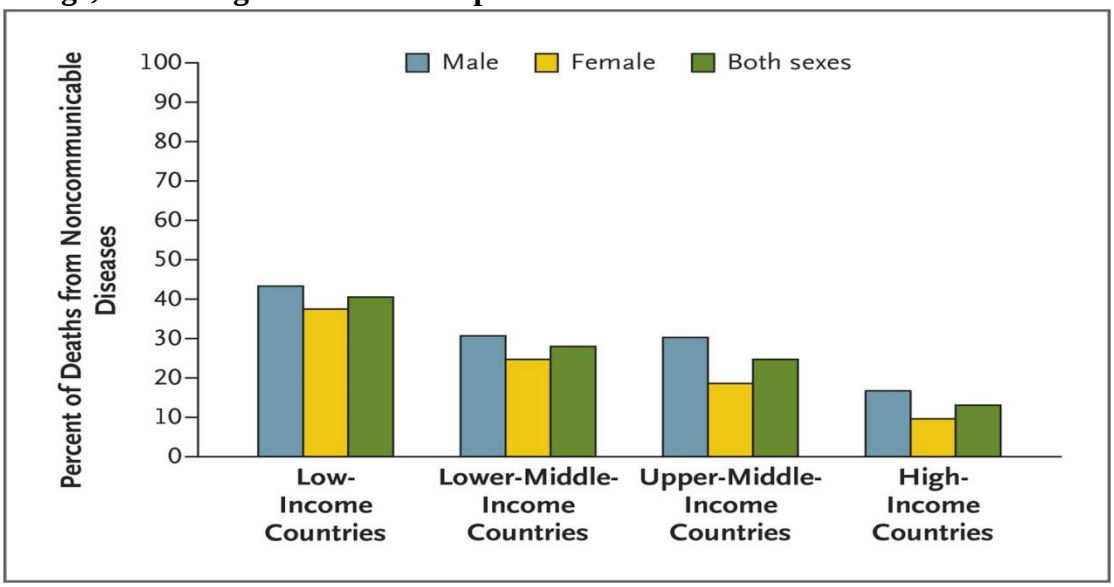
Medical conditions that are degenerative and afflict people for a long time, usually for their entire lives and are not transmittable by any known agent from one person to another are generally referred to as Non Communicable Diseases (NCDs) (Daar et al., 2007). This conditions affects all the age sets across the globe and majorly includes; cancer, diabetes, cardiovascular diseases and chronic obstructive pulmonary diseases. Current World Health Organization (WHO) data shows that NCDs constitute the greatest percentage at 71% (41 million) of the annual global mortality rates (WHO, 2016). NCDs account for more than 85% of premature deaths, those of people between the ages of 15-69 years, and the most economically productive demographic range (WHO, 2018).

Most important in this case is the fact that while NCDs are known to affect people in all regions worldwide, current trends indicate that over 85% of NCDs deaths are majorly in developing countries (WHO, 2018). Notably, shifting from previous trends where NCDs were considered to be afflictions of the most affluent of individuals and (developed) regions or countries (Maina, 2009). A historical review of literature indicates that the current African NCDs challenge is at a 'transitional phase'- where from time to time the leading cause of human mortality and morbidity usually alternates between communicable and NCDs (Kankeu et al., 2013).

Kiarie (2016) points out that for hundreds, possibly thousands of years, unmanageable communicable outbreaks such as cholera, leprosy, pneumonia and malaria, were responsible for huge loss of lives and significantly reduced life expectation. However, the mid-20th century medical advancement particularly in prevention and treatment of infectious diseases lead to a decrease in fatalities due to infectious diseases while deaths due to NCDs and their associated costs have since been on the upsurge (Tawa et al., 2011; Republic of Kenya, 2015). The figure 1.1 below illustrates the mortality rate amongst population less than 60 years of age from NCDs in the different segments of economies in High Income Countries (HIC's), Upper Middle Income Countries

(UMIC's), Low Middle Income Countries (LMIC's) and Low Income Countries's (LIC's).

Figure 1.1: Proportion of Deaths from NCD among Persons Younger than 60 Years of Age, According to Income Group of Countries



Source: Adopted from Global Burden of Non-communicable Diseases (2018)

The looming NCDs epidemic in Sub-Saharan Africa (SSA), attributable to the likes in this case Diabetes and Cardiovascular Disease (CVDs) assumed great significance to policy making circles only recently as its morbidity, mortality and the accompanying socio-economic costs have grown (Kankeu et al., 2013). Kiarie (2016) notes that emerging trends for NCDs such as Diabetes and Cardio-Vascular Diseases (CVDs) indicates that they are growing health challenge with an expanding effect on younger and the most productive groups of the population.

1.1.1 Non Communicable Diseases in Kenya

NCDs have contributed to over 50% admittances in the hospital and nearly 55% in patient deaths throughout the nation. The steady increase in the prevalence of NCDs is illustrated by the long queues of patients attending health facilities for CVDs, Diabetics and Asthmatic conditions or Chronic Obstructive Pulmonary Diseases (COPDs). Data from the Ministry of Health Surveillance (2016) unit also indicates an upsurge of Diabetes and CVD's incidences up to 751,341 from 494,312 and 218,992 from 166,203

for years 2012/13 and 2014/15 respectively. The country NCDs survey also mirrors the global trend in terms of leading cause of death with CVDs accounting for between 6.1%-8% of all annual deaths in Kenya, closely followed by cancer with 7% of annual mortality rates. Annually, Diabetes affects 750,000 and accounts for approximately 4.6% of annual mortality or 20,000 deaths (Kenya STEPwise Report, 2015)

CVDs and Diabetes are also blamed for a proliferation of the increasing cases of mental illnesses, a situation compounded by lifestyle conditions such as physical inactivity and obesity (Kenya STEPwise Survey, 2015). Tawa et al., (2011) argue that the rising cases of NCD-mortality could be attributed to changing lifestyles as incomes improve with economic growth. Crucial components to determining the extent to which NCDs patients' meet the ability of treatment costs of screening, diagnosis and treatment in the continuum of care, is an appreciation not just on the clinical consultations and pharmaceutical costs of NCDs but also the impact it has in society.

1.1.2 Economic Impact of NCD Burden in Kenya

NCDs in Kenya are associated with multiple negative effects on the country's economic growth and development prospects as well as individual households and community (Mwai, 2012). The healthcare sector is hampered by the surging burden of NCDs and constrained healthcare budget strained with communicable diseases. The Kenya Health Sector Strategic Plan (KHSSP II, 2013) prioritizes wavering and reversing the prevailing burden of NCDs that today constitute the largest share of healthcare costs in the country (World Bank, 2014).

At household level, the burden occasioned by NCDs is both financial and social. An evaluation of the periodic Kenya National Bureau of Statistics' (KNBS) and Kenya Demographic Health Surveys' (KDHS) reveals a migration trend underscored by an influx of rural urban migration which exposes a significant population to high NCDs risk environment in urban areas (Kenya Health Policy, (2012)). Cameron et al., (2010) argue that NCDs severely compromise a household's ability to meet the healthcare costs linked to the disease by depleting existing income forays and projected productivity of patients

leading to inability to meet or access basic healthcare. Likewise, most Kenyan households continue to bear the burden of NCDs particularly those without the benefit of medical insurance, employers support and the waning traditional social support networks roles (Waters, 2004). Likewise, Gottret and Schieber, (2006) find that the high costs of medical care reduce the number of household wealth disposal and incomes sending many families into disgraceful situations that they are unable to finance basic items such as food and education. Feenberg and Skinner (1994) and Waters (2004) studies found a direct relationship between prevalence of disease and household health expenditures. Most low income families are disadvantaged by expensive pharmaceutical costs of NCDs and overall post treatment care (Gottret & Schieber, 2006). When poor households are affected by NCDs poverty creeps in their lives. Households' level of income, wealth and existing social networks is a direct factor in determining household's expenditures on healthcare and treatment of diseases such as NCDs (Krishna, 2007). In most developing countries, most poor households sacrifice spending on healthcare to cater for basic needs like food, thereby placing themselves at advanced risks of fatalities in case the illnesses is untreatable (Doorslaer et al., 2006). Subsequently, most of the poor households are wasted further into poverty with lesser productivity of the sick members coupled with low survival rate (Maina, 2009).

Krishna (2007) and Doorslaer et al., (2006) found that on average roughly 75% of individuals in LMIC's of Africa and Asia are pushed into poverty valleys due to heavy burden of healthcare expenditures. Himmelstein et al., (2006) observed that the situation is also not any different in other parts of United States of America which is a rich economy. Over 50 per cent of individuals were declared bankrupt due to huge healthcare spending.

1.2 Problem Statement

In developing countries, the danger posed by NCDs have been perennially relegated to the fringes of official policy making for the three decades as most governments shifted most of the health budgets to deal with what was considered as the most immediate health threat, communicable diseases (Mwai, 2014). There is a realization however

among health practitioners and in policy making circles as can be illustrated by growing policy documents in the last five years to the looming danger of a NCDs epidemic (WHO, 2011; Republic of Kenya, 2011).

