# FACTORS INFLUENCING RATIONAL DRUG USE IN PUBLIC HOSPITALS AMONG DOCTORS AND PHARMACISTS IN MERU COUNTY

# **DENNIS MWITI WAHOME**

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MANAGEMENT, KENYA METHODIST UNIVERSITY

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# **DECLARATION & RECOMMENDATION**

Student:
"This thesis is my original work and has not been presented for a degree or any academic
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Signed Date
Dennis Mwiti Wahome
HSM-3-0880-3/2012
Supervisors
"This Thesis has been submitted for examination with our approval as university
supervisors."
SignatureDate
Ms. Eunice Muthoni Mwangi
Department of Health Systems Management
Kenya Methodist University
Signature Date
Mr. Titus Mutwiri
Department of Health Systems Management

Kenya Methodist University

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# **DEDICATION**

This thesis is dedicated to my family for their unwavering support, the memory of my beloved mother, my supervisors for their unrelenting guidance and everyone who supported me during the study period. I wish you God's favor and protection.

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#### **ABSTRACT**

Access to essential medicines, vaccines and medical technologies is the anchor pillar in this study. Medical products must be of assured quality, safety, effective, scientifically sound and cost effective. Rational use of medicines requires that a patient receives appropriate medications to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time and at the lowest cost to them. It is concerned with how commodities are selected, procured, used and stored to ensure that the patients receive quality and efficacious products appropriate to their medical needs. There are a number of challenges that have been encountered in the rational use of drugs. These include lack of essential drugs, gaps in training and weak implementation of policy guidelines. The broad objective of this study was to assess the factors that influence rational drug use among doctors and pharmacists in public hospitals in Meru County. Specifically the study sought to determine how staff awareness on policy guidelines, management practices, product selection and inventory management influence rational drug use among doctors and pharmacists. A cross sectional study design was adopted having quantitative approaches. The sample size was 102 doctors and pharmacists who work in the public hospitals in Meru County. Both stratified and simple random samplings were used to sample the staff. A five point Likert scale based questionnaire was used to collect data. Quantitative data was analyzed using SPSS Version 23. Correlations were done between the dependent variable RDU and independent variables Staff awareness, inventory management, production selection and management practices. Significance levels were done at both 5% and 1%. There was a significant relationship between RDU and staff awareness (r=.232\*, p=0.019) and inventory management (r=.324\*\*, p=0.001). Coefficient of determination (R) of 0.402 was obtained compared to overall R<sup>2</sup> of 0.162 and this explains 40.2% of total variations that explained factors that influence rational drug use among the healthcare workers in Meru County. The ANOVA findings (F (4.97)=4.68, p=0.002) shows that there is correlation between the predictors variables Staff awareness, management practices product selection, Inventory Management, and the dependent variable Rational drug use. This study recommends: i)The hospitals develop training manuals on rational drug use that will be used to create awareness on importance of Rational drug use among doctors and pharmacists to enhance knowledge and build capacity, ii) departmental heads to offer support supervision, quarterly assessment, appraisals and implement RDU in collaboration with doctors and pharmacists, iii) All the hospitals to constitute active Drugs and Therapeutics Committees in all the facilities to ensure that formularies are developed, policies are communicated and SOPs implemented, to enhance uniformity and build capacity, iv) to constitute procurement committee with all stakeholders including the doctors and pharmacists to ensure they are involved in the budgeting, selection and monitoring of Essential drugs.

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# **ABBREVIATIONS**

Drugs and Therapeutics Committee

EDL:	Essential Drug List
MDG:	Millennium Development Goals
<b>MOH</b> :	Ministry of Health
МоРН:	Ministry of Public Health
MSH:	Managing Science for Health
MTRH:	Meru Teaching and Referral Hospital
NACOSTI:	National Commission for Science, Technology and Innovation

**OTC:** Over The Counter

DTC:

**RDU**: Rational drug use

**SERC**: Scientific Ethics and Research Committee

**SPSS**: Statistical Package for Social Sciences

STG: Standard Treatment Guidelines

WHO: World Health Organization

#### **CHAPTER ONE**

#### INTRODUCTION

# 1.1 Background of the Study

In the year 1985, the World Health Organization convened a conference of experts to discuss on the rational use of drugs. This delegation came up with a definition which posited that rational use of medicine requires that "Patients receive medications and drugs that are appropriate to their medical needs, in doses titrated to their individual needs, for an adequate time frame, and at the lowest affordable cost to them and their community" (World Health Organization [WHO], 1985). The World Bank has a different approach on the definition of rational drug use by employing two prongs: the use of drugs based on empirical data on efficacy, safety, and compliance; and the cost-effective use of drugs within the limits and constraints of a specific health system (Almarsdottir, 2005).

This study is anchored on the Health Systems pillar on medicines, vaccines and technology pillar. The availability of essential drugs (drug that cater for the medical conditions of the larger population) and their affordability to the citizens are paramount for the successful functioning of any health system (Ahmed & Islam, 2012). The rational use of medicines is important in the realization of Universal Health Coverage (UHC), satisfaction of human rights on health and also the achievement of Sustainable development goals on health. The responsibility is upon all healthcare providers, stakeholders and decision makers to enforce the implementation of rational use of medicines (Duke, 2012). Studies have shown that irrational use of drugs encompasses all aspects where drugs are not used correctly as prescribed in totality. Irrational drug use may include polypharmacy a situation whereby more than one drug is used whereby one would have sufficed the use of counterfeit drugs or drugs that are not effective or whose source cannot be ascertained. This can result in self

medication by patients and also deter access to quality drugs. The outcomes of these actions are increased treatment costs, morbidity and mortality. These actions, negatively and cumulatively affect the quality of medication therapy, inflate health care costs, and may cause adverse drug reactions or negative psychosocial impact.

The WHO and the World Bank definitions of rational drug use differ in two key areas: (1) the use of empirical data in prescribing, which is emphasized in the World bank definition; and (2) World Bank definition considers the countries' fiscal capacity in budgeting for drugs while the WHO advocates for the use of drugs of the lowest cost at all times in all health care systems (Almarsdottir, 2005).

