ECONOMIC COSTS OF HYPERTENSION-DIABETES MELLITUS COMORBIDITY IN PRIMARY PUBLIC HEALTH FACILITIES IN KIAMBU COUNTY, KENYA.

BY

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DECLARATION OF ORIGINALITY FORM

This dissertation is my original work and has not been presented to any other examination body.

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ABSTRACT

Background: Hypertension and raised blood sugar are the most significant risk factors for cardiovascular diseases. In Kenya, they are responsible for much of the disease burden and account for most of the hospital admissions. Also, greatly contributes to catastrophic health expenditures incurred by the patients. For the longest time, the public health system structure was organized in favour of communicable diseases and treatment of chronic conditions was centralized at secondary and tertiary levels of care and occasionally in primary health facilities for emergency response and very basic care. Recently, the government has focused on decentralizing treatment and management of hypertension-diabetes Mellitus comorbidity to primary health facilities to increase access and utilization. However, cost information at this level to guide budget allocation is lacking greatly interfering with service provision since they solely depend on government funding.

Objectives: This research sought to estimate the economic costs of hypertension-diabetes Mellitus comorbidity in the public primary health facility. The specific objectives were to estimate the economic cost in level 2 and level 3 health facilities in Kiambu county, Kenya and determine how affordable is the estimated economic unit costs to hypertension-diabetes Mellitus comorbidity patients.

Methods: The study adopted a hospital-based analytical cross-sectional design and Activity-Based Costing technique. Further, an ingredient approach was adopted to retrospectively collect prevalence-based data on cases from a health provider perspective and the time horizon for the study was one year, 1st January 2020 and 31st December 2020. The cost ingredients included: personnel remunerations, supervisory staff time, equipment and furniture, essential medicines, non-pharmaceutical products, utility charges, and building space for rental. The study sites were four health facilities in Kiambu county which were selected using a multi-stage sampling technique. Also, a sample of the cases across all the study sites was interviewed to determine the affordability of hypertension-diabetes Mellitus comorbidity. Descriptive statistics, including frequencies and percentages, were used to summarize categorical variables, whereas continuous variables were summarized and presented in means. Further, univariable, and multivariable regression analysis was done to determine variables that added significance to the affordability of hypertension-diabetes Mellitus comorbidity.

Results: The unit economic cost for treating and managing hypertension-diabetes Mellitus at a level health 2 facility was estimated at US $ 21.73, US $ 48.91 for a level 3 health facility, and US $ 38 for a primary health care level. Among the cost ingredients, labour across all levels of care was the main cost driver estimated at 48% at level 2 and 59% at level 3. Drugs followed at 13% at level 2 and 28% at level 3. Equipment cost contributed approximately 13% for level 2, and 21% and 13% for level 3 respectively. Non-pharmaceutical and utilities contributed to less than 10% in both levels of care. Logistic regression analyses found drug availability to be associated with the affordability of hypertension-diabetes Mellitus comorbidity. Compared to the unavailability of drugs, public primary health facilities with the availability of drugs is 11.9 times more likely to be affordable to hypertension-diabetes Mellitus comorbidity patients (aOR: 2.48; 95% CI; 5.20-27.25; P<0.00) holding all factors constant.

Conclusion and recommendation: The study findings reveal the need for the government at all levels to strengthen primary care facilities with trained and adequate staff, enough mix of medical devices and essential drugs, and adequate space to support the delivery of quality care increasing patients' utilization and affordability. Cost studies on hypertension-diabetes Mellitus comorbidity from a provider perspective are critically missing; no considerable research has been done in Kenya. This calls for more in costing health services, especially referencing the guidelines outlined to make the 'invisible' visible to the decision-makers to inform budgeting and resource allocation are achieve the quality care and sustainable development target on NCDs of reducing one-third of premature deaths from NCDs by 2030.

LIST OF ACRONYMS

ABC	Activity-Based Costing approach
ACEI	Angiotensin-converting enzyme inhibitor
ARB	Angiotensin receptor blocker
BP	Blood Pressure
CCB	Calcium channel blocker
CHVs	Community Health Volunteer
CMEs	Continuous Medical Education
CVDs	Cardiovascular diseases
ECG	Electrocardiogram
ERC	Ethical Review Committee
GDP	Gross Domestic Product
IDF	International Diabetes Federation
IEC	Information, Education and Communication
KEMSA	Kenya Medical Supplies Authority
KEPH	Kenya Essential Package of Health
KNH	Kenyatta National Hospital
Ksh	Kenya Shillings currency symbol
LMICs	Low- and Middle-Income Countries
NCDs	Non-Communicable Diseases
MOH	Ministry of Health
MOPC	Medical Outpatient Clinic
OPD	Outpatient Department
PHC	Primary Health Care
SDG	Sustainable Development Goals
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organization
UHC	Universal Health Coverage
UoN	University of Nairobi
USD	United States Dollar

DEFINITION OF OPERATIONAL TERMS

Hypertension-it is a condition in which the pressure of blood pushing against the walls of the blood vessels is persistently higher than normal with systolic pressure above 130mmHg and diastolic blood pressure above80 mmHg.

Diabetes mellitus-It is a condition that the pancreas doesn't produce enough insulin, or the body cannot use it as well as it should.

Type 2 diabetes- A condition where the body doesn't use insulin well and can't keep blood sugar at normal levels.

Comorbidity- a simultaneous coexistence of two or more health conditions in a patient.

Economic cost- Direct and indirect expenses incurred by the government to provide healthcare services to patients.

Level 2- also referred to as dispensaries. They are the lowest point of the public health system and are the first contact point with the patients. They are run and managed by enrolled and registered nurses who provide antenatal care and treatment for simple medical problems during pregnancy such as anaemia, and occasionally conduct normal deliveries. Enrolled nurses also provide basic outpatient curative care.

Level 3- also known as a health center. They are staffed by midwives or nurses, clinical officers, and occasionally by doctors. They provide a wider range of services, such as basic curative and preventive services for adults and children, as well as reproductive health services. They also provide minor surgical services such as incision and drainage.

Primary health facility-It comprises both Levels 2 and 3 (dispensaries, health centers, and maternity/nursing homes) and they predominantly provide promotive and preventive care, but also various curative and rehabilitative services through community collaboration and full participation. It forms the basis for other levels of health care services (secondary and tertiary). It focuses on the person, not the disease while considering all determinants of health (social and behavioral), integrating care and services when there is more than one health need.

Affordability of hypertension-diabetes Mellitus comorbidity- this can be defined as the measure of the ability of a person with hypertension-diabetes Mellitus comorbidity to pay for healthcare costs with limited sources without unacceptable or unreasonable sacrifices.

CHAPTER ONE: INTRODUCTION

1.1 Background

Cardiovascular, diabetes, chronic respiratory diseases, and cancer are the major non-communicable diseases (NCDs) that contribute to the largest share of global morbidity and mortality(WHO, 2018). In 2016, the public health burden of these conditions accounted for 41 million of the 57 million deaths recorded globally, with 78% occurring in Low Middle-Income countries (LMICs)(WHO, 2018). Thus, suggesting a rapidly rising burden of NCDs alongside communicable diseases. The rising prevalence of these conditions is attributed to various factors, including rapid urbanization and population growth that leads to increasing trends in the consumption of unhealthy diets, physical inactivity, misuse of alcohol, and tobacco smoking (Mendis, 2017).

Hypertension-diabetes Mellitus comorbidity is the largest contributor to reported cardiovascular disease (CVDs) mortality, the leading cause worldwide with LMICs contributing to over three-quarters (WHO, 2018). The WHO (2016) estimated that about 17.9 million people died from CVDs in 2016, representing 31% of all deaths globally. In Kenya, they account for 13% of national mortality and 25% of hospital admissions (MOH Kenya, 2018). Hypertension-diabetes Mellitus comorbidity mainly causes heart attacks and strokes besides other physiological changes such as being obese and raised cholesterol (Mackay, Mensah, & Greenlund, 2004; MOH Kenya, 2018). A combination of risk factors such as smoking tobacco, unhealthy foods and alcohol has been associated mainly with the rise of diabetes and hypertension. Studies have shown that at least 67% of persons with Type 2 Diabetes Mellitus (T2DM) have uncontrolled hypertension or are being treated for raised blood pressure (Patney, Whaley-Connell, & Bakris, 2015). This increasing trend threatens the quality of life; increases mortality; and causes a rise in the health system and household health expenditure (Hurst, Thinkhamrop, & The Tran, 2015).

The most affected population is aged between 30 and 70 years, the active and energized working-age groups leading to productivity losses curtailing a nation's economic growth and increasing societal, economic burden (WHO, 2018). Premature death and disability caused by hypertension-diabetes Mellitus comorbidity have substantial economic implications. A study by Maestas et.al estimated that between 2011 and 2025 the financial loss in LMICs was $3.7 trillion. (Maestas,

Mullen, & Powell, 2016). This is a significant loss for developing economies. In Kenya it is estimated that the household income is decreased by 28.6% once a member has been diagnosed with hypertension-diabetes Mellitus, subjecting the family to catastrophic expenditure spiraling them in the cycle of poverty.

As much as the economic burden of these conditions is felt globally, the intensity varies between developed and developing countries. High-income countries, the financial burden of the disease often affects the government and/or health insurance organizations. In contrast, in resource-limited countries, a more significant proportion of the burden falls on the patient and family members due to limited government health budget allocation and low health insurance coverage (Kankeu, Saksena, Xu, & Evans, 2013; Seuring, Archangelidi, & Suhrcke, 2015). According to research done in Sub-Saharan Africa, out-of-pocket costs are projected to reach 50% of the total health spending (Atun et al., 2017). This shows that the patients feel the economic burden heavily, and their outcome is influenced in equal measure.

Generally, hypertension and diabetes programs in LMICs are often underfunded yet they lead to significantly more deaths in LMICs, the ranking of funding priorities does not match the disease burden (Pastakia, Pekny, Manyara, & Fischer, 2017). In Kenya, health budget allocation is insufficient compared to the demand for care (Mwai & Muriithi, 2016). The national health expenditure on NCD is at 5.2% of the total health expenditure and has been on the decrease over time (MOH Kenya, 2019). Therefore, to reverse the increasing burden there is a need for increased allocation and ring-fence health budgets to minimize reallocation.

Cost analysis is a partial economic method of evaluating health interventions(Drummond, O'Brien, Stoddart, & Torrance, 2002). It is helpful to both national and county governments that depend on the cost estimate and service utilization data to allocate health budget. However, data remitted more so by lower levels of care, dispensaries and health centers, is usually limited to inform decision-making (Mwai & Muriithi, 2016). This leads to underfunding, which negatively affects the health system inputs, including human resources, essential medicines, health infrastructure, diagnostics, and health promotion, among others, to provide care to diabetic and hypertensive patients. Consequently, health services offered in public primary health facilities are either limited or absent altogether pushing patients to access care in other facilities which may not be affordable to all. Due to the chronic nature and complications may result in significant medical care expenditures and reduced productivity for patients and their households, as well as reduced

wellbeing. (Mwai & Muriithi, 2016).This calls for aligning health priorities and allocating resources by providing evidence of the costs of providing care to comorbid patients.

Effective treatment and management of hypertension-diabetes mellitus comorbidity majorly depend on health system capabilities. Developed countries have relatively better health systems and are thus able to manage the condition with few fatalities, unlike developing countries where health systems, for the longest time, have been developed around the need to address infectious diseases and acute conditions (WHO, 2010). It is until recently that they started to evolve to meet the needs of people with chronic conditions, requiring continuous interaction with the broader health system for a longer time to achieve optimal care (NCD Alliance, 2018). In Kenya, for the longest time, the public primary care health system structure was organized in favour of communicable diseases and treatment of chronic conditions was centralized. Patients with chronic conditions were seen at secondary and tertiary levels of care and occasionally in primary health facilities for emergency response and very basic care(MOH Kenya, 2015a). Given limitations in the health system, such as a lack of experts or doctors to meet the expected demand for care, the government has until recently concentrated on decentralizing the management and treatment of diabetes to basic healthcare institutions.

Decentralization of hypertension-diabetes mellitus comorbidity care will involve providing comprehensive outpatient care including access to prescribed medicines. This will not only help save costs both from the health system and patient perspective but also improve patient outcomes, especially for comorbid patients who require continuous interaction with the health system. However, cost information is these levels of care is lacking. A systematic review of provider/system perspective costs study by Moucheraud et.al found the hospital outpatient charges to provide care to hypertensive patients in LMICs were approximately US$17 (median US$11) (Moucheraud, Lenz, Latkovic, & Wirtz, 2019).

