# AVAILABILITY, PRICES, AFFORDABILITY, AND QUALITY OF ESSENTIAL MEDICINES IN PUBLIC HEALTH FACILITIES IN MOMBASA COUNTY, KENYA

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| | |
|---|---|
| AIDs | Acquired Immunodeficiency Virus |
| ARVs | Antiretrovirals |
| CGTRH | Coast General Teaching and Referral Hospital |
| CI | Confidence Interval |
| EML | Essential Medicines List |
| $EML_C$ | Essential Medicines List for Children |
| GCC | Gulf Cooperation Council |
| GMP | Good Manufacturing Practices |
| HIV | Human Immunodeficiency Virus |
| HPT | Health Products and Technologies |
| IQR | Interquartile Range |
| IRP | International Reference Price |
| LMICs | Low and Middle-Income Countries |
| KEML | Kenya Essential Medicines List |
| KEMSA | Kenya Medical Supplies Agency |
| KIPPRA | Kenya Institute for Public Policy Research and Analysis |
| KNH–UoN ERC | Kenyatta National Hospital, University of Nairobi, Ethics and Research Committee |
| Ksh | Kenyan Shilling |
| MPR | Median Price Ratio |
| MSH | Management Sciences for Health |

| | |
|---|---|
| MTC | Medicine Therapeutic Committee |
| MU | Mega Unit |
| NCD | Non-Communicable Diseases |
| NHIF | National Health Insurance Funds |
| NMTC | National Medicines and Therapeutics Committee |
| NRA | National Regulatory Authority |
| PHFs | Public Health Facilities |
| PPB | Pharmacy and Poisons Board |
| S5 | Bin Cards |
| S11 | Counter Requisition and Issue Voucher |
| S12 | Issue and receipt voucher |
| SCM | Supply Chain Management |
| SD | Standard Deviation |
| SOP | Standard Operating Procedures |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights |
| UK | United Kingdom |
| US$ | United States Dollar |
| USA | United States of America |
| WHO | World Health Organization |

## DEFINITION OF KEY TERMS

| TERM | DEFINITION |
|---|---|
| **Access** | Having drugs continuously available and affordable at public health facilities. |
| **Affordability** | The equivalent number of days' wages that is required to pay for a full course of treatment. |
| **Availability** | The number of unexpired medicines on the shelves in a health facility compared to the total expected number of medicines. |
| **Expired medicine** | Medicine whose expiry date indicated on the packaging has elapsed. |
| **Price** | The unit price of a medicine. |
| **Quality** | The presence of expired medicines in dispensing areas and adequate handling and conservation or storage conditions of medicines. |
| **Shelf life** | The period remaining to the expiry date established by the manufacturer. |
| **Stock out duration** | The number of days a health facility temporarily does not have supplies of medicines it should have in stock. |
| **Stock records** | Documentation of all transactions relating to medicine includes reordering level, interval and quantity, lead time, projected consumption rate, and current stocks on shelves. |
| **Storage conditions** | Storeroom and dispensing room temperature control and monitoring, arrangement of medicines, clean and dry. |

## ABSTRACT

**Background:** Access to essential medicines and vaccines can save 10 million lives a year globally with 4 million of these in Africa and South East Asia. A third of the global population lacks reliable access, with poor countries in Africa and Asia having 50% of their populations lacking access to essential medicines. Access to essential medicines relies on rational selection and use, affordable prices, sustainable financing, and reliable health and supply systems. Poor availability of essential medicines due to stock-outs, unreliable funding, unaffordable prices, and inefficient supply chains hinder access, especially for the poor who rely on public healthcare.

**Objective:** To assess essential medicines availability, prices, affordability, quality, and predictors of medicines' availability in public health facilities in Mombasa County.

**Methods:** A cross-sectional descriptive survey was carried out through direct observation from 30 public healthcare facilities in Mombasa County. Data was collected from level II, III, IV, and V health facilities using a pre-tested and structured questionnaire. The survey collected data on availability, prices, affordability, and quality, and analyzed by calculating indicators derived from the WHO operational package for assessing, monitoring, and evaluating country pharmaceutical situations. The data were summarized using standard descriptive statistics. Regression analysis was carried out to determine predictors of medicine availability. The findings of the summary analysis were presented in tables and figures.

**Results:** The average availability of essential medicines was 86.7%. The majority (76.6%) of facilities experienced an average stockout duration of 27 days. 57.7% of facilities did not have all stock records and 43.3% had expired medicines on the shelf. Storerooms and dispensing areas met 82.3% and 81.8% of the adequate storage and handling conditions. The patient prices were 3.7 times the procurement prices. Patient prices were 3.4 times the international reference prices (IRP) while procurement prices were 0.9 times the IRP. Treatment of moderate pneumonia, adult diabetes, and asthma in children costs less than a day's wage. Stock records availability ($p=0.017$) was a statistically significant predictor of medicine availability.

**Conclusion:** Essential medicines were fairly available, but their prices were high and public health facilities did not meet the expected storage and handling conditions with frequent stock-outs and expiries. Available stock records determine essential medicines' availability.

# CHAPTER ONE: INTRODUCTION

## 1.1 Background

World Health Organization (WHO) defines essential medicines as *"those that satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price, the individual and the community can afford"* (1). WHO estimates that a third of the global population lacks reliable access to essential medicines with poor countries in Africa and Asia having 50% of their populations lacking access to essential medicines. Access to essential medicines and vaccines can save 10 million lives a year globally with 4 million of these in Africa and Southeast Asia with major obstacles being affordability and availability in the public health sector (2).

Access to healthcare is a fundamental human right embodied in international treaties and acknowledged by governments all over the world. All nations have to develop policies and action plans to achieve equitable access to healthcare services and commodities, which include essential medicines which are vital for the prevention and treatment of prevalent diseases (3). United Nations defined access to essential medicines as "*having drugs continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the population"* (4). The framework of access to essential medicines comprises; rational selection and use, affordable prices, sustainable financing, and reliable health and supply systems (3).

A supply chain is an ecosystem of organizations, people, technology, activities, information, and resources that collaborate to deliver products or services from the production point to the end customer (5). Supply chains deliver health products and services to the patient, enhancing the quality of care, cost-effectiveness, and efficiency, and communicating critical information on needs, demand, and consumption to health system planners hence the need for regular evaluation to monitor performance (6–8). Efficient and effective supply chains are critical in the provision of quality, safe, and efficacious patient care while optimizing resource utilization and ensuring access to essential medicines. They ensure the consistent availability of high-quality medicines, vaccines, and health products that are affordable at all health service delivery points (7,9).

Supply chain management is the planning and management of all activities involved in sourcing, procurement, conversion, logistics, coordination, and collaboration with all stakeholders to deliver the product to the final customer in the most streamlined and cost-effective way (5). Proper supply chain management (SCM) is critical in achieving Sustainable Development Goal 3 target 3.8; "*achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all* " (10). Inefficient supply chains drive the cost of medicines up, making treatments unaffordable and requiring up to over 15 days' wages for a 30 days course of treatment (2).

Pharmaceutical supply chains in low and middle-income countries have an average performance that varies significantly between countries, regions, health programs, distribution channels, sub-populations, and over time (7). A study of 36 developing and middle-income countries in 2009 found that the availability of 15 key essential medicines in the public health sector was low, ranging from 9.7% in Yemen to 79.2% in Mongolia. A total of 8 African countries were included in the study including Kenya. The mean availability of key essential medicines was 25% in the public sector, while in the private sector - where medicines are often unaffordable to most of the population the mean availability was 54.6%. This compromises treatment programs and undermines the health system's ability to respond to the healthcare needs of the population, thereby affecting equitable access to quality healthcare (11).

Public sector health supply chains in low-income countries are plagued with many problems; coordination problems between multiple stakeholders with diverse objectives in the delivery of medicine to the patient; diffuse accountability in forecasting, requisition, and procurement; uncertainties in financing; lack of accountability in different tiers of the supply chain; long and uncertain lead times; and lack of systematic consumption data and information collecting tools for supply chain planning. This leads to depending on "one-off" monitoring and evaluation to evaluate access to medicines (6,7). These problems lead to an erratic supply of essential medicines to public hospitals which hinder equitable access to affordable healthcare services since patients are forced to purchase medicines from private sector outlets, where medicines are highly-priced. Patients who don't afford the medicines from private outlets are forced to forgo the treatment altogether which affects their quality of life and increases the disease burden (6,8).

## 1.2 Problem statement

A survey in Kenya on access to essential medicines found that on average only 43% of medicines were available (12) and 67% of facilities had stock out durations of more than 30 days with 14% of these facilities having stock out durations of more than 90 days (13). Low availability due to long stock-out duration forces patients to forgo treatment or purchase from the private sector where they are highly-priced. This reduces confidence in the healthcare system and discourages patients from seeking healthcare services therefore availability should be regularly assessed.

Lack of accurate and up-to-date stock records hinders quantification, forecasting, and estimation of needs and demand based on consumption of essential medicines leading to inefficient medicine supply systems compromising availability, increasing occurrence of stock-outs, and out-of-pocket spending from the purchase of medicines from the private sector (7,9). Stock records are vital in ensuring a seamless supply of essential medicines and their availability should be regularly assessed.

Expired medicines have reduced efficacy, safety, and quality and put patients at risk of longer sick days or hospitalization, resistance to drugs, increased healthcare costs, decreased quality of life, and lost productivity (9). Expired medicines lead to wastage of scarce resources in the disposal of pharmaceutical waste and opportunity costs due to disposed of medicines (14). The quality, efficacy, and safety of medicines are preserved by appropriate storage conditions (15). Medicine's shelf life, storage, infrastructure, and handling should be monitored.

Medicine prices are a major obstacle to essential medicines access, with the final medicine price being 5 times the procurement price in LMICs. Prices paid by patients were 11.95 in 36 LMICs (11), 1.84 in Ghana (16), and 2.9 in Kenya (12) times the IRP. Medicine markups are used to cover the operating expenses of public hospitals in Senegal, Uganda, and Kenya (11). Medicine markups drive prices up making medicines unaffordable and leading to catastrophic spending on healthcare hence a need to monitor prices paid for medicines.

Untrained personnel were the most frequent essential medicine dispensers in 62% of public health facilities (13). Unqualified personnel handling medicines leads to medication errors, poor adherence, compromises medication safety surveillance, patient safety, and quantification errors leading to stock outs which affect the outcome of treatment and quality of care.

### 1.3 Study justification

Essential medicines save lives, minimize suffering, and lead to better health if they are of good quality, safe and efficacious, available, affordable, and properly used. Poor availability, high stock-outs, inadequate records, expiries on shelves, unaffordable prices, poor storage and handling conditions, inefficient supply chains, and inadequate qualified pharmaceutical personnel in public hospitals hinder access, especially for the poor who rely on public healthcare.

The county health system in Kenya is uncoordinated with *ad hoc* resource allocation and health infrastructure investment; inadequate health personnel with a skewed distribution; low availability of equipment, essential medicines, and other medical supplies; and inequitable distribution of resources, disease burden, and disparities in health outcomes across the counties (17).

These challenges in county health care management and delivery necessitate county-specific monitoring and evaluation of access to healthcare, availability of essential medicines, and medicine supply management. It is expected that different counties will have different and specific challenges which need to be identified and addressed.

There is currently insufficient monitoring and evaluation of health services in Mombasa County, where there is limited data available on access to essential medicines in public hospitals. Therefore, this study on access to essential medicines in Mombasa County is crucial as it will interrogate the current status of availability, medicine prices, quality, and affordability of essential medicines in public hospitals in Mombasa County.

The findings inform on current gaps, analyze the root cause of problems and identify unmet objectives in the essential medicines supply management. The findings will guide county policymakers in developing and planning county strategies in budget planning, reallocation of resources, efficient SCM, and human resource management.

The pharmacy and pharmacy board (PPB) can use the findings to develop guidelines and policies on required pharmaceutical personnel requirements at each level of the public health care delivery system. The ministry of health can use the findings to assess the need for developing medicine pricing policies for public health facilities. KEMSA can use the findings to assess the level of stockouts, estimate needs and demand, and streamline pharmaceutical supply to county hospitals.

## 1.4 Research Questions

1. Are essential medicines available to Mombasa County residents?
2. What prices do Mombasa County residents pay for essential medicines, and are medicines affordable?
3. What is the quality of essential medicines in public health facilities in Mombasa County?
4. What are the predictors of key essential medicines' availability in public hospitals?

## 1.5 Research Objectives

### 1.5.1 Main Objective

To assess essential medicines availability, prices, affordability, quality, and predictors of medicines' availability in public health facilities in Mombasa County.

### 1.5.2 Specific objectives

1. To assess the availability of essential medicines in public health facilities in Mombasa County.
2. To establish the prices and affordability of key essential medicine in public health facilities in Mombasa County.
3. To determine the quality of essential medicines in public health facilities in Mombasa County.
4. To establish predictors of essential medicines' availability in public health facilities in Mombasa County

## 1.6 Significance of Study

The county government will get data on gaps in qualified pharmaceutical personnel and their training requirements; the need to streamline medicine procurement to minimize stockouts and improve availability; assessment of the need for electronic inventory management tools for seamless supplies management; the need for medicine price policies to streamline medicine prices; and need to improve storage infrastructure and capacity to accepted norms and standards,

The public health facilities will benefit by getting gaps in medicine availability, stock-out duration, and proportion of expiries on shelves to improve medicine supply management. The study will highlight medicines that are highly priced and the data can be used to lower medicine prices, develop price markup policies, and source alternative funding for operating expenses. The gaps highlighted can be packaged into facility needs e.g. increase in the number of pharmaceutical personnel and storage and handling conditions, and support requested from the county.

Implementation of the study recommendations will enhance access, affordability, and provision of quality healthcare services to patients. The findings will inform on current essential medicines cycle management gaps and help pharmacists and county managers in formulating guidelines and policies to ensure efficient SCM and access to affordable essential medicines to the patients.

The findings will help county managers in planning and allocation of finances for ensuring continuous access to affordable, quality, efficacious and safe essential medicines to Mombasa County residents.

# CHAPTER TWO: LITERATURE REVIEW

## 2.1 Introduction

Access to high-quality, affordable, equitable essential medicines and the achievement of universal healthcare coverage (UHC) requires strong health systems with innovative pricing, financing, and efficient supply systems. Levels of access to essential medicines are determined by the financing of the health system, availability of safe effective quality medicines, medicine prices, reliable distribution and supply systems, medicines selection, and appropriate use of essential medicines (18). Access varies in urban and rural areas due to differences and problems in health system development. The concentration of retail pharmacies, wholesalers, distributors, public and private health facilities, and providers is greater in urban than rural areas (19).

Access barriers can arise from the demand and or supply of essential medicines. Demand-side constraints affect individuals', households', and communities' capability to use healthcare services. Supply-side constraints are aspects of the healthcare system that hinder the uptake of healthcare services (18). These include policy, legislation, and regulation; budget and finance; medicine selection; pharmaceutical procurement, logistics, and availability; management and monitoring of information; geographical accessibility; and systems management. Barriers to access can be identified in all dimensions of access; geographical accessibility, affordability, availability, acceptability, and quality of healthcare services (20).

Many aspects affect the provision of essential medicine; unaffordable medicine prices, inequitable health financing mechanisms, unreliable medicines supply, quality of medicines, irrational use of medicines; and poor availability of medicines. Current initiatives which include reinforcing national medicines policy, increasing access; ensuring quality and safety; and promoting medicine rational use are critical in meeting the essential medicines needs of patients (21).

WHO in 2004 developed the access framework to aid all actors in the healthcare system i.e. public, private, and non-governmental sectors in the achievement of Millennium Development Goal 8 target 8e; "*In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries*" (22). The framework consists of four components; rational selection, sustainable financing, affordable prices, and reliable health and supply systems as illustrated in figure 2.1 (3).

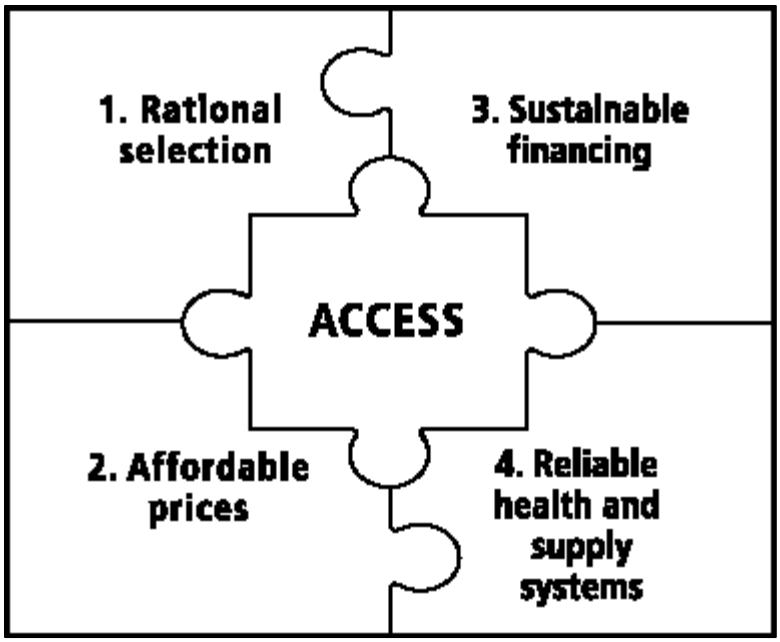



**Figure 2.1: The Access Framework**

*Source: World Health Organization. Equitable access to essential medicines: a framework for collective action. 2004.*

**2.2 Essential Medicine**

Rational selection of essential medicines is a core principle that sets priorities for all aspects of the pharmaceutical system at all levels of the healthcare system in the private and public sectors. Efficient selection of a limited range of essential medicines leads to a higher quality of care, efficient management of medicines, and cost-effective use of scarce health care resources. This is critical in resource-poor settings with a frequent erratic supply of pharmaceuticals in the public sector to ensure a sufficient regular supply of essential pharmaceuticals (23).

The current versions of the lists are the 21$^{st}$ WHO model list of essential medicines for adults and the 7$^{th}$ WHO list of essential medicines for children (EMLc) which were both updated in June 2019 (24,25). The model lists serve as a guide for national governments, public, and private institutions to develop their evidence-based EML. The list is updated every two years to ensure drug selections are up-to-date due to the development of new therapeutic options, changing therapeutic needs of populations, ensuring medicines quality, need to develop better drugs, drugs for emerging diseases, and drugs for changing resistance patterns (24,25).

Essential medicines save lives and minimize suffering since effective drug treatments are available for most leading infectious diseases e.g. tuberculosis, malaria, Human Immunodeficiency Virus (HIV/AIDs), and non-communicable diseases. They are also cost-effective, increase confidence and credibility in the healthcare system and promote trust and participation in health services. Availability of pharmaceuticals is a major determinant of the health care of patients and their satisfaction with the health care services they receive. They also lead to rational drug use, a better quality of care, and health outcomes (20).

Kenya has an EML which was first developed in 1981 but was not well adopted. The list was later reviewed and updated in 1993 and adopted for use in public education and information, public sector procurement, prescribing, and dispensing of medicines. The list was then updated in 2003, 2010, 2016, and the current list was reviewed by the National Medicines and Therapeutics Committee (NMTC) and updated in 2019. The list is a guide on medicines recommended for the treatment of common conditions in children and adults (26). The KEML has 452 medicines yet Kenya Medical Supplies Agency (KEMSA) which is the central procurement agency procures only 116 medicines as per the logistics management information system used by public healthcare facilities to order drugs from KEMSA (27).

### 2.3 Availability of essential medicines

The availability of essential medicines in healthcare facilities increases patients' confidence in the healthcare system and encourages patients to seek healthcare services where they also benefit from preventive services and public health messages. Stock-outs of essential medicines lead to a decrease in the attendance of healthcare services. Available medicines must meet patient needs; be available in sufficient quantities; and meet quality, safety, and efficacy standards to ensure equitable access to medicines. The concept of EML if well implemented and guidelines adhered to in procurement, supply, and use of medicines will lead to a great impact on medicines availability (9).

A national medicines policy that is focused will satisfy the healthcare needs of its population, and with clear priorities has a significant impact on the availability of medicines e.g. Australia. Quantification and forecasting of pharmaceutical needs play a great role in the availability of medicine and planning to ensure the continuous availability of medicines (19).

Training supply and pharmacy healthcare professionals in efficient supply chain management can improve the availability of medicines at all levels of care significantly. Strengthening intellectual property rights and patents globally will increase the cost of medicines and limit availability in developing countries. Compulsory licensing and parallel importation would promote availability and price competition lowering prices and improving access (18).

A study in 2009 in 36 low and middle-income countries (LMICs) found that the availability of 15 key medicines in Africa is 29.4% with low availability in the public sector compared to the private sector. Generics availability in Africa's private sector was low ranging from Chad at 14.8% to Ethiopia at 79.1% (11). Non-communicable disease (NCD) medications have low availability in low-income countries with only 13% of community retail pharmacies having one of these therapeutic classes; angiotensin-converting enzymes i.e. captopril, enalapril, and ramipril; β blockers atenolol and metoprolol; calcium channel blockers amlodipine; and thiazide diuretic hydrochlorothiazide for use in the treatment of hypertension compared to 94% in high-income countries. There is a strong positive relationship between the availability and affordability of multiple therapeutic classes of antihypertensives and the control of blood pressure with the use of combination therapy treatment (28).

Public sector availability of essential medicines is consistently low due to variations in medicines included in EML and poor adherence to the recommendations, insufficient funding, lack of information for planning and forecasting accurately, inefficient distribution systems, and pilferage of medicines for resale in the private sector (2). The availability of essential medicines can be improved by effective and efficient procurement, and sufficient equitable, and sustainable funding. Medications used to treat NCDs can be provided at subsidized prices or promotion of differential pricing to increase access. The public sector may also reduce the number of medicines to purchase due to scarce resources and focus on the priority drugs avoiding duplication in therapeutic classes (9).