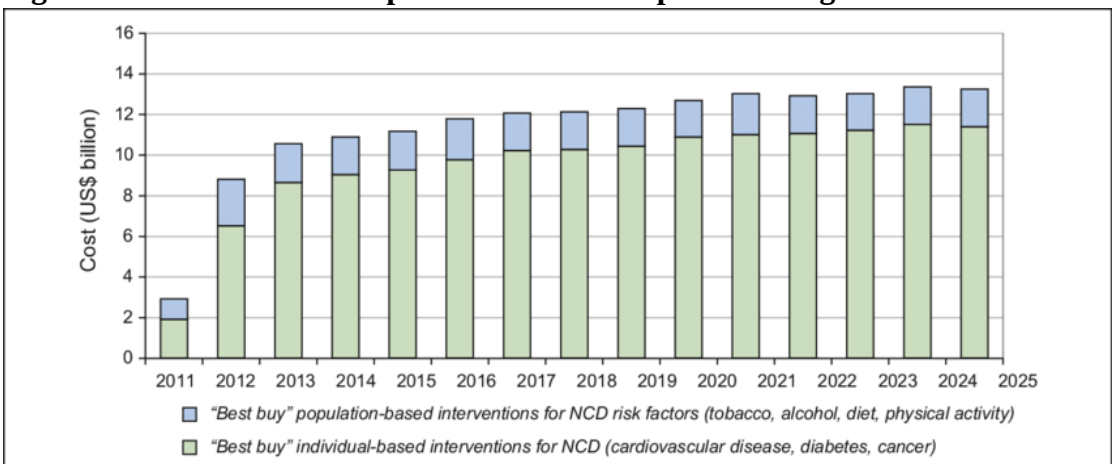
Unfortunately, such policy statements have not been evidenced by a comprehensive body of accurate data on the various and specific facets of the NCD burden to facilitate effective interventions especially in allocation of relevant resources to combat what is deemed 'silent killers' (Tawa, 2009). As a result, the rising NCDs morbidity and mortality rates has created what in Sub Saharan Africa region is now referred to as 'double burden,' the challenge of simultaneously dealing with high cost of both communicable and as well as NCDs (WHO, 2013). This has put immeasurable pressure on the existing resource-strained healthcare systems in the Sub-Saharan region that threaten its prospects of economic growth and sustainable development (Juma, Mohamed & Kyobutungi, 2017; United Nations, 2015).

The health cost and care of chronic NCD patients often condemns generations of families into poverty (Muchira et al., 2012). This is because NCDs characteristically progress slowly and patients do not die immediately and the affected individuals often suffer long periods of ill health before ultimately succumbing. Moreover, due to a combination of factors, NCD's patients only seek medical attention when the disease has turned chronic. Subsequently patients rarely gain full health and productivity even with treatment, nevertheless, most NCDs are curable if early detection and treatment is accorded to patients (Republic of Kenya, 2015). Pharmaceuticals form the largest economic costs in the management of NCD conditions across the globe. The cost of drugs is a determinant factor in the overall prescribing decisions which ultimately affects overall pharmaceutical costs in terms of type of the drug in both generic and originator drugs.

Original drugs (innovator products) are pharmaceutical products that are marketed and sold by the company that developed it and who have patented rights to the medicine. The innovator companies spend humongous amount of financial resource and time in research and development of the drug and therefore expected cost is higher than the generic drugs

to the consumer. Generic drugs have exactly the same biological equivalence to the originator drugs and acts as substitute drugs in many occasions. They are composed of the same active ingredients as in the originator drugs but with differences in their inactive ingredients such as preservatives or filters, colors, size and packaging. When used, they exhibit exact same effects on the patient with the same doses as the originator drugs. Cost is the distinguishing factor comparing prescriptions of generic and originator drugs in the market. Most generic drug companies factor on competition of drug pricing to leverage in the market and keep the business going unlike the originator companies. This competition makes generic drugs have lower prices and usually more affordable to consumers compared to originator brands. Generics medicines saved many developed nations like Americans huge sums of money approximated to be $ 1.727 trillion in the last decade (Klinger, 2019).

Figure 1.2: Worldwide Comprehensive NCD Expense scaling in LMICs



Source: Adapted from WHO (2018) Healthcare System Strengthening: A Pharmaceutical Perspective on Availability and Prices of NCDs

The above figure 1.2 shows the trend of healthcare spending on NCD drugs in LMIC's from the WHO pharmaceutical spending models. The trend shows a steady increase in spending on NCD drugs from the year 2011 and still projected to increase in the coming years up to 2025. The figure illustrates an increase in spending NCD costs with the populations that have been exposed to lifestyle risk factors that exacerbate the disease such as alcohol, tobacco, obesity and sedentary lifestyles. From a pharmaceutical

perspective, availing accurate information on the cost of NCDs management and the patient's ability to meet it at all continuum levels of screening, diagnosis, and treatment, is key not only to the patients and healthcare workers, but is also critical in the formulation of health policies and procedures aimed at curbing the ever increasing burden of NCDs on the healthcare system (Saksena et al., 2011; Vialle-Valentin, 2015). Towards this end, there exists scant literature on the cost and ability of patients or healthcare system to meet this objective. According to the WHO (2016) on vital investments on NCD prevention asserts that the worldwide disease burden emanating from all NCD illnesses usually results in untimely deaths and disabilities. LMIC's are severely affected by approximately 80% these rising mortalities and disabilities.

Furthermore, there is also no quantifiable data as to the pharmaceutical cost of each non-communicable disease and the ability of individual patients, families, and the healthcare system addressing it. The existing literature is limited or at best, generalized. It clearly illustrates the urgency for immediate inquiry into the economic burden of NCDs that is relevant to informing the development of targeted policies on confronting the danger posed by the spiralling NCDs (Republic of Kenya, 2011). This study therefore, while seeking to add to the literature on the NCDs burden in Kenya, offers a distinctly pharmaceutical cost perceptive.

1.3 Research Questions

i. To what extent has Cost of drugs affected the availability of NCD pharmaceuticals at the University Health Services?

1.4 Objectives of the Study

Primary objective was to establish the effect of costs on pharmaceutical availability of Non-Communicable Diseases (NCDs) drugs.

1.4.1 The Specific Objectives

i. To establish the effect of the type of Drugs (the low priced generic and the high priced originator drugs) on the availability of NCD pharmaceuticals at the University of Nairobi Health Services.
ii. To establish the effect of the drug dosing formulation (fixed dose combination therapy and single dose therapy) on the availability of NCD pharmaceuticals at the University Health Services.

1.5 Justification of the Study

NCDs for a long time have undermined economic development of many countries as most of the affected countries are usually are at their peak of economic activities. Kenyan government is rolling out an ambitious universal healthcare program embedded on the interest of governments' big 4 agenda as provided for in the constitution of Kenya 2010 geared towards actualizing universal health services. A major blueprint program in actualizing this is the country's 5 year framework for combating NCD termed the Kenya National Strategy for the Prevention and Control of Non-Communicable Diseases 2015–2020. It contains specific responses targeted at addressing CVDs and Diabetes challenge particularly among the most affected demographic (15-69 years).

The success of these strategies will therefore require specific and accurate information on CVDs and Diabetes particularly from a financial perspective to enable it plan and budget for the allocation of resources in the most cost effective manner. It's from this backdrop that this study sought to establish effects of costs on the availability of NCD's drug for management of CVDs and Diabetes patients as these forms a large group of NCD cases at the University of Nairobi. To policy makers, the success or otherwise of the NCD payment ability and model will thus be vital in informing the development of sustainable pharmaceuticals availability for patients. It will serve as a vital resource tool for health workers particularly those who are involved in public awareness on the dangers of NCDs as they will have accurate information as to the economic burden of NCD's not only at national level, but also to individual patients, households and community at large. Given

the limited literature on the quantifiably costs of NCDs, this study sought to fill the void from a unique pharmaceutical point of view.

1.6 Limitations of the Study

The investigator acknowledged various misgivings in the course of the survey. First, by virtue of the information collected is sensitive and requires confidentiality, the researcher availed the necessary authorization to enable him undertake the research survey at the University of Nairobi Health Services. The study was limited also by having been conducted only at the UHS and other parts of public parastatal health institutions in the country were omitted in this survey.

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

Global health actors embraced measures on the increasing NCD challenges in the field of Sustainable Development Goals (SGD's) as a strategic impulse to contain them (United Nations, 2015). At the same time, access to NCD drugs is a key part of the commitment to slow the progression of NCD in LMIC's (Flood et al., 2017). This chapter elucidates the various theoretical and empirical literatures that relate to factors affecting the pharmaceutical cost on the availability of NCD drugs.

2.2 Theoretical Literature

2.2.1 Cost of Illness (COI)

The cost of illness (COI), also referred to as disease burden (BOD), is a definition that covers several facets that maladies influence on the aftermaths of health interventions in particular nations ,regions, communities or even households. The objective of the COI studies is to assess the financial burden that a society or communities suffer as a result of disease invasion. The only objective of the COI research is a descriptive study that details, evaluates and summarizes the costs of a given problem in order to present its economic burden (Jefferson et al., 2000). In contrast, Clabaugh and Ward (2008) indicated that COI analysis is a useful opportunity to interconnect with community and policy creators on matters to do with the incidences and prevalence on different disease and injuries at advocacy level and how they could be mitigated to impact on quality of life (QoL) and their monetary characteristics. COI studies are considered a significant and essential measuring procedure in medical and medical sciences. By measuring and associating the economic burden of diseases with the community, health policy creators will profit from the creation besides prioritization of health care policies and implementing necessary and productive interventions.