Current treatment and management practice in Kenya allows patients with controlled blood sugar levels and blood pressure to be scheduled for either monthly or quarterly checkups. Those with uncontrolled levels of either blood sugar or blood pressure are scheduled for a shorter time frame, weekly or bi-weekly. These visits come with the cost implication; patients pay for consultation, laboratory tests, imaging, and drugs in other instances they are hospitalized, adding further to the household's economic burden(Mwai & Muriithi, 2015). Therefore, to ease the burden and bring

services closer to the people significant health system components and associated costs must be realized to accelerate the scale-up of hypertension and diabetes control programs.

1.2 Statement of the research problem

With the commitment of the Kenyan Government to strengthen public primary health facilities to provide adequate care to uncomplicated cases of hypertension and Type 2 diabetes mellitus (T2DM), and only refer complicated cases to higher levels of care. Not only will it improve access but also encourage service utilization since services are closer to the people. However, the cost information at this level of care is lacking or insufficient, and this, over time, has greatly affected the budget allocation because the need for services and the resources do not match. Generally, primary health facilities solely depend on government funding since they do not charge for the services provided. With the impact of low budget allocation health services are unavailable to the majority as a result they are forced to seek care in higher levels, sub-counties, and county hospitals, where they are expected to pay out of pocket or national health insurance which its uptake is still low. Therefore, to empower health facilities to provide quality care to comorbid patients and ensure patients don't incur catastrophic expenditure it is a prerequisite for the decision-makers and planners as they allocate health budgets to understand unit economic costs to provide care in these lower levels in relation to the prevalence of the disease and match supply to demand for continuity of care.

1.3 Research questions

1. What is the estimated unit economic cost of hypertension-Mellitus comorbidity at level 2 public health facilities in Kiambu County?
2. What is the estimated unit economic cost of hypertension-diabetes Mellitus comorbidity in level 3 public health facilities in Kiambu county?
3. What is the estimated unit economic costs of hypertension-diabetes Mellitus comorbidity in public primary health facilities in Kiambu County?
4. How affordable is hypertension-diabetes Mellitus comorbidity in public primary health facility in Kiambu county?

1.4 Study Objectives

1.4.1 General objective

The main objective of this study was to estimate the economic cost of hypertension-diabetes Mellitus comorbidity in public primary health facilities in Kiambu County, Kenya.

1.4.2 Specific objectives

1. To estimate the unit economic cost of hypertension-diabetes Mellitus comorbidity at level 2 public health facilities in Kiambu County
2. To estimate the unit economic cost of hypertension-diabetes Mellitus comorbidity in level 3 public health facilities in Kiambu County
3. To determine the unit economic cost of hypertension-diabetes Mellitus comorbidity in public primary health facilities in Kiambu County
4. To determine affordability of hypertension-diabetes Mellitus comorbidity in public primary health facility in Kiambu county?

1.5 Justification of the study

The burden of hypertension-diabetes Mellitus comorbidity is expected to rise. It is projected by 2045, approximately 700 million adults aged between 20 and 79 years will be living with diabetes globally, and the prevalence of hypertension will be even higher than the current 1.1 billion who have raised blood pressure (IDF, 2019). In Kenya alone the prevalence of diabetes is projected to rise to 4.4% in 2035 from the 2019 estimates of 3.1%. Prevalence of hypertension is expected go even higher than the current statistics, of more than half of those aged above 40 years being hypertensive (MOH Kenya, 2015). This implies an increase in the total costs of care from all perspectives with patients absorbing the most hit due to their continuous interaction with the health system. This might lead to increased poverty for individuals or impact the health system's resources, especially in Low Middle-Income countries. Data from sub-Saharan Africa show most people with diabetes have many unmet needs regarding their care, including access to screening for complications, counselling, and medicines. For example, global estimates show that one in two people with type 2 diabetes does not have access to prescribed insulin (Atun et al., 2017). With the transformation in lifestyles in the sprawling urban centres and rural areas, NCDs have become a

new health priority in the African region; however, much progress has not been made due to inadequate data for evidence-based decision-making.

Cost information is one of the crucial information required to allow countries to plan and implement interventions toward meeting the Sustainable Development target on NCD of reducing one-third of premature deaths by 2030, and the in-country UHC commitment by the government (MOH Kenya, 2013a; Okech & Lelegwe, 2016). The financial information from this study will better help planners and policymakers at the various levels prioritize health care policies, allocate scarce public health under budget constraints, and scale up interventions. More so for Kiambu county, the second largest county after Nairobi, with the highest NCD prevalence(MOH Kenya, 2014). Further, the findings will inform health budget formulation and advocacy at the health facility level.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter explores the burden of hypertension and type 2 diabetes mellitus comorbidity globally and in Sub-Saharan Africa. It also looks at how the premature mortality caused by these conditions influences a country's economy and compares its effects in high-income settings and resource-constrained settings. The literature delves into the treatment and management situation in Kenya; the cardiovascular guidelines outlined for primary health care facilities and the health system challenges to manage comorbidity. It further looks at the several related studies undertaken in different contexts to determine the proper costing models that can be used to determine the exact cost of proving quality care and treatment and estimated cost at the primary health facilities level. This study borrowed heavily from some of those articles, research findings, reports, and own observations in primary healthcare settings to necessitate a clear picture of the cost of treating and managing hypertension-diabetes comorbidity.

2.2 The burden of hypertension-diabetes Mellitus comorbidity

Globally, non-communicable diseases (NCDs) are the leading cause of death, accounting for almost 41 million fatalities in 2 016.The major NCDs responsible for these deaths include cardiovascular diseases (44%, i.e., 17.9 million people), cancers (9%), chronic respiratory diseases (7%), and diabetes (4%)(WHO, 2 018). Of all the CVD-related deaths, 85% are due to heart attack and stroke(WHO, 2018). These high mortality rates are attributed to behavioural risk factors such as tobacco use, unhealthy diet, physical inactivity, and harmful use of alcohol. Metabolic risk factors: raised blood pressure/hypertension raised blood glucose and raised blood lipids which are mainly due to long-term and continuous exposure to behavioral risk factors, such as genes(WHO, 2011; Wu et al., 2015). Experts argue that the risk of getting the disease is even higher among individuals with more than one risk factor(Wald & Law, 2003).One of the most intertwined conditions contributing to an increased burden of heart diseases and complications is diabetes and hypertension. This is because underlying risk factors for stroke, coronary heart disease, congestive heart failure, and peripheral vascular diseases significantly overlap.(Long & Dagogo-jack, 2011; WHO, 2013).

The occurrence of hypertension is approximately twice as frequent in patients with diabetes mellitus compared with patients without the disease. Also, more than 75% of cardiovascular diseases and complications among diabetic patients are contributed by hypertension(Sowers, Epstein, & Frohlich, 2001).Statistics by International Diabetes Federation (IDF, 2017) further show diabetes has been on the rise globally for several decades now, and approximately half a billion people are diabetic, and the numbers are expected to increase to 629 million by 2045 from 425 million in 2017 if no action is taken(IDF, 2017). On the other hand, hypertension (raised blood pressure) being a key contributor to the burden of heart diseases, contributes to approximately 9.4 million deaths annually to cardiovascular disease mortality besides 1.1 billion adults estimated by WHO to have raised blood pressure worldwide(WHO, 2013).This implies the magnitude of comorbidity is even higher than thought, and to bring the numbers down there is a need for a holistic approach to health system strengthening and patient effort.

LMICs are the most affected countries; according to IDF(2019),80% of the diabetes burden is in these countries and looking at the entire African continent, it accounts for 16 million diabetic patients alone, and numbers are expected to rise to 41 million by 2045 unless otherwise(IDF, 2019).Equally, hypertension prevalence in Africa is about 46% among the adult population(Nulu, Aronow, & Frishman, 2016). Besides the morbidity burden, these countries are faced with a high mortality rate; the WHO estimated out of the reported 17 million deaths from NCDs in 2015, 82% were from LMICs. Most of which were premature deaths, standing at a rate of 42%. Statistics show this is way higher compared to the 4% in developed countries(WHO, 2018). Despite the high morbidity and mortality in resource constrained settings there still intra variation in comorbidity occurrence as reported by Hurst et al. (2015) and Mohan et al. (2013);Southeast Asia region was found to have an association range of between 20.6% and 78.4%, and the African region to be 9.7% and 70.4%(Hurst et al., 2015; Mohan, Seedat, & Pradeepa, 2013). This means countries need to consider the existing dynamics even as they strategize and develop interventions to strengthen the health system for timely allow population-based screening, treatment, and management.

In Kenya, CVDs are the leading cause of mortality among NCDs cluster accounting for 13% of deaths and 25% of hospital admissions (MOH Kenya, 2018). The 2015 WHO-Kenya STEP-wise survey revealed that that 24% of the population have either raised blood pressure or are under hypertension treatment plan. The survey further shows low adherence to medications among those

diagnosed; only 8% of those living with hypertension are on treatment, and only 4.6% of those on treatment have their blood pressure well-controlled (Mohamed et al., 2018). Its evident more needs to be done to create awareness and increase access to quality care, as the comorbid condition maybe be asymptomatic. Above and beyond the mortality and morbidity burden, hypertension-diabetes Mellitus poses a greater social and economic burden on individuals, families, communities, and the health system (Robinson & Hort, 2012), and due its chronic nature they have the potential to push individuals to poverty due to catastrophic health spending (MOH Kenya, 2015a).

2.3 Overview of the Kenya health system to manage hypertension-diabetes Mellitus comorbidity

In 2013, Kenya devolved public health services from a single central government to 47 county governments. Health service delivery is organized around a four-level system: community services, primary health services, county referral services, and national referral services. The national referral facilities are the apex of the health care system in the country providing sophisticated curative and rehabilitative services. County and sub-county referral hospitals provide specialized care and oversee the implementation of health policies at the lower level of care, mostly primary care facilities and the community level. Community health is the lowest level of the care pyramid tasked with creating awareness of preventive health measures and positive health-seeking behavior to drive demand for health services at the primary care level, which is the first contact of the health system with the patient (MOH Kenya, 2013b).

The primary health care (PHC) facilities are designed to provide the stated scope of services to a catchment population of over 40,000. They are usually equipped with basic infrastructure and equipment to provide curative, minor surgical services, uncomplicated maternity services, and identify conditions that necessitate referral to higher levels of care. In terms of staffing, these facilities are staffed by a mainstream staff comprising of nurses, clinical officers, and occasionally resident or visiting medical doctors, depending on the county mapping of human resources of the facility's health and health conditions. Sometimes augment their service coverage with outreach services for populations that cannot access health facilities that are funded by not-for-profit-making organizations or the corporate social responsibility arm of companies(MOH Kenya, 2013b; Muga, Kizito, Mbayah, & Gakuruh, 2005)

Ideally, to treat and manage hypertension and diabetes comorbid, PHCs are mandated to provide health promotion, conduct population screening, diagnose, and provide treatment on an outpatient basis(Muga et al., 2005). However, the approach of service delivery in Kenyan public health facilities varies. Screening is conducted on suspected and prone cases only during routine triage; while diabetes screening is done after a clinician recommends or during dedicated outreach activity for diabetes, this leaves room for undiagnosed cases(MOH Kenya, 2015b).

To help improve the quality of care within these health facilities, the national Ministry of Health (MOH) recently formulated a cardiovascular disease management guideline to streamline care across the entire health services provision continuum. This is a strategic move in achieving UHC and affordable healthcare for all Kenyans, guaranteeing a healthy nation working towards Sustainable Development Goals and prosperity. To disseminate the guidelines countrywide, MOH, in collaboration with the department of health in the County government, has been training healthcare workers.

2.4 Cardiovascular management guidelines for Primary Health Care

There is no universal guideline for hypertension-diabetes Mellitus but rather a wider one for cardiovascular diseases encompassing treatment protocols for diabetes mellitus only and hypertension only. Therefore, to treat and manage hypertension-diabetes comorbidity there is the need to look at each guideline individually. According to Kenya's cardiovascular guideline (2018), the primary care facilities should be staffed with nurses, clinical officers, nutritionists, medical officers, laboratory personnel, radiographers, pharmacists, and/or pharmaceutical technologists to support the treatment and management of the medical outpatient clinic (MOPC). The guideline further recommends the availability of basic equipment and reagents such as a glucometer, hematology equipment, thermometer, height meter, strips for urinalysis, blood pressure measurement equipment, stethoscope, electrocardiogram (ECG) machine, X-ray, and weighing scale for better diagnosis and treatment at the primary care level. Provision of nutritional advice has also been flagged as one of the mandatory workflows for PHC MOPC since most of the clients present with weight management issues which further increase their risk of macro vascular and micro vascular complications. The guideline further defines the expected laboratory procedures required to ascertain the presence of hypertension and T2DM(MOH Kenya, 2018).