Patients seeking healthcare services in Kenya bypass the nearest PHFs in a quest for a higher quality of care with medicines unavailability (21%) at the nearest health facility as the main reason and motivation for seeking healthcare services elsewhere. Other reasons for bypassing health facilities included unqualified health professionals (18.9%); more expensive services at the facility (12.8%); long waiting times (11.4%); unfriendly health personnel (5.9%); lack of free services requiring the patient to pay for services (5.6%); lack of privacy and dirty facilities (29).

## 2.4 Affordable prices

Medicines prices are one of the main obstacles to access to essential medicines with up to 90% of the population in developing countries purchasing medicine via out-of-pocket payments. The absence of reliable information on medicine prices hinders the development of sound medicine policies and the evaluation of their impact. Lack of information also makes expenditure on medicines evaluations in comparison to other countries difficult and negotiations for a lower price are difficult because purchasers have no reliable basis to start from (2). A study involving 36 countries could only obtain price information from 7 countries in the public sector and 11 countries in the private sector (11).

The price information is fundamental in procuring medicines at affordable prices with WHO providing international and regional price information to member countries and encouraging countries to develop medicine price policies. Price information aids negotiations for best prices, finding the best suppliers and supply sources, and monitoring and evaluation of procurement processes. Price competition through tendering of generic products and competition can lead to a price decrease of up to 75-95% over the originator brand product. Price decreases can also be achieved through therapeutic competition between branded products within the same therapeutic class (3).

Prices of the same drug vary across countries with medicines being more expensive in developing countries than in industrialized countries. In a study carried out in 2009, the public sector procurements in the eastern Mediterranean and South East Asia had generic medicines prices that are close to or lower than the international reference prices (IRP) while Africa, Europe, and western Pacific prices were 34-44% higher. When patients are required to pay for treatment in the public sector the price can be numerous times the IRP though the price is lower compared to the private sector. The percentage difference in price between originator brands and generic brands is 300% in LMICs, 152% in upper-middle-income, and 6% in India. The low difference in India is due to price regulations and a large number of generic manufacturers (11).

Non-communicable diseases (NCDs) have a high burden causing 71% of deaths globally each year. 31.5 million of these deaths occur in low and middle-income countries with 46% being premature deaths occurring before the age of 70. NCD medications are unaffordable for large proportions of the population hence the need for emphasis on reducing their cost (30).

Affordability is constrained by the frequent need for more expensive combinations and patient progress monitoring. In Kenya, NCD treatment is high with low rates of health insurance coverage which significantly hinders affordability for most of the population (31).

The public sector often provides medicines for free or at low cost but medicines availability is inconsistent forcing patients to buy out of pocket in the private sector where medicines are often unaffordable e.g. ranitidine 150mg for the treatment of ulcers for 30 days costs more than 3 days' wages in Africa, Eastern Mediterranean and Europe. In Kenya, Senegal, and Uganda medicine revenue is used to subsidize other healthcare systems which drive the cost of medicines up due to higher markups to generate the revenue (11).

Procurement of essential medicines in bulk while avoiding unnecessary duplication of drugs belonging to the same therapeutic class leads to better economies of scale, purchasing power, and price reductions. This can be accomplished through national procurement agencies, a collaboration between facilities and states, and equitable pricing of essential medicines that are protected by patents if economically feasible while ensuring low-priced medicines don't leak back into high-income countries where patents are enforced (3,32).

Generic policies on expiries of patents are also effective in reducing medicine prices with a fall in price by 60% on the introduction of a generic and a further 29% fall on the introduction of 10 generic products. To initiate and expand the use of generic medicine with confidence well-founded supportive regulations, reliable quality assurance systems, professional and public acceptance, and financial motivation and incentives are essential in the sector (19).

In developing countries, the final price of medicines may be 5 times the manufacturer or importer price due to several intermediaries and middlemen, taxes of over 20% and pharmaceutical import duties as high as 65% in some countries, high distribution costs, and high pharmacy outlet dispensing fees and markups. Duties and taxes are applied in several countries with India - 4% and Mongolia - 15% while cumulative mark-ups by importers, distributors, and wholesalers were 380% and retail mark-ups were 552% in El Salvador (11). For instance, in Kenya, medicine prices in public hospitals are 4 times the procurement price from KEMSA central stores (13). Markups are used to increase revenue to subsidize operating expenses and other healthcare systems and they drive the cost of medicines up due to high markups to generate revenue. This is common in LMICs eg Kenya, Uganda, and Senegal (11).

Prices of drugs can be reduced by decreasing or eliminating import duties, tariffs, and taxes, streamlining the distribution channel by reducing the number of intermediaries, making the supply system efficient and effective to reduce markups on drugs, and introducing price caps for essential medicines. Discounts, incentives, rebates, and trade schemes should be regulated to curtail abuse since they interfere with transparency in medicine pricing and may promote the irrational use of medicines. These measures influence the supply of essential medicines which leads to increased availability, affordability, equity, reduced prices, and encourage rational use of medicines (19).

Local manufacturing can result in low pharmaceutical prices when economically feasible and the quality of products is assured through good manufacturing practices (GMP). National policies should be in place to protect local manufacturers and promote competition between pharmaceutical manufacturers. This can also be achieved by the transfer of technology and GMP inspections to generic companies with capacity for production at low cost e.g. the south-south collaboration where companies in India, Brazil, and Thailand manufacture antiretrovirals for LMICs (32).

### 2.5 Sustainable financing

Healthcare financing should be sustainable as it determines the resources available for the purchase of essential medicines and to achieve UHC. High-income countries spend on average about US$ 400 per capita on pharmaceuticals in contrast to low-income countries which spend US$ 4 hence their allocation of resources to pharmaceuticals is 100 times higher, meaning better access to essential medicines. The lack of essential medicines in the public sector forces patients to purchase medicines from the higher-priced private sector or forgo treatment entirely which increases the disease burden and affects the quality of life (2).

The incidence of financial catastrophe is negatively correlated with the extent to which countries fund their health systems using prepayment methods of taxes or insurance and sound national policies on essential medicines. Out-of-pocket personal expenditure on healthcare leads to financial catastrophe in around 150 million people each year and over 100 million are pushed below the poverty line with more than 90% of these people living in low-income countries (33). To protect vulnerable populations from financial catastrophe there is a global movement from medicines user fees i.e. the revolving fund used to finance struggling healthcare systems to equitable financing of healthcare and risk-protective UHC (18).

In developing countries medicines account for 25-70% of the entire health expenditure in contrast to most high-income countries which spend less than 10%. Medicines are a major burden on government budgets and resources. Efficient and effective management ensures equitable access to essential medicines and reduces disease burden (3). Access to medicines can be improved significantly within current budgets by optimizing rational selection, procurement, supply, monitoring availability, quality assurance, and rational use of medicines (34).

Increasing public funding for health and medicines is critical in the provision of equitable healthcare and achieving UHC. LMICs depend on diverse funding for health and essential medicines which include government funding, user fees i.e. revolving fund, health insurance, grants, and donor funding to sustain their healthcare systems (3). Funding healthcare through user fees in most developing countries is inherently inequitable for the poor who depend on public health facilities for healthcare services. Governments must invest in insurance coverage and UHC to protect the poor from the risk of impoverishment (9).

In Kenya, the insurance coverage is 17.1% of the population, with 6.2 million households impoverished due to high health care costs and 12.7 % of Kenyans not seeking health services when sick due to financial constraints (29). The government of Kenya in the year 2019/2020 allocated only 3.04 % (85.2 billion) of its budget to healthcare for scaling up UHC in all counties and introduced the national hospital insurance fund (NHIF) for the elderly and severely disabled Kenyans (35). This budget allocation violates the Abuja Declaration to allocate at least 15% of the budget to the improvement of the health sector (36).

### 2.6 Essential medicines quality

Transport and storage systems that keep medicines at appropriate temperatures, light, hygiene environments, and humidity from the manufacturing plant, maintain medicines potency, safety, efficacy, and quality. Inadequate medicines packaging and storage lead to the degradation of pharmaceutical products with medicines that met required manufacturing specifications when they left the manufacturing site becoming substandard by the time they reach the patient. Distribution of medicines involves long-distance shipping in freight containers where temperatures are not well monitored or controlled and may be held at the ports for customs clearance under high temperatures and humidity for several days. National regulatory authorities have no clear oversight structures for medicines during transportation and storage (15,37).

In the public sector government, central medical stores meet all the stipulated storage and handling standards in most cases compared to hospitals. Hospitals and dispensaries have inadequate cold storage, storage space, shelves, and pallets and have an unreliable supply of electricity (38). The quality of medicine obtained and maintained during manufacture would be useless, unless the entire distribution and storage comply with appropriate quality management (15).

The World Health Organization (WHO) defines the expiry date as *"The date placed on the container or labels of a medical product designating the time during which it is expected to remain within established shelf-life specifications if stored under defined conditions, and after which it should not be used"* (39). This is the last day the manufacturer of the medication can guarantee fully its quality, stability, potency, and safety by stability testing and beyond this date, the chemical composition of the medicine is unknown for most medicines and not fit for consumption (40).

Expired medicines may be sub-potent, lose efficacy, degraded, change chemical composition, safety, and quality. They put patients at risk of longer sick days o, resistance to antibiotics, adverse drug reactions, drug toxicity, carcinogenicity, increased healthcare costs, decreased quality of life, lost productivity, poor treatment outcomes, morbidity, and mortality (9,41).

Expired medicines lead to wastage of scarce resources in the disposal of pharmaceutical waste and opportunity costs due to disposing of medicines. Most low and middle-income countries experience a severe shortage of essential medicines and these scarce resources, supply should be efficient and effective to avoid waste. Expired medicines should be adequately monitored and disposal regulated to prevent repackaging, sale as falsified medicines, and inappropriate disposal that may be harmful to the environment (14,40).

### 2.7 Health systems and supply systems

An effective healthcare system is the backbone of the provision of equitable healthcare and essential medicines. Versatile health systems are a prerequisite to responding sufficiently to populations' diverse and changing medical and pharmaceutical needs. Health sector development is a vital government responsibility that ensures sufficient equipment for diagnosis and treatment is available, and the capacity of health facilities and health personnel is adequate to meet patients' needs. Health personnel should be well informed, trained, sufficient, and well-motivated to provide quality healthcare services, ensure adherence to treatment guidelines and promote appropriate use of essential medicines (3).

Quality health systems and supply systems ensure timely availability of quality, safe and efficacious essential medicines. Most developing countries have central inefficient public medicine supply systems meant to serve the entire country and private supply systems with several intermediaries (6). Countries with a centralized public procurement system can have a central store or opt for direct delivery from importer or manufacturer to health care facilities or contract a distributor to supply medicines to public health facilities or use a combination of supply chain models. Countries with decentralized procurement systems have individual facilities or administrative areas that purchase their medicines (19).

Efficient and effective medicines regulation ensures quality, safe and efficacious medicines are supplied at all levels of care. Regulatory control is a joint responsibility of national regulatory authorities (NRA), manufacturers, distributors, wholesalers, retailers, and all other players actively involved in medicines management. Manufacturers should fully implement GMP and NRA should be vigilant to combat falsified and substandard medicine distribution, contain drug resistance fueled by uncontrolled supply, and irrational use of essential medicines (20).

Regional and sub-regional procurement increases procurement efficiency due to economies of scale ensuring reliable essential medicines supply. The gulf cooperation council (GCC) organizes pooled procurement for six countries with several benefits to member states. These include cost savings through economies of scale; transparency in tender awards; standardization of medicines used in member states; ensuring quality, safe and efficacious medicines are obtained during emergencies; labor reduction through minimizing administrative and regulatory burdens; enhanced purchasing and supply operations; information sharing; and development of uniform drug policies which ensures sustainable availability and affordability of essential medicines (42).

In developing countries, there is no systematic information collecting tools, well-established infrastructures, and public health information is inconsistent and unreliable for use in planning, forecasting, and purchase of medicines to meet patients' dynamic needs (43). Supply chain risks include unreliable supplier lead times, unreliable flexibility of suppliers, untimely delivery by suppliers, inadequate use of information systems and technology to streamline supplies, and lack of quality management systems. The risks lead to inefficient supply and erratic supply of essential medicines resulting in low availability and unaffordable medicines due to additional cost (44).

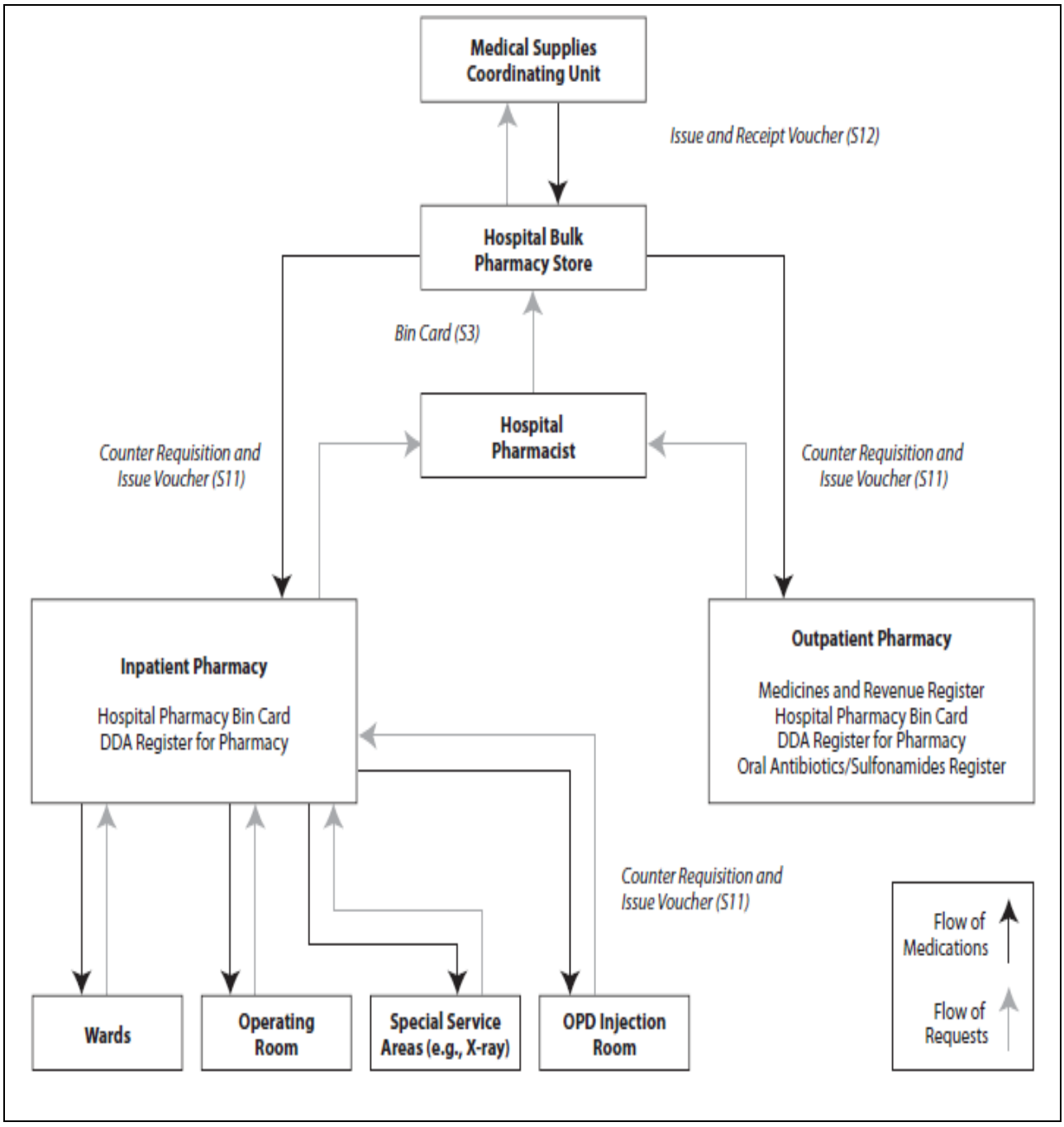
### 2.7.1 Medicine supply system in Mombasa County public health facilities

Medicines in public health facilities in Mombasa County are supplied by KEMSA to the doorstep of each facility as the medical supplies coordinating unit. They distribute essential medicines including reproductive health commodities, nutritional food supplements, tuberculosis/leprosy, and antiretrovirals, and their consumption reports are sent electronically to the respective programs from the facilities. Orders are made using the KEMSA logistics management information system. Facilities order drugs every 3 months based on their consumption. Orders are delivered to the facility and verified by receiving pharmaceutical personnel against the provided issue and receipt voucher (S12) and their condition is checked. The receiving officer signs and stamps the delivery documents as proof of receipt and keeps a copy (9).

Medicines received quantities are all confirmed and all recorded in bin cards (S5) in the receipt column. Counter requisition and issue orders forms (S11) are used to order from the hospital bulk stores to dispensing units which include inpatient pharmacies and outpatient pharmacies. Inpatient pharmacy supplies medicines to the wards, operating rooms, injection administration rooms, and special service areas. Dispensing units enter medicines received from the store into the pharmacy bin cards and the dangerous drugs act registers that are used for controlled drugs for efficient management, by ensuring consumption at the dispensing unit is well recorded for use in medical needs and demand quantification. Daily registers for antibiotics, antiretrovirals, malaria, family planning, and tuberculosis are used to record daily consumption (9,45).

Medicines used are quantified factoring in adjustment for stock-outs, and projected changes in medicine use patterns using the consumption method of quantification. This gives order quantities for procurement, minimum stock levels, average monthly consumption, and estimates budget requirements (9). Every year facilities give out tenders that last a year to the lowest bidder of all essential medicine required by the facility to ensure continuous supply when medicines are out of stock at KEMSA (45).

Large hospitals in Kenya i.e. level V and VI facilities have satellite pharmacies within the hospital that dispense medicines to inpatients and outpatients reducing medicine order turnaround time. Small hospitals have one pharmacy where all dispensing to outpatients and inpatients occurs. Figure 2.2 below illustrates the organization of a hospital pharmacy with satellite sites dispensing to outpatients and inpatients and the flow of information from user points to the supplier (9).




**DDA**- Dangerous drug act; **OPD**- Outpatient department

**Figure 2.2: Pharmaceutical supply chain in Kenya public hospitals**

*Source: Management Sciences for Health (MSH). MDS-3: Managing Access to Medicines and Health Technologies. 2012.*

### 2.8 WHO Operational Package for Monitoring and Assessing the Pharmaceutical Situation

Monitoring, evaluating, and assessing the pharmaceutical sector is critical in determining if key pharmaceutical policy objectives are implemented and achieved over time. The objectives include safety, effectiveness, quality, access to essential medicines, and ensuring that medicines are appropriately and rationally used. Information on pharmaceutical problems, gaps, and needs provides vital inputs for decision-making, planning, health policy development, and health systems management (46).

WHO developed a systematic method to assess the structure and processes of pharmaceutical systems, monitor outcomes, and evaluate the impact of country strategies, policies, and activities on access, use, and quality of medicines (47). As an indicator-based approach for monitoring and evaluation, it should be stable and reliable to deliver high-quality data for decision-making. The WHO pharmaceutical monitoring and assessment use a hierarchy approach with level I, II, and III indicators.

**Level I- core structure and process indicators**; provide a rapid means of assessment to obtain information on existing infrastructure and main processes required within each pharmaceutical sector component. Results provide a wide range of descriptions regarding existing structures, processes, and illustrate the capacity to implement pharmaceutical sector policies (47).

**Level II – core outcomes/ impact indicators on access to essential medicines and rational use of medicines**. This involves the sampling of healthcare facilities with indicators providing systematic data on outcome measures of access which include affordability, medicine prices, availability of key medicines especially to the poor, and geographical accessibility; measures of rational use, and some aspects of quality of medicines at healthcare facilities. Measuring the actual quality of medicines by testing samples is expensive therefore the survey uses the presence of expired medicines in dispensing areas and pharmacy shelves and adequate handling and conservation or storage conditions of medicines as indicators of quality. Rational use is determined by examining prescribing, dispensing habits, and the implementation of standard treatment guidelines and EML (46).

**Level III – in-depth assessment of specific components of the pharmaceutical sector** i.e. pricing, HIV/AIDS, rational drug use, drug supply management, traditional medicines, regulatory capacity, and trade-related aspects of intellectual property rights (TRIPS).

### 2.9 Conceptual framework

Access to essential medicines is determined by many factors as illustrated in figure 2.2 below. This study will look at some of these determinants of access to essential medicines.