2.3 Empirical Literature

2.3.1 Concept of NCD Pharmaceuticals Availability

Drugs are essential for a sustainable health system, in totality they help in decreasing maladies, possible deaths and disability and thus will consequently scale the quality of life (Kohler et al., 2012). The cost of drugs plays an imperative role in there acquisitions and prescribing behavior in many parts of the world. The accessibility and cost of drugs both in government owned and privately owned hospitals constitutes a fundamental basis of treatment. Price and drug availability studies using the standard methodologies, illustrated that destitute drug accessibility particularly in the government owned facilities creates major obstacle in accessing appropriate treatment options (Cameron et al., 2011).

WHO (2013) noted that having access to sufficient and affordable medicines and health technologies assures ability of populations to access universal healthcare. Low availability of drugs particularly NCD medicines is highlighted in most parts of LMIC's to have been affected by cost (Cameron et al., 2011). Concerns about surging rates of illness and deaths related to CVDs, COPD's, Diabetics and Cancer were declared by UN Declaration on NCDs that they require improved pharmaceutical availability and health technologies at the primary level is decisive for preventive measures and control (United Nations General Assembly (UNGA, 2012)). As part of the WHO global response (2013), developed a lucid response to achieve 80% availability of affordable medicines and basic technologies particularly NCD drugs including generic drugs to facilitate best treatment options in combating NCDs in government and privately owned hospitals.

Availability of pharmaceuticals at every health center is imperative in providing optimal treatment modules to patients. However in many occasions, drugs are not available due to stock outs. Stock outs, have a profound effect on the outcome of patients treatments in various ways. Masters et al., (2014) noted that when the drug is not available in the health facility, then the patients who visit the clinic will not get the optimal care desired and consequently have worse outcomes. Secondly, the patients will develop a negative attitude towards the facility and will shun coming for treatment in that facility due to frequent stock outs. Likewise, Cameron et al., (2010) asserts that stock outs of

antiretroviral medicines in comprehensive care centers led to higher mortalities. Masters et al., (2014) find that perceived satisfaction of patients is associated with the availability of medicines in the hospitals and also increase visits for medical attention and care. Hanson et al., (2005) assert that medicines availability in the hospitals is a significant predictor in ensuring the continuity of quality healthcare provision and enhance patients' satisfaction and confidence in the public hospitals.

2.3.2 The Cost of Pharmaceuticals in LMIC's

Drugs are major components of health technology that are widely impactful in the treatment and prevention of maladies. Pharmaceuticals is one the largest components of cost in global health expenditure constituting nearly 15.6% of total pharmaceutical expenditure (TPE) of the total health expenditure (THE) and also weighs down on the gross domestic product (GDP) of a nation (WHO, 2010;OECD 2012). Gerdtham et al., (1998); Chen and Schweitzer (2008) assert that consumption of drugs is basically a function of price and quantity consumed and the intertwined interactions between these two variables. The dynamics leading to the growth of global pharmaceutical spending varies in the consumption and price modalities (Lu et al., 2011). Data on total pharmaceutical expenditure (TPE) for the year 2012, confirmed that medicines makes an imperative aspect in health system expenditures as an integral part of delivery of quality healthcare but it is un-proportional in LMIC's.

The share of drugs expenditure in total healthcare expenditure (THE) varies from an average of 18.9% in HIC's to an average of 32.5% in LIC's. On comparative terms less developed nations expend comparably extra on their health budgets on purchases of medicines than developed nations (WHO, 2014). In countries with lower incomes, there is a sharp price difference between the original drugs and their equivalent generic drugs. In a quantitative price survey evaluation by WHO and Health Action International (HAI) confirmed existence of a significant percentage price difference particularly with the original drugs as compared to the generics drugs that are cheaper in the market. The study found that the price variation was over 300% higher in the private hospitals in Low Income Countries (LIC's) and for High Income Countries (HIC's) and Middle Income

Countries (MIC's) they were significantly lower (152%) and only 6% in India (WHO, 2014, HAI, 2012).

According to a study by Health Action International (HAI), find that nations that depend on International Reference Prices (IRPs) in purchasing their medicines cannot ensure drug availability or affordability in the health delivery system (HAI, 2009). In most cases pharmaceutical procurement is usually inefficient due to unproductive models used. In most of the Middle East and certain Asian nations such as in Pakistan, there are seemingly low and low-cost public procurement charges, consequently it doesn't factor cheap retail charges or sufficient accessibility of pharmaceuticals. It was also established that, lack of medical insurance or other social security systems is a high pointer to exorbitant expenditures more so out of pockets (OOPs) expenditures disproportionate to household incomes (Cameron et al., 2012).

Prices of public procurement in the sector are often low compared to international reference prices (IRP). However, low purchase charges and revenues generated including in the public sector, do not result in low patient prices which causes serious problems with affordability. On a comparative note, drug prices in missions and non-governmental organizations where they're bought remain generally lower in the privately owned than in the government owned facilities. At the same time, drugs in the privately owned facilities are much more expensive and majorly stores original brand of medicines. Patented drugs are much more expensive than generic drugs. Countries with lucid and effective generic policies have been reducing unnecessary medicine spending, but rather concentrate on quality generics (Cameron et al., 2010).

2.3.4 The cost of diabetes

Diabetics are a disorder whereby the human body is unable to yield a hormone called insulin that is responsible for regulating the level of blood sugar through optimal carbohydrate metabolism (Tawa et al., 2011). In developing countries, diabetes is one of the leading NCD. Many practical examples show that direct and indirect costs are incurred for both day care patients and hospitalized patients services.

In general, there are large differences in the percentage of family income payable for diabetic management. Research in India has shown that income support in diabetes care in low-income groups in Madras ranges from 5% to 24.5% (Boutayeb et al., 2004). Expenditure customs vary widely between rich and poor families. It also shows that poorer households (first quintiles) spend their bigger proportion of income on diabetic care as compared to their richer counterparts (the fifth quintile). Again, in some non-exploratory scenarios, some of the differences may be quite amazing. Studies from India have shown that most poor households spend sevenfold on diabetes care than their wealthy counterparts (Mathers et al., 2003).

Only expenses for diabetes can easily be considered as total household health expenditure. Reddy (2002) claims that household expenses for diabetes care for children in Sudan account for about 65% of total income. Pharmaceutical costs of diabetes are often considered to be the largest consumer of financial expenses. For example, drug purchases represent peak areas in different countries (Sudan, India, Mexico and Pakistan). The costs in these countries range from 35% to 64% in their overall outlay on diabetic care in different countries, such as India, Mexico, Pakistan and Sudan. The consumption cost of insulin in parts of countryside Ghana was estimated to be within the precincts of 60% compared total sum of 30 days income in persons who depend on a daily minimum wages. According to Metabolic Syndrome Diabetes Type II and the Congress of Atherosclerosis (MSDAC), the use of patented brand drugs occasioned a significantly surged expense in one of the diabetes survey study that employed random sampling instead of convenient sampling (MSDAC, 2004).

2.3.5 Cost of Cardio-Vascular Diseases

Cardiovascular disease (CVD) refers to a cluster of heart and blood vessel diseases, that includes; cardiac rheumatism, hypertension, congestive heart failure (CHF), coronary heart disease (CHD), cerebrovascular disease (stroke), peripheral vascular disease, congenital heart disease and cardiomyopathy. WHO (2018) health analysis shows that mortality as a result to NCDs; CVDs was responsible for the majority of these deaths

approximately 17.5 million deaths per annum, cancer approximately 8.2 million deaths per annum, respiratory diseases had approximately 4 million deaths per annum and diabetes approximately 1.5 million deaths per annum. The foremost risk factor that aggravates these diseases includes tobacco use, sedentary lifestyle, heavy alcoholic lifestyles and diets that are not balanced.

According to Sari and Langenbrunner (2001), several scientists have examined the costs of cardiovascular disease in developing countries, especially in Asia. Studies of home data from Kazakhstan showed that these cohorts with heart problems spent an average of 24% more compared to colleagues with other health problems. Heeley et al., (2009) argued that the costs incurred by patients using out-of-pocket (OOP) outlays to cover the charges of treating cardiovascular diseases, and in particular drug costs, significantly increased expenses. About 71% of patients in China suffer from disastrous health care expenses, and 37% of them have fallen below the poverty line of $ 1 a day after paying for cardiovascular health plans (Heeley et al., 2009).

In the same way, most families without health insurance suffer from catastrophic payments and are deprived of medicines because of the high costs of cardiovascular medication than those who have health insurance (Heeley et al., 2009). Rao et al., (2011) found that 57% of strategies employed by households to cope with high CVD spending are household savings, 35% of bond purchases and 8% of asset sales. In the poorest groups, 55% of OOP funding contributed to higher expenditure, and 38% was financed with their savings (Rao et al., 2011).