To achieve rational drug use there are in place policies and legal framework that includes Essential drug lists, standard treatment guidelines and laws enacted on procurement, supply, storage and distribution systems which support and mitigate fraud, corruption and wastage (Ahmed & Islam, 2012). The public hospitals in Kenya have perennially experienced stock outs of drugs. Some of the causes of this include lack of adequate funds allocated when budgeting, poor planning and forecasting, high patient demand, disease outbreaks and even losses through expiries. Because of these drug shortages, patients do not receive their prescriptions as required and often causes increases in treatment costs for them through purchasing the drugs from the private sector. In order to streamline and ensure stability in the supply of pharmaceuticals, the Government of Kenya established Kenya Medical and Supplies Authority (KEMSA) in the year 2000 with the sole mandate to procure and supply drugs and pharmaceutical supplies to the public, mission, and private hospitals in the country (KEMSA ACT, 2013). KEMSA role is to ensure the consistent and regular supply of drugs to all health facilities through processing their respective orders. This has not been without

challenges due to budgetary constraints, geography and extreme terrain, harsh weather conditions during delivery of supplies and the supplier stock outs as well, therefore not servicing client requirements.

Duke (2012) posited that among the factors that contribute to irrational use of drugs include lack of proper communication resulting in patient drug misinformation. This could be either to language barrier or failure of the patient to adequately explain their symptoms and to a large degree due to lack of privacy therefore the patient may feel uncomfortable to disclose private information. Misleading beliefs on potency and efficacy of drugs are very common especially due to marketing by pharmaceutical companies due to profit motive. Also patient demands / expectations play a big role whereby the patient has a preconceived mindset prior to consulting a doctor. Another factor leading to irrational drug use is the prescriber's lack of education on the standard treatment guidelines and the absence of reference materials like the drug formularies which should be prepared by the drugs and therapeutics committee. In most hospital settings, training and continuous medical education on rational drug use is lacking either due to poor organization combined with lack of funds for the same. There are also problems of inappropriate role models, lack of objective drug information from the drug marketers which often may cause confusion to prescribers or influence the prescriber's choice of treatment, generalization of limited experiences, misleading beliefs about drugs efficacy, work place conditions like heavy patient load, pressure to prescribe from various quarters, lack of adequate lab capacity, lack of enough trained personnel, drug supply logistics challenges like unreliable suppliers system, inadequate storage space, stock outs /drug shortage, expired drugs, drug regulation weakness, informal prescribers, lack of regulation enforcement, industry / promotional activities and misleading claims.

The impact of all these factors results in reduction in the quality of drug therapy leading to increased morbidity and mortality. It also leads to waste of resources leading to reduced availability of other vital drugs and increased costs to both the patient and the government. In addition, there is increased risk of unwanted effects such as adverse drug reactions which could be expensive to manage and at worse could be fatal. Another consequence would be the emergence of drug resistance more so with antimicrobial agents. This could potentially hamper infectious disease control and threaten us with a return to a pre antibiotic era. A direct outcome of antibiotic resistance is increased health care cost as is the case in the management of multiple drug resistance (MDR) and extensive drug resistance (XDR) tuberculosis. Drug resistance would also jeopardize health care gains to the society; threaten health security and damage trade and economies on large scales. Most importantly, there is psychosocial impact, such as when patients come to believe that there is "a pill for every ill", which may cause an apparent increased demand for drugs.

Many countries in Africa are not eager to develop programs to promote rational use of drug and also in many countries drugs are not available at primary health centers or even in hospitals. Sustainable efforts are needed in order to promote rational use of drug for both general population and for health professionals. In many African countries the health professionals do not know how to communicate and provide information for their patients. Patients also do not have access to essential information on their drugs. Some governments have not prioritized education on promoting rational use of drug in medical education curricula (WHO, 2006). Kenya, Zimbabwe, and Tanzania are the three African countries that have the longest history of implementation of an Essential Drug Programme (EDP). The EDP was developed 1981 as a formulated response to the problem that a majority of the population was not able to get affordable basic drugs within their area. The EDP started slowly and

spread to rural areas until eighty-five percent of the population had access to essential drugs. The Kenyan Vision 2030 prioritizes the Health Sector as one of the key sectors to spur economic growth and development. The vision's goal for the Health Sector is to provide equitable and affordable quality Health services to all Kenyans. This is in recognition of the fact that good Health and Nutrition boosts the human capacity to be productive, consequently enhancing economic growth, contributing to poverty reduction and the realization of the Vision's social goals (Mungu, 2013).

Irrational prescribing and dispensing practices are widespread across many nations. Inadequate or inaccurate information about drugs and lack of standard treatment guidelines leads to improper treatment and irrational use of drug (Harper & Strote, 2011). Furthermore, in Kenya, there is gap in implementation and enforcement of regulation coupled with poor resources allocation, both financial and human resources. These are big obstacles related to rational use of drugs.

#### 1.2 Statement of the Problem

The rational use of medicines is fundamental to the provision of universal health care, satisfaction of health related human rights and the attainment of health-related Sustainable development goals. It is therefore, incumbent upon all health providers, stakeholders and policy makers to take crucial measures for improving rational use of medicines (Duke, 2012).

Worldwide, it is accounted that more than half of all medicines are prescribed, dispensed, or sold inappropriately, while half of patients fail to take them correctly. About one-third of the world's population lacks access to essential medicines (Haque, 2017). In our local context, there is a general tendency to over-prescribe medicines especially antibiotics a practice

known as polypharmacy. A national median of 78% patients received antibiotics in clinical setting. Irrational dispensing was also demonstrated in 70% of public health facilities, more than three-quarters of dispensed medicines were inadequately labeled (Ministry of Health [MOH], 2003). Irrational drug use puts patients at risk of adverse drug reactions, unwanted side effects, increased morbidity and mortality, wastage of scarce resources that could have been used to tackle other pressing health needs (Hamilton, 2009).

The service charters are available in all the public hospitals but they are not adhered to and the drugs and therapeutic committees in the sub county hospitals are either nonexistent, improperly constituted and have not developed hospital formularies (Meru County, 2013). There is lack of a proper logistics management system, inventory control, lack of adequate, efficient and reliable storage facilities for essential drugs as well as improper management of returns. The poor inventory management practices results to chronic stock out of essential drugs (Shadrack, 2015). The MeTRH has faced continuous stock outs of pharmaceutical products despite being the largest hospital in the County. For example, according to the County Health Management Team, malaria remained the leading cause of outpatient morbidity in Meru County (Ministry of Health, 2012b),

This study seeks to assess the factors influencing rational drug use among Doctors and Pharmacists in Meru County, identify the gaps, build capacity and draw recommendations to strengthen rational drug use for better patient outcomes and set benchmarks for excellence.

# 1.3 Broad Objective

The main objective of this study was to assess the factors influencing rational drug use among Doctors and Pharmacists in Meru County.

# 1.3.1 Specific Objectives

- To establish how staff awareness on policy guidelines influence rational use of drugs among doctors and pharmacists in Meru County.
- ii. To determine if management practices influence rational use of drugs by doctors and pharmacists in Meru County.
- iii. To determine how product selection of essential drugs influence rational use of drugs among doctors and pharmacists in Meru County.
- iv. To establish how inventory management affects rational drug use among doctors and pharmacists in Meru County.