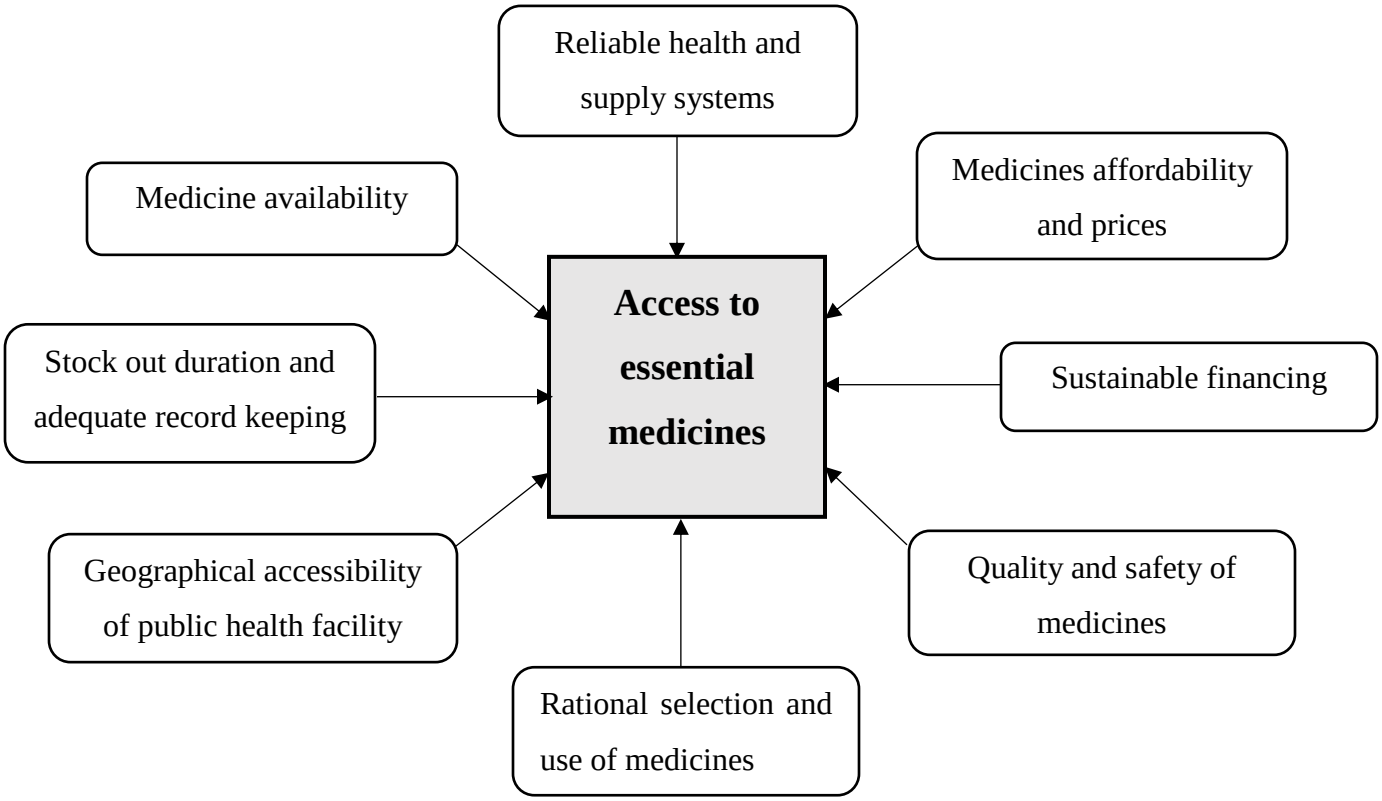



**Figure 2.3: Conceptual framework of access to essential medicines**

The major obstacles to access to essential medicines are low availability, unaffordable prices, unreliable funding, and inefficient supply chains and this study examined aspects of these major obstacles. These included medicines available, stock out duration, record keeping, affordability, prices, expired medicines, storage and handling of medicines, personnel dispensing, pharmacovigilance reporting, medicines supply, and source of funds for medicine supply.

# CHAPTER THREE: METHODOLOGY

## 3.1 Study area

The study was carried out at public health facilities (PHFs) in Mombasa County. The county has a total of 41 operational PHFs comprised of level II- Dispensaries (25), level III- Health Centres (12), level IV- Sub-county Hospitals (3), and level V Hospital (1) (Appendix XII). These PHFs provide healthcare services to the entire population of about 939,370 (2009) residents of Mombasa county and neighboring counties of Kilifi, and Kwale. The level V - Coast General Teaching and Referral Hospital (CGTRH) serves as a regional referral hospital serving patients from 6 counties - Lamu, Tana River, Taita Taveta, Kwale, Kilifi, and Mombasa Counties (48).

## 3.2 Research Design

The study adopted a cross-sectional descriptive survey research design. This was the most appropriate research design for collecting information and data to describe the characteristics of the facilities under study at a given point in time. The survey on essential medicines' access, safety, and quality was carried out through direct observation.

## 3.3 Study Population

The study population was all 41 currently operational PHFs in Mombasa County including all levels of PHFs in the county.

## 3.4 Eligibility criteria

The survey was conducted at all levels of public health facilities in Mombasa County.

| ***Inclusion criteria*** | ***Exclusion criteria*** |
|---|---|
| i. Public facility (Levels II, III, VI, and V facilities) in Mombasa County | i. Private and Missionary facilities<br>ii. Facilities that are non-operational at the time of the study<br>iii. Facilities with incomplete data |

### 3.5 Sampling

#### 3.5.1 Sample size

According to the WHO Operational Package for Assessing, Monitoring, and Evaluating Country Pharmaceutical Situations (46), at least 30 PHFs that provide general outpatient care and have a medicine dispensing area should be included in a cross-sectional survey to describe access and quality of essential medicines. Based on this criterion, the minimum target sample size is 30 PHFs.

The study set out to sample 34 PHFs, which is 4 facilities more than the minimum 30 PHFs required. The extra 4 level II PHFs were included to cater to the possibility of any sampled facilities having few patients or inadequate records.

#### 3.5.2 Sampling procedure

A mixed sampling strategy was applied to sample 34 PHFs, as follows. Universal sampling was applied for level III, IV, and V facilities, whereby all levels III (12), IV (3), and V (1) PHFs were included in the study. All level II PHFs in Nyali (1), Changamwe (2), Jomvu (3), and Likoni (3) sub-counties were also included in the study.

Stratified random sampling was used to sample 9 level II PHFs from Kisauni and Mvita sub-counties. A sampling interval of 2 was calculated by taking the total number of facilities in the sub-county (7) divided by 4 for Kisauni and (9) divided by 5 for the Mvita sub-county.

### 3.6 Data collection

Data was collected by the researcher and 3 research assistants through direct observation and recorded on structured data collection forms (Appendix I – VII) which are derived from the WHO Operational Package for Monitoring and Assessing the Pharmaceutical Situation in Countries tool (46). Data were collected on various aspects of access, quality, and supply chain logistics. Data collection focused on collecting information on 15 key essential medicines from the KEML as well as an additional 10 medicines to treat common conditions also from the KEML.

Medicine's availability and stock record availability were restricted to levels of PHFs where they were expected to be available for use as per the KEML 2016. This is the lowest level of the healthcare delivery system where the medicine is expected to be appropriately and rationally used by competent healthcare personnel.

The 15 key essential medicines included 14 medicines expected to be available at all the PHFs sampled while Salbutamol Inhaler 100 mcg/dose was expected to be available at level IV (3) and V (1) PHFs. Medicines (10) used to treat common conditions included 4 medicines expected to be available at all the PHFs sampled; enalapril tablets 5mg and furosemide tablets 40mg expected to be available at levels III, IV, and V; and glibenclamide tablets 5mg, insulin soluble (human) 100IU/ml, morphine sulphate Injection 10mg/ml and phenytoin tablets 100mg expected to be available at level IV and V as listed in Table 3.1 and 3.2 respectively.

**Table 3.1: 15 key essential medicines from KEML**

| | **15 Key essential medicines for treating common conditions** | **Level of Use** | **PHFs medicine is expected to be available** |
|---|---|---|---|
| 1 | Adrenaline Injection 1mg/mL | 2 | 30 |
| 2 | Amoxicillin 250mg or 500mg capsules | 2 | 30 |
| 3 | Amoxicillin 250mg (dispersible, scored) tablets | 2 | 30 |
| 4 | Artemether / Lumefantrine (20 / 120mg) tablets (any pack size) | 1 | 30 |
| 5 | Combined oral contraceptive pills | 2 | 30 |
| 6 | Benzylpenicillin (600mg=1 MU) Injection | 2 | 30 |
| 7 | Ferrous salt tablets (any salt; alone or in combination with Folic acid) | 2 | 30 |
| 8 | Gentamicin Injection 10mg/ml, 2ml ampoule *OR* 40 mg/ml, 2ml ampoule | 2 | 30 |
| 9 | Albendazole tablets 400mg | 1 | 30 |
| 10 | Malaria Rapid Diagnostic Test | 2 | 30 |
| 11 | Paracetamol tablets 500mg | 1 | 30 |
| 12 | Paracetamol syrup / suspension 120mg/5mL | 1 | 30 |
| 13 | Rapid HIV 1+2 Test 1 - Screening | 2 | 30 |
| 14 | Rifampicin/Isoniazid/Pyrazinamide /Ethambutol 150/75/400/275mg tablets | 2 | 30 |
| 15 | Salbutamol Inhaler 100 mcg/dose | 4 | 4 |

**Table 3.2: Medicines to treat common conditions from KEML**

| | 10 Essential medicines for treating common conditions | Level of Use | PHFs medicine is expected to be available |
|---|---|---|---|
| 1 | Ceftriaxone Injection IM/IV 1gm Vial | 2 | 30 |
| 2 | Enalapril tablets 5mg | 3 | 16 |
| 3 | Furosemide tablets 40mg | 3 | 16 |
| 4 | Glibenclamide tablets 5mg | 4 | 4 |
| 5 | Ibuprofen tablets 200mg | 2 | 30 |
| 6 | Insulin, Soluble (human), 100IU/ml | 4 | 4 |
| 7 | Morphine sulphate Injection 10mg/ml | 4 | 4 |
| 8 | Oxytocin Injection 10IU | 2 | 30 |
| 9 | Phenytoin tablets 100mg | 4 | 4 |
| 10 | Tenofovir/Lamivudine/Efavirenz 300/300/400mg Tabs | 2 | 30 |

These medicines were selected on basis that they are used to treat common acute and chronic health problems, they are on the national essential medicines list (KEML), they are vital therapeutically based on national treatment guidelines and they are most widely used.

### 3.7 Research Instruments

The following research instruments were used for data collection: general information on PHFs pharmacy (Appendix I), key essential medicines availability and quality (Appendix II), prices of key medicines (Appendix III), affordability of treatment (Appendix IV), supply chain logistics (Appendix V), quality (Appendix VI) and medicine supply management (Appendix VII).

#### Appendix I: General information on public health facility pharmacy

This appendix presents information on the PHFs and determined facilities that complied with the requirements of the law for a pharmacist or a pharmaceutical technologist to be present during operational hours of the facility. It also determined the profile of health professionals in charge of the PHFs pharmacy and those dispensing medicines. This was important to identify PHFs with competent personnel to ensure safe medication use and management systems.

#### Appendix II: Key essential medicines availability and quality

This appendix checks the availability and presence of expired medicines on shelves for 15 key medicines and 10 medicines used to treat common conditions.

**Appendix III: Prices of key medicines**

This appendix checks for the lowest unit price of key essential medicines to the patient and the PHFs.

**Appendix IV: Affordability of treatment**

This appendix provides information on the equivalent number of days' wages required to pay for treatment of moderate pneumonia in adults and children, insulin-dependent diabetes in adults, and pediatric asthma without hospitalization.

**Appendix V: Supply chain logistics**

This appendix collected information on adequate record-keeping and stock-out duration of 15 key medicines and 10 medicines for treating common conditions.

**Appendix VI: Quality**

This appendix collected information on adequate storage conditions and handling of medicines at storage areas and dispensing areas.

**Appendix VII: Medicine supply management**

This appendix collected information on various aspects of medicines supply management which include; selection and use, management support, pharmaceutical human resources, information management system, procurement and financing, and inventory management.

### 3.8 Study variables

The study variables included;

1. Key medicines and medicines used to treat common conditions that were in stock at the time of the survey (table 3.1 and table 3.2).
2. Expired key medicines and medicines used to treat common conditions that were on shelves at the time of the survey (table 3.1 and table 3.2).
3. Unit prices of key essential medicines to the patient and the public health facility.
4. The equivalent number of days' wages for treatment of pneumonia, diabetes, and asthma without hospitalization.
5. Number of stock out days for key medicines

6. Adequacy of record-keeping for key medicines
7. Descriptions of the storage and handling of medicines, selection, and use of medicines, management support, human resource, information management, procurement and financing, and inventory management

### 3.9 Data management and quality assurance

The pre-designed data collection tools (Appendix I – VII) were pre-tested in 4 PHFs, one facility from each level. All survey forms were filled and summarized, and the findings were used to modify the data collection tools, address difficulties in data collection and summary computation, and correct inconsistencies in data entry.

The research assistants used were qualified pharmacists. They were trained on the survey and the use of all indicator research instruments by the researcher. The training emphasized data quality, accuracy, completeness, consistency, and integrity.

Data were checked for completeness and consistency during the field survey. Missing information was completed and checked again before final calculations. The summary form (Appendix VIII) was used to record a summary of all indicators. The data was coded and transcribed into Microsoft Excel 2016 and cleaned for missing variables. The data was then exported to Stata Statistical Software version 13.1 (StataCorp, USA) for analysis. The level of significance was set at α-(0.05) and for model building in multivariable regression analysis was set at α-(0.2).

Data collection authorization was sought from the Mombasa County ethics review committee and hospital authorities. Confidentiality and security of collected data were ensured by storing all data collecting instruments under lock and key in cabinets accessible to the researcher only. Electronic data was stored in password-protected computer folders and files.

### 3.10 Data analysis

Continuous variables were tested for normal distribution using the Shapiro-Wilk test. Normally distributed variables were summarized as the mean and standard deviation of the mean, while those not normally distributed were summarized as median and interquartile range. Categorical variables were coded into binary or ordinal variables, analyzed, and summarized in frequencies and percentages. The findings of the summary analysis were presented in tables and figures.

Availability, medicine prices, quality, and affordability of essential medicines data were analyzed by calculating indicators derived from the WHO operational package for assessing, monitoring, and evaluating country pharmaceutical situations, as described below (46).

All variables were dichotomized and their proportions were compared across PHFs with 100% key essential medicines available and those with less than 100% key essential medicines available. Fisher's exact was used for inferential data analysis.

Regression analysis was done to identify the key predictors of key essential medicines' availability in PHFs. Penalized maximum likelihood logistic regression analysis was used since the outcome was dichotomous and to reduce bias in logistic regression due to the small sample data sets (n=30) in the study. Bivariate data analysis was done and the crude measure of association (odds ratio) was presented. All variables with a p-value less than 0.2 ($p < 0.2$) were selected for multivariable logistic regression.

Multivariable penalized maximum likelihood logistic regression was done to determine the independent predictor variables for medicines' availability and their adjusted odds ratio presented.

### 3.10.1 Medicines availability

Medicines availability was assessed by calculating two indicators, i.e. the percentage of 15 selected key medicines and the percentage of 10 selected medicines used in the treatment of common conditions in stock, restricted to levels of PHFs where they were expected to be available for use.

| **Medicine availability indicators** | |
|---|---|
| **Indicator** | **Calculation** |
| Percentage (%) of 15 key essential medicines in stock | The total sum of key medicines in stock was divided by 15 for level IV and V or 14 for level II and III PHFs, then multiplied by 100 |
| Percentage (%) of 10 medicines used to treat common conditions in stock | The total sum of medicines used to treat common conditions in stock was divided by, 10 for levels IV and V, 6 for level III, and 4 for level II, then multiplied by 100 |

### 3.10.2 Expired medicines on shelves

The percentage of expired 15 key medicines and 10 medicines used in the treatment of common conditions on shelves indicated the quality of drugs dispensed to patients.

| Expired medicines on shelves indicators | |
|---|---|
| **Indicator** | **Calculation** |
| Percentage (%) of expired 15 key medicines on shelves | The Sum of expired key medicines on shelves was divided by the total sum of medicines in stock and multiplied by 100 |
| Percentage (%) of expired 10 medicines used to treat common conditions on shelves | The Sum of expired medicines on shelves was divided by the total sum of medicines in stock and multiplied by 100 |

### 3.10.3 Prices of key essential medicines

The price of key medicines was assessed for selected 15 adult and pediatric medications using two indicators; the lowest unit price of medicine paid by patients and the PHFs. Selected medicines are used to treat common acute and chronic medical conditions in children and adults. They are selected from the 15 key essential medicines, 10 medicines for common conditions, and medicines used in assessing affordability in appendix IV. A minimum of four-unit prices per medicine from different PHFs must have been obtained for patient prices and one procurement price of medicine for the median price ratio to be calculated.

| Medicine prices indicators |
|---|
| The lowest unit price of the medicine paid by patients |
| The lowest unit price of the medicine paid by the PHFs |

### 3.10.4 Medicines affordability

The affordability of treatment indicator was estimated as the equivalent number of days' wages required to pay for a full course of treatment of selected acute and chronic disease conditions common in adults and children.

Selected conditions included pneumonia which is an acute condition common in adults and children while chronic conditions included diabetes in adults and asthma in children. A full course of treatment was considered to be affordable if it cost one day's wage or less.

| **Medicine affordability indicators** | |
|---|---|
| **Indicator** | **Calculation** |
| Equivalent number of days' wages required to pay for treatment of moderate pneumonia | The total cost of the entire treatment divided by the lowest daily government salary |
| Equivalent number of days' wages required to pay for treatment of adult diabetes insulin-dependent | Cost of a 10 ml human insulin vial divided by the lowest daily government salary |
| Equivalent number of days' wages required to pay for treatment of asthma in pediatrics | Cost of a beclomethasone inhaler divided by the lowest daily government salary |

### 3.10.5 Supply chain logistics

Supply chain logistics indicators were average stock-out durations and estimates of adequate record-keeping of 15 key medicines and 10 medicines used in the treatment of common conditions.

| **Supply chain logistics indicators** | |
|---|---|
| **Indicator** | **Calculation** |
| Percentage adequate records of 15 key medicines | Sum of 15 medicines with stock records covering at least 6 months within the past 12 months divided by 15 for level IV and V or 14 for level II and III PHFs, then multiplied by 100 |
| Percentage adequate records of 10 medicines used to treat common conditions | Sum of 10 medicines with stock records covering at least 6 months within the past 12 months divided by10 for level IV and V, 6 for level III, and 4 for level 2 PHFs, then multiplied by 100 |
| The average number of stock-out days of 15 key medicines | The sum of the equivalent number of stock out days per year divided by the percentage of adequate records of 15 medicines |
| The average number of stock-out days of 10 medicines used to treat common conditions | The sum of the equivalent number of stock out days per year divided by the percentage of adequate records of 10 medicines |

### 3.10.6 Storage conditions and handling of medicines

Quality indicators included adequate storage conditions and handling of medicines in the storeroom and dispensing areas.

| Storage conditions and handling of medicines indicators | |
|---|---|
| **Indicator** | **Calculation** |
| Percentage available storeroom conditions and handling | Available conditions on the checklist divided by 10 multiplied by 100 |
| Percentage available dispensing area conditions and handling | Available conditions on the checklist divided by 11 multiplied by 100 |

### 3.10.7 Medicine supply management

Medicine supply management practices were evaluated, they included selection and use of medicines, management support, human resource, information management, procurement, and financing; inventory management storage, and handling of medicines.

These indicators were summarized in summary form (Appendix VIII).

## 3.11 Ethical considerations

Ethical approval to carry out the study was obtained from the Kenyatta National Hospital- the University of Nairobi Ethics and Research Committee (KNH – UoN ERC) Ref: KNH-ERC/A/10 (Appendix XI).

The availability, affordability, and quality survey were carried out in healthcare facilities and did not directly involve human participants, therefore no informed consent was sought because the survey was facility-based. However, authorization to collect data was also sought from Mombasa County Research Committee and the respective facilities.

Privacy and confidentiality of data were maintained by serializing PHFs' names to conceal their identity. All data collecting instruments were stored in secure cabinets under lock and key only accessible to the researcher and research assistants. All electronic data was stored in password-protected computer files.

# CHAPTER FOUR: RESULTS

## 4.1 General characteristics of public health facility

The study sampled and collected data from 34 PHFs. Data analysis included 30 PHFs excluding 4 PHFs due to inadequate records and missing information on the filled questionnaire. This met the target sample size of 30 PHFs. The characteristics of the PHFs sampled and analyzed are presented in table 4.1 below.

**Table 4:1 Characteristics of public health facilities**

| **PHFs Characteristics** | | **Frequency N=30** | **% (95% CI)** |
|---|---|---|---|
| Level | II | 14 | 46.7 |
| | III | 12 | 40.0 |
| | IV | 3 | 10.0 |
| | V | 1 | 3.3 |
| Qualified pharmaceutical personnel present during operational hours | Pharmacist or Pharmaceutical technologist | 21 | 70.0(50.5-84.2) |
| | Non-Pharmaceutical personnel | 9 | 30.0(15.8-49.5) |
| Pharmacy-in charge | Pharmaceutical technologist | 16 | 53.3 (34.8 - 71.0) |
| | Pharmacist | 8 | 26.8 (13.3 - 46.2) |
| | Nurse | 4 | 13.3 (4.8 - 32.0) |
| | Pharmacy intern/student | 1 | 3.3 (0.4 - 22.2) |
| | Clinical officer and nurse | 1 | 3.3 (0.4 - 22.2) |

The majority of PHFs sampled were level II PHFs (46.7%). All the PHFs sampled are required by law to have a pharmacist or a pharmaceutical technologist present during operational hours. At the time of the study, the proportion of PHFs that had a qualified pharmacist or pharmaceutical technologist present at the pharmacy was 70.0% (95% CI: 50.5-84.2).

The pharmacy was under the management of diverse clinical personnel with pharmaceutical technologists being in charge of the pharmacies in more than half of the PHFs (53.3 %). Non-pharmaceutical personnel; nurses and clinical officers were in charge of pharmacies in 16.7% PHFs while a pharmaceutical technologist intern was in charge in 3.3% of PHFs.

Personnel dispensing during the time of visit were diverse with pharmaceutical technologists dispensing in 36.7% of the PHFs and pharmacists accompanied by a pharmaceutical technologist in 10% of the PHFs. Figure 4.1.1 below shows the distribution of personnel involved in pharmaceutical dispensing.