2.3.6 The Cost of NCDs to the Healthcare System

Kiarie (2016) argues that the costs of NCDs in Africa have several negative economic effects because they reduce economic efficiency and the burden on family resources, posing a serious threat to economic and social development. A study of global trends in NCDs shows that in industrialized countries, the disease accounts for only 13% of the young, productive population, compared to 30% of African teenagers who are dying of NCDs in Africa. According to WHO (2014) the challenge of NCD prevention and

control strategies in SSA is due to insufficient resources and attention, as dealing with NCD and infectious illnesses is a double burden at the same time. In Africa, NCDs are the foremost cause of deaths in entire regions. Present forecasts illustrate that there will be surging deaths due to NCD by 2020 in Africa (WHO, 2014). The report estimates that disabilities from NCDs will surpass deaths due to perinatal maternal, nutritional and infectious diseases (WHO, 2014).

In addition, African governments have insufficient institutional and political capacity to undertake the necessary public health reforms necessary to meet healthy standards, which is crucial for the primary health advocacy on NCDs prevention and management (Shobhana et al. 2000). Necessary reforms, for example to combat tobacco and alcohol abuse, are usually too late, weak or insufficiently enforced, making them largely ineffective (Nunget and Brouwer 2015). Nunget and Brouwer (2015) noted that in most African countries, alcohol and tobacco control laws restrict or prohibit smoking and smoking at certain times and places, e.g. at work, however 18 to 30% smoking individuals are still exposed.

As is typical for most African countries, poverty and inequality, which are the most common causes of risky lifestyles, unhealthy diets, smoking and drinking, are the main causes of the increasing incidence of NCD (Kankeu et al., 2013). Such low socio-economic indicators have led to a terrible cycle of poverty that exposes citizens to spiralling risk of NCDs. In response to NCD, the government is forced to channel funds for development in creating human and institutional capacity that can cope with diseases that could be prevented in the best of circumstances (Muchira, 2015).

2.4 Overview of the Literature

The study utilizes theoretical Cost of Illness (COI) that explicates the structural view of this study. The COI underscores on the cost of diseases and also evaluates the monetary burden that maladies inflict on a society as a whole. The literature emphasizes on concept availability of pharmaceuticals which captures on accessibility and cost of drugs both in government owned and privately owned hospitals that constitute a fundamental basis of

treatment of NCDs. The literature has illustrated that high drug costs increases the total cost of treatment. This is significantly worse in individuals with chronic diseases, and it is further aggravated with high price and unforeseeable availability of drugs as these treatments are perpetual nature.

Kohler et al., (2012) and Cameron et al., (2011) find that drugs are essential for a sustainable health system, and looked at price and drug availability of essential medicines in government owned facilities. Likewise, studies by Masters et al., (2014) looked at drug availability and stock outs of essential medicines across levels of care in Ghana, Kenya and Uganda and find that stock outs of drugs is an obstacle to accessing optimal treatment modules for patients and a possibility of worse outcomes . The gap in these studies is that there is no evidence looking at the availability of NCD drugs in their study facilities. Essential medicines are supposed to satisfy the priority needs of healthcare needs of a population. Therefore, they are the bare minimum drugs that should be available at any facility of care. NCD drugs make a huge impact on the welfare of patients with chronic illness that their availability is an imperative approach to realization of optimal treatment and better outcomes. Thus, ensuring a steady supply of NCD drugs will ensure better patient management and reduce possible disabilities and high mortality rates.

From the aforementioned, there should be lucid and enabling structures that facilitate treatment plans by ensuring that ministries concerned put measures that streamlines timely purchase and delivery of quality drugs to health facilities. This measures should focus on strengthening healthcare system in terms of adequate financing, good governance and human resources for health that are fundamental in ensuring the wheels of operations and continuity of a progressive healthcare system.

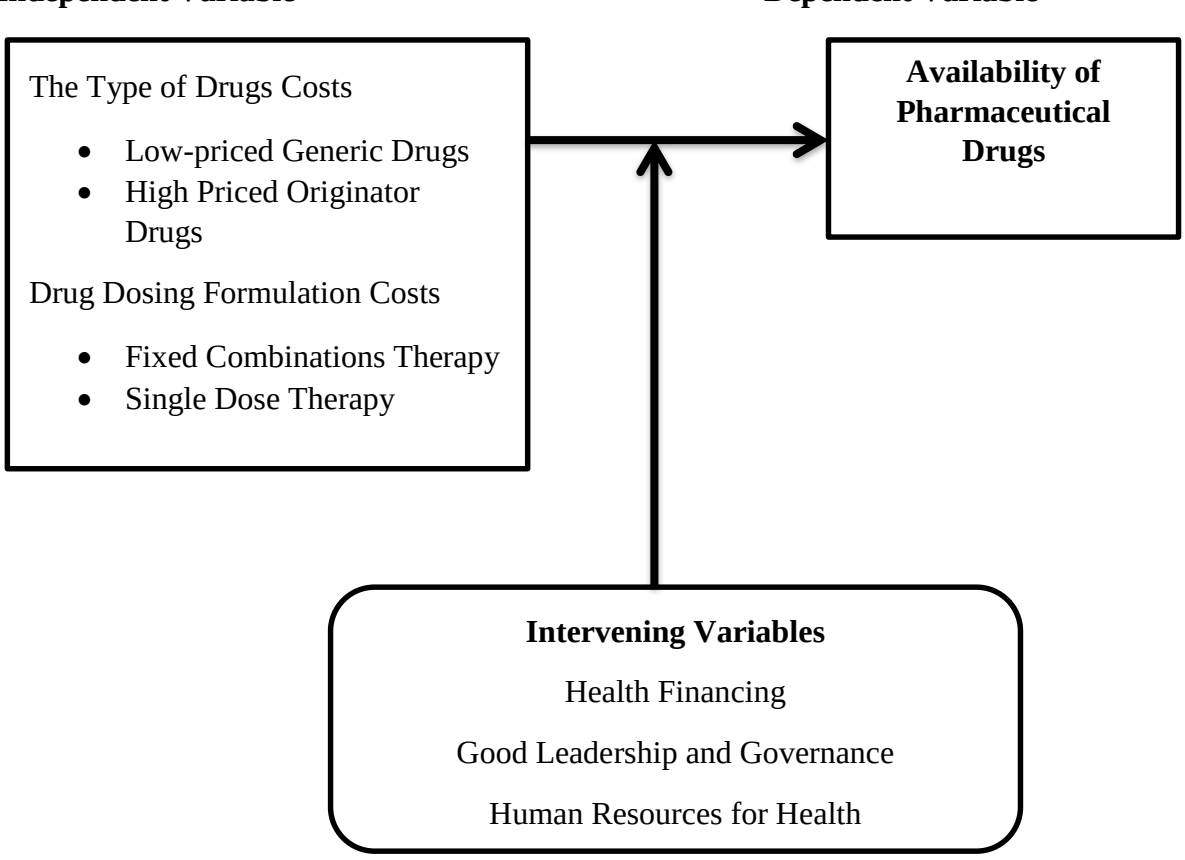
CHAPTER THREE
RESERCH METHODOLOGY

3.1 Introduction

This chapter discusses the methodology that was used to analyse the research study. It comprises of conceptual framework, empirical model, research design, data collection and instrumentation, data analysis, operationalization and definition of variables and ethical consideration.

3.2 Conceptual Framework of the Research Study

Figure 3.1: Conceptual Framework of the Research Study



Source: Researcher, (2019)

Major obstacles confronting optimal patient's healthcare is the inability to get quality and affordable pharmaceuticals at every level of care. Problems that are common across the entire range of drug management cycles includes; the price of drugs in the market which in most cases are determined by the prices of either low priced generic drugs or the high priced originator drugs. The other aspect is the drug dosing formulation which can either

be fixed dose combinations or single dose therapies. The study used the aforementioned as independent/predictor variables to predict the dependent /response variable which is (pharmaceutical availability). Prices of drugs vary from originator drugs that are usually high priced compared to their generic equivalents in the market which are somewhat low priced. This definitely determines the cost of NCD drugs that can be available for management of diabetes and cardiovascular diseases. Another aspect of interest is the form in which the drug is formulated as either fixed dose combination or either single dose therapy. Drug forms may add in the overall cost of drugs to the patient, for instance fixed drug dose combinations are costly and have a better adherence compared to single drug dose therapies.

The dependent/response variable estimated was the pharmaceutical availability. Pharmaceutical availability was measured in three nominal levels (never available = coded 1, sometimes available= coded 2, and always available = coded 3) at the time of the survey. The intervening variables were health financing, good leadership and governance and human resources for health. The three aspects are central in the realization of proper health care for all in all the levels of health care delivery system.

3.3 Empirical Model

3.3.1 Multinomial Logistic Regression (MLR) Model

Multinomial logistic regression (MLR) is analytical program that run analysis on response variables that are more than three components. This helps to explicate the relationship that exists between dependent variables and independent variables when their values are used to calculate their estimates (Washington et al., 2003; Hosmer et al., 2013).

The regulation of multiple end-to-end networks, which is more than a dependency, segregation and categorization that contains property names and spatial distribution is an increasingly distributed process. Multinomial logistic regression with dependent variables is one factor that should have "J-1" logistic regression models (Liao, 1994; Long and Greese, 2006).