# 1.4 Research Questions

- i. How does staff awareness on policy guidelines influence rational use of drugs in Meru County among doctors and pharmacists?
- ii. How does management practices influence rational drug use by doctors and pharmacists in Meru County?
- iii. How does product selection of essential drugs influence rational drug use among doctors and pharmacists in Meru County?
- iv. How does inventory management affect rational drug use among doctors and pharmacists in Meru County?

# 1.5 Justification of the Study

Tackling the issue of irrational medicine use is considered to be essential not only to improve healthcare delivery towards ensuring patient safety, but also to allow for optimal utilization of resources. This stems from the fact that as much as 25%–70% of overall health expenditure in

developing countries is spent on medicines whereas, around 10% of health expenditure in most high-income countries is consumed by medicines (WHO, 2008).

Irrational drug use can lead to increased morbidity and mortality, increased treatment costs, increased risk of adverse drug reactions, side effects and the emergence of antimicrobial drug resistance (WHO, 2014). There is scanty information in our local context on factors influencing rational drug use among health professionals. This research will add to the pool of knowledge on rational drug use. This research will generate evidence based information which will be used in making recommendations to informed rational drug use policies thus building capacity on rational drug use.

# 1.6 Limitations and Delimitation

#### 1.6.1 Limitation

The study was carried out only in the Public Hospitals in Meru County. The private hospitals were not included in the study. Thus the results will have a bearing only similar to the Public hospitals and other similar facilities.

The primary source of data is entirely based on the participants and can therefore not be independently ascertained. As such bias cannot be ruled out. To mitigate this, adequate sample size was used in the study.

# 1.6.2 Delimitations of the Study

The study assessed factors that affect Rational Drug Use among doctors and pharmacists only and did not involve other health care professionals. Also the patient's perspectives were not included in the study.

# 1.7 Significance of the study

This is study is important because it will establish perceptions of doctors and pharmacists on factors influencing rational drug use in public hospitals in Meru County. This will assist in policy formulation to develop mechanisms that will bridge the gaps that lead to irrational drug use. This study will draft recommendations to ensure rational drug use is implemented resulting in better therapeutic outcomes for patients. The findings will form a basis for policy formulation and better access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost effectiveness in Meru County.

# 1.8 Assumptions of the Study

The assumptions are that all the respondents were honest when completing the questionnaires. The use of drugs is similar across the entire public sector hospitals and as such the results can be generalized.

# 1.9 Operational definition of terms

Drug and Therapeutics This committee develops and implements policies

and guidelines on the use of medicines.

Essential medicines: These are those that satisfy the priority health care needs

of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety,

and comparative cost-effectiveness.

Health professionals: Refers to the doctors and pharmacists who are involved in

prescribing and dispensing of drugs in hospitals.

Polypharmacy: This is the use of multiple medications to treat a patient.

Rational drug use: Requires that "patients receive medications appropriate to

their clinical needs, in doses that meet their own individual requirements, for an adequate period of time,

and at the lowest cost to them and their community".

Self medication: Is deciding by oneself on which medicines one needs. The

forces that drive one to use medicines include real or perceived ill health, ignorance, and addiction or

dependence on certain medications.

Standard treatment guidelines: Are systematically developed statements that assist

prescribers in deciding on appropriate treatments for specific clinical problems. They usually reflect the consensus on the optimal treatment options within a health system and aim at beneficially influencing

prescribing behavior at all levels of care.

#### **CHAPTER TWO**

#### LITERATURE REVIEW

#### 2.1 Introduction

Medicines have an integral part in the health care system all over the world. When the appropriate use of medicine is done, they can cure the different ailments and promote the health of the patients and results in the wellbeing of the patients. However, the irrational use of drugs is the major issue in this regard and it is practiced all over the world (Sabir, 2018)

The Conference of Experts on the Rational Use of Drugs, convened by the World Health Organization in Nairobi in 1985 defined that "Rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and the lowest cost to them and their community (WHO, 1985). This is often simplified as the five rights – the right drug at the right dose by the right route at the right time for the right patient (Mehta, 2005). Complementary terms such as responsible use of medicines, prescribing efficiently have also been used by some instead of 'rational use'. If the use of medicine is not as per these conditions, it is considered as irrational or incorrect, improper and inappropriate use (Holloway & Van, 2011).

It is recognized that one third of the world's population has no access to essential medicines. This is a global problem with the developing countries being most affected. The appropriate prescription and use of medicines – rational drug use (RDU) – is a crucial part of national health policy, particularly since more than 50% of national and 60% - 80% of individual of healthcare spending in developing countries goes towards medicines (WHO, 2000). Irrational use of medicines is an extremely serious global problem that is wasteful and harmful. In developing and transitional countries, less than 40% of patients in the public sector and 30%

of patients in the private sector are treated in accordance with standard treatment guidelines (WHO, 2011). Irrational drug use lowers quality of life, increases morbidity and mortality and wastes resources. There are often out of pocket payments by patients which result in significant patient harm in terms of poor patient outcomes and adverse drug reactions (Green, 2012). There is a general tendency to over-prescribe medicines especially antibiotics. According to Ahmed and Islam (2012), correcting irrational use of medicines starts by measuring its magnitude. The system must be assessed as part of measuring the magnitude of the problem. Prescribing, dispensing and patient use of medicines must be regularly monitored in terms of the types of irrational use of medicines in order to design change strategies. Green (2012), posited that there are many reasons for the irrational use of medicines. These include lack of unbiased information on the currently used drugs. Majority of our practitioners rely on medical representatives. There are differences between pharmaceutical concern & the drug regulatory authorities in the interpretation of the data related to indications & safety of drugs. Lack of proper clinical training regarding writing a prescription during training period, dependency on diagnostic aid, rather than clinical diagnosis, is increasing day by day in doctors. Lack of skills or independent information, poverty, unrestricted availability of medicines, overwork of health personnel, inappropriate promotion of medicines and profit motives from selling medicines all contribute to the irrational use of drugs (Ambwani & Mathur, 2014).

# 2.2 Rational Drug Use

Rational use of drugs requires patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (Syed, 2012). Only 12% value of budgetary allocation for drugs in developing countries are received by consumers. Irrational drug use

may cause considerable waste and poor quality of care. The appropriate, effective and fiscally responsible use of pharmaceutical products is often a neglected issue in international health programmes in developing countries. They have focused on low-technology, low-cost interventions for family planning, maternal health, child survival, malnutrition, prevention of sexually transmitted infections and environmental health problems. However, regular availability and proper use of pharmaceuticals is key to the success of many of these interventions, e.g. malaria prophylaxis and treatment, directly observed treatment short course (DOTS) strategy for tuberculosis, supplementation and management of complications of pregnancy and delivery, among a host of other chronic communicable and non-communicable conditions. Medical consequences of irrational use of drugs include: adverse, possible lethal effects; limited efficacy; antibiotics resistance; drug dependence; risk of infection due to improper use of injections (Alex, 2011).