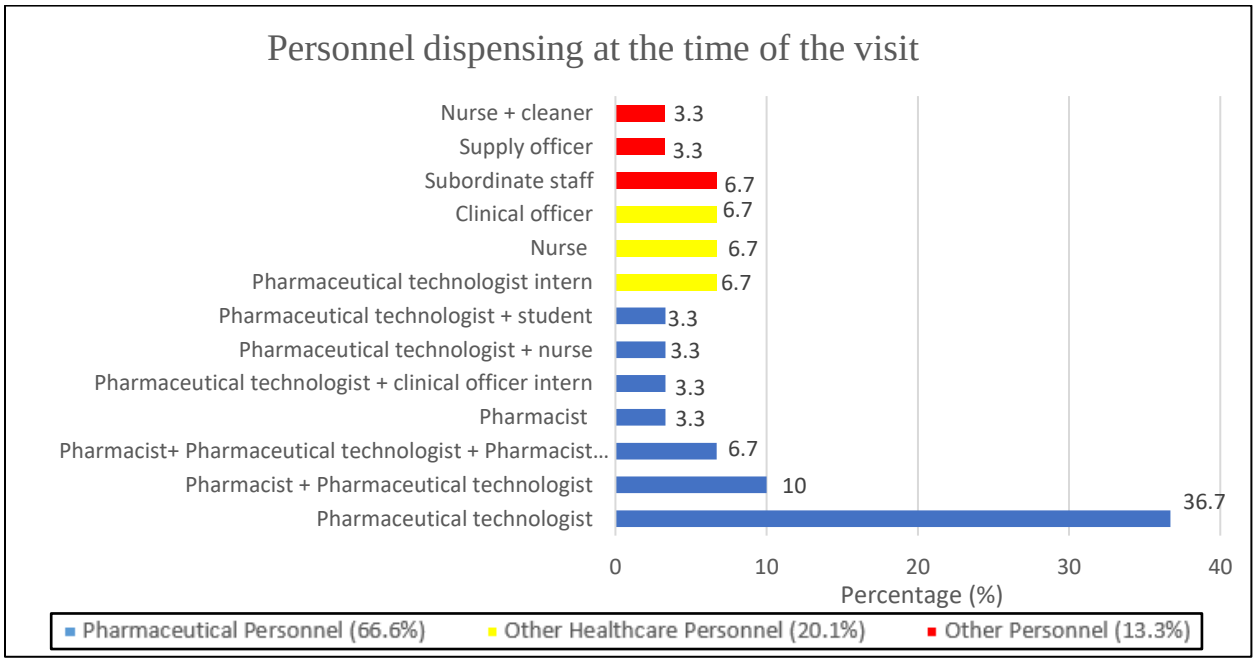



***Figure 4.1 Personnel dispensing at the time of the visit***

Qualified pharmaceutical personnel, other healthcare personnel, and other personnel were dispensing medicines in 66.7%, 20.0%, and 13.3% of PHFs. Of note was personnel with no form of healthcare training were dispensing medicines in 13.3% of PHFs with subordinate staff, supply officers, and a nurse accompanied by a subordinate staff dispensing medicines in 6.7%, 3.3%, and 3.3% of the PHFs, respectively.

## 4.2 Essential Medicines Availability and Quality

### 4.2.1 Essential Medicines Availability

On average 86.7% (SD: 10.8) of the 15 key essential medicines and 75.7% (SD: 18.8) of medicines used to treat common conditions were available at the PHFs at the time of the survey.

Figure 4.2 and 4.3 below shows the proportion of PHFs where each of the individual essential medicines was available.

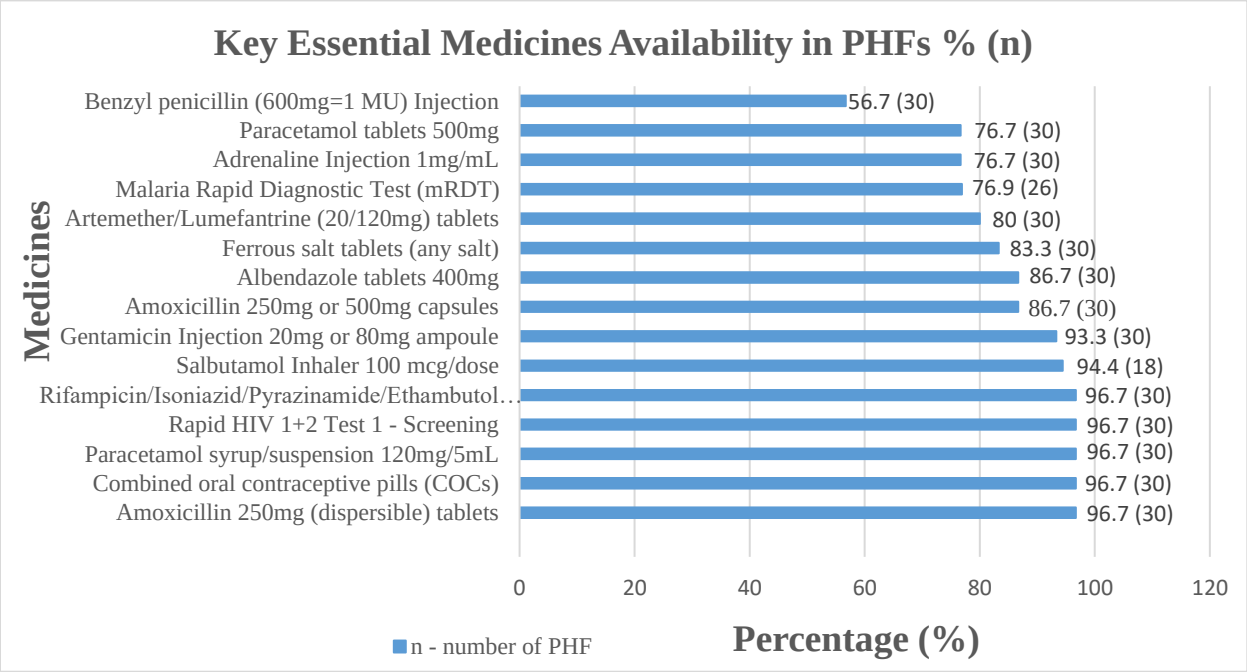



***Figure 4.2 Key essential medicines availability in PHFs***

Benzylpenicillin (600mg=1 MU) Injection was available in only 56.7% of the PHFs while 14 of the 15 key essential medicines were each available in more than 76.7% of the PHFs. Salbutamol inhaler 100 mcg/dose is a key essential medicine for level 4 use; however, it was available in 57.1% of level II and 50.0% of level III PHFs.

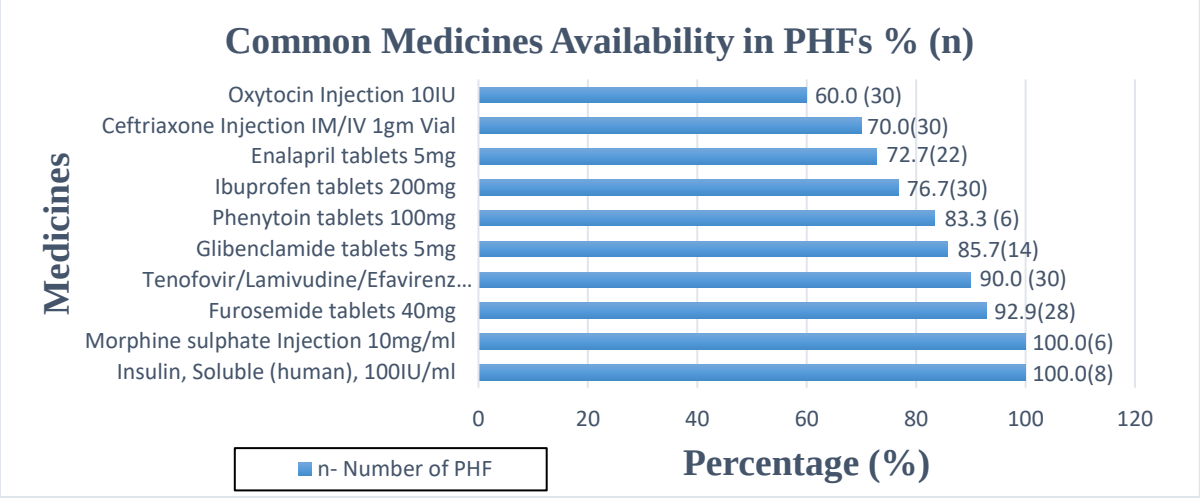



***Figure 4.3 Availability of medicines used to treat common conditions***

Medicines used to treat common conditions had different levels of use where they were expected to be available all the time (Table 3.2). The majority of medicines used to treat common conditions were available in more than 76.7% of the PHFs where they were expected to be available. Oxytocin Injection 10IU, ceftriaxone Injection IM/IV, and enalapril tablets were available in 60.0%, 70.0%, and 72.7% of the PHFs respectively. Soluble insulin 100 IU/ml and morphine sulphate injection 10mg/ml were available in 100% of the PHFs.

Enalapril tablets and furosemide tablets have a level III level of use, yet they were available in 42.9% and 85.7% of level II PHFs, respectively. Glibenclamide tablets, soluble insulin (human), morphine sulphate injection, and phenytoin tablets have a level 4 level of use however they were available in 41.7%, 25.0%, 16.7%, and 8.3% of level III PHFs, respectively. Glibenclamide tablets, soluble insulin (human), and phenytoin tablets were also available in 35.7%, 7.1%, and 7.1% of level II PHFs respectively.

**Table 4.2 Personnel dispensing medicines with different levels of use**

| | **Facilities available (N)** | **Qualified pharmaceutical personnel n (%)** | **Other healthcare personnel n (%)** | **Other personnel n (%)** |
|---|---|---|---|---|
| Enalapril Tablets | 22 | 17 (77.3) | 3 (13.6) | 2 (9.1) |
| Furosemide Tablets | 28 | 19 (67.9) | 6 (21.4) | 3 (10.7) |
| Glibenclamide tablets | 14 | 11 (78.6) | 2 (14.3) | 1 (7.1) |
| Morphine sulphate injection | 6 | 5 (83.3) | 1 (16.7) | 0 |
| Phenytoin tablets | 7 | 5 (71.4) | 2 (28.6) | 0 |
| Salbutamol inhaler | 19 | 13(68.4) | 3 (15.8) | 3 (15.8) |
| Soluble insulin (human) | 8 | 6 (75.0) | 1 (12.5) | 1 (12.5) |

The availability of the 15 key essential medicines in PHFs did not differ significantly with the level of PHFs (p= 0.221), and personnel in charge of PHFs pharmacies (p=0.323). The availability of medicines used to treat common conditions differed significantly with personnel in charge of pharmacies (p= 0.048) but no statistically significant difference was observed between the levels of PHFs (p= 0.155). PHFs that had a pharmacist as the in-charge of the pharmacy had better availability (91.5%) of medicines used to treat common conditions than those that had a pharmaceutical technologist (68.6%), and a nurse (74.2%) as the in-charge.

### 4.2.2 Expired essential medicines on shelves

The median proportion of the 15 key essential medicines and 10 medicines used in the treatment of common conditions that were found expired on shelves was 0% [IQR: 0, 8.33] and 0% [IQR: 0,0] respectively. Overall, at least one expired key essential medicine was found on the shelves of 43.3% (95%CI: 26.2-62.2) of PHFs. The proportion of level II, III, and IV PHFs that had at least one expired key essential medicine on the shelves was 42.9% (95% CI:19.2-70.2), 41.7% (95% CI: 17.0-71.4), and 66.7% (95% CI: 8.5-97.7) respectively. At least one expired medicine used to treat common conditions was found on shelves of 6.7% (95% CI: 1.5-24.7) of the PHFs with at least one expired medicine used to treat common conditions found on shelves of 8.3% (95% CI: 0.9-0.45) and 33.3% (95% CI: 2.3-91.5) of the level III and IV PHFs, respectively.

From the perspective of the individual medicines, more than a third (40.0%) of the 15 key essential medicines had expired on shelves of at least one PHF. Expired adrenalin injection and artemether/lumefantrine tablets were found on the shelves of 16.7% PHFs and each accounted for 26.3% of the instances of expired key medicines.

Benzylpenicillin injection and gentamicin injection expiries were found in shelves of 13.3% and 10.0% of PHFs, and they accounted for 21.1% and 15.8% of the instances of expired key medicines respectively. Appendix IX summarizes the entire list of expiries. Only two (20%) of the 10 medicines used to treat common conditions had expired on shelves of at least one PHF and included ceftriaxone injection and phenytoin tablets.

The proportion of expired key medicines on shelves did not vary significantly with the level of PHFs (p= 0.745) or personnel in charge of PHFs pharmacies (p=0.147). Also, the proportion of expired 10 medicines used to treat common conditions on shelves did not vary significantly with the level of PHFs (p=0.246) or personnel in charge of PHFs pharmacies (p=0.941).

## 4.3 Prices of key essential medicines

Essential medicines are offered free of charge in 46.7% of the PHFs which include 50.0% and 58.3% of level II and III PHFs respectively. Therefore, there were no available patient medicine prices to measure in these PHFs. The procurement and patient medicine unit prices are presented in table 4.3 below.

**Table 4.3 Median unit patient and procurement medicine prices in Kenyan shillings (Ksh)**

| Medicines | Median patient unit price [Range] Ksh | Median procurement unit price [Range]Ksh | The ratio of median patient unit price to median procurement unit price |
|---|---|---|---|
| Adrenaline 1mg/ml injection ampoule | 50 [8,100] | 6 [6,6] | 8.3 |
| Enalapril 5 mg tablets | 5 [1.7,10] | 0.65 [0.65,3] | 7.7 |
| Gentamicin 20mg ampoule injection | 50 [7,100] | 8 [5,11] | 6.3 |
| Paracetamol 120mg/5mL syrup/susp | 45 [20,50] | 8.4 [8.4,30] | 5.4 |
| Furosemide 40 mg tablets | 2.5 [1.3,10] | 0.52 [0.52,1] | 4.8 |
| Phenytoin 100 mg cap/tab | 5 [3,10] | 1.05 [0.4,1.69] | 4.8 |
| Glibenclamide 5mg tab/cap | 4.15 [1.7,5] | 0.89 [0.89,2.97] | 4.7 |
| Oxytocin 10 IU Injection | 40 [20,100] | 13 [13,13] | 3.1 |
| Ceftriaxone 1g/vial injection | 100 [45,150] | 38 [30,38] | 2.6 |
| Ibuprofen 200 mg tablets | 2.2 [1.7,3.3] | 0.95 [0.95,0.95] | 2.3 |
| Co-trimoxazole 240mg/5ml suspension | 50 [40,100] | 22 [20,22] | 2.3 |
| Amoxicillin 250mg capsules | 3.3 [2,6.7] | 1.48 [1.45,4.15] | 2.2 |
| Amoxicillin 250mg (dispersible) tablets | 6.69 [3,10] | 4.19 [2.25,8.9] | 1.6 |
| Beclomethasone Inhaler 100mcg / dose | 450 [300,500] | 300 [300,363] | 1.5 |
| Human Insulin (biphasic) 30/70 100IU/ml vial | 400 [100,500] | 300 [240,300] | 1.3 |
| Salbutamol 100 mcg/dose Inhaler | 250 [100,350] | 230 [140,230] | 1.1 |
| **Mean ratio of median patient price to median procurement price (SD)** | | | 3.7(2.3) |

The mean ratio of median patient unit price to median procurement unit price in Table 4.4 above means that, on average, the median prices paid by patients were 3.7(SD:2.3) times the median procurement prices paid by the PHFs for the medicines.

There was no statistically significant difference in the patient and procurement prices of any medicine with the level of PHFs and personnel in charge of PHFs pharmacies.

### 4.3.1 Median price ratio (MPR)

The median price ratio is the median patient or procurement local unit medicine price to the international reference unit price. The median patient and procurement unit medicine prices were compared to the Management Sciences for Health (MSH) international buyer or supplier prices.

The 2015 MSH international reference prices (IRP) were used in the analysis since it was the existing classification in use in 2020 (49). IRP unit prices are in United States dollars (US$) therefore the PHFs unit medicine prices were converted to US$ from Ksh at a rate of 1US$ = 106.85 Ksh which was the average exchange rate in June and July 2020, when data was collected (50). The IRP was adjusted for inflation with the value of 1US$ in 2015 being equivalent to 1.09 US$ in 2020 (51). Table 4.4 below presents the median patient and procurement medicine unit prices in PHFs in US$, their corresponding buyer and supplier IRP in US$, and the patient and procurement median price ratios.

**Table 4.4 Patient price, procurement price, and median price ratios**

| **Medicines** | **PHFs median patient price US$** | **IRP patient price US$** | **Patient MPR** | **PHFs Procurement prices US$** | **IRP procurement Price US$** | **Procurement MPR** |
|---|---|---|---|---|---|---|
| Salbutamol 100 mcg/dose Inhaler | 2.34 | 0.01 | 370.1 | 2.15 | 0.01 | 214.7 |
| Co-trimoxazole 240mg/5ml suspension | 0.47 | 0.00 | 102.2 | 0.21 | 0.01 | 39.4 |
| Paracetamol 120mg/5mL syrup | 0.42 | 0.01 | 60.4 | 0.08 | 0.01 | 13.9 |
| Human Insulin 30/70 100IU/ml vial | 3.74 | 0.52 | 7.2 | 2.81 | 0.27 | 10.4 |
| Enalapril 5 mg tablets | 0.05 | 0.01 | 6.9 | 0.01 | 0.01 | 0.5 |
| Glibenclamide 5mg tablets | 0.04 | 0.01 | 6.7 | 0.01 | 0.01 | 1.3 |
| Furosemide 40 mg tablets | 0.02 | 0.01 | 3.5 | 0.00 | 0.01 | 0.7 |
| Amoxicillin 250mg (dispersible) tablets | 0.06 | 0.02 | 3.3 | 0.04 | 0.03 | 1.1 |
| Ibuprofen 200 mg tablets | 0.02 | 0.01 | 2.7 | 0.01 | 0.01 | 1.2 |
| Adrenaline 1mg/ml injection | 0.47 | 0.21 | 2.2 | 0.06 | 0.19 | 0.3 |
| Oxytocin 10 IU Injection | 0.37 | 0.18 | 2.1 | 0.12 | 0.17 | 0.7 |
| Ceftriaxone 1g/vial injection | 0.94 | 0.46 | 2.0 | 0.36 | 0.43 | 0.8 |
| Amoxicillin 250mg capsules | 0.03 | 0.02 | 1.2 | 0.01 | 0.02 | 0.8 |
| Phenytoin 100 mg cap/tab | 0.05 | 0.05 | 1.0 | 0.01 | 0.01 | 0.9 |
| Gentamicin 20mg injection | 0.47 | - | - | 0.07 | 0.19 | 0.4 |
| **Median MPR [Range]** | | | **3.4[1.0,370.1]** | | | **0.9[0.3,214.7]** |

The median price paid by patients for essential medicines in PHFs was 3.4 [Range: 1.0, 370.1] times the IRP. Salbutamol 100 mcg/dose inhaler, co-trimoxazole 240mg/5ml suspension and paracetamol 120mg/5mL syrup had high MPR of 370.1, 102.2 and 60.4 respectively. The median medicine procurement prices in PHFs are 0.9 [Range: 0.3, 214.7] the procurement IRP is slightly lower. This indicates that the procurement system was obtaining essential medicines at competitive prices. Medicines with high MPR included salbutamol 100 mcg/dose inhaler, co-trimoxazole 240mg/5ml suspension, paracetamol 120mg/5mL syrup, and human insulin (biphasic) 30/70 100IU/ml vial with their prices being 214.7, 39.4, 13.9, and 10.4 times the IRP.

### 4.3.2 Affordability of treatment

The affordability of treatment of moderate pneumonia in adults and children, diabetes in adults, and asthma in children was estimated as the equivalent number of days' wages of the lowest daily government wage required to pay for a full course of treatment. The lowest daily government wage used during the analysis was Ksh 653.1 (Approx. US $ 6.11) (52).

The mean affordability of amoxicillin 250mg capsules complete dose of 42 capsules for the treatment of moderate pneumonia in adults was 0.2(SD: 0.072) days' wages, with a mean unit price per capsule at 3.78 (SD: 1.121) Ksh and total cost of treatment at 158.76 Ksh. Amoxicillin 250mg dispersible tablets full course of 21 tablets for the treatment of moderate pneumonia in children under 5 years mean affordability was 0.2[SD: 0.078] days' wages, with a mean unit price of a tablet at 7.25(SD: 2.563) Ksh and total cost of treatment at 152.25 Ksh.

The median affordability of a vial of human insulin 30/70 100IU/ml for treatment of diabetes in adults was 0.6[IQR: 0.613, 0.727] with a unit price of 400 [IQR: 400,500] Ksh. Beclomethasone inhaler 50mcg for treatment of asthma in children had median affordability of 0.7[IQR: 0.643, 0.766] and a unit price of 433.33(SD: 75.277) Ksh per bottle. Treatment of moderate pneumonia, adult diabetes, and asthma in children without hospitalization was therefore found to be affordable since it was less than a day's wage.

The affordability of treatment of moderate pneumonia in adults and children, diabetes in adults, and asthma in children was below a day's wage as illustrated in figure 4.4 below.