In a multivariate logistic regression model, the probability of a dependent variable to be in the nth category is expressed as stated in equation 1 (Liao, 1994).

$$\pi_J = \frac{\exp(\sum_{k=1}^{K} \beta jk\hat{}xk)}{1+ \sum_{j=1}^{J-1} -(\sum_{k=1}^{K} \beta jk\hat{}xk)} j=1, 2\ldots j-1 \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (1)$$

This definition can also be written in equation 2:

$$\pi_J \frac{1}{1+ \sum_{j=1}^{J-1} exp- (\sum_{k=1}^{K} \beta jk\hat{}xk)} \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (2)$$

Since the input statistics from k to ... in version 2 indicate the dependent variable, input (subscript) j is used to indicate the dependent variable.

The total probability of the components in the variable being "1" as binary modeling, multinomial logistic regression in this study has 3 levels of dependent variables (*D*); the sum of the unique values of each class is equal to "1".

$$P(D=0 \mid x) + P(D=1 \mid x) + P(D=2 \mid x) = 1 \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (3)$$

This model has more than 2 categories of dependent variables; therefore, the baseline was classified by comparison or analysis. The base class (*J*) can also be arbitrarily chosen by the software package (Hosmer and Lemeshow, 2000). In this study, the base class was chosen as 1 for a variable consisting of 1, 2 and 3 classes. Consequently, in the comparison, two different planning models are obtained which consist of 1 and 2, 1 and 3. Consequently, for this model that has three variables, two probability ratios are calculated, each class is compared with these ratios and the model it is linear by taking natural logarithms of these probability ratios to obtain logical models.

If *J* is selected as the baseline category, the probability of the dependent variable to lie within the baseline category is defined as given in Equation 4 (Liao, 1994).

$$\pi_J = P(y=J) = \frac{1}{1+ \sum_{j=1}^{J-1} exp- (\sum_{k=1}^{K} \beta jk\hat{}xk)} j=1, 2\ldots J-1 \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (4)$$

Furthermore, the probability of being in the base category can be calculated using the other probabilities provided in equation 5, if the other probabilities are (Liao, 1994).

π_J=P(y=J) =1-[P(y=1) + P(y=2) +….+ P(y=J-1)] ……..(5)

In the MLR model, the logit transformation is achieved by constructing the logarithmic probability ratio after selecting the reference category. For example, for all three categories, when 1 is selected as the refence category, it is possible to obtain logarithmic odds ratios as indicated in Equation 6 and Equation 7 (Kienbaum and Klein, 2010).

$$\text{In } \left[\frac{p(y=2 \mid X2)}{p(y=1 \mid X2}\right] = \beta_{2+} \beta_{2\,(2)} X_2 \quad \text{.....(6)}$$

$$\text{In}\left[\frac{p(y=3 \mid X3)}{p(y=1 \mid X3}\right] = \beta_{3+} \beta_{3\,(3)} X_2 \text{ ……...…..(7)}$$

3.4 Research Design of the Study

The research study was descriptive and the survey done in a cross-sectional design. A descriptive design was used because it facilitates the collection of quantitative data about the study (Cooper & Schindler, 2000).

3.4.1 Study Area

The research survey was conducted at the University Health Services Senior Staff Clinic located along Lower State House Road, Nairobi Kenya.

3.4.2 Target Population

Borg & Gall (1989) defined the study population as members of a series of real or imaginary persons or happenings that an investigator desires to draw some comprehensive understanding using the results of the research study. The study population consisted of 790 chronic patients who are documented to periodically attend their clinical reviews at the UHS Senior Staff and Student Clinic.

Table 3.1 Target Population

Health Facility	No. of Chronic Patients	Target Population as a Percentage of No. of Chronic Patients	Target of Chronic Patients Per Facility
Senior Staff Clinic	620	78	620
Students' Clinic	170	22	170
Total	**790**	**100**	**790**

Source; University Health Service -Health Records (2019)

3.4.3 Sampling Procedure

Bernard, (2002) argues that sampling is part of the statistical practice of choosing an impartial or random subset of individual observations with a population of individuals that aim to provide some information about the population of well-being, particularly for the purpose of deducting a fair generalization of the results to the population from which they were selected. It is also a procedure that involves choosing a part of the population to observe it and being able to consider something about the entire population. Bernard (2002) suggested that 10% of the accessible population is sufficient to serve as a study sample. Of a population of 790 chronic patients who attended UHS staff and the student clinic, 12% was used to cover the study sample. The study used a stratified sampling technique to obtain the sample. The population was divided into two levels made up of senior staff and the Student Health Clinic, from which the researcher randomly selected a random sample from each stratum (a random sample of senior staff and a random sample from the Student Health Clinic).

3.4.4 Sample Size

The study sample size was drawn from a population of 790 chronic patients. The sample size was calculated using Yamane (1967) formula as shown below;

The sample size was computed based on Yamane formula of (1967)

$$\mathbf{n = {N}/{1 + N\sigma^2}}$$

Where,

n is the desired sample size

N is the population (790)

σ is the level of precision (10%)

$\mathbf{n} = {}^{790}/_{1 + (790[0.1]\text{^}2)}$

= 88.76

=89 Chronic Patients

Table 3.2 Sample size

Health Facility Category	Sample of Chronic Patients	% cumulative no. of patients
Senior Staff Clinic	64	72
Students' Health Clinic	25	28
Total	**89**	**100**

Source; Researcher, (2019)

3.5 Data Collection and Instrumentation

Structured questionnaires which were self-administered was used to collect data from chronic patients visiting UHS (64) at senior staff and (25) at students' health clinic. A structured questionnaire was designed consisting of demographic section and a section pertinent to effect of cost on pharmaceuticals availability. The questionnaire method was a good instrument for data collection in the study since it allowed intensity and richness of patients' experience and perception in responding adequately to the questions (Bernard (2002). The study used questionnaire method due to its flexibility and ease to facilitate in-depth capturing of knowledge to probe further clarifications of issues (Kothari, 2004).

3.6 Data Analysis

Before setting to data analysis, the dependent variable of interest that had a multinomial response was coded with the view to replicate the projected target category (pharmaceutical availability). The response category was coded into three multinomial levels (i.e never available =1, sometimes available =2, and always available =3). Multinomial Logistic Regression (MLR) was used to determine the effects of the type of drugs which was nominal in measure (i.e low priced generic drugs = coded 1 and high

priced originator drugs =coded 2) and the drug dosing formulation which was also nominal in measure (i.e fixed dose combination therapy =coded 1 and single dose therapy =coded 2) on the pharmaceutical availability. Basic demographic information such as gender and age was also analysed and their descriptive statistics reported. Using a sample of (N=89), data was analysed using the Statistical Package for Social Sciences software IBM (SPSS) ver. 20. Descriptive and regression results were presented on tables and bar charts to ensure easy and quick interpretation of data. An MLR model was used for estimates in which the discrete dependent variable had more than two categories, which had nominal characteristics and were not ordered; so the dependent variable has a multinational distribution, although restrictions exist on independent variables (Hosmer and Lomeshow, 2000).

3.7 Operationalization and Definition of Variables

Table 3.3 Operationalization of Variables

Objective	Variable	Indicators	Measurement Scale	Type of Data Analysis
Pharmaceutical availability	Dependent	Never available =1 Sometimes available =2 Always available =3	Nominal	MLR
The type of the Drug -Low priced Generic Drugs -High priced Original Drugs	Independent	YES =1 NO =2	Nominal	MLR
Drug Dosing Formulation -Fixed Dose Combination Therapy -Single Dose Therapy	Independent	YES =1 NO =2	Nominal	MLR

3.8 Ethical Considerations

Ethics was considered in conducting the research study. Participant privacy and confidentiality was accorded utmost attention and consent was obtained first before commencing the study. The investigator ensured compliance with the rules of ethical investigation throughout the study period, taking the necessary measures to comply with the principles of autonomy, charity, justice and informed consent.

CHAPTER FOUR
RESULTS PRESENTATION AND DISCUSSIONS

4.1 Introduction

This chapter reports the model parameter estimates discussed in chapter three. This section is divided into three parts; 4.1 descriptive statistics, 4.2 regression results and 4.3 discussion results.

4.2 Descriptive Statistics

This section presents the descriptive statistics for the dependent and independent variables used in the study. Data analysis was based from a survey that had a sample size of 89 patients regularly attending their chronic clinic at the University Health services.

4.2.1 Response Rate

Table 4.1: Response Rate

Response Category	**Frequency**	**Percentage**
Responded	89	100
No Response	0	0
Total	**89**	**100**

Source; (Research Findings 2019)

All the 89 questionnaires presented for the study survey were fully answered and returned contributing to 100% response rate as shown is the table 4.1 above.