2.4.1 T2DM treatment and management guidelines

Diagnosis for diabetes is through laboratory measurement of fasting capillary glucose in blood samples. T2DM diagnosis guideline recommends specific measurements for all clients aged 40+ years old such as waist circumference, blood pressure, fasting or random plasma glucose, urine protein, urine ketones, plasma cholesterol, and testing of foot pulses (Who, 2012). Additional tests for persons with T2DM are screening for diabetic retinopathy by an ophthalmologist once diagnosed and every two years thereafter, or as recommended by the ophthalmologist(MOH Kenya, 2018).

2.4.2 Hypertension treatment and management guidelines

According to Kenya's cardiovascular guideline (2018), hypertension is diagnosed positive when the blood pressure (BP) reading is greater than 140/90 mmHg on three separate readings(MOH Kenya, 2018). Most hypertensive patients are asymptomatic, making it necessary to conduct additional investigations, including urea and creatinine lipid profile, chest X-ray, and echocardiogram.

Additionally, cardiovascular guideline defines the essential medicine that primary health facilities can prescribe to patients with hypertension and diabetes comorbidity. They include a Thiazide-like diuretic, calcium-channel blocker, ACEI/ARB, Furosemide, Statins, Aspirin, plus oral hypoglycemic agents (OHA for treatment and management of hypertension and T2DM (MOH Kenya, 2018). Besides drugs, health facilities require consumable products for optimal functionality, products that do not return to the storeroom once they have been dispensed. Examples of consumables include syringes, gloves, and disinfectant fluids to carry out basic tests for comorbid patients. At the MOPC, most of the consumable products are utilized in the laboratory while conducting tests and occasionally during consultation.

2.5 Health system challenges to manage hypertension-diabetes Mellitus comorbidity

Traditionally, most health systems in developing countries are oriented to manage communicable diseases and are only beginning to cope with the rising burden of NCDs(Islam et al., 2014). The few healthcare facilities that can help screen, treat, and manage comorbidity are urban-biased and favor high-income households(Chikafu & Chimbari, 2019; Lulebo et al., 2015).There are inadequacies in the health system to provide care and management for patients with diabetes and

hypertension comorbid conditions. A study done in Kenya found PHCs have limited screening expertise and infrastructure, which make it hard to detect and initiate appropriate medical attention, leading to late detection and at very advanced stages of disease progression(Marwa, Gugu, & Mtshali, 2017). A nationwide assessment of health facilities' performance in Kenya further documented inadequate laboratory equipment; more than half of public level 3s and dispensaries did not have the equipment to test blood glucose, which is critical to test to diagnose diabetes and monitor blood sugar levels(Institute for Health & Evaluation, 2014). The ripple effect of these health system inadequacies is witnessed in the health outcome as documented in the WHO-Kenya STEP-wise survey, where more than half (56%) of Kenyans have never been tested for raised blood pressure (MOH Kenya, 2015b).

Training of health professionals also plays a crucial role in the management of the condition; studies done in Kenya show gaps in Continuous Medical Training (CMEs) among clinicians hindering their capacity to perform a timely diagnosis, and treatment and conduct timely and proper referrals to avoid complications. A study by Mwai et al. indicated an increased number of referrals to higher-level facilities from PHCs, and because of poor seeking behavior, most patients take longer before seeking care or fail to seek care altogether, which potentially leads to poor outcomes and further complications(Mwai, 2017; Price et al., 2018).

Care delivery guidelines on the prevention and treatment of NCDs have been developed to serve as clinical decision-making tools for physicians as well as other healthcare providers who work toward achieving care goals and making appropriate referrals in case an anomaly is detected. However, in most health facilities, the availability of these guidelines is low leave alone adherence, as demonstrated by Thandi et al. (2015). The authors reported poor adherence by healthcare workers and compliance with care guidelines declined with subsequent visits, contributing to increased costs of care and poor quality of life (Thandi, Jalang'o, & Tsolekile, 2015).

A review of literature in five countries in Sub-Saharan Africa by Chikafu and Chimbari, shows low utilization of health services among comorbid patients despite the increasing prevalence in the region (Chikafu & Chimbari, 2019). The low utilization is attributed to several factors, including poor knowledge of the risk factors, poor health-seeking behaviours because of distance, age, gender, and economic activities they are engaged in besides exorbitant healthcare costs to access medicines and conduct required biochemical investigations. This is fostered by limited budget

allocation to PHCs as reported in resource-poor settings such as Bangladesh (Huque et al., 2018; Stewart & Sliwa, 2009)

2.6 Economic effect of hypertension-diabetes Mellitus comorbidity

Over 85% of NCD-related premature mortality occurs in LMICs, where the most productive age groups (30 to 70 years) are affected (WHO, 2018). The high burden of hypertension-diabetes Mellitus comorbidity is associated with significant economic and societal costs that threaten the quality of life of households due to catastrophic expenditure and overburdens the health systems, broadly jeopardizing the attainment of UHC (Marwa et al., 2017). For instance, hypertension alone has been estimated to cost approximately 4.5% of the global disease burden due to its long treatment period and a loss of $3,633 per diabetic patient (Oladimeji et al., 2018). A study done in 2009 estimated the economic burden of diabetes in the WHO African region countries, where 7.02 million cases of diabetes resulted in a total economic loss of $25.51 billion (Kirigia, Sambo, Sambo, & Barry, 2009). Developed countries also have reported a high economic loss due to NCDs. Premature diabetic patient deaths are predicted to cost the American economy USD 19.9 billion yearly, and diabetes is also indirectly responsible for USD 90 billion.(America diabetes, 2018; IDF, 2019).

To manage the disease comorbidity, years of investment in the entire health continuum by governments, private sectors, and development partners in health need to encourage timely screening, access to treatment, and referral to prevent complications among those already diagnosed. Most countries in Africa incur huge costs to treat and manage NCD patients. An economic cost analysis done in the WHO countries in Africa found that the direct costs incurred by countries with Gross National Income of less than 2000, was approximately $6.7 billion. The cost increases 2 to 3.5-fold once the patient develops complications. Hospitalization costs account for the largest proportion (30-65%) of the overall cost (Kirigia et al., 2009). The situation is not any different in developed countries, a study comparing the economic cost of diabetes in the US between 2012 and 2017 showed an increase in the national prevalence of the disease by 11% and a 13% increase in the average annual diabetes-attributed cost per person. The study also found medical costs as the major cost driver associated with the management of diabetes, with the largest portion of the costs going into the care of comorbid patients(America diabetes, 2018). Diagnosis delays can directly increase complications and lead to higher direct and indirect costs. In SSA, the cost of diabetes is estimated at US$ 19.45 billion as of 2015. The main cost drivers include

hospitalization, physician services, laboratory tests, and drugs (Moucheraud et al., 2019). Without a doubt, the comorbid condition largely influences a country's economy not only in terms of high cost but also in lost productivity and income that could have been realized. Therefore, there is a need for a multidisciplinary approach to managing this situation.

2.7 Costing models

Methods of costing health services depend on the source of expenditure data, type of data, costing approach, and who bears these costs (public provider, private provider, or the patient) because costing studies tries to inform different decision-makers (Drummond et al., 2002; Mogyorosy & Smith, 2005). According to Abdulkadir et al. (2009). Different approaches have been employed in studying the economic burden of illnesses such as cost of illness, microeconomics, and macroeconomics. Overall, the cost of illness approach has been widely applied in the estimation of the economic burden of diseases (Nugent, 2008).

Expenses and benefits included in the analysis depend on the perspective of the study. Two common perspectives are; societal perspective, which accounts for all costs and benefits, and the provider or patient's perspective, which makes use of part of the data.(Frick Kevin, 2009). Choosing appropriate methods to estimate costs in healthcare is crucial as it provides vital information on the funds likely to be required for specific health services, assesses the use of personnel in delivering the health service, and the efficiency of supplies and other inputs. Conventional costing methods consider two main aspects: how the cost is identified and how it is valued. Combining these dimensions gives four standard costing methods, micro-costing, or gross costing for identification and top-down or bottom-up for valuation (Drummond et al., 2002).

Micro-costing focuses on a granular accounting of inputs. It breaks down the expenses of a certain output into the components that are utilized, such nursing time and consumable supplies. Whereas gross costing, only considers total expenditures. It simply estimates all relevant costs, typically from program expenditure data, and divides by the associated outputs such as patient episodes. Gross costing may also be done using tariffs and fees(Frick Kevin, 2009). Top-down, on the other hand, describes how each resource is assigned to the projected unit cost. While "bottom-up" costing measures input quantities at the client or activity level, "top-down" costing divides total program costs or expenditures, which frequently include those above the service level, by the

number of outputs to get the unit cost. Top-down gross costing is typical, whereas bottom-up micro costing often measures resource and service utilization directly at the patient level.(Xu, Nardini, & Ruger, 2014).

In practice, to deal with missing data and/or gathering data that is frequently not gathered, many studies employ a mixed method costing technique. (Mogyorosy & Smith, 2005; Špacírová et al., 2020; Xu et al., 2014). The most common analysis approach is top-down micro-costing (49%), followed by top-down gross-costing (37%) and bottom-up micro-costing (14%) based on a study done by (Špacírová et al., 2020).

To estimate the total costs, it is important to identify all the relevant costs (direct and indirect). Direct costs are those costs, which can be directly linked to the use of resources. They include (drugs, medical equipment, diagnostics, hospitalization, consultations, nursing, medical transport, etc.) and indirect costs, i.e., economic losses caused by decreased productivity of employees (presenteeism) due to temporary and/or permanent disability, their absence from work caused by sickness (absenteeism) and premature death (Abdulkadri, Cunningham-myrie, & Forrester, 2009).

A systematic review of the cost of hypertension by Wierzejska et al. shows the average total costs of hypertension calculated per person amounted to $ 630.14 and this was seen to be in an upward trajectory from the previous years, thus increasing the financial burden on society and the entire health system in addition to costs from pain and suffering, resources from care provided by nonpaid caregivers (Wierzejska et al., 2020). A similar trend was observed in the United States, where the economic cost of diabetes increased by 26% from 2012 to 2017 (America diabetes, 2018).

The major cost drivers in the treatment and management of hypertension- diabetes Mellitus comorbidity include the cost of laboratory tests, consultations, medicines, imaging, and hospitalization costs, among others (Ngalesoni, Ruhago, Norheim, & Robberstad, 2015; Nguyen et al., 2014). This cost varies with the level of care and whether it's a public or private health structure. A study on NCDs screening, diagnosis, and treatment in Kenya showed that patient's cost to treat and manage hypertension, diabetes, and asthma was modest in the public sector ranging from US $26 to US $ 234 and US $ 418 to US $ 987 in private facilities (Subramanian et al., 2018). This shows that the cost incurred to diagnose and treat hypertension-diabetes Mellitus is significant even in the public sector. Besides being subsidized by the government representing a substantial economic burden that can result in catastrophic expenditures.

To determine the unit costs of a particular service, the total departmental costs are calculated and later share out the total departmental costs between different services. The costs assigned to one unit of service, or one patient will depend on the number of patients treated or services provided (Shepard, Hodgkin, & Anthony, 2000). There are several ways to calculate unit costs, although most methods follow the full absorption cost principles. This means that all costs (direct and indirect) relating to the provision of a particular service are included in the cost calculation (Mogyorosy & Smith, 2005). Thereafter, to estimate the economic unit cost per patient per visit, the total number of patients seen is divided by the total number of visits. A study conducted at Tanzania, level 3 and hospital levels estimated the unit economic cost of providing cardiovascular medical primary preventive services varied from US$30-41 to US$52-71 per patient per year, respectively. (Ngalesoni et al., 2015).

2.7 Conceptual framework

The conceptual framework was organized based on the variables thought to influence the affordability of hypertension-diabetes Mellitus comorbidity.