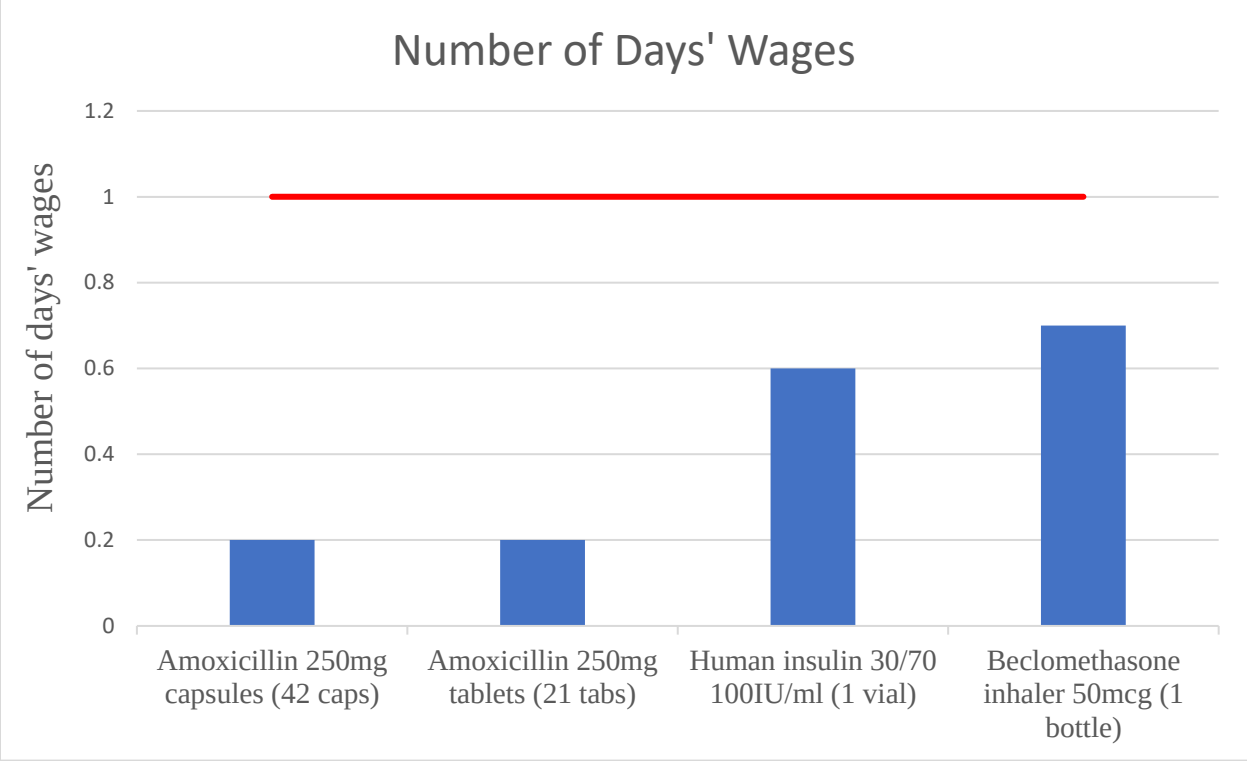



***Figure 4.4 Number of days' wages required to purchase a course of treatment***

### 4.4 Stock-Outs

The majority of PHFs 76.6% experienced stock-outs of at least one key essential medicine and 46.7% at least one medicine used to treat common conditions. The majority of PHFs experienced no stock-outs in the medicines used to treat common conditions (53.3%), while only 23.3% of PHFs had no stock-outs in key essential medicines. The majority of key essential medicines (93.3%) and medicines used to treat common conditions (80.0%) experienced a stock out over the 12 months.

The median number of key essential medicines and medicines to treat common conditions that were stocked out at least once over the 12 months per PHFs was 4 (Range: 0, 12) and 0 (Range: 0, 6) respectively. Medicines that had more than 30% PHFs experiencing stock-outs and the average stock out days are listed below in table 4.5, for the complete table of all medicines see Appendix X. Individual key essential medicines stock out days ranged between [0,312] days while for common medicines was [0,324] days.

**Table 4.5 Medicines experiencing the most stock-outs**

| Medicine | PHFs that experienced stock out (%) N = 30 | Average stock-out duration (SD) | Range |
|---|---|---|---|
| Paracetamol 500mg tablets | 42.9 | 45 (76) | [0,270] |
| Albendazole 400mg tablets | 40.0 | 42 (69) | [0,242] |
| Artemether/Lumefantrine (20 / 120mg) tablets | 37.9 | 49 (76) | [0,242] |
| Ibuprofen 200mg tablets | 34.5 | 48 (94) | [0,305] |
| Amoxicillin 250/500mg capsules | 33.3 | 42 (70) | [0,240] |

Overall more than 30% of PHFs experienced a stock out of artemether/lumefantrine tablets, paracetamol 500mg tablets, ibuprofen 200mg tablets, albendazole 400mg tablets, and amoxicillin 250/500mg capsules at some point within the 12 months. Rifampicin/Isoniazid/Pyrazinamide /Ethambutol 150/75/400/275mg tablets, soluble insulin human 100IU/ml, and Tenofovir/Lamivudine/Efavirenz 300/300/400mg tablets did not experience a stock out in any facility.

The average stock-out duration for PHFs within the previous 12 months for key essential medicines was 27 [Range: 0, 96] days while for medicines used to treat common conditions was 22 [Range: 0, 98] days. The stock-out duration was evaluated for each PHFs and the findings are displayed in figure 4.4 below.

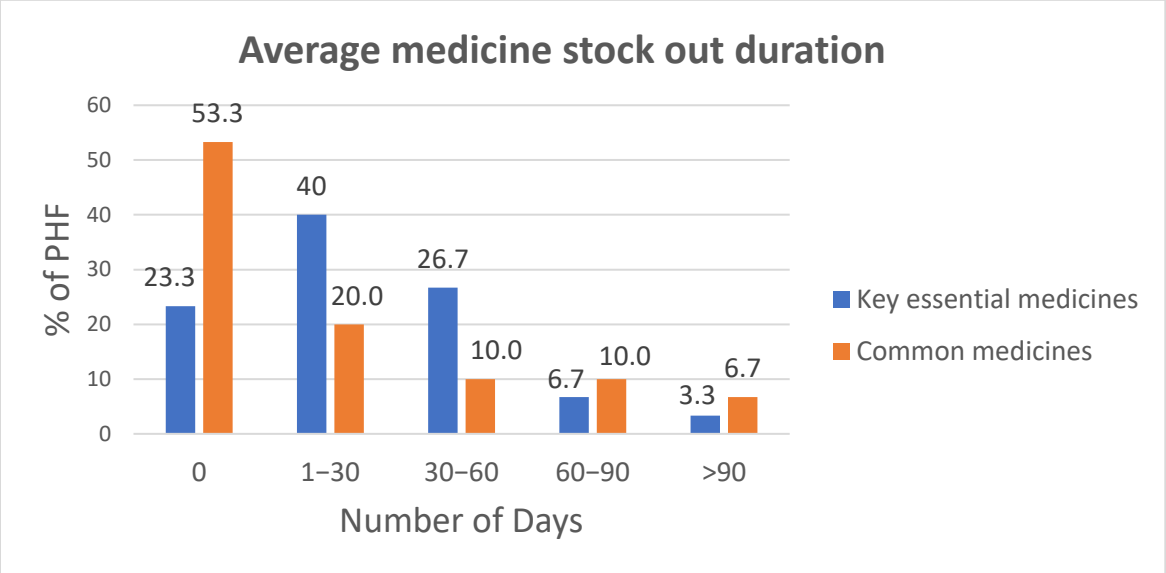



***Figure 4.5 Stock-out duration of essential medicines***

Most PHFs experienced stock-out days ranging between 1 and 30 days for key essential medicines, while most PHFs did not experience stock-outs for medicines used to treat common conditions. Drug stock-outs may extend beyond 30 days and sometimes 90 days for some PHFs. There was a statistically significant difference in duration of stock out of albendazole 400mg tablets with personnel in charge of PHFs (p=0.028), with stock-outs being experienced in 68.8% and 25% of PHFs where pharmaceutical technologists and nurses were respectively in charge. There was no statistically significant difference in the duration of stock out of the rest of the medicines between the levels of PHFs or personnel in charge of the PHFs pharmacies. The number of medicines stocked out over the 12 months in each PHF did not vary significantly with the levels of PHFs or personnel in charge of PHFs.

### 4.5 Stock records

Adequate stock records contain documentation of all transactions relating to medicine which include; reorder level, interval and quantity, lead time, projected consumption rate, and current stocks on shelves. The majority of PHFs maintain bin cards for recording receipts, issues, physical counts, and stock balances for each medicine strength in each storage area. This survey only checked the availability of records, there was no verification of accuracy, completeness, and quality of records.

The proportion of key essential medicines and medicines used to treat common conditions with stock records was 93.3% [93.3, 100] and 80.5% (SD: 16.8) respectively. Only 43.3% and 30.0% of PHFs had all stock records on key essential medicines and medicines used to treat common conditions respectively available, with the rest of PHFs having at least one record missing.

**Table 4.6 PHFs with missing stock records**

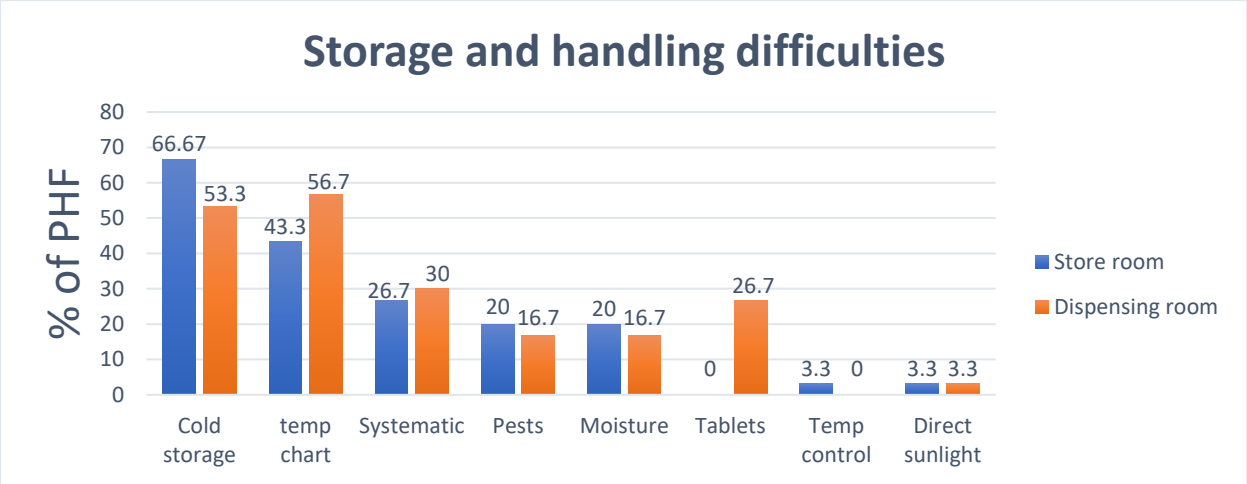
| PHFs with missing stock records | | |
|---|---|---|
| **Number of missing stock records** | **Key essential medicines n (%)** | **Medicines for common conditions n (%)** |
| None | 13 (43.3) | 9 (30.0) |
| 1 | 12 (40.0) | 14 (46.7) |
| 2 | 3 (10.0) | 5 (16.7) |
| 3 | 1 (3.3) | 2 (6.7) |
| 4 | 1 (3.3) | 0 |

Medicines that had stock records in all PHFs included amoxicillin 250mg capsules, amoxicillin 250mg (dispersible) tablets, combined oral contraceptive pills, ferrous salt tablets, albendazole tablets, paracetamol syrup, rapid HIV 1+2 Test kits, glibenclamide tablets, and morphine sulphate Injection. The rest of the medicines had available stock records in more than 90% of PHFs except; adrenaline injection, ceftriaxone injection, enalapril tablets, and oxytocin injection which were available in only 80.0%, 80.0%, 73.9%, and 60.0% of PHFs respectively.

The availability of key essential medicines stock records did not differ significantly with personnel in charge (p=0.062) or the level of PHFs (p=0.085). There was no statistically significant difference in the availability of stock records for medicines used to treat common conditions with personnel in charge (p=0.123), and level of PHFs (p=0.173).

### 4.6 Storage and handling conditions

Storerooms and dispensing areas on average met 82.3% (SD: 13.0) and 81.8% (SD: 15.8) of the criteria for adequate storage and handling conditions for medicines. The storage conditions in storerooms and dispensing areas were similar, though handling and manipulation of medicines with naked hands were meant for dispensing areas only. Figure 4.5 below illustrates the frequent conservation and medicine handling problems encountered by PHFs.




**Cold storage** - lack of cold storage facilities i.e. working fridge or cold room; **temp chart** - lack of a regularly filled temperature chart/log for storage and dispensing areas; **systematic** - medicines are not stored or arranged systematically; **pests** – the presence of pests; **moisture** – leaking roof, ceiling, drains or tap; **tablets** – manipulation of tablets or capsules by naked hand; **temp control** – lack of temperature control methods; and **direct sunlight** – lack of curtains or blinds, and painted windows.

***Figure 4.6 Medicine storage and handling difficulties***

The majority of PHFs lack cold storage facilities i.e a working fridge or a cold room in the storeroom (66.7%) and dispensing area (53.3 %). Other problems include; the lack of a regularly filled temperature chart/log for storage and dispensing areas; medicines are not stored or arranged systematically e.g. alphabetically; the presence of pests i.e. rats, cockroaches; the presence of moisture i.e. leaking roof, ceiling, drains, or taps; manipulation and handling of tablets or capsules by naked hand; lack of temperature control methods e.g. roof and ceiling with space between, air conditioners, fans; and direct sunlight in storage and dispensing area due to lack of painted window panes, curtains or blinds to protect against the sun.

All PHFs storerooms and dispensing areas had; air vents and windows that were open to allow air circulation; pallets and shelves for storing medicines; and medicines were stored and arranged the first expiry, first out. There was a statistically significant difference in storage and handling conditions in storerooms with the level of PHFs (p= 0.013), and personnel in charge of the pharmacies (p=0.027). Level V PHFs had better storage and handling conditions (100%) than level IV (93.3%), III (86.7%), and II (75.0%) PHFs. PHFs that had a pharmacist as the in-charge of the pharmacy had better storage and handling conditions (93.8%) than those that had a pharmaceutical technologist (78.75%), and a nurse (72.5%) as the in-charge.

There was a statistically significant difference in storage and handling conditions in dispensing areas with personnel in charge of pharmacies (p=0.002) and no statistically significant difference in the level of PHFs (P=0.07). PHFs that had a pharmacist as the in-charge of the pharmacy had better storage and handling conditions (98.8%) than those that had a pharmaceutical technologist (76.7%), and a nurse (68.2%) as the in-charge.

### 4.7 Medicine supply management aspects

Medicines and therapeutics committees (MTC) were absent in the majority (86.7%) of PHFs and 93.3% of PHFs had no terms of reference. Explicit member composition of the MTC was available in 13.3% of the PHFs, they included; pharmacists, pharmaceutical technologists, clinical officers, nurses, and laboratory technicians. Minutes of meetings held 3 months before the study (March-May 2020) was only available in 6.7% of the PHFs with key issues including; availability of essential medicines, regular continuous medical education, understaffing, and inadequate personal protective equipment.

Pharmacovigilance reporting tools (adverse drug reaction and poor quality medicinal products reporting tools) were available in 76.7% of PHFs. The national pharmacovigilance guidelines were available in publication years 2014, 2016, and 2018 each in 3.3% of PHFs representing only 10.0 % of PHFs. In 12 months, a majority of PHFs did not report any adverse drug reaction (80.0%) and poor quality medicines (67.7%). The majority of filled reports were submitted to sub-county pharmacists (72.7%) while only 27.3% were submitted online in the pharmacovigilance electronic reporting system portal.

There was a statistically significant difference in the number of adverse drug reactions (p=0.000) and poor quality medicine reports (p=0.001) with the levels of PHFs. Level IV and V PHFs accounted for 54.8% and 35.5% of adverse drug reaction reports respectively. Level III PHFs accounted for the highest (57.1%) number of poor quality medicines reports while level VI and V accounted for 28.6% and 14.3% of reports respectively. Level II PHFs did not report any poor-quality medicines. Personnel was trained on the use of pharmacovigilance reporting tools in 63.3% of PHFs while 36.7% had no personnel trained with the median number of personnel trained 1[0,1].

The pharmacy in charge was responsible for pharmaceutical products management in 66.7% PHFs, pharmacy, and facility in charge in 13.3% PHFs, and facility plus pharmacy in charge in 10.0% PHFs. Other personnel involved included nurses, clinical officers, and supply officers each in 3.3% of PHFs. The nurse in charge was responsible for other healthcare product technologies management in all PHFs, (alone in 90.0%, with the facility in charge in 6.7%, and with the pharmacy in charge and supply officer in 3.3% of PHFs). Laboratory in-charge was responsible for laboratory products management in all PHFs, (alone in 86.7%, with facility in-charge in 10.0%, and with supply officer in 3.3% of PHFs).

Integrated supportive supervision within 3 months before the study (March-May 2020) was done in 83.3% of PHFs. The supervision was done by the sub-county health management team in 43.3% of PHFs and the county health management team accompanied by the sub-county health management team in 20.0% of PHFs. Others involved in supportive supervision included the Ministry of health's national tuberculosis, leprosy, and lung disease program, the national AIDs and sexually transmitted infections control program, the national reproductive health program, and the Afya Pwani Project.

The supervision addressed health products and technologies management and gave feedback to 96.0% of PHFs that received supervision, with half of 50.0% of these PHFs receiving support. Support received by the PHFs included; supply of pharmaceuticals in 41.6% PHFs; personnel trained on drug ordering, quantification, filling reporting tools, coronavirus (COVID-19) prevention and control; supply of pallets, fans, air conditioner, shelves, masks, sanitizers, computers; and employment of a nurse and a clinical officer.

Health products and technologies management standard operating procedures (SOPs) and job aids were available in 60.0% of PHFs. The SOPs included; good dispensing practices in 53.3%; pharmacovigilance in 26.7%; medication use counselling, medicine quantification, and good inventory management in 10.0%; good storage practices and good record keeping in 6.7%; and expiry tracking tool in 3.3% of PHFs.

The majority of personnel engaged in the pharmaceutical functions were pharmaceutical technologists (50.6%) and pharmacists (40.3%). Other personnel included nurses (6.5%), clinical officers (1.3%), and pharmaceutical technologist students (1.3%). 84.4% of the personnel were employed by the county government while 13.0% and 2.6% were employed by PHFs and donors respectively. Personnel was trained on pharmacovigilance in 93.3% of PHFs and inventory management, appropriate use of medicines, medicines quantification, and commodity management in 96.7% of PHFs.

Computers with internet access were available in 60.0% of PHFs and were located in the pharmacy, in-charges office, and the store in 43.3%, 13.3%, and 3.3% of PHFs respectively. The computers are maintained by PHFs technicians, information technology department CGTRH, and hired technicians in 10.0%, 26.7%, and 23.3% of PHFs respectively. Working electronic inventory management tool was available and in use in only 10.0% of PHFs. The computers are used for health services, health products and technologies (HPT) stock records, quantification, and reports.

Tools used to record daily medicines consumptions included; malaria daily registers available in all PHFs and used in 93.3% PHFs, family planning daily activity registers available and in use in all PHFs, antibiotics daily register available and in use in 60.0% of PHFs, daily prescription registers available and use in 36.7% of PHFs, and antiretrovirals (ARVs) and opportunistic infections (OIs) daily activity registers available and in use in 93.3% of PHFs.

Facility consumption data report and request form (F-CDRR) in PHFs included; malaria available and antiretroviral therapy each available and in use in 96.7%, expanded program for immunization (EPI), KEMSA logistics management information system (LMIS), and family planning available and in use in all PHFs.

Pharmaceuticals and other health products were supplied by KEMSA and 46.7% of PHFs were procured from other sources when products were out of stock at KEMSA. 13.3% of PHFs procured medicines from the Mission for Essential Drugs and Supplies (MEDS). Other suppliers included Mombasa surgical, Medisel, Transwide, Eldohosp, Atom, Njimia, Shifa, Surgipharm, Laborex, Harleys, Sai, and Makadara chemists. 10.0% of PHFs had more than four different suppliers supply them with drugs within 6 months (December 2019-May 2020). The sources of funds for procurement from other sources included daily collection from facilities (23.3%), sub-county (10.0%), Linda mama, (10.0%), and national government (3.3%) of PHFs.

Quantities of essential medicines and medical supplies ordered by PHFs were determined by monthly consumption in 73.3% of PHFs and by rough estimation in 26.7% of PHFs. Order fill rate from KEMSA for amoxicillin 500mg, paracetamol 500mg, surgical masks, gloves, and malaria rapid diagnostic test were all at 100[IQR; 100,100]. Physical stock counts are conducted weekly in 3.3%, monthly in 76.7%, quarterly in 3.3%, triannual in 6.7%, biannual in 3.3%, and no stock counts in 6.7% of PHFs. Stock count discrepancies are reconciled with bin cards (S5), counter requisition, and issue orders (S11) and adjusted in 73.3% of PHFs. Short expiry medicines are redistributed within the sub-county in 86.2%, price reduced or given for free in 6.9%, and returned to CGTRH in 6.9% of PHFs. Expired medicine stocks are sorted, recorded, stored, and collected by the sub-county pharmacist in 75.9%, incinerated within the PHFs in 13.8%, sent to a PHFs with an incinerator in 3.4%, and sent to CGTRH in 6.9% of PHFs for disposal.

### 4.8 Predictors of key essential medicines availability

Penalized maximum likelihood logistic regression analysis was done to identify the key predictors of key essential medicine availability. This method was used to reduce bias in logistic regression due to the small sample data sets (n=30) in the study. Essential medicines should be available at all PHFs at all times in adequate amounts, and therefore for purposes of logistic regression, the continuous variable availability was converted to a binary variable with PHFs that had 100% available medicines in one arm and those with less than 100% availability in the second arm.

Bivariate penalized maximum likelihood logistic regression was conducted on selected variables, and the crude odds ratios are presented in table 4.7 below.