Rational drug use attained more significance nowadays in terms of medical, socio economical and legal aspect. Factors that have led to sudden realization for rational drug use are; Drug explosion thus the increase in the number of drugs available has incredibly complicated the choice of appropriate drug for particular indication. There are concerted efforts to prevent the development of resistance therefore irrational use of drugs may lead to the premature demise of highly efficacious and life saving new antimicrobial drug due to development of resistance. The Growing awareness and information about drug development, its uses and adverse effects travel from one end of the planet to the other end with amazing speed through various media and this is important for knowledge transfer on new global trends on medicines use. Increased cost of the treatment increases economic burden on the public as well as on the government. This can be reduced by rational drug use and result in huge financial

savings. The Consumer protection Act (CPA) in medical profession may restrict the irrational use of drugs. All these activities have greatly reduced irrational drug use (Sabir, 2018)

The use of pharmaceuticals is influenced by factors both inside and outside the Public Health Programs. Medical directors and clinicians as well as policymakers and managers usually collect data on patterns of drug use, specific drug use problems and monitor drug use over time. The drug prescribers, pharmacist and patients all require information on drugs. The sources of drug use information can be classified into: Primary (articles or papers on original research), secondary (reviews of the primary literature), and tertiary (formulary manuals, standard treatment manuals, textbooks and review articles or drug product information approved by drug regulatory agencies) (Kisengi, 2013).

# 2.2.1 Rational Prescribing

There are various strategies that have been put forward. These strategies can be classified into three broad classes, namely, educational, managerial and regulatory (Charles, 2014). Bulletins, seminars, printed materials and face-to-face interventions are examples of educational strategies. Managerial strategies are generally restrictions on prescribing and they include cost restrictions, endorsement by higher qualified consultants, a maximum number of drugs per prescription and structured prescription forms. Scheduling drugs in different categories of sale, specifying the minimum level of prescriber or health facility to handle certain drugs and procedures to critically evaluate drugs and product information before market approval is given, form the bulk of regulatory strategies. Essential drug lists (EDL) have also helped a lot in promoting irrational prescribing. WHO established the first Model List of Essential Medicines in 1977. This was a key step towards promoting rational drug use. This model list was aimed at assisting countries in formulating their own national

essential drug lists. WHO defines essential drugs as "those that satisfy the health care needs of the majority of the population and they should therefore be available at all times, in adequate amounts and in the appropriate dosage forms (WHO, 1997)." Essential drugs are necessary to fight ill health, increase access and rational use of these drugs will improve health status of the society especially in developing countries (WHO, 2000-2003). For instance, the Ministry of Health (2016) is the current EDL for Kenya. Moreover, certain healthcare facilities have compiled their own hospital formularies based on the specific hospital needs. Most of these hospital formularies borrow a lot from the country's EDL. These strategies have helped in promoting rational drug use.

Prescribing is the most important tool used by physicians to cure illness, relieve symptoms and prevent future disease. It is also a complex intellectual task that requires formulation of an appropriate treatment regimen from the many thousands available, taking into account the infinite variation in the patients they encounter. Unfortunately, the selection of a medicine and dosage regimen is sometimes suboptimal, leading to poor patient outcomes (eg treatment failure, avoidable adverse reactions). Rational prescribing implies using the right drug for the right patient in the right dose and manner of administration, at affordable cost and with right information. A prescription has to be tailor-made for an individual patient. It should take into account the diagnosis, age, sex, weight, drug and food interactions, vital functions as well as socio-economic, spiritual beliefs and background of the individual patient. The underlying principles or criteria include safety, accessibility and efficacy/ effectiveness (Akhtar, 2009). The impact of irrational drug use is predictable. Reduction in the quality of drug therapy leads to increased morbidity and mortality, wastage of resources leading to reduced availability of other vital drugs, increased costs, increased risk of unwanted effects and the emergence of antimicrobial drug resistance (Srinivasan, 2004).

# 2.2.2 Rational Dispensing

The basic duty of a pharmacist is to check prescriptions from physicians before dispensing the medication to the patients to ensure that the patients don't receive the wrong drugs or take an incorrect dose of medicine. Dispensing the wrong drugs or giving incorrect usage instructions can have serious consequences for patients, including death. Pharmacists also offer guidance on the side effects; medication can have and warn against actions that could be dangerous while the patient is using the medicine, such as consuming alcohol or operating heavy machinery. Much of their work is related to patient safety, so a pharmacist makes sure the patient isn't prescribed a medication that they might be allergic to, or that will interact with food or another medication they are already taking. Patients very often are prescribed different medicines from different doctors, and patients receiving treatments from multiple specialists for different complaints might be issued drugs that could make them unwell if combined with other medicines. Although preventing dangerous drug interactions is primarily a physician's responsibility, pharmacists provide a check against this possibility (Sinha, 2014).

Inadequate labeling was reported as source of discrepancy in providing improved patient care. Drugs with similar labeling pose greater risk of dispensing errors so requires strict consideration and monitoring to minimize dispensing errors and therefore it is important to adopt standard guidelines. Color coded labels could prevent dispensing errors of lookalike sound alike drugs (Lopes, 2012). Labeling of medications dispensed in hospitals is done in order to give comprehensive and detailed information of medicine and give ease of identification to the patients. Name of medicine, identification of patient, dosage, storage and frequency information, date of manufacturing and expiry in addition to administration route are labeled.

The inconsistency of labeling practice may result in inadequate information for the patients and in return increase the chances of medication errors. There can be a number of factors causing inconsistent labeling like absence of pharmacist, look alike drugs, lack of trained dispensers, erroneous prescription and verification (Naunton, 2015).

#### 2.2.3 Evidence based Medicine

Correct diagnosis is an important step toward rational drug therapy. Doctors posted in remote areas have to face a lot of difficulty in reaching to a precise diagnosis due to non-availability of diagnostic facilities; this promotes poly-pharmacy (Sabir, 2018). Evidence based medicine (EBM) is the conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients. EBM integrates clinical experience and patient values with the best available research information. It is a movement which aims to increase the use of high quality clinical research in clinical decision making. EBM requires new skills of the clinician, including efficient literature-searching, and the application of formal rules of evidence in evaluating the clinical literature. The practice of evidence-based medicine is a process of lifelong, self-directed, problem-based learning in which caring for one's own patients creates the need for clinically important information about diagnosis, prognosis, therapy and other clinical and health care issues (Masic, Miokovic & Muhamedagic, 2008).