4.2.2 Gender Category

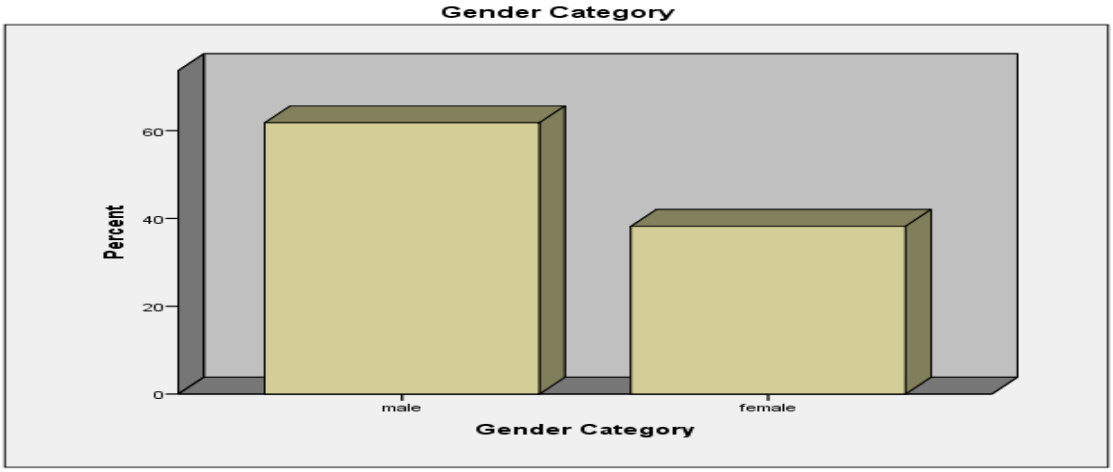
Table 4.2: Gender Category

Gender Category					
		Frequency	**Percentage**	**Valid percent**	**Cumulative percentage**
Valid	Male	55	61.8	61.8	61.8
	Female	34	38.2	38.2	100.0
	Total	**89**	**100.0**	**100.0**	

Source; (Research Findings 2019)

Table above 4.2 shows a gender category distribution and shows 61.8% male participation compared to 38.2% female who participated in the research survey.

Figure 4.1: Gender Category



The above figure 4.1 illustrates the gender distribution as depicted from the research findings.

4.2.3: Case Processing Summary

Table 4.3 Case Processing Summary

Case processing Summary			
		N	Marginal Percentage
Pharmaceutical Availability	Never available	25	28%
	Sometimes available	33	37%
	Always available	31	35%
The type of Drug Prescribed	Low Priced Generic Drugs	46	51.7%
	High Priced Original Drugs	43	48.3%
Drug Dosing Formulation	Fixed Dose Combination Therapy	61	68.5%
	Single Dose Therapy	28	31.5%
Valid		89	100%
Missing		0	
Total		89	
Sub population		4	

Source; (Research Findings 2019)

The above table 4.3 is the case processing summary that illustrates how participants responded to the variable questionnaires as per the research findings. The dependent/response variable was pharmaceutical availability with three unordered/

nominal levels (never available= 28%, sometimes available= 37% and always available= 35%). The independent variables were the type of drug prescribed which took nominal measure as either (low priced generic drugs=51.7% or high priced original drugs=48.3%) and drug dosing formulation which also took nominal measure as either (fixed dose combination therapy=68.5% or single dose therapy=31.5%).

4.3 Multinomial Logistic Regression (MLR) Results

4.3.1: Model Fit Information

Table 4.4: Model Fit Information

Model fit information						
	Model Fitting Criteria			Likely Ratio Tests		
Model	AIC	BIC	-2log Likelihood	Chi-Square	df.	Sig.
Intercept only	78.936	83.913	74.936			
Final	30.111	45.043	18.111	56.824	4	0.000

Source; (Research Findings 2019)

From the table above 4.4 shows information about fitting a model with the chi-square test probability ratio, where the model is zero (i.e., with all the predictors) compared to null (or intercept only model, ie, with all the predictors). Statistical translation suggests that the null model is a significant improvement relative to the null model. In this study, the experiment of the model is significant [X^2 = 56.824, p <.000], indicating that the final model is significantly better, or more accurate, than the null model.

4.3.2: Goodness of -Fit

Table 4.5: Goodness of- Fit

Goodness -of -Fit			
	Chi-square	df.	Sig.
Pearson	.523	2	.770
Deviance	.487	2	.784

Source; (Research Findings 2019)

The Goodness of –Fit shown in table 4.5 above contains Deviance and Pearson chi-square tests, which are useful for determining whether a model exhibits good fit to the data. Non-significant test results are indicators that the model fits the data well. Therefore the data shows that the model is adequately fit as the significance value is above the p-value (0.05).

4.3.3: Pseudo R- Square

Table 4.6: Pseudo R-Square

Pseudo R-Square	
Cox and Snell	.472
Nagelkerk	.535
McFadden	.299

Source; (Research Findings 2019)

The table 4.6 shows the Pseudo R square shows variation from the two independent variables ranging from 0 and 1. The Nagelkerk variation value (0.535) is considered a perfect variation for the two independent variables in the model.

4.3.4: Likelihood Ratio Tests

Table 4.7: Likelihood Ratio Tests

Likelihood Ratio Tests						
Effect	Model Fitting Criteria			Likelihood ratio tests		
	AIC of reduced model	BIC of reduced model	-2 Log Likelihood of Reduced Model	Chi-Square	df.	Sig.
Intercept	30.111	45.043	18.111[a]	0.000	0	
Drug_ Type	80.130	90.085	72.130	54.019	2	0.000
Drug_Dosing Formulation	26.746	36.700	18.746	.635	2	0.051

The chi-square statistic is the difference in -2 log-likelihood between the final model and a reduced model. The reduced model is formed by omitting an effect from the final model. The null hypothesis is that all parameters of that effect are 0.

a. This reduced model is equivalent to the final model because omitting the effect does not increase the degrees of freedom.

Source; (Research Findings 2019)

The table 4.7 above shows the results containing likelihood ratio tests of the overall contribution of each independent variable to the model. Using the conventional $\alpha = 0.05$ threshold, the type of drug prescribed was absolutely significant predictor in the model with a p-value of (0.000). The first predictor variable was the Type of Drug (i.e the Low Priced Generic Drugs or the High Priced Originator Drugs) had a significant impact on the dependent variable (pharmaceutical availability). The second predictor variable was the Type of Drug Dosing Formulation (i.e Fixed Dose Combination Therapy or Single Dose Therapy) with a p-value of (0.051) which was nearly significant.

4.3.5: Parameter Estimates

Table 4.8: Parameter Estimates

Parameter estimates									
Pharmaceutical Availability[a]		B	Std.E	Wald	df	Sig.	Exp(B)	95% Confidence Interval for exp (B)	
								Lower Bound	Upper Bound
Sometimes available	Intercept	1.194	1.490	.157	1	0.000			
	DrugType =1.00	2.664	0.802	1.458	1	0.000	1.801	2.781	4.609
	DrugType =2.00	0[b]	.	.	0	.	.	.	.
	DrugDose =1.00)	-0.406	0.630	0.415	1	0.051	1.501	0.437	1.156
	DrugDose =2.00	0[b]	.	.	0	.	.	.	.
Always available	Intercept	-2.725	0.940	2.412	1	0.004			
	DrugType =1.00	1.528	0.010	.	1	0.010	0.435	3.5132	5.132
	DrugType =2.00	0[b]	.	.	0	.	.	.	.
	DrugDose =1.00	-0.671	0.865	0.601	1	0.138	0.156	0.359	1.660
	DrugDose =2.00	0[b]	.	.	0	.	.	.	.

a. The reference category is: never available

b. This parameter is set to zero because it is redundant.

Source; (Research Findings 2019)

The table 4.8 above provides study findings on parameter estimates comparing group of patients' response information on pharmaceutical availability against the reference

category (never available). Specifically, the regression coefficients indicate which predictors significantly discriminates between patients who sometimes got the drugs available (coded2) in this portion of the model) against those patients who never got the drugs available (coded1); and secondly, is between patients who always got the drugs available (coded3 in this portion of the model) against those patients who never got the drugs available (coded1).

The first set of coefficients represents comparisons between patients who never got the drugs available (never available= coded 1) and those patients who sometimes got the drugs available (sometimes available= coded 2) in this portion of the output. The study find that low priced generic drugs was a significant predictor in the model (b=2.664, s.e= 0.802, Exp (B) =1.801, p> 0.000). The coefficient (b=2.664) indicates that patients being prescribed for low priced generic drugs were more likely to sometimes get the drug available rather than never getting it available at the clinic. The odds ratio of 1.801 indicates that for every one unit increase on fixed dose combination, the odds of a patient sometimes getting the drug available is changed by a factor of (1.801). In the same model, the study find that patients prescribed for fixed dose combinations was also significant (b= -0.406, s.e =0.630,Exp (B) =1.501, p< 0.041).The coefficient (b=-0.406) indicates that those patients on fixed dose combination therapy were less likely to sometimes get the drug available rather than never getting it available at the clinic. The odds ratio of 1.501 indicates that for every one unit increase on fixed dose combination, the odds of a patient sometimes getting the drug available is changed by a factor of 1.501.

For the second set of coefficients represents comparisons between patients/participants who never got the drugs available (never available= coded 1) and those patients who always got the drugs available (always available= coded 3) in this portion of the output. The study find that low priced generic drug was a significant predictor in the model (b= 2.528, s.e =0.010, Exp (B) =0.435, p< 0.010). The coefficient (b=1.528) indicates that those patients prescribed for low priced generic drugs were more likely to get the drug available rather than never getting it available. The odds ratio of 0.435 indicates that for every one unit increase on low priced generic drugs, the odds of a patient always getting the drug available is changed by a factor of (0.435).