**Table 4.7 Characteristics of PHFs with all key essential medicines available and those missing one or more essential medicines**

| | | PHFs with 100% key essential medicines available N= 6 | PHFs with less than 100% key essential medicines available N= 24 | OR (95% CI) | p-value |
|---|---|---|---|---|---|
| **Categorical variables N (%)** | | | | | |
| **Level of PHFs** | II & III | 4 (66.7) | 22 (91.7) | 0.2 (0.03 - 1.5) | 0.169 |
| | IV & V | 2(33.3) | 2 (8.3) | | |
| **Qualified personnel present at the PHFs** | | | | 1.9 (0.3 - 13.8) | 0.400 |
| Present | | 5 (83.3) | 16 (66.7) | | |
| Absent | | 1 (16.7) | 8 (33.3) | | |
| **Personnel in charge of pharmacy** | | | | 1.1 (0.1 - 7.9) | 0.656 |
| Qualified pharmaceutical personnel | | 5 (83.3) | 19 (79.2) | | |
| Other healthcare personnel | | 1 (16.7) | 5 (20.8) | | |
| **Personnel dispensing during the visit** | | | | 0.5 (0.06 - 3.2) | 0.326 |
| Qualified pharmaceutical personnel | | 5 (83.3) | 15 (62.5) | | |
| Other healthcare personnel | | 1 (16.7) | 9 (37.5) | | |
| **Expired medicines found on pharmacy shelves** | | | | 1.4 (0.3 - 7.4) | 0.531 |
| Expired medicines on shelves | | 3 (50.0) | 10 (41.7) | | |
| No expired medicines on shelves | | 3 (50.0) | 14 (58.3) | | |
| **Stock records available during the visit** | | | | 22.5 (2.7 - 189.5) | **0.002** |
| All records available | | 5 (83.3) | 3 (12.5) | | |
| At least one record is not available | | 1 (16.7) | 21 (87.5) | | |
| **Stock out of at least one key essential medicine** | | | | 0.09 (0.01 - 0.6) | **0.016** |
| No stock out | | 4 (66.7) | 3 (12.50 | | |
| Stockout occurred | | 2 (33.3) | 21 (87.5) | | |
| **Storeroom conditions available** | | | | 16.2 (2.1 - 122.6) | **0.007** |
| All storeroom conditions are available | | 4 (66.7) | 2 (8.33) | | |
| At least one storeroom condition is not available | | 2 (33.3) | 22 (91.7) | | |
| **Dispensing room conditions are available** | | | | 8.2 (1.3 - 52.3) | **0.029** |
| All dispensing room conditions are available | | 4 (66.7) | 4 (16.7) | | |
| At least one dispensing room condition is not available | | 2 (33.3) | 20 (83.3) | | |

There was a statistically significant difference in availability of stock records (p=0.002), medicine stock-outs (p=0.016), available storeroom conditions (p=0.007), and dispensing room conditions (p=0.029) between PHFs with all essential medicines available and PHFs with less than 100% key essential medicines available.

All variables that had a p-value less than 0.2 were included in the multivariable penalized maximum likelihood logistic regression analysis to determine the independent predictor variables for medicines' availability. Level of PHFs, available stock records, stock out duration, storeroom, and dispensing area conditions available were included in the multivariable logistic regression and their adjusted odds ratios are presented in table 4.8.

**Table 4.8: Adjusted odds ratios of predictor variables**

| **Characteristics of the facility** | **Adjusted OR (95% CI)** | **p-value** |
|---|---|---|
| Level of PHFs | 4.0 (0.1 – 325.0) | 0.539 |
| Stock records available | 49.6 (2.0 – 1233.2) | 0.017 |
| Stock out of at least one medicine | 0.1 (0.003 – 1.1) | 0.057 |
| Storeroom storage conditions are available | 3.1 (0.05 – 186.8) | 0.595 |
| Dispensing room conditions are available | 0.3 (0.01 – 21.4) | 0.615 |

There was a statistically significant difference in the availability of stock records (p=0.017) between PHFs with all essential medicines available and PHFs with less than 100% key essential medicines available. PHFs with all key essential medicines available have 49.6 times the odds of having stock records compared to those with one or more medicines not available.

# CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS

## 5.1 Discussion

Access to safe, effective, quality, and affordable essential medicines and vaccines is a priority in achieving Sustainable Development Goal 3 target 3.8 of the United Nations (10). The results of this study on availability, quality, prices, affordability, aspects of supply management, capacity for storage, and handling of medicines contribute to the assessment of the progress made by Mombasa county in achieving this goal.

The findings of this study show that 13.3% of PHFs had subordinate staff and supply officers dispensing while 20.0% had nurses and clinical officers dispensing. Qualified pharmaceutical personnel is vital in providing patients with accurate information on dosage, drug and food interactions, side effects, adherence, storage of medicines, and reducing incidences of drug-related problems. Medicine dispensing by unqualified pharmaceutical personnel results in the emergence of multiple drug resistance, adverse drug reactions, drug and food interactions, drug toxicity, non-adherence to treatment, and treatment failures which lead to increased treatment costs, morbidity, and mortality (53,54).

Medicines in Kenya should only be dispensed by a registered pharmacist or under the immediate supervision of a registered pharmacist, which is not the case in the majority of PHFs in Mombasa County, hence the law is not well enforced (55). The county government needs to employ qualified pharmaceutical personnel in compliance with the law to improve patient adherence to treatment and outcomes of treatments. PPB should enforce the law on medicine handling and dispensing in public health facilities to safeguard patient safety and develop policies on the number of required pharmaceutical personnel per level of the healthcare delivery system.

Essential medicines are intended to be available at all times in functioning health systems. This study found that 86.7% of the key essential medicines were available in PHFs and hence fairly available. The availability of essential medicines in Mombasa county is higher than the availability of essential medicines in Ghana (64.1%) (16), Rwanda (55.2%) (56), and 36 LMICs whereas countries in Africa had 29.4% availability (11). Medicines for treating common conditions included medicines for the treatment of NCDs which had an average of 76.7% availability which is slightly below the WHO recommended 80% availability (57).

Medicines surveyed had different levels of use; salbutamol inhalers, enalapril tablets, furosemide tablets, glibenclamide tablets, soluble insulin (human), morphine sulphate injection, and phenytoin tablets were available in levels of use not expected to be available. This was in design to improve access to essential medicines for the treatment of NCDs. Improved access to NCDs should match the rational use of medicines by ensuring qualified pharmaceutical personnel is involved in dispensing these medicines intended for long-term care of chronic diseases. These were dispensed by personnel with no healthcare training (subordinate staff and supply officers) which compromises the quality of care and outcomes of treatment negating the value of improved access. Therefore, the county should employ qualified pharmaceutical personnel to handle these medicines to ensure sufficient adherence counselling to achieve desired treatment outcomes.

The majority of PHFs had missing and incomplete bin cards of at least one medicine. Stock records are vital for effective and efficient medicine supply systems ensuring high availability and minimizing stock-outs of medicines. Monthly consumption recorded from daily activity registers of medicines determined medicine order quantities in 73.3% of PHFs while the rest used rough estimation. Missing and incomplete stock records affect demand estimation which could lead to overstocking or stock-outs as experienced by most PHFs. Computers with internet access were available in 60% of PHFs, they were used for medicine orders and reports, quantification, inventory management, and pharmacovigilance reports.

Stock-out of essential medicines is a major threat to access to equitable essential medicines and the achievement of universal healthcare coverage (6,58). This study found that the majority of PHFs experienced stock-outs, this was similar to a study in Kenya (13) and Ethiopia (59). The majority of PHFs experienced a stock-out duration of 1 to 30 days with a median stock-out duration of 27 days which is an improvement from a majority experiencing a stock-out duration of 56 days in Kenya (13) and similar to a study in Ethiopia 30.5 days (59).

A majority (73.3%) of key essential medicines experienced a stock-out duration of more than 240 days in a year in some PHFs. Stock-outs adversely affect treatment outcomes due to missing treatment, under-treatment, and an increase in the chances of medication error occurrence from attempts to substitute missing medicines. Inadequate financing of treatment programs is the major bottleneck to the continuity of medicine supply in Kenya, Uganda, and Tanzania and is similar to causes of shortages in high-income countries the USA, Canada, Germany, Italy, and the UK (60).

All essential medicines surveyed in the study experienced stock-outs except for donor-funded medicines for the treatment of tuberculosis, diabetes, and HIV. This indicates that unsustainable funding and inefficient supply chains are major contributors to medicine stock-outs. The county should improve healthcare financing and train personnel adequately on medicine supply chain management to ensure medicine orders match the needs and demands of patients. The supply and management of essential medicines should be streamlined to ensure continuous availability of all medicines to increase healthcare utilization, reinforce confidence in the healthcare system, improve treatment outcomes and decrease disease burden.

Essential medicines should be of assured quality, effective and safe (23), yet almost half (43.3%) of PHFs had an expired medicine on the shelf. The presence of expired medicines on shelves of PHFs compromises patient safety as they pose a risk of being dispensed to patients. Short expiry medicines are redistributed within the sub-county in the majority of PHFs, price reduced, and given for free in other PHFs.

The incidence of expired medicines on shelves was 2.3% in a 2010 study in Kenya (13). The incidence of expired medicines on dispensing shelves was 0% though some PHFs experienced expiries of up to 8.3% of key medicines surveyed in this study. Mombasa County is a malaria-endemic zone yet expired antimalarial artemether/lumefantrine tablets were found on dispensing shelves of 16.7% of PHFs and accounted for most of the expiries. Expired medicines lead to wastage of scarce resources in the disposal of pharmaceutical waste and opportunity costs due to disposed of medicines (14). Expired medicines are disposed of by collection by the supplier (KEMSA) in the majority of PHFs while a few PHFs incinerate in the facility incinerator.

Storerooms and dispensing areas met 82.3% of conservancy and medicine handling criteria with most of PHFs lacking cold storage facilities, temperature control methods, tablets counters, presence of pests, and moisture. The quality, efficacy, and safety of medicines are preserved by appropriate storage conditions. Undesirable temperatures, exposure to sunlight, moisture, and pests compromise the efficacy and safety of medicines (15,61). PHFs that had a pharmacist as the in-charge of the pharmacy had statistically significant ($p=0.027$) better storage and handling conditions in dispensing rooms and storerooms. This is due to better infrastructure and qualified personnel involved in medical management. The county should improve storage and infrastructure to accepted norms and standards to ensure the quality and safety of medicines are maintained.

Medicine prices are not regulated and there are no policies on prices charged or markups in Kenya. There is low health insurance coverage that manages to cover only 17.1% of the population (29). Patient prices of medicines surveyed were 3.7 times the PHFs procurement price, with paracetamol syrup, gentamicin injection, adrenalin injection, and enalapril tablets patient prices being higher than 5 times the procurement prices. These findings are similar to the 2009 ministry of health survey where the median patient to procurement price was 4.51 (13). The county should develop and implement medicine pricing policies to ensure uniform markups, streamline medicine prices, and increase healthcare budgets to achieve universal health coverage.

Lack of price controls and excess profits in PHFs are the major reasons for medicine markups in the public hospitals of 370%, which is higher than public sector mark-ups in Tanzania (17%), Mongolia (32%), China (Shandong) (35%), Malaysia (46%), Uganda (66%), Ethiopia (83%) and Mali (84%). Medicine markups in the public sector are used to generate revenue to subsidize other healthcare systems especially covering operating expenses which drive the cost of medicines up due to high markups to generate the revenue (11). The county should collaborate with NHIF to enroll a large number of its population in an insurance scheme to reduce out-of-pocket spending, improve financial risk protection, access to healthcare and essential medicines and achieve universal health coverage.

Medicines are procured from KEMSA and other sources including MEDS in 13.3% PHFs and 12 other suppliers when stocked out at KEMSA. Funds for procuring from other sources were from the daily collection in the facility for the majority of PHFs, county government, and Linda Mama donations. The use of daily collections means adding user fees to medicines to increase revenue collection. Funding healthcare through user fees in most developing countries is inherently inequitable for the poor who depend on public health facilities for healthcare services (9).

Patient prices in PHFs were 3.4 times the international reference price, salbutamol inhaler, paracetamol syrup, and cotrimoxazole syrup prices were 370.1 60.4, and 102.2 times the IRP respectively which is substantially higher than the IRP. The majority of medicines surveyed (57.1%) had patient prices 3 times or more than the IRP in PHFs making medicines costlier than what can be achieved or availed in the facilities hindering access for the poor. These prices are higher than WHO findings in 2004 where patient medicine prices were 1.99 times the IRP (62) and 1.66 in a survey by the ministry of health in 2009 (13), but lower than 1.84 times in Ghana (16) and 11.95 times in 36 LMICs countries (11).

Medicine procurement prices were 0.9 times the procurement IRP, meaning PHFs procure medicines at 10.0% less than the IRP. This is higher compared to 0.61 and 0.44 the IRP in 2004 (62) and 2010 (13) surveys in Kenya and lower than 1.11 in a study including 36 LMICs countries. (11). The prices ranged from 0.3 for an adrenalin injection to 214.7 for a salbutamol inhaler bottle. This indicates that the procurement system was obtaining essential medicines at competitive prices but procurement efficiency for the substantially priced medicines should be improved. Similar to patient prices, procurement prices for salbutamol inhaler, cotrimoxazole syrup, and paracetamol syrup were 214.7, 39.4, and 13.9 times the IRP respectively which is substantially high.

Treatment of moderate pneumonia in adults and children, adult diabetes, and asthma in children without hospitalization was less than a day's wage therefore, affordable to patients. Treatment of moderate pneumonia in adults and children, and asthma in children increased from nil day's wages in 2009 to 0.2 and 0.7 day's wages respectively while treatment of adult diabetes decreased from 1.2 day's wages to 0.6 day's wages (13). In Ghana, moderate pneumonia treatment in adults and children was 0.7 and 0.5 day's wage which is similar to these findings. Adult disease conditions treatment required 1.7 days' wages and 0.8 days' wages for a child's disease conditions (16).

Medicine therapeutic committees are critical in the rational use of medicines and medicine selection in hospitals was not available in most of PHFs. There were no adverse drug reactions and poor quality medicine reports from the majority of PHFs 80.0% and 67.7% respectively in a year meaning pharmacovigilance guidelines are not well implemented in Mombasa County. There was a statistically significant difference in the level of PHFs and adverse drug reaction reports ($p=0.000$) with levels V and IV accounted for 90.3% of reports. Level IV and V PHFs have pharmacists managing medicines, dispensing, and sufficient resources for electronic reporting of adverse drug reactions. Level III PHFs accounted for 57.1% of poor-quality medicines, these facilities did not have adequate storage conditions and medicine conservancy which affects medicine quality and efficacy.

Pharmacovigilance reporting should be improved by identifying and training focal persons per hospital department and all healthcare workers. Continuous medical education on current electronic reporting tools will also improve reporting and can be used to disseminate feedback from PPB.

PHFs with all key essential medicines available were much more likely to have adequate stock records available (OR = 22.5, 95% CI: 2.7 - 189.5, p = 0.002), to have adequate storeroom conditions (OR = 16.2, 95% CI: 2.1 - 122.6, p = 0.007) and to have adequate dispensing room conditions (OR = 8.2, 95% CI: 1.3 - 52.3, p = 0.029) when compared with PHFs with less than 100% key essential medicines available. In addition, PHFs with all key essential medicines available were much less likely to experience essential medicine stock-outs when compared with PHFs with less than 100% key essential medicines available conditions (OR = 0.09, 95% CI: 0.01 – 0.6, p = 0.016).

Stock records availability was the most important predictor variables for medicines availability (OR = 49.6, 95% CI: 2.0 – 1233.2, p = 0.017). Facilities with all medicine available had 49.6 times the odds of those with one or more medicine missing of having stock records. Stock records are used in, accurate medicine quantification, forecasting, and stock management which ensure high medicine availability and minimize stockouts (9). Daily updating of logistic management information system records is critical in reducing health commodities stock-outs and ensuring their availability (63).

### 5.2 Conclusion

Essential medicines were fairly available. Facilities experienced frequent stock-outs which jeopardizes the availability of the majority of medicines with donor-funded medicines experiencing no stock-outs. Treatments for pneumonia, asthma, and diabetes were affordable since they were less than a day's wage. A huge proportion of Kenyans earn less than the lowest-paid government worker hence medicines would still be unaffordable to this population. Patient prices were 3.7 times procurement prices and 3.4 times the IRP yet procurement prices are 10% below the IRP. Procurement efficiency for the substantially priced medicines should be improved.

Storage infrastructure and medicine handling were inadequate with the presence of expired medicines on shelves, pests, lack of temperature control methods, and cold storage which compromises medicines' quality, safety, efficacy, and effectiveness. The critical shortage of qualified pharmaceutical personnel with a third of PHFs lacking qualified personnel for inventory management, supply management, dispensing, patient counseling, and pharmacovigilance, lead to medicine stock-outs, the presence of expired medicines on shelves, and inadequate and incomplete stock records.

## 5.3 Limitations of the study

Availability and prices of medicine were determined by the specific list of medicines included in the study, they did not account for alternate dosage forms of the same products or therapeutic equivalents. Affordability did not account for full costs of treatment including diagnostics and consultation, hence the true degree of affordability may be underestimated. Record-keeping does not allow verification of whether records are accurate which is important for efficient and effective medicines supply management. The quality of stock records influences stock-out duration results. The study only involved PHFs excluding mission and private health facilities which also play a major role in the provision of healthcare.

## 5.4 Recommendations

### 5.4.1 Recommendations for Policy and Practice

The Pharmacy and Poisons Board should fully enforce the law on handling and dispensing medicines in all public health facilities to ensure patient safety.

The county health management team in collaboration with the NHIF should run campaigns to enroll a large population of Mombasa County residents into the insurance scheme to reduce out-of-pocket spending, improve financial risk protection, access to healthcare, and essential medicines.

Improve pharmaceutical procurement efficiency of medicines from prequalified suppliers for all hospitals in case of stock-outs at KEMSA, to negotiate for better prices due to economies of scale, and ensure uniformity of prices for all hospitals and Mombasa residents.

The county government should improve storage infrastructure and capacity to accepted norms and standards to safeguard the quality and safety of medicines.

The county should prioritize the employment of qualified pharmaceutical personnel in compliance with the law to improve medication management, safety surveillance, dispensing, and safeguard patient safety.

Develop and implement medicine pricing policies in public health facilities, to ensure uniform price markups and streamline prices of medicines in all PHFs to ensure equitable access to essential medicines.

Availability, affordability, quality, prices, supply management, storage capacity, and infrastructure should be monitored and evaluated every two years to assess the effectiveness of policies and interventions to improve access to medicines.

Electronic inventory management tools and expiry tracking charts should be adopted in all public health facilities for seamless supply management to minimize expiries and stock-outs.

Stock records quality should be assessed regularly and standard intervals between physical counts developed to ensure uniform medicine supplies management within the county.

Personnel should be trained on medicine quantification, needs, and demand estimation, medication safety surveillance, and supplies management.

To improve pharmacovigilance reporting health workers and focal persons should be trained on pharmacovigilance reporting and the value of reports using continuous medical education and extensive one-day training for focal persons.

To achieve universal health coverage equitable health system financing through insurance coverage for all should be implemented and the county should increase resource allocation to healthcare.

### 5.4.2 Recommendations for Future Research

A more comprehensive survey including a broad list of medicines should be carried out in public, mission, and private health facilities as they all play a major role in health care provision.

A study that includes the full cost of treatment including diagnostics and consultation for common diseases to provide the true degree of affordability of treatment and access to healthcare services.

Cost of illness studies of common diseases to identify and measure all costs associated with these diseases and their economic burden on society.

## REFERENCES

1. World Health Organization. The Selection of Essential Medicines [Internet]. 2002 [cited 2019 Apr 28]. Available from: https://apps.who.int/iris/bitstream/handle/10665/67375/WHO_EDM_2002.2_eng.pdf

2. World Health Organization. Measuring Medicine Prices, Availability, Affordability and Price Components (2nd Ed.) [Internet]. Health Action International. 2008 [cited 2019 Apr 22]. Available from: http://haiweb.org/publication/measuring-medicine-prices-availability-affordability-and-price-components-2nd-ed/

3. World Health Organization. Equitable access to essential medicines: a framework for collective action [Internet]. Geneva; 2004 [cited 2019 Apr 28]. Available from: http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf

4. United Nations Development Group, United Nations. Statistical Division., editor. Indicators for monitoring the Millennium Development Goals: definitions, rationale, concepts, and sources [Internet]. New York: United Nations; 2003 [cited 2019 Apr 28]. 106 p. Available from: http://mdgs.un.org/unsd/mdg/Resources/Attach/Indicators/HandbookEnglish.pdf

5. Haniefuddin S, Baba SS. Essentials of Logistics and Supply Chain Management [Internet]. Lulu.com; 2013 [cited 2019 May 7]. 520 p. Available from: https://books.google.co.ke/books?