# 2.3 Staff Awareness on Guidelines on Rational Drug Use

# 2.3.1 Policies on Rational Drug Use

Less than half of all countries are implementing many of the basic policies needed to ensure appropriate use of medicines, such as regular monitoring of use, regular updating of clinical

guidelines and having a medicine information center for prescribers or drug (medicine) and therapeutics committees in most of their hospitals or regions (WHO, 2011).

Unlike many developed countries we don't have regular facility which provides us up to date unbiased information on the currently used drugs. Majority of our practitioners rely on medical representatives. There are differences between pharmaceutical concern and the drug regulatory authorities in the interpretation of the data related to indications and safety of drugs (Naunton, 2015). Less than 40% of patients are treated according to STGs in the public sector, a figure that drops even lower in private sector settings. Together with EMLs and medicine formularies, the development and adoption of STGs reduces excessive, unnecessary, and inappropriate prescribing practices. Essential medicines are those that fulfill the need social insurance needs of the population. Using a Essential medicine list (EML) makes medication administration less demanding in all regards; obtainment, stockpiling and dispersion are simpler with less things, what's more, recommending and administering are less demanding for experts in the event that they need to think about less things. A national EML ought to be founded on national clinical rules (WHO, 2010). The Kenya Essential Drug List is a scientific endeavor to meet the health care needs and social needs of the population of Kenya. It is the basis for managing drug supply in the public health sector. It also serves as the basis for formulating the curriculums on drugs and therapeutics for medical, pharmacy, nursing, and other health training programmes; for prescribing in public hospitals, health centers, and dispensaries; for the supply of drugs to health facilities; and for encouraging the local production of the most essential drugs. It also serves as a pointer to donor agencies on the pharmaceutical requirements of Kenya. One sign that the concept of essential drugs has been accepted is the development, dissemination and use of a national essential drugs list or a local essential drugs formulary

The goal of the Kenya National Drug Policy (KNDP) of 1994 is to use available resources to develop pharmaceutical services to meet the requirements of all Kenyans in the prevention, diagnosis and treatment of diseases using efficacious, high quality, safe and cost–effective pharmaceutical products. The policy states that each health institution must have Pharmacy and Therapeutics Committee (PTC) consisting of the Medical Superintendent/Medical Officer In–Charge (Chairman), Pharmacist In–Charge (Secretary), consultants and other members of the medical staff, Nursing Officer In–Charge, and other health professionals as appropriate. The PTC is responsible for overseeing drug selection and formulary management, policies on prescription, drug utilization review, and policies on dispensing and administration of drugs. All drugs available at major health institutions must be approved by the PTC. The PTC should also establish policies for promotional activities by drug company representatives and evaluate their promotional material.

# 2.3.2 Standard Operating procedures

SOPs play a fundamental role in continuous quality assurance and ensuring best practice at the pharmacy, in order to assist in protecting the safety of patients and members of the public. The implementation of SOPs, which are specific to the pharmacy, will help to: ensure quality and consistency of service to patients, ensure good practice is achieved at all times, utilize the expertise of the pharmacy team effectively, facilitate delegation of appropriate tasks to trained members of the pharmacy team, provide role clarification for all members of the pharmacy team, provide assurance of staff understanding of processes to be followed in the pharmacy, provide an opportunity for pharmacists to define and assess their practice and facilitate communication and team work (Cumann, 2016). SOPs need to remain current to be useful. It is the responsibility of the superintendent and supervising

pharmacist to ensure they are updated and reviewed regularly, at a minimum annually or when any element of the process changes, for example if legislation or PSI Guidance has been updated or as a result of an error or incident. SOPs should be clearly marked with a scheduled date for the next review. When a review takes place, the review should be documented, i.e. dated and signed by the appropriate person, and the policy or procedure should be updated if necessary. As part of your review, if an SOP is available for a service that is no longer provided then it should be withdrawn from the current set and archived (Cumann, 2016)

The consistent, repeated use of Good dispensing practices (GDPs) is vital in ensuring that errors are detected and corrected at all stages of the dispensing cycle. Dispensing covers all activities from receiving the prescription to issuing the prescribed medicines to the patient. The development and use of written SOPs for dispensing process improve consistency and can be used for training and reference. The framework for such SOPs may be based on the 6 major areas which include receipt and validation of the prescription, understanding and interpreting the prescription, preparing and labeling items for issue, making a final check, recording action taken and issuing medicines to the patient with clear instructions and advice (WHO, 2011).

#### 2.3.3 Reference Materials.

STG is an organized and systematic tool for treatment of appropriate medical conditions that helps prescriber make decision on treatment choices. This clinical guideline is an important guideline for promoting rational use of drug. This guideline need to be adapted at all levels of health care; primary, secondary and tertiary (WHO, 2010). STG helps health professionals to

use the drugs which are from EDL. Furthermore, based on guideline, patient will receive the optimal treatment with the lowest cost (Green, 2012).

A large number of experienced clinicians have contributed in the preparation of these guidelines. The manual begins with a brief introduction to the concept of Rational Use of Medicines along with its important components. This is followed by chapters on common diseases and emergency conditions which may be general to all specialties. Remaining chapters describe frequent clinical conditions in each specialty, for example ENT, Psychiatry, Obstetrics and Gynecology etc. The format of the guidelines includes important salient features, diagnostic tests followed by non-pharmacological, pharmacological treatment plan and patient education, if applicable. Medicines are mentioned in generic names and choice is based on the balanced criteria of efficacy, safety, suitability and cost (Sabir, 2018).

When implemented effectively, STG offers advantages to patients (e.g. it provides more consistency and treatment efficacy), providers (e.g. it gives an expert consensus, quality of care standard, and basis for monitoring), supply managers (e.g. it makes demand more predictable and allows for prepackaging), and health policy makers (e.g. it provides focus for therapeutic integration of special programs and promotes efficient use of funds). Effective implementation, however, is perhaps the greatest challenge in introducing STGs.

Treatment guidelines for hospitals and outpatient health facilities in Kenya are regularly updated and made available to government, private, mission and other health services. The use of these guidelines is encouraged through information campaigns and pre–service and in–service training (MOH, 1994).

The KEML (Kenya Essential Medicines List) 2016 is an investment guide for the investment of healthcare funds in financing the most appropriate medicines to achieve therapeutic aims in response to prioritized public health need. This EML is based on the Concept of Essential Medicines, defined by WHO as those that meet priority health care needs of the population, carefully and systematically selected using an evidence-based process, with due consideration of public health relevance, clear evidence on efficacy and safety, comparative cost-effectiveness meant to be always available in a functioning health-care system, inadequate amounts, in appropriate dosage forms, with assured quality and adequate information at an affordable price for the individual & community.