The study find that fixed dose combination therapy was not a significant predictor in this segment of the model (b=-0.671, s.e = 0.865, Exp (B) =0.156, p<0.138). The coefficient (b=-0.671) indicates that patients/participants prescribed for fixed dose combination therapy were less likely to always get drugs available rather than never getting them available at the clinic. The odds ratio of 0.156 indicates that for every one unit increase on fixed dose combinations therapy, the odds of a patient always getting the drug changed by a factor of (0.156). In other words the odds were always decreasing. The other parameter high priced original drugs and single dose therapy in both cases were redundant and did not have any meaningful explanation for the study.

4.3.6 Classification

Table 4.9: Classification

Classification				
Observed	Predicted			
	Never available	Sometimes available	Always available	Percent Correct
Never available	9	11	0	45.0%
Sometimes available	7	14	17	36.8%
Always available	1	1	29	93.5%
Overall percentage	19.1%	29.2%	51.7%	58.4%

Source; (Research Findings 2019)

The table 4.9 shows classification statistics used to determine which observed response predicted model. Those patients who never got drugs (Never available) response was correctly predicted by the model 45% of the time **[**as 9 of 20 patients/participants who did not get drugs (never available) were predicted to do so by the model; 9/ (9+11+0) = .45]. Those patients who sometimes got the drugs available were correctly predicted by 36.8% of the model and those patients who always got the drugs were predicted by 93.5% of the model.

4.4 Discussion of Findings

Sample description of the study shows that the response rate was 100%; that all the 89 samples were valid with 61.8% males and 38.2% females responded respectively. The dependent variable (pharmaceutical availability) was set in three nominal levels of response category (i.e never available 22.5%, sometimes available 42.7% and always available 34.8%). The independent/predictor variables in the study was the type of drug prescribed which took nominal measure as either (low priced generic drugs=51.7% or high priced original drugs=48.3%) and drug dosing formulation which also took nominal measure as either (fixed dose combination therapy=68.5% or single dose therapy=31.5%).

In the study, the dependent variable (pharmaceutical availability) had three nominal levels of response category. The first level "never available" coded 1 was taken as the baseline category, the second level was "sometimes available" coded 2 and third level "always available" coded 3 and the results were interpreted accordingly. The study find the validity of the MLR model was statistically fit [X^2 =56.824, p<.000]. The goodness of-fit also exhibited the good fit to the data as characterised by deviance (0.784) and pearson (0.770) chi-square tests with a p-value above conventional (0.05). The Pseudo R-square test results showed that Nagelkerk variation value of (0.535) was considered as a perfect variation for the two independent variables in the model.

The strongest predictor variable was the type of drug prescribed as generic (coded 1) and had an impact on the dependent variable (pharmaceutical availability) which had a p-value of (0.000) and a p-value of (0.010) in the two segments of models comparing those patients who sometimes got the drug available and those who always got the drug available against those who never got the drug available at the clinic. The same predictor variable type of drug prescribed as original (coded 2) was redundant and did not have an impact in the model.

The second predictor variable the drug dosing formulation as fixed dose combination therapy (coded 1) had a slight impact on the dependent variable (pharmaceutical availability) with a p-value of (0.051) when comparing between those patients who sometimes got the drug available and those who never got the drug available. The other

segment comparing between those patients who always got the drug available and those who never got the drug available did not have an impact on the response variable pharmaceutical availability with a p-value (0.0138). The same predictor the drug dosing formulation as single dose therapy (coded2) was redundant and did not have an effect in the model.

CHAPTER FIVE
SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Summary and Conclusions

The goal of this research study was to establish the effect of pharmaceutical cost on the availability of non-communicable disease (NCD) drugs affecting chronic patients attending regular clinic at the University Health Services. The impact of NCD on economic growth is humongous and therefore treatment and care is fundamental in mitigating the effects on many patients and their wellbeing.

The study sought to understand how the type of drug prescribed (either generic or originator drugs) affects the availability of drugs used in the treatment and management of patients suffering from chronic conditions. The study suggests that generic drugs had a stronger impact on the availability of pharmaceuticals with a p-value of (0.000) and a p-value of (0.010) in both segments of MLR model. This result is in tandem with empirical studies that use of generic medicines, compared to their branded counterparts, has the potential to substantially reduce out-of-pocket expenditure on drugs for patients with chronic diseases. Generic substitution of brand prescriptions is an accepted practice in many parts of the world, and this is often done for economic reasons. Cost is the major difference between the generic and originator prescription drugs (Cameron et al., 2009). Unlike originator companies, generic manufactures compete directly on the price, resulting in lower prices for the consumer. Generics have saved Americans huge sums of money approximated to be $ 1.67 trillion over the last decade (Klinger, 2019).

The study also suggests that the originator drugs was redundant and had no impact on the availability of pharmaceuticals. This finding resonates with the empirical studies that in countries with lower incomes, there is a sharp price difference between the original drugs and their equivalent generic drugs and many healthcare units are unable to stock the drugs (WHO, 2014). In a quantitative price survey evaluation by WHO and Health Action International (HAI) confirmed existence of a significant percentage price difference particularly with the original drugs as compared to the generics drugs that are cheaper in the market (HAI, 2009). The study result illustrates the difficulties that

patients go through to get original drugs at the facility compared to their generic equivalents which has been confirmed to be readily available.

The study also sought to understand how the drug dosing formulation either in form of (fixed dose combination or single dose) affects the availability of pharmaceuticals used in the treatment and management of patients suffering from chronic conditions. The study result suggests that fixed dose combination therapy had a slight impact on the availability of pharmaceuticals with a p-value of (0.051) for those who sometimes get the drug available rather than not available in the clinic. The single dose therapy did not have an impact on the pharmaceutical availability as it was redundant in the model of the study. The result illustrates that pharmaceutical availability is not dependent largely on the form in which the drug comes is marketed as either fixed dose combinations or single dose therapy which did not have an impact with a p-value (0.0138).

The study has some limitations. The survey data is self-reported and might have some inaccuracies as it may not be verifiable from other sources. The recall period on pharmaceutical availability was also short and can be a limitation since it is difficult to ascertain possible inaccuracies if the drug was available in which type and form. Despite the limitations, the study provides critical and useful insights which can evoke important suggestions that can inform pharmaceutical management to allow lucid channels that enhance availability of quality and cost effective drugs for treatment and management of chronic patients across the nation.

5.2 Policy Implications

This study has pointed out that generic drugs have a significant impact on the availability of pharmaceuticals on the management and treatment of patients suffering from chronic conditions. The economic benefits of generic drug use are well-known and undisputed. The limited availability of quality generic formulations appears to be an important hindrance to the widespread adoption of generic prescribing and dispensing activity. Patients with degenerative diseases such as CVDs and Diabetes need unswerving source of inexpensive chronic drugs to their disposal to enhance the treatment options. There

will be more rates of morbidity, disabilities and mortalities due to these degenerative diseases if there is no ample supply of NCD drugs the right time and in their optimal quality. The study therefore strongly recommends adoption of use of low priced generic drugs in the treatment chronic conditions particularly on patients with diabetes and hypertension diseases. As shown in the study, the use of generic drugs will allow continuity of treatment and less economic depression that the patient will be subjected to in cases of medicine unavailability.

Several government policy options are being rolled up to meet the demand of chronic medicines in the fight against chronic diseases in the country today. The government through its lucid program "The Agenda Four" which anchors issues of economic development through Universal Health Care (UHC) has concerted efforts in ensuring the continuity of healthcare provision from the primary level to tertiary level to all her citizens. In light of these developments, the government should zero rate the cost of chronic medications to her citizens as an essential part in the fight against four major killer NCDs like Cancer, CVDs, Diabetes and COPDs.

Lu et al., (2011) points out that the dynamics leading to the growth of global pharmaceutical spending varies in the consumption and price modalities The government and institutions of health should propagate and reassure the use of cost effective generic drugs in terms of perceived effectiveness, safety and adherence to treatment for the patients who acquire generic drugs for use in many healthcare systems across the country. This will increase the rate of confidence on patients and the psychological satisfaction that is important in the treatment outcomes of patients.

5.3 Suggestions for Further studies

The study investigated a generalized pharmaceutical availability and not specific drugs in treatment and management of chronic conditions. The study suggests that particular drugs used in treatment need to be studied to understand their availability in chronic conditions across health systems.

REFERENCES

Agresti, A. (2007) "An Introduction to Categorical Data Analysis" John Wiley & Sons, Inc

Bernard, (2002) "Research methods in anthropology: Qualitative and quantitative approaches". 3rd Alta Mira Press; Walnut Creek, CA: 2002

Borg, W.R and Gall, M.D (1989) "Educational Research, An introduction" 5th Ed New York:

Boutayeb, A., Twizell, E. H., Achouyab, K., Chetouani, A., (2004) "A Mathematical Model for the Burden of Diabetes and its Complications" BioMedical Engineering

Cameron et al.,(2009) "Medicine prices, availability, and affordability in 36 Developing and Middle-Income Countries" A secondary analysis. Lancet, 2009

Cooper & Schindler, (2000) "Business Research Methods" (9th edition), USA: McGraw-Hill.