6. Yadav P. Health Product Supply Chains in Developing Countries: Diagnosis of the Root Causes of Underperformance and an Agenda for Reform. Health Syst Reform. 2015 Feb 17;1(2):142–54. Available from: https://doi.org/10.4161/23288604.2014.968005

7. Kraiselburd S, Yadav P. Supply Chains and Global Health: An Imperative for Bringing Operations Management Scholarship into Action. Prod Oper Manag. 2013 Mar 1;22(2):377–81. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/j.1937-5956.2011.01315.x

8. Pisa M, McCurdy D. Improving Global Health Supply Chains through Traceability CGD Policy Paper. Washington, DC: Center for Global Development. 2019;29. Available from: https://www.cgdev.org/publication/improving-global-health-supply-chains-through-traceability

9. Management Sciences for Health (MSH). MDS-3: Managing Access to Medicines and Health Technologies | Management Sciences for Health [Internet]. 2012 [cited 2019 Apr 28]. Available from: /resources/mds-3-managing-access-to-medicines-and-health-technologies

10. United Nations. Transforming our world: The 2030 agenda for sustainable development. Gen Assem 70 Sess [Internet]. 2015 [cited 2019 Jul 17]; Available from: https://sustainabledevelopment.un.org/content/documents/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf

11. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. The Lancet. 2009 Jan;373(9659):240–9. Available from: https://www.sciencedirect.com/science/article/pii/S0140673608617626

12. Ongarora D, Karumbi J, Minnaard W, Abuga K, Okungu V, Kibwage I. Medicine Prices, Availability, and Affordability in Private Health Facilities in Low-Income Settlements in Nairobi County, Kenya. Pharm J Pharm Educ Pract. 2019 Apr 24;7(2):40. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6631117/

13. Ministry of Medical Services and Ministry of Public Health & Sanitation. Access to Essential Medicines in Kenya: A Health Facility Survey [Internet]. 2009 [cited 2019 Apr 26]. Available from: https://apps.who.int/medicinedocs/documents/s18696en/s18696en.pdf

14. Dewi E, Dahlui M, Chalidyanto D, Thinni, Rochmah N, Rochmah T. Expert Review of Pharmacoeconomics & Outcomes Research Achieving cost-efficient management of drug supply via economic order quantity and minimum-maximum stock level Achieving cost-efficient management of drug supply via economic order quantity and minimum-maximum stock level. 2019 Jun 24; Available from: https://www.researchgate.net/publication/334130219_Expert_Review_of_Pharmacoeconomics_Outcomes_Research_Achieving_costefficient_management_of_drug_supply_via_economic_order_quantity_and_minimum-_maximum_stock_level_Achieving_cost-efficient_management

15. Aziz Ali S, Suhail N. Storage of medicines a review. P. 2018 May 12; Available from: https://www.researchgate.net/publication/325106135_Storage_of_medicines_a_review_P

16. Nyanwura EM, Esena RK. Essential Medicines Availability And Affordability: A Case Study Of The Top Ten Registered Diseases In Builsa District Of Ghana. Int J Sci Technol Res. 2013 Aug 25;2(8):208–19. Available from: http://www.ijstr.org/paper-references.php?ref=IJSTR-0813-7106

17. Mugo P, Onsomu E, Munga B, Nafula N, Mbithi J, Owino E. An Assessment of Healthcare Delivery in Kenya under the Devolved System [Internet]. 2018 [cited 2019 Apr 29]. Available from: http://kippra.or.ke/download/148/special-papers/5502/an-assessment-of-healthcare-delivery-in-kenya-under-the-devolved-system-sp19.pdf

18. Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B, et al. Access to medicines from a health system perspective. Health Policy Plan. 2013 Oct;28(7):692–704. Available from: https://academic.oup.com/heapol/article-abstract/28/7/692/819804

19. World Health Organization, Health Action International. Medicine Prices and Availability [Internet]. 2011 [cited 2019 Apr 27]. Available from: https://haiweb.org/wp-content/uploads/2015/07/Working-Paper-3-Regulation-of-Mark-ups.pdf

20. Management Sciences for Health. Managing Access to Medicines and Health Technologies [Internet]. 2014 [cited 2019 Apr 28]. Available from: http://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf

21. World Health Organization. WHO Medicines Strategy - Countries at the Core - 2004 - 2007 [Internet]. 2004 [cited 2019 Apr 29]. Available from: http://apps.who.int/medicinedocs/en/d/Js5416e/

22. United Nations. WHO | Delivering on the Global Partnership for achieving the Millennium Development Goals [Internet]. WHO. 2008 [cited 2019 Apr 22]. Available from: https://www.who.int/pmnch/knowledge/topics/mdggapreport/en/

23. World Health Organization. The Selection of Essential Medicines [Internet]. Geneva; 2002 [cited 2019 Apr 28]. Available from: https://apps.who.int/iris/bitstream/handle/10665/67375/WHO_EDM_2002.2.pdf?

24. World Health Organization. World Health Organization Model List of Essential Medicines for Children: 7th List 2019 [Internet]. WHO; 2019 [cited 2019 Jul 17]. Available from: https://apps.who.int/iris/bitstream/handle/10665/325772/WHO-MVP-EMP-IAU-2019.07-eng.pdf?ua=1

25. World Health Organization. World Health Organization Model List of Essential Medicines: 21st list 2019 [Internet]. WHO; 2019 [cited 2019 Jul 17]. Available from: https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1

26. Ministry of Health. Kenya-Essential-Medicines-List-2019.pdf [Internet]. 2019 [cited 2022 Sep 1]. Available from: https://www.health.go.ke/wp-content/uploads/2020/03/Kenya-Essential-Medicines-List-2019.pdf

27. Prashant Y. Kenya Medical Supplies Authority (KEMSA) A case study of the ongoing transition from an ungainly bureaucracy to a competitive and customer-focused medical logistics organization [Internet]. Washington, DC: World Bank; 2014 [cited 2019 Jul 23]. Available from: http://documents.worldbank.org/curated/en/876311468277741016/pdf/918640WP0P14870e0ongoing0Transition.pdf

28. Attaei MW, Khatib R, McKee M, Lear S, Dagenais G, Igumbor EU, et al. Availability and affordability of blood pressure-lowering medicines and the effect on blood pressure control in high-income, middle-income, and low-income countries: an analysis of the PURE study data. Lancet Public Health. 2017;2(9):e411–9. Available from: https://pubmed.ncbi.nlm.nih.gov/29253412/

29. Ministry of Health, Government of Kenya. 2013 Kenya Household Health Expenditure and Utilisation Survey [Internet]. 2014 [cited 2019 Jul 17]. Available from: https://www.healthpolicyproject.com/pubs/745_KHHUESReportJanuary.pdf

30. World Health Organization. WHO | NCD mortality and morbidity [Internet]. WHO. 2017 [cited 2019 Jul 21]. Available from: http://www.who.int/gho/ncd/mortality_morbidity/en/

31. Subramanian S, Gakunga R, Kibachio J, Gathecha G, Edwards P, Ogola E, et al. Cost and affordability of non-communicable disease screening, diagnosis, and treatment in Kenya: Patient payments in the private and public sectors. PLOS ONE. 2018 Jan 5;13(1):e0190113. Available from: https://pubmed.ncbi.nlm.nih.gov/29304049/

32. World Health Organization. Increasing access to HIV treatment in middle-income countries Key data on prices, regulatory status, tariffs, and the intellectual property situation [Internet]. WHO; 2014 [cited 2019 Jul 21]. Available from: https://www.who.int/phi/publications/WHO_Increasing_access_to_HIV_treatment.pdf

33. Xu K, Evans DB, Carrin G, Aguilar-Rivera AM, Musgrove P, Evans T. Protecting Households From Catastrophic Health Spending. Health Aff (Millwood). 2007 Jul 1;26(4):972–83. Available from: https://pubmed.ncbi.nlm.nih.gov/17630440/

34. Hogerzeil HV, Liberman J, Wirtz VJ, Kishore SP, Selvaraj S, Kiddell-Monroe R, et al. Promotion of access to essential medicines for non-communicable diseases: practical implications of the UN political declaration. Lancet Lond Engl. 2013 Feb 23;381(9867):680–9. Available from: https://pubmed.ncbi.nlm.nih.gov/23410612/

35. The National Treasury and Planning. Budget Statement for Year 2019/2020: Creating Jobs, Transforming Lives - Harnessing the "Big Four" Plan [Internet]. 2019 [cited 2019 Jul 22]. Available from: http://www.treasury.go.ke/component/jdownloads/send/201-2019-2020/1442-budget-statement-for-fy-2019-20-final.html

36. Union A. Abuja Declaration on HIV/Aids, Tuberculosis and Other Infectious Diseases. [Internet]. 2001 [cited 2019 Jul 21]. Available from: https://www.un.org/ga/aids/pdf/abuja_declaration.pdf

37. World Health Organization. WHO Global Surveillance and Monitoring System for substandard and falsified medical products. 2017; Available from: https://apps.who.int/iris/bitstream/handle/10665/326708/9789241513425-eng.pdf

38. Iqbal MJ, Geer MI, Dar PA. Medicines Management in Hospitals: A Supply Chain Perspective. Syst Rev Pharm. 2017 Apr 15;8(1):80–5. Available from: https://pubmed.ncbi.nlm.nih.gov/23410612/

39. World Health Organization. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fourth report. WHO Technical Report Series, No.1025-annex8 [Internet]. 2020 [cited 2022 Sep 1]. Available from: https://cdn.who.int/media/docs/default-source/medicines/who-technical-report-series-who-expert-committee-on-specifications-for-pharmaceutical-preparations/trs1025-annex8.pdf?sfvrsn=dfb3eca3_2&download=true

40. Alnahas F, Yeboah P, Fliedel L, Abdin AY, Alhareth K. Expired Medication: Societal, Regulatory and Ethical Aspects of a Wasted Opportunity. Int J Environ Res Public Health. 2020 Jan;17(3):787. Available from: https://www.mdpi.com/1660-4601/17/3/787

41. Ogunshe A, Adinmonyema P. Evaluation of bacteriostatic potency of expired oral paediatric antibiotics and implications on infant health. Pan Afr Med J. 2014 Dec 15;19:378. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4427466/

42. Hassan R, Sher HA, Khokhar R, Hussain R. Pharmaceutical Policy in the UAE. In: Babar ZUD, editor. Pharmaceutical Policy in Countries with Developing Healthcare Systems [Internet]. Cham: Springer International Publishing; 2017 [cited 2022 Sep 1]. p. 365–79. Available from: https://doi.org/10.1007/978-3-319-51673-8_18

43. Gonul Kochan C, Nowicki DR, Sauser B, Randall WS. Impact of cloud-based information sharing on hospital supply chain performance: A system dynamics framework. Int J Prod Econ. 2018 Jan 1;195:168–85. Available from: https://www.sciencedirect.com/science/article/pii/S0925527317303237

44. Moktadir MdA, Ali SM, Mangla SK, Sharmy TA, Luthra S, Mishra N, et al. Decision modeling of risks in pharmaceutical supply chains. Ind Manag Data Syst. 2018 Jan 1;118(7):1388–412. Available from: https://doi.org/10.1108/IMDS-10-2017-0465

45. Laws of Kenya. The Public Procurement and Asset Disposal Act, 2015 – Public Procurement Regulatory Authority [Internet]. 2015 [cited 2022 Sep 1]. Available from: https://ppra.go.ke/ppda/

46. World Health Organization. WHO operational package for assessing, monitoring, and evaluating country pharmaceutical situations: guide for coordinators and data collectors. [Internet]. WHO; 2007 [cited 2019 May 16]. Available from: http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf

47. World Health Organization. WHO Expert meeting on pharmaceutical indicators, monitoring, and assessment. Geneva. 2006;67. Available from: http://digicollection.org/hss/documents/s17058e/s17058e.pdf

48. County Government of Mombasa. Second County Integrated Development Plan (2018-2022) [Internet]. 2018 [cited 2019 Jul 23]. Available from: http://www.mombasa.go.ke/wp-content/uploads/2018/11/MSA-FINAL-CIDP-2018-22.pdf

49. Management Sciences for Health (MSH). International Medical Products Price Guide | Management Sciences for Health [Internet]. 2015 [cited 2021 Feb 17]. Available from: /resources/international-medical-products-price-guide

50. Central Bank of Kenya. Foreign Exchange Rates | CBK [Internet]. 2020 [cited 2020 Oct 27]. Available from: https://www.centralbank.go.ke/rates/forex-exchange-rates/

51. $1 in 2015 → 2020 | Inflation Calculator [Internet]. [cited 2021 Apr 15]. Available from: https://www.in2013dollars.com/us/inflation/2015?amount=1

52. Government of Kenya. The Regulation of Wages (General) (Amendment) Order, 2018. [Internet]. The Labour Institutions Act; 2018. Available from: http://kenyalaw.org/kl/fileadmin/pdfdownloads/LegalNotices/LN_No.116__117_of_2015_1_.pdf

53. Tangcharoensathien V, Chanvatik S, Sommanustweechai A. Complex determinants of inappropriate use of antibiotics. Bull World Health Organ. 2018 Feb 1;96(2):141–4. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5791781/

54. Sergeevna SM, Efimovna LE, Irina K, Vladimirovna AI. Pharmaceutical Consultation as a Basis for Drug Care Continuity. 2020;7. Available from: https://pharmacophorejournal.com/storage/models/article/BIZcKnL627a6yWGprFaKsT4iJ9kAeKIK07PzJ01im3K75a1r6aaL9aIsN6qN/pharmaceutical-consultation-as-a-basis-for-drug-care-continuity.pdf

55. National Council for Law. Pharmacy and Poisons Act_Cap.244 [Internet]. [cited 2021 Jul 21]. Available from: http://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/PharmacyandPoisonsAct_Cap.244.pdf

56. Bizimana T, Kayumba PC, Heide L. Prices, availability and affordability of medicines in Rwanda. PLOS ONE. 2020 Aug 3;15(8):e0236411. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0236411

57. World Health Organization. Sixty-Sixth World Health Assembly. Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases. 2013; Available from: https://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R10-en.pdf

58. Yadav P, Stapleton O, Van Wassenhove LN. If Access is the Symptom, What is the Cause? Comparing Medicine and Consumer Product Supply Chains in the Developing World. Fac Res Work Pap. 2010;15. Available from: https://doi.org/10.4161/23288604.2014.968005

59. Somasundaram J. Availability of Essential Medicines and Inventory Management Practice in Primary Public Health Facilities of Gondar Town, North West Ethiopia. J Pharma SciTech. 2015 Jun 15;4:54–6. Available from: http://www.pharmascitech.in/admin/php/uploads/90_pdf.pdf

60. World Health Organization. Technical Consultation on Preventing and Managing Global Stock Outs of Medicines [Internet]. 2015. Available from: https://www.who.int/medicines/areas/access/Medicines_Shortages.pdf?ua=1

61. World Health Organization. Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-Fourth report. Geneva, World Health Organization. WHO Technical Report Series. 996. [Internet]. 2016 [cited 2021 Jul 30]. Available from: https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_web.pdf

62. World Health Organization, Health Action International. Medicine Prices Kenya. 2004; Available from: http://www.haiweb.org/medicineprices/

63. Karimi A, Mishra A, Natarajan KV, Sinha KK. Managing Commodity Stock-outs in Public Health Supply Chains in Developing Countries: An Empirical Analysis. Prod Oper Manag [Internet]. [cited 2021 Aug 14];n/a(n/a). Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/poms.13420

# APPENDICES

## Appendix I: General information on public health facility pharmacy

| Survey Forms | |
|---|---|
| **Public health facilities** | |
| **SF 1** | % key medicines available<br>% medicines expired |
| **SF 2** | Price of key medicines<br>Price of pediatric medicines |
| **SF 3** | Affordability of treatment for adults and children under 5 years of age (pneumonia with no hospitalization) |
| **SF 4** | Average stock-out duration<br>Adequate record keeping |
| **SF 5** | Adequate storage conditions and handling of medicines at the storeroom and dispensing area |

## General information: Public health facility pharmacy

Facility Serial No. _____ Level of Facility _____

Date _____ Investigator _____

Does the law require a Pharmacist / Pharmaceutical technologist (Pharm Tech) to be present during hours of operation of public / government / faith-based pharmacies/medicines outlets?

☐ Yes ☐ No

Is a Pharmacist / Pharm Tech present at the time of the visit?

☐ Yes ☐ No

Assessment

1☐ complies with the law (items 1 and 2 are both Yes)

2☐ does not comply with the law (item 1 Yes and item 2 No)

Who is in charge of the facility pharmacy? (check all that apply)

☐ Pharmacist (1=Yes; 0=No) ☐ Pharmacy assistant (certificate) (1=Yes; 0=No)

☐ Nurse (1=Yes; 0=No) ☐ Pharmacy Intern / Student (1=Yes; 0=No)

☐ Pharm Tech (1=Yes; 0=No) ☐ Clinical officer (1=Yes; 0=No)

☐ Untrained staff (1=Yes; 0=No)

☐ Other (1=Yes; 0=No): please specify_____

Who is dispensing during the time of visit? (check all that apply)

☐ Pharmacist (1=Yes; 0=No) ☐ Pharmacy assistant (certificate) (1=Yes; 0=No)

☐ Nurse (1=Yes; 0=No) ☐ Pharmacy Intern / Student (1=Yes; 0=No)

☐ Pharm Tech (1=Yes; 0=No) ☐ Clinical officer (1=Yes; 0=No)

☐ Untrained staff (1=Yes; 0=No)

☐ Other (1=Yes; 0=No): please specify_____

## Appendix II: Key essential medicines availability and quality

| Public Health Facility Serial No. |
|---|
| _____ |

**Survey form 1: Public health facility pharmacy**
**Indicators: % key medicines available % medicines expired**

**Level of Facility** _____ **Date** _____
**Sub-County** _____ **Investigator** _____

| | **Key health products use in the management of common conditions** **[A]** | **In stock Yes=1, No=0,** *(indicate NA if not applicable)* **[B]** | **Expired medicines on shelves Yes=1, No=0** *(indicate NA if not applicable)* **[C]** |
|---|---|---|---|
| 1 | Adrenaline Injection 1mg/mL | | |
| 2 | Amoxicillin 250mg or 500mg capsules | | |
| 3 | Amoxicillin 250mg (dispersible, scored) tablets | | |
| 4 | Artemether / Lumefantrine (20 / 120mg) tablets (any pack size) | | |
| 5 | Combined oral contraceptive pills | | |
| 6 | Benzylpenicillin (600mg=1 MU) Injection | | |
| 7 | Ferrous salt tablets (any salt; alone or in combination with Folic acid) | | |
| 8 | Gentamicin Injection 10mg/ml, 2ml ampoule *OR* 40 mg/ml, 2ml ampoule | | |
| 9 | Albendazole tablets 400mg | | |
| 10 | Malaria Rapid Diagnostic Test | | |
| 11 | Paracetamol tablets 500mg | | |
| 12 | Paracetamol syrup / suspension 120mg/5mL | | |
| 13 | Rapid HIV 1+2 Test 1 - Screening | | |
| 14 | Rifampicin/Isoniazid/Pyrazinamide /Ethambutol 150/75/400/275mg tablets | | |
| 15 | Salbutamol Inhaler 100 mcg/dose | | |
| | | **[$B^1$] = Sum of B =** | **[$C^1$] = Sum of C =** |
| | | **[$B^2$] = % in stock = $B^1$ ÷ 15 x 100 =** | **[$C^2$] = % expired = $C^1$ ÷ $B^1$ x 100 =** |

## Additional medicines to treat common conditions availability and quality

**Indicators: % key medicines available % medicines expired**

| **Key health products use in the management of common conditions**<br><br>**[A]** | **In stock Yes=1, No=0** *(indicate NA if not applicable)*<br><br>**[B]** | **Expired medicines on shelves Yes=1, No=0** *(indicate NA if not applicable)*<br>**[C]** |
|---|---|---|
| Ceftriaxone Injection IM/IV 1gm Vial | | |
| Enalapril tablets 5mg | | |
| Furosemide tablets 40mg | | |
| Glibenclamide tablets 5mg | | |
| Ibuprofen tablets 200mg | | |
| Insulin, Soluble (human), 100IU/ml | | |
| Morphine sulphate Injection 10mg/ml | | |
| Oxytocin Injection 10IU | | |
| Phenytoin tablets 100mg | | |
| Tenofovir/Lamivudine/Efavirenz 300/300/400mg Tabs | | |
| | **[$B^1$] = Sum of B =** | **[$C^1$] = Sum of C =** |
| | **[$B^2$] = % in stock = $B^1$ ÷ 10 x 100 =** | **[$C^2$] = % expired = $C^1$ ÷ $B^1$ x 100 =** |

## Appendix III: Key essential medicines prices

| Public Health Facility Serial No. |
|---|
| _____ |

**Survey form 2: Public health facility pharmacy**
**Indicators: Price of key medicines**
**Price of pediatric medicines**

**Level of Facility** _____ **Date** _____
**Sub-County** _____ **Investigator** _____

| | **Key medicines to treat common conditions** **[A]** | **Preparation unit** **[B]** | **The lowest unit price of the medicine paid by the patient** **[C]** | **The lowest unit price of the medicine paid by the facility** **[D]** |
|---|---|---|---|---|
| 1 | Adrenaline | 1mg/mL ampoule injection | | |
| 2 | Ceftriaxone | 1g/vial injection | | |
| 3 | Enalapril | 5 mg tablets | | |
| 4 | Furosemide | 40 mg tablets | | |
| 5 | Gentamicin | 20mg ampoule injection | | |
| 6 | Glibenclamide | 5mg tab/cap | | |
| 7 | Oxytocin | 10 IU Injection | | |
| 8 | Ibuprofen | 200 mg tablets | | |
| 9 | Phenytoin | 100 mg cap/tab | | |
| 10 | Salbutamol | 100 mcg/dose Inhaler | | |
| **Paediatric medicines** | | | | |
| 12 | Co-trimoxazole | 240mg/5ml suspension | | |
| 11 | Paracetamol | 120mg/5mL syrup/susp | | |
| **Medicines used to assess affordability** | | | | |
| 12 | Amoxicillin | 250mg (dispersible, scored) tablets | | |
| 13 | Amoxicillin | 250mg capsules | | |
| 14 | Human Insulin (biphasic) 30/70 | 100IU/ml vial injection | | |
| 15 | Beclomethasone | Inhaler 100mcg / dose | | |

## Appendix IV: Affordability of treatment

| Public Health Facility Serial No. |
|---|
| _____ |

**Survey form 3: Public health facility pharmacy**

**Indicator: Affordability of treatment - moderate pneumonia for adults and children under 5 years of age (equivalent number of days' wages)**