# 2.4 Management factors and Rational Drug Use

# 2.4.1 Support supervision

Supervision is fundamental to guarantee great level of care. Supervision that is strong, instructive and confront, will be more powerful acknowledged by prescribers over straightforward examination and discipline. Including peers in review and input is especially successful. Effective forms of supervision include prescription audit and feedback, peer review and group processes of identifying medicine use problem (Edwards, 2008).

#### 2.4.2 Training

Lack of proper clinical training regarding writing a prescription during training period, dependency on diagnostic aid, rather than clinical diagnosis, is increasing day by day in doctors. The first step towards institutionalizing a culture of rational drug use is sensitization of the prescribing doctor. The concept and its importance requires to be stressed at every possible training opportunity – for the undergraduate, the intern, the postgraduate resident, the medical officer and nursing staff undergoing in-service courses and so on (Singh, 1995).

Teaching institutes must conduct regular research work & proper training of undergraduates & post graduates. Motivation of NGO to organize various programmes for public awareness lastly, the patient himself should observe strict compliance to the physician' prescription and never indulge in self-medication (Ambwani & Mathur, 2014). The importance of concepts such as Essential Medicines, P-drugs (evidence-based personal drug selection according to criteria of efficacy, safety, suitability and cost), pharmaco-vigilance, pharmaco-economics, antibiotic policy, etc. require to be reinforced at professional gatherings as well as in the course of routine teaching-learning activities. And then of course, there is role-modelling. No amount of teaching, training or sermonizing can replace the need for ideal prescribing behavior by 'seniors' at all levels: the senior intern, the senior medical officer, the senior resident and the senior specialist. Prescribing practices need to be justifiable, evidence-based and illustrative of sound clinical and pharmacological principles (WHO, 2007).

All pharmacology and therapeutics training in medical, paramedical, pharmacy, veterinary, dental and nursing schools and all prescribing in teaching hospitals are based on the Essential Drugs Concept. The curricula of these institutions include detailed information on the national drug policy, the concept of essential drugs, the Essential Drugs List, the use of generic names, the drug supply system, and rational prescribing. Various licensing bodies establish continuing education programs, attendance at which is necessary for renewal of professional licenses (MOH, 1994).

The National and County Governments should support efforts by departments and national professional associations to offer independent unbiased CME course to health professionals, including medicine dispensers. Most effective in-service training is likely to be problem

based, repeated on multiple occasions, focused on practical skills and linked to STGs and EDL.

# 2.4.3 Drug and Therapeutics Committee

The Drug and Therapeutics Committee (DTC) is an essential component of a health care organization's medicine selection, use, and distribution program. This committee has many different functions that will contribute to the goal of improving medicine selection and rational use of medicines. Many countries will spend 30 to 40 percent of their health care budgets on pharmaceuticals, and much of that money is wasted because of irrational use and inefficiencies in procuring medicines. Other serious problems that health care organizations face include the overuse of antibiotics, increasing antimicrobial resistance, increasing adverse drug reactions (ADRs), and considerably higher costs associated with pharmaceutical use. DTCs can provide the leadership and structure to select appropriate medicines for the formulary, identify medicine use problems, promote rational use of medicines, and help reduce pharmaceutical costs (MSH, 2010). The committee's functions are numerous and may be only partially performed by other committees. The primary functions advising medical, administrative, and pharmacy departments on pharmaceutical related issues, developing pharmaceutical policies and procedures, evaluating and selecting medicines for the formulary and providing for its periodic revision, identifying medicine use problems, Promoting and conducting effective interventions to improve medicine use (including educational, managerial, and regulatory methods) and managing ADRs and medication errors (Holloway & Van, 2011).

Effective implementation of systems and procedures which are already in place is another area which could do with some attention. Every hospital administrator is aware of the need for a 'Drugs and Therapeutics Committee' in hospitals (WHO, 2003). In many hospitals,

however, these committees may not be as active as they are required to be. It may be worthwhile for these committees to actively undertake their various roles which include guiding and monitoring drug use in the hospital by way of conducting prescription audits, monitoring adverse drug reactions, monitoring drug dispensing practices, formulating antibiotic policy with the active participation of the clinician as well as the laboratory and effecting course corrections whenever required.

The multiplicity of medicines available and the complexities surrounding their safe and effective use make it necessary for hospitals to have an organized, sound program for maximizing rational use of medicines. The Ministry of Health recognizes the Medicines and Therapeutics Committee as the organizational keystone of the program. The Medicines and Therapeutics Committee is an advisory group of medical staff and serves as the organizational line of communication between medical staff and pharmacy department. It is the policy-recommending body to the medical staff and the administration of the hospital on matters related to the therapeutic use of medicines (MOH, 2013).

#### 2.5 Product selection

Absence of well organized drug regulatory authority and presence of large number of drugs in the market leads to irrational use of drugs. The cycle of inventory management involves the supplies chain management and extends to the point of use where the commodities are finally utilized for service delivery. Ensuring availability of health commodities including essential drugs to meet the needs of the clients that it serves is the ultimate goal of an inventory management system which is to make patients (clients) receive the right medicines, in right quantities and at right quality, delivered at the right place, right time and for the right cost, (AMREF, 2007). According MSH (2010) commodity management refers to overseeing

the logistics of receiving, storing, transporting and distributing health commodities along with commodity accounts, documents, preparing commodity report and keeping commodity losses at an acceptable minimum. Managing drugs, diagnostic test kits, and other health commodities in any setting whether public or Private sector and at any level follows a well-recognized system that can be viewed as a cycle of selection, procurement, distribution, and use. At the center of the cycle is management support. The functions of management support include financing, information management and staffing, monitoring, and evaluation which hold the cycle together. The cycle rests on a policy and legal framework that establishes the mechanisms for each function and supports the commodity management system (WHO, 2011).

### 2.5.1 Selection of Essential Drugs

KEMSA should circulate the list of essential drugs which should be updated from time to time. It must monitor the safe and proper use of these drugs and enforce a uniform regulation for promotional literature. Drug selection, preferably linked to national clinical guidelines, is a crucial step in ensuring access to essential drugs and in promoting rational drug use, because no public sector or health insurance system can afford to supply or reimburse all drugs that are available on the market. Key policy issues are: the adoption of the essential drugs concept to identify priorities for government involvement in the pharmaceutical sector, and especially for drug supply in the public sector and for reimbursement schemes; procedures to define and update the national list(s) of essential drugs and selection mechanisms for traditional and herbal medicines (WHO, 2002).