Definition and measurement of variables

Table 1. Study variables and their assessments

Variable	Definition and Method of assessments
Affordability of hypertension-diabetes comorbidity	Defined as the unit economic cost of hypertension-diabetes comorbidity at the primary health facilities being the dependable variable of interest. Captured a continuous variable computed as the unit economic cost of hypertension-diabetes comorbidity estimated at Ksh 337.00 and categorized as affordable when < Ksh. 377.00 and unaffordable when > Ksh. 377.00
Independent variables	
Age	Referred to the age of the hypertension-diabetes Mellitus comorbidity patient at the time of the study. Captured in years, and categorized as <20, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79, and ≥ 80
Sex	This was captured as male or female
Residence	This was captured as rural or urban
Marital status	Referred to hypertension-diabetes Mellitus comorbidity patient situation. Captured as married, never married, divorced/separated, or widowed
Education level	Captured as none, primary, secondary, college, university
Family size	Defined as the number of members the hypertension-diabetes Mellitus comorbidity patient is residing within his/her household. Entered as continuous, and categorized as 1-3, 4-6, 7-9, and ≥10
Occupation	Defined as the current job engaged by the hypertension-diabetes Mellitus comorbidity patient to earn a living. Captured and categorized into unemployed, self-employed, informally employed, formally employed
Level of income	Described as the amount realized by the hypertension-diabetes Mellitus comorbidity patient from the occupation engaged in.

	Captured as continuous, and categorized as Ksh ≤1000, Ksh 1,001-10,000, Ksh 10,001-20,000, and Ksh >20,000.
Drug availability	Referred to whether hypertension-diabetes Mellitus comorbidity patients accessed all the prescribed drugs at the time of the visit. This was entered as yes or no

The conceptual framework was organized based on the variables above. The predictor-outcome relationship is displayed in figure 1.

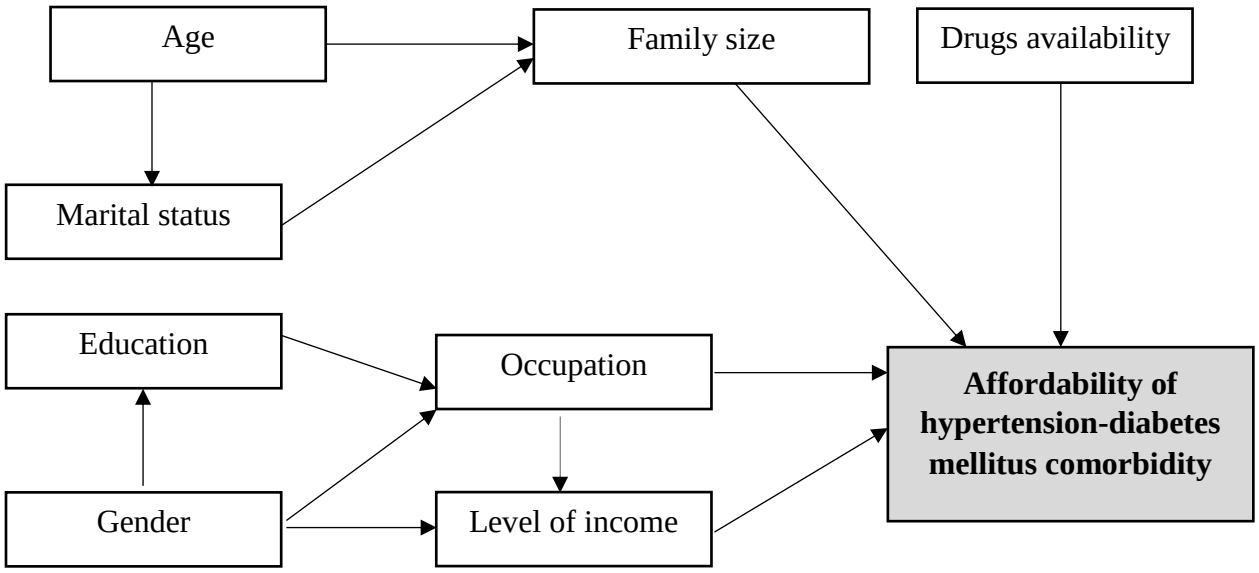

Figure 1: Casual diagram of factors thought to influence affordability of hypertension-diabetes Mellitus comorbidity

2.8 Overview of Literature

Primary care facilities are closer to the people, decentralizing care of hypertension-diabetes Mellitus will not only decongest higher levels of care but also increase early and timely access to care improving outcomes and minimize catastrophic health expenditure among the affected and infected. To effectively do so there is a need to determine the economic unit costs to inform health budget allocation.

CHAPTER THREE: METHODOLOGY

This chapter describes the research methods used in the study, including the study design and setting, study population; data collection; and data analysis.

3.1 Study design and settings

The study adopted a hospital-based analytical cross-sectional design to estimate the economic cost of hypertension-diabetes Mellitus comorbidity in public primary health facilities in Kiambu County, Kenya and assess affordability of hypertension-diabetes Mellitus comorbidity. The study used Activity-Based Costing (ABC) techniques-a system of assigning overhead and indirect costs such as utilities and salaries to specific services such as laboratory- to estimate caseload (prevalence data) of hypertension-diabetes Mellitus comorbidity for a one-year time horizon to estimate the unit economic costs. Further, an ingredient approach was used to gather data retrospectively on the cost drivers of hypertension-diabetes Mellitus comorbidity from health care providers' perspectives. The study used a one year time horizon from 1st January 2020 and 31st December 2020. The study was conducted in four health facilities consisting of two level-two health facilities (Magina and Githunguri dispensaries) and twolevel-three health facilities (Kagaa and Githurai-Langata health centers) situated in two sub-counties, Ruiru and Lari inKiambu County.

According to the 2019 census, the county has a population of 2,417,735 Ruiru sub-county having a population of 371,111 and Lari sub-county having 135,303. A study by the MoH 2014 ranked the county second with the highest number of NCDs cases, approximately 126,754 (MOH, 2014).The health system follows tiered public referral system, and comorbid patients in need of specialized care are referred to a higher level of care, either public or private. Following the public health system, patients from the Ruiru sub-county are referred to the Ruiru sub-county hospital, Gatundu or Thika level 5 hospital, while patients from the Lari sub-county are referred to Lari sub-county hospital or Tigoni hospital.

3.2 Sampling techniques

This study utilized a multi-stage sampling technique. The first stage involved sampling public primary health facilities with high caseloads of hypertension-diabetes Mellitus comorbidity.

Followed by purposive sampling of the four study sites in consultation with the Kiambu county department of health to provide the rural and urban dynamics. Magina and Kagaa were selected as rural health facilities, while Githunguri and Githurai Langata were selected as urban health facilities.

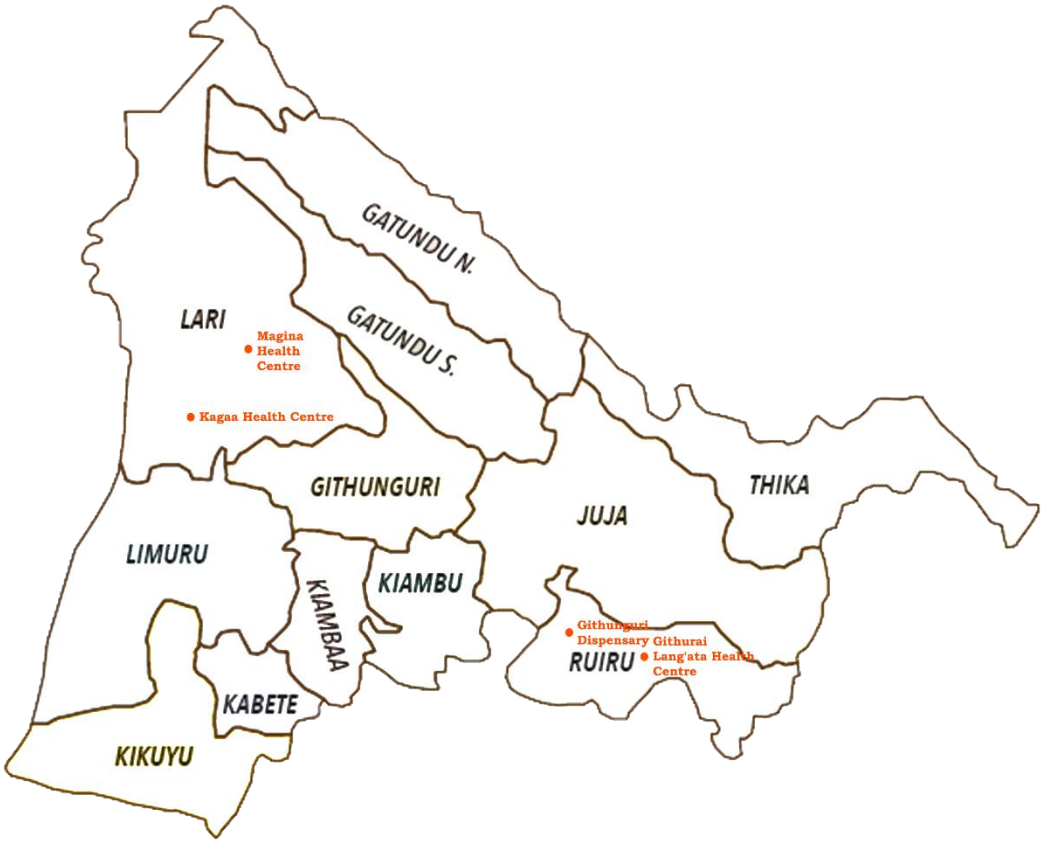

Figure 2: Map of Kiambu County showing selected health facilities

3.3 Study population and eligibility criteria

All patients with hypertension-diabetes mellitus comorbidity who visited medical outpatient clinics between January 1 and December 31, 2020, made up the study population. Cases were defined as patients diagnosed with hypertension-diabetes Mellitus comorbidity in the tertiary level of care and referred for the continuation of care in the medical outpatient clinic in primary health facilities. Cases with other complications and/or comorbidities, including cognitive heart failure, stroke, and dementia, were excluded from the study.

3.4 Study perspective, time horizon, and discount rate

The cost data were collected retrospectively from a health provider perspective over a period of one year, 1st January 2020 and 31st December 2020. The health provider perspective was used to and only the direct medical costs are included but productivity losses and patient-related costs from the patient perspectives were excluded. The discount rate was not considered in this study because only current costs were used for the analysis.

3.5 Data collection process

Before the study began, the primary investigator hired and trained two research assistants with bachelor's degrees in public health to assist with data collection. The PI engaged the assistants through a discussion on how to abstract data and document study findings. The data collection spanned two months, from 1st August 2021 to 31st October 2021. We adopted an ingredient approach to retrospectively collect prevalence-based data on cases for the cost analysis of treatment and management of hypertension and diabetes mellitus comorbidity in a medical outpatient clinic. The cost ingredients included: personal remunerations, supervisory staff-time, equipment and furniture, essential medicines, non-pharmaceutical products, utility charges, and building space for rental. The prevalence-based morbidity data were abstracted from the medical outpatient registers. The information captured in these registers were personal identification number, patient's name, date of the next clinic visit, patient's age, residence, and diagnosis, among others. A predefined inclusion criterion determined 712 and 1032 cases for level 2 and level 3. Associated cost drivers were also identified, measured, and valued following the prevailing market prices and entered an already predefined data abstraction tool. On the other hand, staff time for hospital management, comprising the medical superintendent, the nursing officer in charge, and the health facility administrator, was collected qualitatively through interviews. Additionally, they were engaged to clarify costs that might not be clear and provide context with which to interpret quantitative information. The data gathered comprised of the following:

Comorbidity data/cases: Comorbid cases, 712 in the level 2 and 1032 in level 3 were considered for the cost analyses. Other comorbidities besides hypertension and diabetes mellitus were excluded, and various stages of hypertension were excluded. A sample of 105 cases from all the study sites was interviewed to assess how their sociodemographic and health utilization factors were associated with estimated economic costs to provide care in a public primary care facility.

Equipment and furniture: Equipment and furniture were identified and quantified along the patient clinical pathway; namely, triage, consultation, laboratory, and pharmacy were considered. Dispensaries and level 3sare equipped similarly but with varying quantities. At triage, they are equipped with blood pressure monitor machines, an adult weighing scales with height meter, office desks, office seats, and waiting benches. Consultation rooms have stethoscopes, examination couches, office desks, and seats. At the laboratory, for the benefit of comorbid patients, the facilities are equipped with glucometer and urine analyzer but only in the level 3s. At the pharmacy, dispensaries have no furniture or fixtures while level 3s have tablet counter and counting tray.