**Level of Facility** _____ **Date** _____

**Sub-county** _____ **Investigator** _____

| **Medicine / INN and Preparation [A]** | **Number of units needed to complete treatment [B]** | **Unit price (one vial, tablet, or capsule) [C]** | **The total cost of treatment [D] = B x C [D]** | **Equivalent number of days' wages [F] = D ÷ E [F]** |
|---|---|---|---|---|
| | | | | |
| **Moderate pneumonia (without hospitalization):** | | | | |
| Adult treatment of choice:<br><br>Amoxicillin 250mg capsules* | 42 capsules | | | [F¹] = |
| Child <5 treatment of choice:<br><br>Amoxicillin 250mg (dispersible, scored) Tablets | 20 tablets | | | [F²] = |
| | | | | |
| **Chronic conditions** | | | | |
| **Adult: Diabetes - Insulin-dependent (without hospitalization):** | | | | |
| Adult treatment of choice:<br><br>Human Insulin (biphasic) 30/70 100IU/ml | 10ml | | | [F³] = |
| | | | | |
| **Paediatric: Asthma (without hospitalization):** | | | | |
| Child <5 treatment of choice:<br><br>Beclomethasone Inhaler 50mcg / dose | 1 inhaler | | | [F⁴] = |
| [E] = Lowest daily government salary = **653 KSh** | | | | |

| Public Health Facility Serial No. |
|---|
| _____ |

## Appendix V: Supply chain logistics

**Survey form 4: Public health facility pharmacy**

**Indicators: Average stock-out duration Adequate record keeping**

**Level of Facility** _____ **Date** _____

**Sub-county** _____ **Investigator** _____

| | **Key medicines to treat common conditions** | **Records cover at least 6 months within the past 12 months Yes=1, No=0** | **Collect data for medicines from available records up to 12 months prior** **Capture in your notes the number of days and dates/months covered by available* | | |
|---|---|---|---|---|---|
| | | | **Number of days out of stock** | **No. of days covered by the review** *(i.e. number of days where records are available)* | **Equivalent No. of stock-out days per year [E] = C x 365 ÷ D** |
| | [A] | [B] | [C] | [D] | [E] |
| 1 | Adrenaline Injection 1mg/mL | | | | |
| 2 | Amoxicillin 250mg or 500mg capsules | | | | |
| 3 | Amoxicillin 250mg (dispersible) tablets | | | | |
| 4 | Artemether / Lumefantrine (20 / 120mg) tablets (any pack size) | | | | |
| 5 | Combined oral contraceptive pills | | | | |
| 6 | Benzylpenicillin (600mg=1 MU) Injection | | | | |
| 7 | Ferrous salt tablets (any salt; alone or in combination with Folic acid) | | | | |
| 8 | Gentamicin Injection 10mg/ml, ampoule | | | | |
| 9 | Albendazole tablets 400mg | | | | |
| 10 | Malaria Rapid Diagnostic Test | | | | |
| 11 | Paracetamol tablets 500mg | | | | |
| 12 | Paracetamol syrup /120mg/5mL | | | | |
| 13 | Rapid HIV 1+2 Test 1 – Screening | | | | |
| 14 | Rifampicin/Isoniazid/Pyrazinamide /Ethambutol 150/75/400/275mg tablets | | | | |
| 15 | Salbutamol Inhaler 100 mcg/dose | | | | |
| | | **[$B^1$] = Sum of B =** | | | **[$E^1$] = Sum of E =** |
| | | **[$B^2$] = % adequate records = $B^1 \div 15 \times 100$ =** | | | |
| **[F] = Average number of stock-out days = $E^1 \div B^1$ =** | | | | | |

## Additional medicines to treat common conditions

| **Key medicines to treat common conditions**<br><br>**[A]** | **Records cover at least 6 months within the past 12 months Yes=1, No=0**<br><br>**[B]** | **Collect data for medicines from available records up to 12 months prior** | | |
|---|---|---|---|---|
| | | **No. of days out of stock**<br><br>**[C]** | **No. of days covered by the review** *(i.e. number of days where records are available)*<br>**[D]** | **Equivalent No of days per year [E] = C x 365 ÷ D**<br><br>**[E]** |
| Ceftriaxone Injection IM/IV 1gm Vial | | | | |
| Enalapril tablets 5mg | | | | |
| Furosemide tablets 40mg | | | | |
| Glibenclamide tablets 5mg | | | | |
| Ibuprofen tablets 200mg | | | | |
| Insulin, Soluble (human), 100IU/ml | | | | |
| Morphine sulphate Injection 10mg/ml | | | | |
| Oxytocin Injection 10IU | | | | |
| Phenytoin tablets 100mg | | | | |
| Tenofovir/Lamivudine/Efavirenz 300/300/400mg Tabs | | | | |
| | **[$B^1$] = Sum of B =** | | | **[$E^1$] = Sum of E =** |
| | **[$B^2$]= % adequate records = $B^1$ ÷ 10 x 100 =** | | | |
| **[F] = Average number of stock out days = $E^1$ ÷ $B^1$ =** | | | | |

## Appendix VI: Quality

| Public Health Facility Serial No. |
|---|
| _____ |

**Survey form 5: Public health facility pharmacy/dispensary**

**Indicator: Adequate storage conditions and handling of medicines at the storeroo and dispensing area**

**Level of Facility** _____ **Date** _____

**Sub-county** _____ **Investigator** _____

| Checklist | Storeroom True=1, False=0 [A] | Dispensing Area/Room True=1, False=0 [B] |
|---|---|---|
| There is a method in place to control temperature (e.g. roof and ceiling with space between them in hot climates, air conditioners, fans, etc) | | |
| Some windows can be opened or there are air vents | | |
| Direct sunlight cannot enter the area (e.g. window panes are painted or there are curtains/blinds to protect against the sun) | | |
| The area is free from moisture (e.g. leaking ceiling, roof, drains, taps, etc.) | | |
| There is cold storage in the facility (*working* fridge / cold room) | | |
| There is a regularly filled temperature chart for the cold storage | | |
| Medicines are not stored directly on the floor (e.g. pallets, shelves) | | |
| Medicines are stored systematically (e.g. alphabetical, pharmacological) | | |
| Medicines are stored first-expiry, first-out (FEFO) | | |
| There is no evidence of pests in the area | | |
| Tablets/capsules are not manipulated by naked hand | | |
| | **[$A^1$] = Sum of A =** | **[$B^1$] = Sum of B =** |
| | **[$A^2$] = Score = $A^1$ ÷ 10 x 100 =** | **[$B^2$] = Score = $B^1$ ÷ 11 x 100 =** |

## Appendix VII: Medicine supply management

**Questions assessing practices of medicine supply management**

***Selection & Use***

1a) Does the facility have a Medicine and Therapeutics Committee (MTC)? (Y/N)[__]
1b) Are Terms of Reference (TORs) for the MTC available? [*Check*] (Y/N) [__]
1c) Do the TORs indicate the MTC composition (members)? [*Check*] (Y/N) [__]
Specify:

1c) Are meeting minutes available for at least 1 meeting held over the last 3 months? [*Check*] (Y/N) [__]
1d) Below, summarize key issues and recommendations from the minutes if available.

2. Pharmacovigilance (PV) / capture & reporting of Adverse drug reactions (ADRs)
2a) i) Does the facility have the form for Reporting Suspected ADRs in stock? [*Check*] (Y/N) [__]
ii) Does the facility have the form for Reporting Poor Quality Medicinal Products in stock? [*Check*] (Y/N) [__]
2b) Does the facility have the Guidelines for the National Pharmacovigilance System in Kenya? [*Check*] (Y/N) [__]
Indicate Publication date (year) _____
2c) How many ADR reports have been prepared in the last 12 months? [*Check*]

2d) How many Poor Quality medicine reports have been prepared in the last 12 months? [*Check*]

2e) How many of *each filled report type* have been posted online in Pharmacovigilance electronic reporting system (PV-ERS) portal? If not submitted online, did the facility submit manual forms to County/Sub-county level?

2f) Indicate the number of people trained on the use of the PV forms in this facility.

***Management support (Supportive supervision, SOPs, organization & management, governance)***

3a) Who is responsible for pharmaceutical product management in the facility? (*Check all that apply*)

☐ Pharmacy in-charge (1=Yes; 0=No) ☐ Supply officer (1=Yes; 0=No)
☐ Nurse in-charge (1=Yes; 0=No) ☐ Facility in-charge (1=Yes; 0=No)
☐ Other staff (1=Yes; 0=No) (*please specify*)

_____

3b) Who is responsible for other HPT product management in the facility? (*Check all that apply*)

☐ Nurse in-charge (1=Yes; 0=No)
☐ Pharmacy in-charge (1=Yes; 0=No)
☐ Other staff (1=Yes; 0=No) (*please specify*)
☐ Supply officer (1=Yes; 0=No)
☐ Facility in-charge (1=Yes; 0=No)

---

3c) Who is responsible for laboratory product management in the facility? (*Check all that apply)*

☐ Laboratory in-charge (1=Yes; 0=No)
☐ Pharmacy in-charge (1=Yes; 0=No)
☐ Other staff (1=Yes; 0=No) (*please specify*)
☐ Supply officer (1=Yes; 0=No)
☐ Facility in-charge (1=Yes; 0=No)

---

4. Supportive supervision
4a) Has the facility received any integrated supervisory visits over the last 3 months? (Y/N) [__]
(*Check supportive supervision book/records if available*)

4b) Who conducted the integrated supervision? (*Check all that apply*)
☐ A team from the CHMT (1=Yes; 0=No)
☐ A team from the Sub-county HMT (1=Yes; 0=No)
☐ A team from the National level MoH staff (1=Yes; 0=No) *Please specify which national level program / dept*_____

☐ Other (1=Yes; 0=No) (*please specify*) _____

---

4c) Did the supervision address **health products & technologies management (pharmaceutical, laboratory, other medical supplies, etc.) services**? (Y/N) [__]
4d) Did the facility receive any feedback from the supervision team? (Y/N) [__]
4e) Did the facility receive any support following this supervision? [__]
Below, summarize feedback and support received if available.

5. SOPs
5a) List any SOPs and Job aids related to health products & technologies management (pharmaceutical, laboratory, other medical supplies, nutrition, etc) available at the facility [*check*]

6. ***HR***

6a) Indicate the number of staff engaged in pharmaceutical functions in the facility

| Cadre | Specify cadre for Other staff | GoK | Partner-supported | Facility | Total |
|---|---|---|---|---|---|
| Pharmacist | | | | | |
| Pharm. Tech. | | | | | |
| Other 1.: *Specify* | | | | | |
| Other 2.: *Specify* | | | | | |
| Other 3.: *Specify* | | | | | |

6b) How many staff in the facility have received training in the following areas?

| Training | *# Trained* | | | | | Total |
|---|---|---|---|---|---|---|
| | *Pharmacist* | *Pharm Tech* | *Lab tech* | *Nurse* | *Others** | |
| Inventory Management | | | | | | |
| Pharmacovigilance (PV) | | | | | | |
| Appropriate Medicines Use | | | | | | |
| Quantification | | | | | | |
| Commodity management *(whether lab, pharma, etc)* | | | | | | |

***Information management (LMIS, health products data collection & reporting)***

7a) Does the **facility** have a working computer and Internet access that can be used for health services/health products & technologies (HPT) stock & usage reporting? [*Check*] (Y/N) [__]
Comments (e.g. location of the computer/ease of access by staff, under repair, who maintains it, etc):

7b) Check if the following records/reports are available and if in use. (*Request facility staff to provide you with the tools. Check all that apply. Indicate NA where not applicable)*

| Record / reporting form | Available? (Y/N) (*check at service points*) | In use? (Y/N) [*To rate as "Yes in use", the tool must be updated until the previous working day; else rate as "No"*] | Comments (E.*g. if not updated or not in use, why?)* |
|---|---|---|---|
| Records (e.g. Daily activity register) for capturing HPT product usage data | | | |
| Malaria | | | |
| Family planning (FP) | | | |
| Antibiotics | | | |

| **Record / reporting form** | **Available? (Y/N)** (*check at service points*) | **In use? (Y/N)** [*To rate as "Yes in use", the tool must be updated until the previous working day; else rate as "No"*] | **Comments** (E.*g. if not updated or not in use, why?)* |
|---|---|---|---|
| Prescription register | | | |
| Records (e.g. Daily activity register) for capturing HPT product usage data | | | |
| ARVs and medicines for OIs (MoH 367) | | | |
| Any tool used to record consumption for EMMS (except the Antibiotics register, unless this register was not available) | *[If available, specify the name of the tool]* _____ | | |
| Facility consumption data report & request form (F-CDRR) or equivalent [*In use for F-CDRR: Rate as Y if a report for the last reporting period (month/quarter) has been completed*] | | | |
| EPI (MoH 710) | | | |
| Malaria | | | |
| FP | | | |
| KEMSA LMIS Ordering Tool | | | |
| ART (MoH 730B or 730A) | | | |
| Lab (MoH 643) | | | |

7c) Does the **facility pharmacy** have a working computer that can be used for data capture for health products & technologies (HPT) inventory management? [*Check*] (Y/N) [__]
Comments (e.g. location of the computer, who maintains it):

7d) i) Does the facility pharmacy have a working electronic inventory management tool? [*Check*] (Y/N) [__]
ii) Is the tool in use? [*Check*] (Y/N) [__]

***Procurement & Financing***
8a) Has the facility procured any health products from other sources in the last 6 months? [*Check*] (Y/N) [__]
For what reasons?

8b) List the other sources and the latest date of procurement from them

8c) Which source of funds does the facility utilize for procurement from other sources?

***Inventory management (incl. Ordering / requesting health products' resupply)***
9a) How does the facility determine the quantity to order essential medicines & medical supplies?

9b) Tracking of health products
(i) Order fill rate
Request for KEMSA invoices or delivery notes and the facility's KEMSA Order forms for the last 6 months (Sept 2019 to Feb 2020). Pick 5 products (2 pharmaceuticals, 2 other medical supplies, and 1 laboratory) and fill in the table below.

| # | **HPT name, description, batch number** | **Unit pack size** | **Quantity ordered by the facility** *(total of all orders)* | **Quantity received by the facility** *(total of all receipts)* | **Order fill rate (%) = Qty ordered/Qty received** |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |

9c) i) How often does the facility conduct regular physical stock counts? [*Check*] (Y/N)

ii) From the stock cards or any other evidence provided by the facility for the above-listed items, indicate the date when the stock count was last done. [*Check*]

iii) How are stock count discrepancies addressed?

9e) Disposal
Describe the process used by the facility to address short expiry stock, expired stock, and disposal.
(*E.g. does the facility engage in re-distribution of short expiry stock? How?)*

***Other Remarks/comments:***

## Appendix VIII: Access, quality, and safety indicators summary form

| Facility | % of medicines in stock | % of expired medicines in stock | Equivalent number of days' wages required to pay for treatment of pneumonia | Equivalent number of days' wages required to pay for treatment of adult diabetes | Equivalent number of days' wages required to pay for treatment of asthma in pediatrics | Percentage of adequate records of medicines | The average number of stock-out days of medicines | % available dispensing area conditions and handling | % available storeroom conditions and handling |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
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| | | | | | | | | | |
| | | | | | | | | | |
| **Total** | | | | | | | | | |
| **Average** | | | | | | | | | |
| **Percentage** | | | | | | | | | |

## Appendix IX: Medicines expired on shelves

| Key essential medicine expired on shelves | % of PHFs with expiry | % of expiry the medicine accounts |
|---|---|---|
| Adrenaline Injection 1mg/mL | 16.7 | 26.3 |
| Artemether / Lumefantrine (20 / 120mg) tablets (any pack size) | 16.7 | 26.3 |
| Benzylpenicillin (600mg=1 MU) Injection | 13.3 | 21.0 |
| Ferrous salt tablets | 10.0 | 15.8 |
| Gentamicin Injection 10mg/ml | 3.3 | 5.3 |
| Albendazole tablets 400mg | 3.3 | 5.3 |
| **Medicines for common conditions expired on shelves** | | |
| Ceftriaxone Injection IM/IV 1gm Vial | 3.3 | 50.0 |
| Phenytoin tablets 100mg | 3.3 | 50.0 |

## Appendix X: Public Health Facilities that experienced stock out

| Key essential Medicine | PHFs that experienced stock out (%) | Average stock out duration (SD) | Range | Medicines for treating common conditions | PHFs that experienced stock out (%) | Average stock out duration (SD) | Range |
|---|---|---|---|---|---|---|---|
| Paracetamol tablets 500mg | 42.9 | 45 (76) | [0,270] | Ibuprofen tablets 200mg | 34.5 | 48 (94) | [0,305] |
| Albendazole tablets 400mg | 40.0 | 42 (69) | [0,242] | Glibenclamide tablets 5mg | 21.4 | 23 (58) | [0,183] |
| Artemether / Lumefantrine (20 / 120mg) tablets (any pack size) | 37.9 | 49 (76) | [0,242] | Phenytoin tablets 100mg | 20.0 | 3 (7) | [0,14] |
| Amoxycillin 250mg or 500mg capsules | 33.3 | 42 (70) | [0,240] | Ceftriaxone Injection IM/IV 1gm Vial | 17.4 | 8 (20) | [0,64] |
| Adrenaline Injection 1mg/mL | 28.0 | 29 (63) | [0,242] | Morphine sulphate Injection 10mg/ml | 16.7 | 10 (25) | [0,60] |
| Benzylpenicillin (600mg=1 MIU) Injection | 25.0 | 30 (70) | [0,266] | Furosemide tablets 40mg | 15.4 | 27 (79) | [0,324] |
| Salbutamol Inhaler 100 mcg/dose | 23.5 | 44 (96) | [0,312] | Enalapril tablets 5mg | 5.9 | 18 (74) | [0,304] |
| Amoxycillin 250mg (dispersible, scored) tablets | 23.3 | 27 (59) | [0,240] | Oxytocin Injection 10IU | 5.6 | 1 (4) | [0,14] |
| Malaria Rapid Diagnostic Test | 23.1 | 31 (60) | [0,146] | Tenofovir/Lamivudine/Efavirenz 300/300/400mg Tabs | 0.0 | 0 (0) | [0,0] |
| Gentamicin Injection 10mg/ml, 2ml ampoule *OR* 40 mg/ml, 2ml ampoule | 20.7 | 20 (42) | [0,186] | | | | |
| Ferrous salt tablets (any salt; alone or in combination with Folic acid) | 16.7 | 16 (50) | [0,246] | Insulin, Soluble (human),100IU/ml | 0.0 | 0 (0) | [0,0] |
| Paracetamol syrup / suspension 120mg/5mL | 13.3 | 17 (54) | [0,240] | | | | |
| Combined oral contraceptive pills | 6.7 | 12 (48) | [0,246] | | | | |
| Rapid HIV 1+2 Test 1 – Screening | 3.3 | 1 (6) | [0,29] | | | | |
| Rifampicin/Isoniazid/Pyrazinamide /Ethambutol150/75/400/275mg tablets | 0 | 0 | [0,0] | | | | |

# Appendix XI: KNH-UoN Ethics Approval Letter

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KENYATTA NATIONAL HOSPITAL
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Ref: KNH-ERC/A/10

14th January 2020

KENYATTA NATIONAL HOSPITAL APPROVED 14 JAN 2020 KNH/UoN-ERC P.O. BOX 20723 - 00202 NAIROBI

Geraldine Kawira Munene
Reg. No.U51/11995/2018
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Geraldine

**RESEARCH PROPOSAL - ASSESSMENT OF SELECTED DETERMINANTS OF ACCESS TO ESSENTIAL MEDICINES IN PUBLIC HEALTH FACILITIES IN MOMBASA COUNTY, KENYA (P836/10/2019)**

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 14th January 2020 – 13th January 2021.

This approval is subject to compliance with the following requirements:

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

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
The Chair, Dept. of Pharmacology and Pharmacognosy, UON
Supervisors: Dr. Eric M. Guantai, Dept. of Pharmacology and Pharmacognosy, UoN
Prof. George Osanjo, Dept. of Pharmacology and Pharmacognosy, UoN
Dr. Mercy Mulaku, Dept. of Pharmacology and Pharmacognosy, UoN

## Appendix XII: PHFs in Mombasa County

| | **LEVEL FIVE** | | **LEVEL TWO** |
|---|---|---|---|
| 1 | Coast Province General Hospital | 17 | Maweni Dispensary |
| | | 18 | Ganjoni Dispensary |
| | **Level Four** | 19 | King'orani Prison Dispensary |
| 2 | Likoni District Hospital | 20 | Mvita Dispensary |
| 3 | Port Reitz Subcounty Hospital | 21 | Senior Staff Medical Clinic |
| 4 | Tudor District Hospital | 22 | Mwembe Tayari Dispensary |
| | | 23 | Kaderboy Medical Clinic |
| | **Level Three** | 24 | Majengo Dispensary |
| 5 | Bokole Health Centre | 25 | Statehouse Dispensary |
| 6 | Jomvu Model Health Centre | 26 | Railway Dispensary |
| 7 | Kongowea Health Centre | 27 | Magongo Dispensary |
| 8 | Mbuta Model Health Centre | 28 | Moi Airport Dispensary |
| 9 | Mlaleo Health Centre | 29 | Jomvu Kuu Dispensary |
| 10 | Mrima Health Centre | 30 | Mikindani Dispensary |
| 11 | Shimo-La Tewa Health Centre | 31 | Miritini Dispensary |
| 12 | Ziwa La Ng'ombe Health Centre | 32 | Junda Dispensary |
| 13 | Chaani Health Centre | 33 | Marimani Dispensary |
| 14 | Kisauni Health Centre | 34 | Maunguja Dispensary |
| 15 | Bamburi Health Centre | 35 | Mwakirunge Dispensary |
| 16 | Vikwatani Health Centre | 36 | Shimo Borstal Dispensary |
| | | 37 | Utange Dispensary |
| | | 38 | Mtongwe Dispensary |
| | | 39 | Nys Dispensary (Kilindini) |
| | | 40 | Shika Adabu Dispensary |
| | | 41 | Tononoka Administration Police Dispensary |

**Appendix XIII: Similarity Report**

# Thesis - AVAILABILITY, PRICES, AFFORDABILITY, AND QUALITY OF ESSENTIAL MEDICINES IN PUBLIC HEALTH FACILITIES IN MOMBASA COUNTY, KENYA

*by* Geraldine Munene

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**Submission date:** 11-Sep-2022 05:15PM (UTC+0300)
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# Thesis - AVAILABILITY, PRICES, AFFORDABILITY, AND QUALITY OF ESSENTIAL MEDICINES IN PUBLIC HEALTH FACILITIES IN MOMBASA COUNTY, KENYA

ORIGINALITY REPORT

Endorsed
Dr. E.M. Guantai - Chairman
11th September 2022

14.09.2022

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