The product selection process allows you to lay a sound basis for selecting commodities. It guides by giving the reasons and criteria that should be used for deciding which products to

procure (AMREF, 2007). In any health logistics system, health programs must select products. In a health logistics system, a national formulary and therapeutics committee, pharmaceutical board, board of physicians, or other government-appointed group may be responsible for product selection. Most countries have developed essential medicine lists patterned on the World Health Organization (WHO) Model List. Products selected for use will impact the logistics system, so the logistics requirements must be considered during the product selection. A study by Action Africa Help International (AAH-I) revealed that essential medicines are available in only 50% of the health facilities and 65% of hospitals in Kenya (AAH-I, 2010).

Essential drugs should therefore be selected based on their relevance to the pattern of prevalent disease, proven efficacy and safety, adequate scientific data and evidence of performance in a variety of settings, good quality, favorable cost benefit ratio, desirable pharmacokinetic properties, and possibilities for local manufacture (Koskei, 2002). When the drug selection is inefficient, the results include; the purchase of too many products, purchase of unnecessarily expensive products, purchase of inappropriate products and purchase of inappropriate quantities (Koskei, 2002).

#### 2.5.2 Quantification of Essential Drugs

Deciding how much of each commodity to buy is the first practical step in procurement. The principles for estimating quantity are the same at the national level and the service delivery level. Quantification can only be done successfully if users follow agreed policies and guidelines and have based their selection of commodities on them. Accurate quantification is important for ensuring that a sufficient amount of each product is purchased with adequate expiry dates, so that stock-outs do not occur and all patients receive what they need at the

right time, an excessive amount of each product is not bought, in order to avoid wastage and over expenditure associated with the expiry of products before they can be used.

Quantification, a critical supply chain management activity, links information on services and commodities from the facility level with program policies and plans at the national level to estimate the quantities and costs of the commodities required for a health program. Quantification is important for informing supply chain decisions on product selection, financing, procurement, and delivery. The results of a quantification exercise help program managers identify the funding needs and gaps for procurement of the required commodities, leverage the sources, amounts, and timing of funding commitments to maximize the use of available resources, advocate for additional resources, when needed, develop a supply plan to coordinate procurements and shipment delivery schedules to ensure a continuous supply of commodities (MSH, 2010). The government of Kenya channels a lot of financial resources to the Ministry of Health in order to provide essential drugs. Pharmaceuticals are the largest item of expenditure within the public health sector budgets of developing countries, ranging from 8 to 12% of recurrent health budget, hence, asking for prudence in inventory management of pharmaceuticals or health commodities (National Institute of Health and Family Welfare [NIHFW], (2011). In Kenya in 2008, drugs accounted for 14% of the health budget and one of the areas targeted was to improve essential drug supply particularly in selection and quantification, (Ministry of Public Health & Sanitation [MPHS], 2008).

#### 2.5.3 Procurement of Essential Drugs

In many countries drug expenditure constitutes a large proportion of health expenditure. Drug procurement is therefore a significant factor in determining total health costs, and it is important to develop a system that helps to ensure efficient procurement for the public sector.

In Kenya, before devolution procurement of drugs was handled at a national level where all the drugs were procured nationally as all hospitals would send their requisitions to the Ministry of Health and they would then be distributed to the various hospitals nationwide and the settlement of funds to the supplier was done by the national government. After devolution, this is the sole responsibility of the county governments where the money is distributed to the various counties which are responsible for the running of all services in that county such as health. As a result some counties may have adequate drugs while others experience shortages at different times depending on the county management (Muhia, 2017). According to WHO (2011), one-third of the world's population does not have access to essential medicines. In Sub-Saharan Africa and South Asia the figure is closer to 50 percent. The problem is in part financial. The combination of donor support, multilateral loans, country financing, and out-of-pocket expenditures is inadequate to meet the growing need among poor populations for essential medicines, including contraceptives and other reproductive health products. On closer examination, the inability of country programs to procure medicines effectively and efficiently is also a major cause of poor access. Procurement agencies in parts of the world where access is low are paying many times more than standard international reference prices for essential medicines. In low-income countries, the process is often constrained by limited human resources, corruption, inadequate financing, an absence of information on prices and suppliers, a lack of awareness of government and donor regulations, overlapping systems, and unsynchronized or outdated rules and guidelines. These constraints can contribute to delayed shipments, high prices, and, ultimately, reduced access to essential medicines for consumers. The lack of capacity to select, forecast, and quantify product requirements, and to manage the procurement process, disrupts the distribution of health commodities to the client. In this context, commodity

security cannot be strengthened unless there is product availability in clinics and hospitals (WHO, 2006).

Drug procurement should also be limited to the essential drugs list or formulary list since no health program can afford to purchase all drugs available on the market. This simplifies and reduces inventory holding costs. In 2006, the Ministry of Health developed a Position Paper on Health Sector Procurement whose goal was to facilitate a more efficient and effective procurement process in the Public Health Sector. An effective procurement process ensures the availability of the drug in the right quantities, at reasonable prices, and at recognized standards of quality. Drugs may be acquired through purchase, donation or manufacture. Procurement of pharmaceuticals must be done based on good pharmaceutical procurement practices. This involves procuring drugs by "generic name" as this eliminates the issue of bias towards branded drugs since good quality medications are available at a lower price (WHO, 2010).

#### 2.6 Inventory Management

Proper drug traceability and accountability must be an essential component of a pharmacy's operations to maintain adequate control over inventory, adhere to state regulatory requirements, and minimize medication errors to ensure patient safety and quality standards are met. Proper medication management requires pharmacies to maintain complete and accurate records of drugs purchased, received, stored, distributed, dispensed, and disposed, in the event of drug recalls or adverse events (Delloite, 2014). Availability of essential medicines is commonly cited as the most important element of quality by health care consumers, and the absence of medicines is a key factor in the underuse of government health services. Improving pharmaceutical supply management is one of the elements among many

health sector reform efforts. Promising improvements in pharmaceutical supply systems have been made in some countries; however, many continue to struggle with a mix of inefficient public and private health sector supply systems. Decentralization of health sectors has in some cases intensified the problem, establishing logistics systems in the absence of trained human resources, infrastructure, and management systems at the decentralized levels (Aronovich, 2001).