The prevailing market price was used to determine the costs, sourced from the KEMSA website. The study considered costs only; brand name and year of manufacturer were excluded. The annualized cost of the devices was not considered in the study.

Staff remuneration: The healthcare personnel involved full-time in the provision of care at the two levels of care were identified, valued, and costed. Level 2medical outpatient clinic comprised of specialized clinical officer, specialized nurse, laboratory technologist, and pharmacy technologist. While the level 3, had a nutritionist as an additional direct key staff.

The costs were estimated following the allocation of remuneration based on time spent on the MOPC. The remuneration was based on their respective service scheme for staff with at least 10 years of work experience. Their pay included basic salary plus other benefits such as house allowance, commuter allowance, health risk allowance, extraneous allowance, and uniform allowance. The monthly salary of clinical officer at Grade “CSG9” was valued at Ksh 106,000, nurse at Grade “C3” was valued at Ksh.101,000, and support staff at grade “B3” was valued at “Ksh. 25,000”. While the time spent on offering services at the dispensaries was estimated based on 8-hour day fortnightly and weekly for level 3 facilities.

Supervisory Staff time: The staff-time was only applicable to the level 3s personnel, and the team comprised of the medical doctor in charge, nurse officer in charge, and health administrator whose allocation was identified and measured through professional judgment and the data was collected through face-to-face interviews with them. The staff-time for medical superintendent was measured as specialized medical practitioner’s consultant valued at Ksh 11,363 per 8-hour

workday and quantified for 4 hours per day, adding to 208 hours in one calendar year. The staff-time for the health facility administrator was measured as a consultant and valued as Ksh 3409 per day, assuming an 8-hour workday, and quantified for half an hour a day for 26 hours in calendar year. The nursing officer in charge consultant daily rate was valued at Ksh 8,181 per day, assuming 8-hour workday for 52 hours in year.

Essential medicines: The antihypertensive and ant diabetics dispensed were identified, measured, and valued. Drugs acquisition costs were determined from the KEMSA online product catalogue portal. The stages of hypertension and type of therapy as, either monotherapy or polytherapy were not considered in the study. Qualitative data collection revealed that KEMSA supplied drugs on quarterly basis.

Non-pharmaceutical products: The unit costs were determined from KEMSA online product catalogue and calculated from KEMSA quarterly supply. Insights from qualitative interviews with the nurse, and pharmaceutical technologist showed approximately 20% of the total acquired items were utilized in the MOPC for comorbid patients.

Utility charges: Utilities included electricity, water, and sewerage estimated at 15% and 10% of the rental building space respectively. This is line with rental estimates costing.

Renting building space: within respective study hospital medical outpatient clinics were identified whose floor surfaces were measured in square feet and valued using current market prices for renting. The renting space for dispensaries was estimated at 80 square feet and valued at Ksh. 3,000.00 local market prices. Whereas level 3 renting space was estimated at 144 square feet and valued at Kshs.4,500 local market price. The costs were assumed to be similar irrespective of the rural and peri-urban dynamics.

3.6 Data processing and analysis

Following collection of data, the two research assistants separately entered both the primary data obtained through interviews and the secondary data abstracted into a Microsoft Excel spreadsheet to avoid bias and potential errors. The principal investigator cross-checked the digital data against the predefined abstraction tool for computation using Microsoft Excel Spreadsheet. Descriptive statistics, including frequencies and percentages, were used to summarize categorical variables, whereas continuous variables were summarized and presented in means. Additionally, univariable

logistic regression analysis was carried out to assess the effect of each variable on the odds of affordability at P-value (P≤0.20). Firstly, all the continuous variables were categorized into groups before they were fitted into the model. Age for instance was categorized as <20, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79, and ≥ 80. The family size which was entered as continuous was categorized as 1-3, 4-6, 7-9, and ≥10, and levels of income were categorized as Ksh ≤1000, Ksh 1,001-10,000, Ksh 10,001-20,000, and Ksh >20,000. Afterwards, variables that were found to be statistically significant in the univariable analysis were fitted to a multivariable logistic regression analysis, The P-value of <0.05 was a threshold of determining the variables that were associated with the affordability of the hypertension-diabetes Mellitus comorbidity, those whose P-value >0.05 were eliminated. Two-way interactions were fitted between the remaining variables of the final model and assessed for significance. All the logistic regression analyses were done using Stata software (version 14).

3.7 Unit costs, Currency conversion, and study assumptions

The unit economic costs were computed by dividing the total economic costs of hypertension-diabetes Mellitus (numerator) and the total caseload (denominator). The unit economic cost for hypertension-diabetes Mellitus at level 2 health facilities by dividing the caseload and costs at level 2. Similarly, the unit economic costs of level 3 were calculated by dividing the total economic costs (numerator) by the prevalence data of hypertension-diabetes Mellitus (denominator) at the level 3 health facilities. To calculate the unit economic cost for the primary health facility, the total costs of both levels of care were added (numerator) divided by total caseload of both facilities. Direct costs included labor costs for full-time employees, essential medicines, non-pharmaceutical, equipment, and furniture whereas Overheads costs, on the other hand, included number of medical doctors, nursing officers and health facility administrative and their associated time as well as utility charges for electricity, water, and sewerage. The unit economic expenses were initially determined in Kenyan shillings and then converted to U.S. dollars using the Ksh 107 average exchange rate for the year 2020.

3.8 Minimization of errors and biases

Information, participant, and recall were potential biases in this study. Information bias was reduced by developing a pre-defined abstraction tool and training data assistants on the secondary data collection techniques and data entering process. Participant bias was avoided by asking open-ended questions to engage the study participants instead of yes/no questions. Questions were asked in different ways when the answers did not sound true. Recall bias, especially for the cost data, was overcome by looking at the trend, as most information is based on the use of historical data to estimate.

3.9 Ethical Clearance

Authorization to carry out the study was sought from Kenyatta National Hospital/University of Nairobi Ethical Research Committee (P114/02/2021), a research permit was obtained from the National Commission of Science and Technology (NACOSTI/P/21/12129), and authorization to conduct the study was sought from the County health department and the health facility in-charges. Participants in the study who were taking part in interview sessions were asked for written informed permission. Unique identifiers were utilized instead of collecting personal identifying information like names, phone numbers, and personal identity numbers in order to maintain privacy and confidentiality.

CHAPTER FOUR: RESULTS

This section elaborates on the results obtained from the study in relation to the above objectives.

4.1 Descriptive statistics

The total number of respondents was 105. Majority of the respondents were female (Female = 70.5%, Male = 29.5%). Most of them were married (75.2%) and resided in rural areas (Rural = 67.6%, Urban = 32.4%). The level of education for many of the participants was primary (46.7%), and a huge number of them were self-employed engaging mainly in subsistence farming and micro businesses (80%). The mean age of the patients was 55.3 years (SD 13.6), the minimum age was 12.0 years, and the maximum was 81.0 years. The mean income of the hypertension-diabetes Mellitus comorbid patients was Ksh. 6,429.5 (SD 7,383.7), the minimum was Ksh. 400.0 and maximum Ksh. 40,000.

The mean drug price of the patients was Ksh. 670.4 (SD 701.0), the minimum was Ksh. 40.0 and maximum Ksh. 5,000, while the median Ksh. 500.0 (IQR 300.0 – 780.0) Furthermore, more than half of cited drugs were unavailable during their routine visits (No=58.1%, Yes = 41.9%).

The mean charge for consultation of the patients was Ksh. 3,449.2 (SD 6,583.0), the minimum was Ksh. 50.0 and maximum Ksh. 30,000, while the median Ksh. 1,000.0 (IQR 300.0 – 3000.0)

Table 2. Descriptive statistics of the study participants (N=105*)*

Variable	**Frequency (n=105)**	**Percent (%)**	**Cumulative percent (100%)**
Gender			
Male	31	29.5	29.5
Female	74	70.5	100.0
Age			
<20	1	1.0	1.0
20-29	2	1.9	2.9
30-39	7	6.7	9.6
40-49	28	26.7	36.3
50-59	26	24.8	61.1
60-69	24	22.9	84
70-79	14	13.3	97.3

>=80	3	2.9	100.0
Marital status			
Married	79	75.2	75.2
Never married	6	5.7	80.9
Divorced/Separated	7	6.7	87.6
Widowed	13	12.4	100.0
Family size			
1-3	11	10.5	10.5
4-6	55	52.4	62.9
7-9	35	33.3	96.2
≥10	4	3.8	100.0
Residence			
Rural	71	67.6	67.6
Urban	34	32.4	100.0
Education level			
None	19	18.1	18.1
Primary	49	46.7	64.8
Secondary	33	31.4	96.2
Tertiary	4	3.8	100.0
Occupation			
Formally employed	4	3.8	3.8
Informally employed	7	6.7	10.5
Self-employed	84	80.0	90.5
Unemployed	10	9.5	100.0
Level of income (Ksh)			
≤1000	20	19.0	19.0
1,001-10,000	70	66.7	85.7
10,001-20,000	10	9.5	95.2
>20,000	5	4.8	100.0
Drug availability			
Available	44	41.9	41.9
Unavailable	61	58.1	100.0

4.2 Cost of providing care at the level 2 level

4.2.1 Equipment identification and cost estimation at level 2

The total cost estimate of equipment at level 2 was valued at Ksh. 220,000(US $ 1869) as shown in Table 3 below.

Table 3. Identification, measurement, and valuation of equipment, and furniture at the level 2

Clinical pathway	**Item description**	**Quantity**	**Unit cost (Ksh)**	**Total cost (Ksh)**	**Total cost (US $)**
Triage	Automatic upper arm Blood pressure monitor machine with cuff[1]	4	6,500.00	26,000.00	242.99
	Digital adult weighing scale & height meter, one per health facility	2	18,500.00	37,000.00	345.79
	Stethoscope, one per health facility	2	6,000.00	12,000.00	112.15
	Office desk, one per health facility	2	5,500.00	11,000.00	102.80
	Office seat, one for the patient, and the nurse per health facility	4	4,000.00	16,000.00	149.53
	Waiting bench-wooden and metallic[2]	4	6,500.00	26,000.00	242.99
Consultation	Office seat, one for the patient, and the nurse per health facility	2	4,000.00	8,000.00	74.77
	Examination couch, one per health facility	2	17,500.00	35,000.00	327.10
	Office desk, one per health facility	2	5,500.00	11,000.00	102.80
Laboratory	Glucometer, two per facility	4	4,500.00	18,000.00	168.22
Total cost				**200,000.00**	**1,869.16**

4.2.2 Identification, measurement, and valuation of essential medicine at the level 2

The study found Enalapril, hydrochlorothiazide and Losartan quantities to be more among the antihypertensive and Metformin among the antidiabetics. The estimated total cost of drugs was valued at Ksh. 460,360 (Table 4).

Table 4. Quantification of essential medicines for comorbid patients at level 2

Inputs	**Packaging of drugs**	**Quantity**	**Unit cost (Ksh)**	**Total cost (Ksh)**	**Total cost (US $)**
Antihypertensive					
Amlodipine 5mg	100s	16	200.00	3,200.00	18.82
Nifedipine 20mg	100s	160	360.00	57,600.00	338.82
Hydrochlorothiazide 50mg	1000s	512	360.00	184,320.00	1,084.24
Enalapril 5mg	28s	640	70.00	44,800.00	263.53
Enalapril 10mg	28s	176	250.00	44,000.00	258.82
Losartan 50mg	30s	396	70.00	27,720.00	163.06
Losartan Potassium 50mg+ hydrochlorothiazide 12.5 mg	30s	520	60.00	31,200.00	183.53
Atorvastatin 20mg	30s	128	80.00	10,240.00	60.24
Cardisprin 75mg	28s	64	65.00	4,160.00	24.47
Anti-diabetic					
Metformin 500mg	30s	192	35.00	6,720.00	39.53
Ascard	30s	80	580.00	46,400.00	272.94
Total cost				**460,360.00**	**`4,302.43**

4.2.3 Identification, measurement, and valuation of non-pharmaceutical products

Non-pharmaceutical products were the least costs amounting to Ksh. 74,338 (Table 5).