Clabaugh G, Ward M (2008) "Cost-of-illness studies in the United States": A systematic review of methodologies used for direct cost. Value Health 2008

Daar et al., (2007) "Grand challenges in chronic non communicable diseases" An Economic Perspective (Oxford Health Alliance, London, 2006)

Doorslaer et al., (2006) "Equity in health care finance and delivery".In: Newhouse JP, editor. Handbook of health economics, Amsterdam:

Feenberg and Skinner (1994) and Waters (2004)" Measuring Financial Protection in Health in United States" Health Policy

Flood, D., Mathieu, I., Chary, A., García, P. and Rohloff, P., (2017) "Perceptions and Utilization of Generic Medicines in Guatemala": A Mixed-Methods Study with Physicians and Pharmacy Staff: BMC Health Services Research

Gerdtham et al., (1998); Chen and Schweitzer (2008) "Policy options for pharmaceutical pricing and purchasing: issues for low and middle income countries" Health Policy and Planning .Oxford Academic .Journal

Gottret & Schieber, (2006) "Health Financing Revisited" A Practitioner's Guide

Hanson et al., (2005) "Preferences for hospital quality in Zambia: results from a discrete choice experiment". Health Econ 14: 687–701. doi:10.1002/hec.959.

Health Action International (2009) "Measuring medicine prices, availability, affordability and price components" 2nd Ed. Geneva, Switzerland; 2008 [http://www.haiweb.org/ medicineprices/manual/documents.html]

Heeley et al., (2009) "Role of Health Insurance in Averting Economic Hardship in Families after Acute Stroke in China" 40:2149–2156.

Himmelstein et al., (2006) "The changing Landscape of Non Communicable Diseases and associated Risk Factors" UN –Dep. of Economics and Social Affairs

Hosmer, D. W. and Lemeshow, S. (2000) "Introduction to the Logistic Regression Model, in Applied Logistic Regression" 2nd Ed. John Wiley & Sons, Inc., Hoboken, NJ, USA.

Jefferson et al., (2000) "Cost-of-illness studies, elementary economic evaluation in health care" 2nd ed. London: BMJ Publishing Group; 2000. pp. 17–29

Juma, P., Mohamed, S. and Kyobutungi, C., (2017) "Analysis of Non-communicable Disease Prevention Policies in Kenya" African Population and Health Research Centre, Nairobi

Kenya Health Policy, (2012) "Kenya National Strategy for the Prevention and Control of Non Communicable Diseases" M.o.H Strategic Paper-2015-2020

Kankeu, T. H., Saksena, P., Xu, K. and Evans, B. D., (2013) "The Financial Burden from Non-Communicable Diseases in Low- and Middle-Income Countries": a Literature Review

Kothari, (2004) "Research Methodology: Methods and Techniques", Wishawa Publication, Delhi.

Kohler et al., (2012) "Access to medicines from a health system perspective" Health Policy and Planning-Oxford Journal pub.

Klinger, E. (2019) "Resources from the US Generics & Bio-similar Industry" Association for Accessible Medicines; Washington DC

Kleinbaum, D.G. and Klein M. (2010) "Logistic regression, a self-learning text, third edition" Springer

Krishna (2007) and Doorslaer et al., (2006) "Impoverishing Effects of Healthcare Payments in India" New Methodology and Findings

Kiarie, K., (2016) “Tackling the Rise in Non-Communicable Diseases and Conditions in Kenya”; Ministry of Health Policy Brief: Government Printer, Nairobi

Liao, T.F.(1994). “Interpreting Probability Models. Logit, Probit and Other Generalized Linear Models” Quantitative Applications in the Social Sciences. Sage Publications

Maina, W., (2009) “Control of Non-Communicable Disease in Kenya, Past Present and Future” Nairobi: Ministry of Health Kenya: Government Printer, Nairobi

Mathers, C. D, Bernard C., Iburg KM, Inoue M, Fat DM, Shibuya K, Stein C, Tomijima N, Xu H., (2003) “Global Burden of Disease in 2002 Data Sources, Methods and Results”

Masters et al., (2014) “Pharmaceutical Availability across Levels of Care” Evidence from Facility Surveys in Ghana, Kenya, and Uganda

MSDAC, (2004) “Metabolic Syndrome, Type II Diabetes, and Atherosclerosis Congress” Available at: http://http:/www.msdac.com Accessed on June 30, 2018

Muchira, J., Stuart-Shor, E., Kariuki, J., Mukuna, A., Ndigirigi, I., and Gakage, L., (2015) “Distribution and Characteristics of Risk factors for Cardio-Vascular–Metabolic Disease in a Rural Kenyan Community” International Journal of Africa Nursing Sciences.

Mwai, N. D., (2014) “Non-Communicable Diseases in Kenya: Economic Effects and Risk Factors” Department of Economics: University of Nairobi

OECD (2008) “Pharmaceutical pricing policy in a global market” OECD Publishing, 2008; Paris

Rao, K. D., Bhatnagar, A. and Murphy, A., (2011”) “Socio-Economic Inequalities in the Financing of Cardiovascular & Diabetes Inpatient Treatment in India” Indian J Med Res; 133:57–63

Reddy, K.S., (2002) “Cardiovascular Diseases in the Developing Countries: Dimensions, Determinants, Dynamics and Directions for Public Health Action” Public Health Nutrition: 231–237

Republic of Kenya, (2015) “Kenya STEPwise Survey for Non-Communicable Diseases Risk Factors” Division of Non Communicable Diseases: Ministry of Health: Government Printer- 2015 Report

Sari, N. and Langenbrunner, J. C., (2001) "Consumer Cut-of-Pocket Spending for Pharmaceuticals in Kazakhstan" Implications for Sectoral Reform- Health Policy Plan. 2001

Shobhana, R., Rama, R. P., Lavanya, A., Williams, R., Vijay, V. and Ramachandran, A., (2000) "Expenditure on Health Care Incurred by Diabetic Subjects in a Developing Country" - a Study from Southern India: Diabetes Research and Clinical Practice

Tawa, N, Frantz J, and Waggie F (2011) "Risk Factors to Chronic Non-Communicable Disease in Mombasa, Kenya" Epidemiological study using WHO stepwise approach. African Journal of health science

Vialle-Valentin, C. E., Serumaga B., Wagner, A. K. and Ross-Degnan D., (2015) "Evidence on Access to Medicines for Chronic Diseases from Household Surveys in Five Low- and Middle-Income Countries" Health Policy and Planning

Washıngton, S., Karlaftıs, M., Mannering, F. (2003) "Statistical and Econometric Models for Transportation Data Analysis" Boca Raton FL.CRC Press

World Bank, (2014) "Laying the Foundation for a Robust Health Care System in Kenya" Kenya Public Expenditure Review VOL II, p. 2: World Bank Group, Washington DC

World Health Organization (2014) "Non Communicable Diseases Country Profiles" World Health Organization Press, Geneva, Switzerland

Yamane, T. (1967) "Statistics, An Introductory Analysis" 2nd Ed., New York: Harper and Row.

APPENDICES

APPENDIX I: RESEARCH LETTER

Dear respondent,

A request to participate in a research study titled “The Effect of Costs on Pharmaceutical Availability of Non-Communicable Diseases Drugs": A Case Study on Diabetes and Cardiovascular Disease (CVDs) at the University of Nairobi Health Services. This was a research study intended for the purpose satisfying the requirements to accomplish the degree of Master of Science in Health Economics and Policy at the University of Nairobi, School of Economics.

Their participation in this research project was voluntary. Their answers remained confidential and anonymous. Data from this research was kept under wraps and reported only as a collective grand total. The exercise took about a minimum of 20 minutes for the process to complete.

Yours sincerely,

Samson Oduor Okello

APPENDIX II: DATA COLLECTION TOOL(S)/ INSTRUMENTS

Please answer the following questions by placing the (√) in the appropriate box or by giving the necessary details in the provided spaces. This is a survey on availability of pharmaceuticals that are used to manage patients who are currently being treated on Diabetes and Hypertension Disease at the UHS Clinic. Your participation will be highly useful to inform the quality service provision and my academic work.

Participant S/No. ----------

SECTION A: DEMOGRAPHIC PROFILE OF RESPONDENTS

1. Gender: i) Male [ ] ii) Female [ ]

2. Age: i) Between 18- 30 years [ ] ii) Between 31-40 years [ ]

iii) Between 41-50years [ ] iv) 51 years and above [ ]

3. Level of Education i) High school graduate [ ] ii) Undergraduate [ ]

iii) Graduate [ ] iv) Postgraduate [ ]

4. Which type of drug dosing form(s) were you prescribed for to manage your chronic condition?

i) Fixed Dose Combination Therapy [ ]

ii) Single Dose Therapy [ ]

5. Which type of drugs were you prescribed for to manage your chronic condition?

i) Low Priced Generic Drugs [ ]

ii) High Priced Original Drugs [ ]

6. Did you get the drugs you were prescribed for the management of your chronic condition in the last one month you visited the facility (University Health Services)? Rate your satisfaction level on a 3 point likert scale below.

i) Never Available [ ] ii) Sometimes Available [ ] iii) Always Available [ ]

7. In your opinion, what other things can we do to improve availability of pharmaceuticals for management of non-communicable conditions?

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Thank you so much for creating some part of your precise time to participate in this survey.