Table 5.Quantification of non-pharmaceutical products at level 2 level

Items	**Packaging**	**Quantity**	**Unit cost (Ksh)**	**Total cost (Ksh)**	**Total cost (US $)**
Cotton wool	Roll	4.2	800.00	3,360.00	31.40
Disinfectant fluid	Liters	15	1280.00	19,200.00	179.44
Disposable surgical rubber gloves	50 pairs	13.4	1070.00	14,338.00	134.00
Syringes, insulin,1mlwith 29G	100s	46.8	800.00	37,440.00	349.91
Blood glucose test strips	50 packs	18	1900	34,200.00	319.63
Total cost				**108,538.00**	**1,014.38**

4.3.4 Quantification and measurement of labour

The labor costs for the dispensaries were valued at Ksh 796,800 (US $ 7,446) yearly (Table 6).

Table 6.Quantification of labour cost at level 2 level

Cadre	**Gross monthly salary (basic+ allowances)**	**Unit cost (Ksh) hourly salary**	**Number of working hours per year (8*2*12)**	**Number of staff***	**Total cost (Ksh)**	**Total cost (US $)**
Clinical officer	106,000.00	662.50	192	2	254,400.00	2,377.57
Nurse	101,000.00	631.25	192	2	242,400.00	2,265.42
Laboratory technologist	50,000.00	312.50	192	2	120,000.00	1,121.50
Pharmacy technologist	50,000.00	312.50	192	2	120,000.00	1,121.50
Cleaner	25,000.00	156.25	192	2	60,000.00	560.75

Total cost					**796,800.00**	**7,446.73**

*One staff per level 2- costs were estimated assuming 8-hour shift (40-hour week)

4.2.5 Quantification and measurement of rent and utilities

The study revealed both dispensaries incurred a cost of Ksh 72,000 in rent, and Ksh. 10,800 and Ksh. 7,200 for electricity and water at respectively (Table 7).

Table 7.Rent and utilities costs at level 2

Resource inputs	**Item description**	**Quantity**	**Unit cost (Ksh)**	**Total cost (Ksh)**	**Total cost (US $)**
Estimated rent for building space	80 (8x10) square feet	2 health facilities for 12 months	3000	72,000.00	672.90
Utilities	water & sewerage estimated at 10% of the estimated rent	2 health facilities for 12 months	Estimated @ Ksh 300 per month per health facility (300*2*12)	7,200.00	67.29
	Electricity estimated at 15% of the rent	2 health facilities for 12 months	Estimated @ Ksh 450 per month (450*2*12)	10,800.00	100.93
Total costs				**90,000.00**	**841.12**

4.2.6 Total cost and unit cost at level 2

The total economic costs for the two level 2were valued at Ksh. 1,655,698 (US $ 15,474), and the labor cost was the main cost driver contributing to approximately 48%, followed by drugs (28%). Generally, the two components of the health system accounted for at least three-quarters of the costs. Utilities electricity, and water was roughly 1% of the total costs as shown in Table 8.

Table 8.Total economic cost and unit costs per level 2

Resource inputs	**Item description**	**Total cost (Ksh)**	**Total cost (US $)**	**Percent (%)**
Equipment	medical devices and furniture	200,000.00	1,869.16	12.08%
Labour costs	10 health professionals at the two level 2s	796,800.00	7,446.73	48.1%
Drugs	Antihypertensives and antidiabetic drugs dispensed	460,360.00	4302.43	27.80%
Non-pharmaceutical	proportion of non-pharmaceutical products utilized at comorbidity clinic	108,538	1,014.38	6.56%
Estimated renting building space in square feet	80 square feet	72,000.00	672.90	4.35%
Utilities	water and sewerage	7,200.00	67.29	0.43%
Utilities	electricity	10,800.00	100.93	0.65%
Total cost		**1,655,698.00**	**15,473.81**	**100.00%**

The unit economic costs for the level 2were calculated using the formula:

Total cost per level 2

$$=\frac{Totalcost(Equipment+labour+drugs+non-pharmaceutical+rent+utilities)}{Total\ numberof\ level-2\ health\ facilities}$$

$$=\frac{Totalcost(200{,}000+796{,}800+460{,}360+108{,}538+72{,}000+7{,}200+10{,}800)}{2}$$

$$=\frac{1{,}655{,}698}{2}=\text{Ksh. } 827{,}849$$

Total cost per

$$\text{case}=\frac{Totalcost(Equipment+labour+drugs+non-pharmaceutical+rent+utilities)}{Total\ number\ of\ cases}$$

$$=\frac{1{,}655{,}698}{712}=\text{Ksh. } 2{,}325.47\text{per year}$$

Total cost per patient per visit=Total cost per case/Number of visits

=2,325.47/24= Ksh. 96.89

Thus, the unit economic cost for one level-two facility was estimated at Ksh.2,325.75 (US $ 21.73). The cost per patient per visit is estimated at Ksh. 96.89 (US $ 0.91).

4.3 Estimation of the cost of providing care for comorbid patients at level 3.

4.3.1 Quantification of Equipment at level 3

The total cost of equipping the two level 3s was valued at Ksh. 1,107,8800 (US$ 10,354) as shown in Table 9.

Table 9.Quantification of equipment at two level 3

Inputs	Item description	Quantity	Unit cost (Ksh)	Total cost (Ksh)	Total cost (US $)
Triage	Automatic Blood pressure monitor machine- two per health facility	4	6,500.00	26,000.00	242.99
	Adult Weighing scale & height meter, one per health facility	2	18,500.00	37,000.00	345.79
	Patient monitor, one per health facility	2	350,000.00	700,000.00	6,542.06
	Stethoscope, one per health facility	2	6,000.00	12,000.00	112.15
	Office desk, one per health facility	2	5,500.00	11,000.00	102.80
	Office seat, one for the patient, and the nurse	4	4,000.00	16,000.00	149.53
	Waiting bench, three per health facility	6	6,500.00	39,000.00	364.49
Consultation	Office seat	4	4,000.00	16,000.00	149.53
	Examination couch, one per facility	2	17,500.00	35,000.00	327.10
	Office desk, one per health facility	2	5,500.00	11,000.00	102.80
Laboratory	Glucometer	4	4,500.00	18,000.00	168.22
	Blood glucose test strips (50 packs)	24	1,900.00	45,600.00	426.17
	Urine analyzer*	1	96,280.00	96,280.00	899.81
Pharmacy	Tablet counter, one per facility	2	15,000.00	30,000.00	280.37
	Counting tray, one per facility	2	7,500.00	15,000.00	140.19
Total cost				**1,107,880.00**	**10,354.02**

*Available in urban level 3 only

4.3.2 Identification, measurement, and valuation of essential medicines

Similarly, Enalapril, hydrochlorothiazide, Losartan, and Metformin were drugs that were in large quantities in both level 3s. Carvedilol was available in one facility. The cost incurred by the two levels was Ksh. 730,420 (US$ 6,826) (Table 10).

Table 10.quantification of essential medicines for comorbid patients at level 3

Inputs	Item description (packaging of drugs	Quantity utilized by comorbid patients in 2020	Unit cost (Ksh)	Total cost (Ksh)	Total cost (US $)
Antihypertensive					
Amlodipine 5mg	100s	48	200	9,600.00	89.72
Nifedipine 20mg	100s	100	360	36,000.00	336.45
Hydrochlorothiazide 50mg	1000s	316	360	113,760.00	1,063.18
Enalapril 5mg	28s	400	70	28,000.00	261.68
Enalapril 10mg	28s	208	250	52,000.00	485.98
Losartan 50mg	30s	264	70	18,480.00	172.71
Losartan Potassium 50mg+ hydrochlorothiazide 12.5 mg	30s	400	60	24,000.00	224.30
Atorvastatin 20mg	30s	52	80	4,160.00	38.88
Carvedilol 6.25mg	28s	24	200	4,800.00	44.86
Hydralazine 25mg	100s	20	635	12,700.00	118.69
Methyldopa 250mg	1000s	40	2700	108,000.00	1,009.35
Furosemide 40mg	1000s	80	440	35,200.00	328.97
Cardisprin 75mg	28s	120	65	7,800.00	72.90
Anti-diabetic					
Metformin 500mg	30s	328	35	11,480.00	107.29
Metformin 850mg	30s	416	145	60,320.00	563.74
Glibenclamide 5 mg	1000s	120	495	59,400.00	555.14
Digoxin	500s	36	2300	82,800.00	773.83
Mixtard insulin	100 IU/mL, 10ml vial	72	320	23,040.00	215.33
Gliclazide 80mg	28s	144	270	38,880.00	363.36
Total cost				**730,420.00**	**6,826.36**

4.3.3 Identification, measurement, and valuation of non-pharmaceutical products

The additional component at the level 3 was test strips for a urinalysis and was among the key cost drivers. The total cost of non-pharmaceutical products was valued at Ksh. 236,564 (US $ 2,210) for both health facilities, and approximately Ksh 118,282 per facility (Table 11).

Table 11.Quantification of non-pharmaceutical products at level 3

Inputs	Item description	Quantity	Unit cost (Ksh)	Total cost (Ksh)	Total cost ($)
Cotton wool	Roll	7.4	800.00	5,920.00	55.33
Disinfectant fluid	Liters	22.8	1280.00	29,184.00	272.75
Disposable surgical rubber gloves	50 pairs	22	1070.00	23,540.00	220.00
Syringes, insulin, 1 with 29G	100s	111.6	800.00	89,280.00	834.39
syringes, insulin,1ml with 30G	100s	10.8	800.00	8,640.00	80.75
Test strips for urinalysis	50 packs	80	1000.00	80,000.00	747.66
Total cost				**236,564.00**	**2,210.88**

4.3.4 Quantification and measurement of labor

The costs were valued at Ksh. 3,191,311 (US $ 29,825) for study sites (Table 12).

Table 12.Quantification of level 3 labor cost

Cadres	Gross monthly salary (basic+ allowances)	Unit cost (Ksh) salary per day	Working hours per year	Number of staff	Total cost (Ksh)	Total cost (US$)
Clinical officer	106,000.00	662.50	416	4	1,102,400.00	10,302.80
Nurse	101,000.00	631.25	416	4	1,050,400.00	9,816.82
Laboratory technologist	50,000.00	312.50	416	2	260,000.00	2,429.91
Pharmacy technologist	50,000.00	312.50	416	2	260,000.00	2,429.91
Nutritionist	50,000.00	312.50	416	2	260,000.00	2,429.91
Cleaner	25,000.00	156.25	416	2	130,000.00	1,214.95
						-
Supervisory time						
Health facility administrator	A daily rate of Ksh 3409	426.13	26	2	22,158.50	207.09
Nursing officer in charge	Consultant daily rate of Ksh 8,181	1,022.63	52	2	106,353.00	993.95

Medical superintendent	The daily rate of Ksh 11,363	1,420.38	208	2	590,876.00	5,522.21
Total costs				**22**	**3,191,311.50**	**29,825.34**

4.3.5 Quantification and measurement of rent and utilities

The rent and utilities of the level 3s were valued at Ksh. 135,000 (US$ 1,261) as shown in Table 13.

Table 13.Quantification of rent and utilities for a level 3

Resource inputs	**Item description**	**Quantity**	**Unit cost**	**Total cost (Ksh)**	**Total cost (US $)**
Estimated renting building space in square feet	144 (12x12) square feet	2 health facilities for 12 months	4,500 (4500*12*2)	108,000.00	1,009.35
Utilities	water & sewerage estimated at 10% of the estimated rent	2 health facilities for 12 months	Ksh 450 per month per health facility (450*2*12)	10,800.00	100.93
	Electricity is estimated at 15% of the rent	2 health facilities for 12 months	Estimated @ Ksh 450 per month (450*2*12)	16,200.00	151.40
Total costs				**135,000.00**	**1,261.68**

4.3.6 Total economic cost of providing care per patient at level 3

The total economic cost for level 3 study sites was estimated at Ksh. 5,401,176. Similarly, labor costs were the main contributor to costs accounting for 59%, followed by equipment at 21%, and drugs at 14%. The other components accounted for 8% as shown in Table 14 below.

Table 14.Summarized quantification of annual inputs for 1032 cases

Resource inputs	**Item description**	**Total cost (Ksh)**	**Total cost (US $)**	**Percent (%)**
Equipment	medical devices and furniture	1,107,880.00	10,354.02	20.51%
Labor costs	22 health professionals at the two level 3s	3,191,311.50	29,825.34	59.09%
Drugs	antihypertensives and antidiabetic drugs dispensed	730,420.00	6,826.36	13.52%
Non-pharmaceutical	the proportion of non-pharmaceutical products utilized	236,564.00	2,210.88	4.38%
Estimated renting building space in square feet	144 (12x12) square feet	108,000.00	1,009.35	2.00%
Utilities	Water and sewerage	10,800.00	100.93	0.20%
Utilities	Electricity	16,200.00	151.40	0.30%
Total cost		**5,401,175.50**	**50,478.28**	**100.00%**

By dividing the total expenses by the number cases, the unit economic cost at the level 3 level was determined:

$$\text{Cost per level 3}= \frac{Totalcost(Equipment+labour+drugs+non-pharmaceutical+rent+utilities)}{Totalnumber\ of\ level\ 3}$$

$$\text{Cost per level 3}=\frac{Total\ cost(1{,}107{,}800+3191311.50+730420+236564108800+10800+16200)}{2}$$

$$=\frac{5{,}401{,}176}{2}=\text{Ksh } 2{,}700{,}587.75$$

$$\text{Cost per case }=\frac{Total\ cost(1{,}107{,}800+3191311.50+730420+236564108800+10800+16200)}{1032}$$

$$=\frac{5{,}401{,}176}{1032}=\text{ Ksh.5233.70 per year}$$

$$\text{Cost per patient per visit}=\frac{Total\ cost\ per\ cases}{Number\ of\ visits}$$

$$=\frac{5,233.70}{24}= \text{Ksh. } 218.07$$

Therefore, the total cost per level 3 health facility was estimated at Ksh 2,700,587.75 (US $25,239.14), the unit economic cost to provide care per patient is Ksh. 5, 233.70 (US$ 48.91), and the cost per patient per visit was estimated at Ksh. 218.07(US $ 2.04).

4.4 Unit economic cost in a public primary health facility

The unit economic cost at the public primary health facility was calculated based on the numerator, total economic costs of both Level 2 and level 3, and denominator total number of cases in both levels of care using the formula:

$$\text{Total Unit cost}=\frac{Total\ cost\ per\ health\ center+Total\ cost\ per\ Dispensary}{Total\ number\ of\ cases}$$

$$=\frac{5,401,176+1,655,698}{1032+712}=\text{Ksh } 4,046$$

Therefore, the unit economic for a public primary health facility was estimated at Ksh4,046 (US$ 38).

4.5 Logistic regression analysis

4.5.1 Univariable analysis

The factors assessed for statistical significance in the univariable analysis at P≤0.20 include age, residence, marital status, family size, level of education, occupation, level of income and drug availability. Among the variables, residence, family size, level of education, level of income, occupation and drug availability were found to be associated with the affordability of hypertension-diabetes Mellitus comorbidity. The other variables added no significant contribution to the model (Table 15).

Table 15. Univariable analysis of factors associated with the affordability of hypertension-diabetes Mellitus comorbidity among patients in Kiambu county

Variable		Crude OR (80% CI)	p-Value
Age (years)			
	<40	1.1 (0.2 – 5.4)	0.8

40 – 49	0.8 (0.3 – 2.8)	0.78
50 – 59	1.0 (0.3 – 3.3)	0.95
60 – 69	1.6 (0.5 – 5.5)	0.48
≥70	Reference	
Residence*	0.5 (0.3, 0.8)	0.09
Marital status		
Married	Reference	
Divorced	1.2 (0.4- 3.3)	0.85
Never married	3.1 (0.9- 9.8)	0.21
Widowed	0.9 (0.4- 2.1)	0.96
Family size*		
1 – 3	0.5 (0.1 – 2.0)	0.34
4 – 6	0.4 (0.2 – 0.9)	0.04
≥7	Reference	
Level of education*		
None	Reference	
Primary level	0.9 (0.5-1.9)	0.97
Secondary level	0.4 (0.1, 0.9)	0.15
Tertiary level	0.5 (0.1- 2.9)	0.65
Occupation*		
Unemployed	Reference	
Informal employed	0.3 (0.0- 1.0)	0.21
Self-employed	0.2 (0.0- 0.5)	0.03
Formally employed	0.3 (0.0-1.7)	0.42
Level of income (Ksh)*		
≤1000	7.4 (1.6 – 35.5)	0.012
1001 – 10000	4.0 (1.0 – 15.4)	0.044
>10000	Reference	
Drug availability`*	7.9 (4.4- 14.0)	0.00

* Variables eligible for inclusion in the multivariable model (P≤0.20)

4.5.2 Multivariable analysis

In the multivariate analysis, only drug availability was shown as the significant predictor for the affordability of hypertension-diabetes Mellitus comorbidity at a 5% significance level (Table 16). Compared to the unavailability of drugs, public primary health facilities with the availability of drugs are 11.9 times more likely to be affordable to hypertension-diabetes Mellitus comorbidity patients (aOR: 2.48; 95% CI; 5.20- 27.25; P<0.00) holding all factors constant.

Table 16. Multivariable analysis

Variables	**Adjusted. B**	**Adjusted OR (95% CI)**	**P-value**
Family size	-0.31	0.74 (0.56-, 0.93)	0.09
Residence	1.15	3.14 (1.21- 8.21)	0.125
Self-employed	1.33	0.26 (0.07- 0.96)	0.185
Level of income	0.80	0.45 (0.19- 1.08)	0.242
Drug availability	2.48	11.9 (5.19- 27.25)	<0.000

CHAPTER FIVE: DISCUSSION

5.1 Introduction

The study noted that all the health facilities provided basic care and treatment to comorbid patients. At the time of the study, facilities reported having adjusted their clinic days to minimize hospital visits unless it is very important due to the second wave of the COVID-19 pandemic. Also, the study noted the MOPC services in all the study sites were only available during the hospital operating hours, 8 am to 5 pm. Despite the level 3s operating for 24 hours for maternity services, MOPC was limited to only normal working hours. This implies that in case of emergencies, patients seek care in either private or tertiary level facilities located miles away even though these levels of care are in close proximity and easily accessed by walking or motorbike ride. The findings are instrumental in informing policymakers and the government about cost estimates of providing care at different levels of health facilities. This section further explains the findings in the context of other studies.

5.2 Economic cost of providing care at level 2

The estimated total economic costs of providing care at the level 2 level are USD 7,737, with labor driving 50% of the cost. The study found that there was a constant availability of basic functioning equipment in the two dispensaries. However, compared to the population, including hypertensive and diabetic cases, the devices were insufficient, and the situation is even worse in case of breakdown when patients are forced to seek care in the nearby private clinic and drug shop. The deficit of proper equipment largely hindered operations due to late diagnosis of hypertension, leading to insufficient care for patients. This collaborates with Mwai and Muriithi's (2016) findings that the allocation of equipment at lower levels of care is insufficient compared to more advanced health facilities that offer the same service (Mwai, 2016).

At the time of the study, all first-line drugs for antihypertensives and antidiabetics were available across all health facilities. The estimated total cost of essential medicines was USD 4,302. But due to the high traffic of patients in these facilities, it was noted that there were constant stockouts of medicine, forcing patients to seek alternative sources, e.g., pharmacies. Similar findings are reported in other studies in developing countries that have shown persistent stock out of drugs and reagents for laboratory tests, including basic routine tests such as random blood sugar tests(Mohan et al., 2013). The limited scope of services increases the costs of accessing care, because patients

are expected to seek care in private health facilities or higher levels of care where they pay out of pocket making it unaffordable to the majority thus contributing to poor health outcomes. This frequent stock out of drugs is caused by underfunding and under-provision of funds relative to demand. This gap is brought by limited cost information to inform decision-making, as evident in this study. However, with the reported stock-outs in health facilities, the study doesn't give a true reflection on the ideal cost of essential medicines relative to the demand.

The study revealed an adequate supply of non-pharmaceutical products against the demand. These were products that were mostly used during laboratory tests and could not be reused. However, the study showed that the demand for the products was provided at the clinicians' discretion rather than employing logistical data management systems that could provide accurate data for an inventory of non-pharmaceutical products.

Effective management of hypertension-diabetes Mellitus comorbidity depends on human resources. According to the study's findings, one level 2 had one nurse who cut across other service points while still providing care to more than fifty patients per clinic day. This indicates a significant gap in human resources inhibiting quality care. The understaffing issue was also reported in Uganda at the hospital and lower-level facilities in a study to assess the capacity of health facilities to manage the hypertension (Musinguzi et al., 2018). The benefits of having the adequate and the right mix of personnel cannot be over-emphasized. A study in Iran reported positive outcomes by having a larger outlay of personnel to treat and manage non-communicable diseases and their risk factors for effective management (De Boer et al., 2017; Farzadfar et al., 2012). Other cost ingredients observed in this study were rent and utilities. The general unit costs associated with renting and paying for utilities at both dispensaries were valued at USD 841.12 annually. The issues raised during the study were the delay and sometimes lacked funds to cover these expenses, yet they are essential to providing care. A study by MOH (2014) revealed that rural health facilities did not receive adequate funding due to fiscal constraints and political directives from the central government. This calls for timely disbursement to increase efficiency.

5.3 Economic cost of providing care at level 3

Health services provided to hypertension-diabetes comorbidity patients at a Level 3 (health center) included consultation, laboratory tests, nutritional assessment, and advice as well as access to prescribed drugs. The estimated economic unit cost was US$ 48.91. At the time of the study, the blood pressure monitor machines were down in both health facilities implying patients had to seek

care in the nearby private pharmacies and clinics. To realize the dream of universal health coverage, there is a need to equip them better and implement clear guidelines on the process of repairing and maintaining the equipment, especially the small-sized critical equipment.

The study results also showed the total cost of drugs per level 3 was USD 3,413 annually. The facilities highlighted commonly prescribing a two-drug combination. Among antihypertensives, ACE inhibitors and Thiazide diuretics were the most prescribed drugs, followed by ARBs and metformin for diabetes treatment. It was also noted that stock out of drugs was still an issue forcing patients to seek alternative sources that in some cases lead to purchasing generic drugs that had little or no impact on their condition, further endangering their health. A study done by WHO (2015) compounded this problem because of inadequate funding and supply of basic medicine to rural and urban level 3s. A study by the World Health Organization reported in 2015 found only 51% of the SSA nations had access to metformin on a regular basis, and that the availability of insulin was just 40% below the 80% target (Godman et al., 2020). The inadequate supply of these basic drugs in primary care facilities is a major concern not only to the patient outcome but to the economy as well.

Human resource, a major factor in providing healthcare to hypertension-diabetic comorbid patients. The study estimated the total labor cost at USD 14,913 per year. Also, the study found a delay in the remuneration of salaries and other allowances that greatly impacted their ability to perform. In extreme cases, they have been forced to strike, affecting service delivery. Previous studies have shown a positive impact on human resource practices (such as pay), and social support, such as supervisor support in health facilities can be achieved through organizational support (Farzadfar et al., 2012).

Rent and utilities enable the day-to-day operations of the level 3s. During the study, it was estimated a level 3 total cost of USD 631 per year. As much as the cost is less compared to other drivers, sometimes the disbursement of said amounts from the county government is delayed causing temporary disruption of the health services (MOH Kenya, 2014). To improve efficiency the county government needs to streamline fiscal constraints in the health system to enable the quick release of funds.

5.4 Economic cost of providing care at public primary health facilities

The estimated health provider cost of providing care for comorbid patients per year is USD 38. This finding conquers with the findings from Tanzania estimated that estimated the unit cost of providing CVD medical primary prevention services ranged from USD 30–41 per patient per year at the level 3 (Ngalesoni et al., 2015). Generally, the study found limited studies in Sub-Saharan Africa that estimated the cost of treating and managing the comorbid condition. One research in Kenya revealed that patients pay a modest amount in the public sector for managing hypertension, diabetes, and asthma, ranging from USD 26 to USD 234.(Subramanian et al., 2018). This implies that more cost studies are needed to inform budgeting and expenditure planning.

5.5 Affordability of hypertension-diabetes Mellitus comorbidity

Like any other chronic illness, patients with the hypertension-diabetes Mellitus comorbidity condition are expected to have frequent interactions with the health system for management. However, high health-related expenditures create a financial barrier to accessing healthcare or lead to financial hardship for people using the health services (WHO, 2019). Consequently, patients frequently only seek treatment when they have the money to do so or when they are really sick with uncontrolled blood pressure and blood sugars affecting the continuity of care. (Zawudie, Lemma, & Daka, 2020). This study found that the drug availability in health facilities increased the affordability of hypertension-diabetes Mellitus comorbidity care significantly. At the primary care level where services are exempted from user-fees charges. Patients need not incur out-of-pocket payments to purchase the drugs one of the cost contributors for hypertensive patients as reported by Gnugesser et al in the comprehensive analysis of the financial costs of treating uncomplicated hypertension in SSA. Gnugesser et al found costs of drugs ranged from USD 0.09 to USD 193.55(Gnugesser et al., 2022). Therefore, ensuring drugs are always available by matching supply to demand will greatly improve the utilization of health services by hypertension-diabetes Mellitus comorbidity patients in public primary health facilities.

5.6 Study Limitation

This study is not without limitations. First, the findings are not nationally representative, the study area was limited to four facilities in Kiambu County. Secondly, information concerning staff time allocation to MOPC was self-reported, lending itself to recall bias. There is a need to take into account access and quality of treatment obtained for every dollar spent. These limitations

notwithstanding, the study provides a useful assessment of the unit economic cost of managing hypertension-diabetes Mellitus comorbidity in public primary health facilities in Kiambu County, Kenya to inform budgeting and priority setting.

CHAPTER SIX: CONCLUSION AND RECOMMENDATION

6.1 Conclusion

There is a call for players in health including policymakers to join to protect the health and well-being of current and future generations by financing activities for the common good. The study findings reveal the need for the government at all levels to strengthen primary care facilities with trained and adequate staff, enough mix of medical devices and essential drugs, and adequate space to support the delivery of quality care increasing patients' utilization and affordability. The findings further show information on the cost of hypertension-diabetes Mellitus from a provider perspective is critically missing; no considerable research has been done in low- and middle-income countries more so in Kenya yet the burden of disease is high. This calls for the urgent need for more cost of health services to make the 'invisible' expenditures visible to the decision-makers for adequate resource allocation required to achieve the quality care and sustainable development target on NCDs of reducing one-third of premature deaths from NCDs by 2030.

6.2 Recommendation for implementation of MOPC and future research

- To conduct comprehensive cost estimation of essential drugs and laboratory reagents to match supply and demand at both level 2 and level 3.
- To invest adequate funds geared towards extensive research on the cost of health services in primary health facilities for better planning, budgeting, and resource allocation.
- Strengthen the health system to offer quality services to hypertension-diabetes Mellitus comorbidity patients to increase affordability. Healthcare tends to be the least affordable where the healthcare system is the least efficient.
- To conduct a comprehensive cost study to determine how much it costs over the duration of the comorbidity from the time of diagnosis to when a patient develops complications.

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CHAPTER EIGHT: APPENDICES

Appendix 1: Informed Consent Form

Research title	**Cost analysis of managing hypertension and diabetes mellitus comorbidity in public primary health facilities in Kiambu county, Kenya**
Principal investigator	Alice Jebet Tarus
Organization	School of Public Health, University of Nairobi
Supervisor	1. Prof. Joseph Wang'ombe. Professor of Health Economics, School of Public Health, University of Nairobi

This informed consent form has two parts:

- Information sheet (shares information about the study with you)
- Consent form (for signatures if you choose to participate)

Part 1: Information sheet

Introduction

I am Alice Tarus, a master's student at the University of Nairobi, School of Public Health. I am doing a study on **Cost analysis of managing hypertension and diabetes mellitus comorbidity in public primary health facilities in Kiambu county, Kenya** I am going to share information related to the study and invite you to participate.

Please let me know if there are words and/or sections that you do not understand, and I will take the time to explain further.

Purpose of the research

The purpose of this study is to determine the cost of the health facility to offer health services to you and how the absence or presence of the required services influences your ability to seek care.

Duration of your participation in the study

You will be engaged by the principal investigator through interviews. The interview session will take approximately 30 to 45 minutes.

Participation in the study

Your participation in the study is voluntary and you can stop your participation in the study at any time without giving reason. For the continuity of the study, a replacement will be sought.

Potential risks and benefits of participating in the study

There are no known risks that you will be exposed to by participating in this study since you will be providing information about the services you access in this health facility and how its absence/presence of it has influenced your health. Additionally, there will be no direct benefits to the participants. However, in the long run, the study findings will help to recommend policy or program interventions to improve sustainable financing for managing hypertension and type 2 diabetes mellitus in a primary health facility.

Confidentiality

Any information you provide and your decision to participate in the study we will protect to the best of our ability. No personally identifiable information such as name, personal identification number, the mobile number will be collected subsequently it won't appear anywhere in the report. After data collection, all the data collection tools will be securely stored and will only be accessed by the research team.

Sharing of the results

The results of this study will be shared with you through feedback sessions before sharing it widely through publication and conferences. Summarized results of the study will be used in presentations and reports will be shared with the county government and the broader national and international stakeholders. No individually identifiable information or direct reference to any specific participant will be used.

Withdrawal from the study

You do not have to take part in this research if you do not wish to. If you wish to stop participating in the study after you begin, you can stop at any time.

Whom to Contact

If you have any questions now or later, you can contact the principal investigator, Alice Tarus on the mobile number: 0721294892 or via email at alicetarus@yahoo.com or the KNH-UoN Ethics Review Committee (ERC), Kenya through email at uonknh_erc@uonbi.ac.ke.

Part 2: Informed Consent Form

I confirm that the information above was accurately read and explained to me. I have had the opportunity to ask questions about the study, and all the questions were answered correctly to my satisfaction.

I hereby consent to participate in this study:

Name of the participant……...

Signature ……

Date ……...

Statement by the researcher

I confirm that the participant was allowed to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of the researcher…….....

Signature……...

Date…….....

Appendix2 : Costing questionnaire

General Information Respondent: Medical doctor/nurse in charge of MOPC	**Item**	**Record Response**
Geographical location: Rural/Urban		
1) When did the MOPC clinic start?	_____	
2) How many patients do you see per clinic?	_____	
3) How frequently does the clinic run?	_____	
4) What is the catchment population of the health facility	_____	
5) Where do your MOPC patients come from mostly?	1) Walk-ins	
	2) OPD referrals	
	3) Community/CHVs referrals	
	4) Referral from dispensaries 5) private clinic	

1. **Labor costs**

- How many staff and their cadres provide care to hypertensive and diabetic patients? _____
- *Staff time allocations*

How much time do you usually spend per month on different service points?

Type of Activity	**Medical doctor**		**Clinical officer**		**Nurse**		**Laboratory technician**		**Pharmacist**		**Nutritionist**	
Frequency	**R**	**O**	**R**	**0**	**R**	**O**	**R**	**O**	**R**	**O**	**R**	**O**
Antenatal care												
General Outpatient clinic												
Child welfare clinic												
Family planning												

Postnatal care												
Maternity												
Comprehensive care clinic												
Outreach												
Medical outpatient clinic												
Administrative work												
Total	100%		100%		100%		100%		100%		100%	

Key; R- routine service, O-occasional

- *Labor costs*

List all health staff by cadre working in the facility that spends time on the medical outpatient clinic and how much they earn per month.

Position	**Job grade**	**Salary (A)**		**The proportion of time worked a MOPC (B)**	**Total (A*B)**
		Gross pay (inclusive of allowances or deductions)	Locum fee		
Medical doctor					
Clinical officer					
Nurse					
Laboratory technologist					
Pharmacist					
Nutritionist					
Biomedical engineer					

Note: health professionals can either be paid on a locum basis or salary based on the terms of engagement. (Please fill one)

2. Details of equipment

Equipment	Quantity	Estimated Useful life	Purchase price/market price
Triage/consultation equipment			
Blood pressure machine			
Stethoscope			
Weighing scale			
Thermometer			
Height meter			
ECG machine			
Laboratory equipment			
Strips for Urinalysis			
Glucometer			
Biochemistry equipment			
Hematology equipment			
Diagnostic equipment			
X-ray equipment			

3. Essential drugs consumed

a) How are the NCD medicines and drugs acquired by the health facility?	1) Health facility purchases 2) Purchased by the county government 3) Patients self- purchase	
b) What type of drugs does the health facility dispense for the management of hypertension? (*Tick appropriately*)	1) Quarterly	
	2) Bi-annually	
	3) Annually	
	4) Need to need basis	
c) Does the health facility experience drug stock-outs?	1) Yes	
	2) No	
d) If yes, how does the health facility handles stock-outs?	1) 1.Facility purchases drugs	
	2) 2.Patient buys the drugs elsewhere	
	3) 3 County government supplies	
	4) 4.Inter-facility transfers	
	5) 5.Others(*specify)*_____	

- What are the quantity and the unit cost of the drugs dispensed?

Note: *Quantity implies the number of drugs procured within the financial year.*

Class of the drug	**Type of drug**	**Quantity**	**Unit cost**	**Total**
Antihypertensive				
Long-acting Calcium Channel blockers	Amlodipine			
	Felodipine			
	Nifedipine			
Thiazide diuretic	Chlorthalidone			
	Hydrochlorothiazide			
	Metolazone			
ACE inhibitor	Captopril			
	Enalapril			
	Lisinopril			
	Ramipril			
ARB	Losartan			
	Telmisartan			
	Valsartan			
Anti-diabetic medication				
Metformin				
Insulin				
Glibenclamide				
Saxagliptin				
Pioglitazone				

4. Non-pharmaceutical products

Which non-pharmaceutical products do you use in the MOPC?

Expenditure item	**Quantity**	**Unit price**	**Total**
Bandages			
Cotton wool			
Disinfectant fluids			
Disposable surgical rubber gloves			
Surgical tape			
Bio-waste polythene			
Digital film			
Developer			

Appendix 3: Patient questionnaire

Section A: sociodemographic questions	
1. At what age were you diagnosed with the condition?	_____
2. Gender	_____
3. Where do you reside?	1) Rural 2) Urban
4. What is your marital status?	1) Never married 2) Married 3) Divorced /Separated 4) Widowed
5. What is your family size?	_____
6. What is your level of education?	None Primary school Secondary school College/University
7. What is your occupation?	1) Formally employed 2) Informal employee 3) Self-employed (small-scale farmer / trader) 4) Unemployed
8. Whom are you living with?	1) Alone 2) With family 3) With non-family
9. What is your level of income per month? (Ksh)	_____
Section B: Health service utilization	
How many times do you visit a health facility or any other provider in a **MONTH**?	
During your last visit to the health facility, were all the prescribed drugs available at the facility?	1. YES 2. NO
Do you seek health services from any other place apart from this facility?	1. YES 2. NO
How much do you pay per visit when you visit the other facilities?	Ksh_____

Appendix 4: Work plan

The work plan for the study is as shown in the table below.

	2021-2022							
Activity	**July 2021**	**August 2021**	**Sept 2021**	**Oct2021**	**Nov2021**	**Dec 2021**	**Jan-June 2022**	**June-Oct 2022**
Finalize research proposal and submit for ethical approval								
Recruitment and training of research assistants								
Data collection								
Data cleaning & processing								
Data analysis & report writing								
Feedback, and discussion of research findings								

Appendix 5: Study Budget

The expenses incurred during the study to meet logistics are outlined below.

Item	**Unit cost**	**Quantity (Days)**	**Total costs (Ksh)**
Research assistant allowances	3000	2 for 10 days	60,000
Stationery			5,000
Transport to and from the health facility for data collection	500	3 for 10 days	15,000
Lunch during fieldwork	300	3 for 10 days	9,000
Total			89,000
10% Contingency			8,900
Total			**97,900**

Alice's Thesis

ORIGINALITY REPORT

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P. O. BOX 19676 - 00202, NAIROBI
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15/11/2022

UNIVERSITY OF NAIROBI

SCHOOL OF PUBLIC HEALTH

INTERNAL MEMO

FROM: Dr. Pamela Godia, Dept PGH **DATE:** 16th November 2022

TO: **Alice Jebet Tarus** **RE:** H57/8319/2017

RE: BINDING OF DISSERTATION

According to your Supervisors, you have already addressed the issues raised by the examiners of your dissertation as well as those raised during the defense. Therefore, you are authorized to bind your dissertation entitled **"ECONOMIC COSTS OF HYPERTENSION- DIABETES MELLITUS COMORBIDITY IN PRIMARY FACILITIES IN KIAMBU COUNTY, KENYA."**

You are **also** required to submit **a soft copy** of your complete dissertation, duly signed by your supervisor(s) and Chairman, to the Department of Public and Global Health, University of Nairobi. This exercise should be done within **three days** from the date of this letter

Yours Sincerely,

Dr. Pamela M. Godia
MPH Programme Coordinator

CC: Chair, Department of Public and Global Health Prof Joseph Wangombe - Supervisor