Inventory control reports on stock management are useful sources of information for monitoring the PSM system. It is important that inventory control reports be sent in a timely manner from all levels to the central level in order to facilitate real-time data analysis, reporting and decision-making. This indicator is easy to measure, as the information is available. Timely assessment of reporting systems is critical for strong logistics management system performance and for an effective monitoring and evaluation system. Inventory control reports should include all the necessary information required to monitor PSM system performance: opening balance, quantities requested, quantities received, stock in hand, stock-out duration if any, quantities distributed or dispensed, number of patients on treatment by regimen, new patients, minimum and maximum stocks and losses for various reasons (e.g. expiry, theft, damage). It is important that the information submitted in the reports is consistent with the actual situation of the supply system. It is recommended that supervision be conducted randomly to assess the accuracy and validity of reported data (WHO, 2011).

Transparency International [TI], (2011) established that there was acute shortage of medicines and other essential supplies in most of the public hospitals in Kenya. Although, many stop-gap actions have been implemented over time, the problems still persist. In public health facilities most health clients are given the appropriate prescription on consultation after

which they have to purchase the drugs from chemists dotting the facility at inflated prices. In case the doctor recommends an injection, patients are forced to buy needles, syringes and gloves from the private chemists or clinics around the public facility, (TI, 2011). Adequate access to functioning healthcare systems is particularly difficult in rural districts in Kenya. Lack of a consistent drug supply is identified as a primary reason why health centers are not utilized with resulting high morbidity and mortality rates from malaria, diarrhea and HIV/AIDS (Mungu, 2013). A survey by WHO in 39 low and middle income countries including Kenya established that there was a wide variation on the availability of essential drugs which was at 20% in public sector and 56% in private sector (WHO, 2010). The extent to which inventory management practices contributes to the variation in availability.

## 2.6.1 Monitoring and evaluation

Monitoring is routine, timely tracking of the performance of continuous record-keeping, reporting or surveillance systems. Effective, frequent monitoring helps managers to make decisions in a timely manner. Evaluation is episodic assessment of progress towards a programme's targets. The purpose of indicators is to establish whether a programme's inputs result in the desired outputs and outcomes. Evaluation helps managers to determine the added value of investments in the programme. Monitoring indicators often show the areas that require in-depth evaluation; evaluation is conducted at longer intervals and requires significant investment in a rigorous method. Monitoring and evaluation are used to assess a system's strengths and weaknesses. Monitoring should cover all components of a logistics management system, and monitoring and evaluation should trigger correction of all aspects that do not reach the target. Monitoring can therefore ensure continuous quality assurance of a national procurement system. Implementation of an effective monitoring and evaluation programme requires trained personnel and financial and other resources, which should be

well planned. M & E will provide information about the factors associated with stock-outs and overstocking e.g. lead time, insufficient quantities procured (WHO, 2011). Inadequate inventory management leads to unavailability of essential drugs due to poor stock control that also results in drugs expiring in the shelves or used irrationally (Mungu, 2013).

#### 2.6.2 Distribution of Essential Drugs

Timely distribution is important, as it determines product availability and an uninterrupted supply of medicines to health facilities. This indicator applies to all levels of the supply and distribution system and to each sector in which medicines are distributed or dispensed (public, private, non governmental). A study by Action Africa Help International revealed that essential medicines are available in only 50% of the health facilities and 65% of hospitals in Kenya. A survey by WHO in 39 low and middle income countries including Kenya established that there was a wide variation on the availability of essential drugs which was at 20% in public sector and 56% in private sector (WHO, 2010). The extent to which inventory management practices contributes to the variation in availability.

In healthcare, ensuring that there are adequate drugs and supplies for every patient is paramount, as partial or intermittent treatment can lead to less than optimal results and in some cases, this can even be disastrous, both for the individual patient and the public at large. One of the major problems of lack of uninterrupted treatment includes treatment failure and the risk of developing drug resistance. This is a serious consideration in dealing with infectious diseases and in chronic ailments such as diabetes which require continuous treatment in order to keep the disease under control. Adequate drug supplies including contraceptives contribute to improved quality of health care and satisfaction of health workers. Well-supplied health programs can provide superior service, while poorly supplied

programs cannot. Likewise, well-supplied health workers can use their training and expertise fully, directly improving the quality of care for clients. Customers are not the only ones who benefit from the consistent availability of commodities. An effective logistics system helps provide adequate, appropriate supplies to health providers, increasing their professional satisfaction, motivation, and morale. Motivated staff are more likely to deliver a higher quality of health care service (USAID, 2011).

Designing a system for storing and distributing drugs, medical supplies and equipment is complex and important storage and distribution costs are a significant component of a health budget. An effective drug distribution system relies on good system design and good management. A well designed and well managed distribution system should maintain a constant supply of drugs while keeping the drugs in good condition throughout the distribution process. The distribution system should minimize drug losses due to spoilage and expiry, maintain accurate inventory records, rationalize drug storage points, efficiently use available transportation resources, reduce theft and fraud and provide information for forecasting drug needs. A distribution system requires systematic cost effectiveness analysis and operational planning (WHO, 2011).

### 2.6.3 Storage of Essential Drugs

Good storage and inventory control practices at the national and the point-of-service levels are similar. Written SOPs that document accepted practices for ordering/requisitioning, receiving, inventory management including storage and stock control, issuing and disposing of expired stock should be available at all levels of health care system (Walkowiak, 2008). The guidelines for good storage of essential drugs recommend that the storage space should be a secure, lockable area which should be accessible to the people needing the health

commodities. The storage place should also be clean and dry with organized shelves and pallets to raise the products from the ground. Ventilation through the use of air conditioning and adequate lighting are also key considerations for a good storage place for essential health commodities. Availability of cold storage for any commodities requiring refrigeration and of cold chain during transportation and availability of fire safety equipment are vital for locations where essential drugs are stored. The storage location for health commodities should also provide for separation of expired, damaged or obsolete commodities from usable ones and free of harmful insects and rodents (AMREF, 2007).

During storage cartons should be arranged so that arrows point up ensuring that identification labels, expiry dates, and manufacturing dates are visible. Store supplies should also be arranged in a manner accessible by FEFO (First Expiry, First Out), counting and general management. Damaged and expired drugs should be separated and disposed without delay (USAID, 2011).

#### 2.7 Theoretical framework

### 2.7.1 The General Systems Theory

This study is premised on the systems theory. This is an interdisciplinary theory about the nature of complex systems in nature, society and science. This provides a framework that can be used to investigate items that work together to produce some result (Ferlie & Shortell, 2001). The variables in a system entail an input, process, output, outcome and people. Systems theory requires all components to function interdependently in a beneficial relationship (Ferlie & Shortell, 2001). This is related to this study in that, for rational drug use to be achieved, doctors and pharmacists have a role to play. Staff awareness, management

practices, product selection and inventory management work together to achieve rational drug use like the components in GST work together seamlessly.

## 2.8 Conceptual Framework

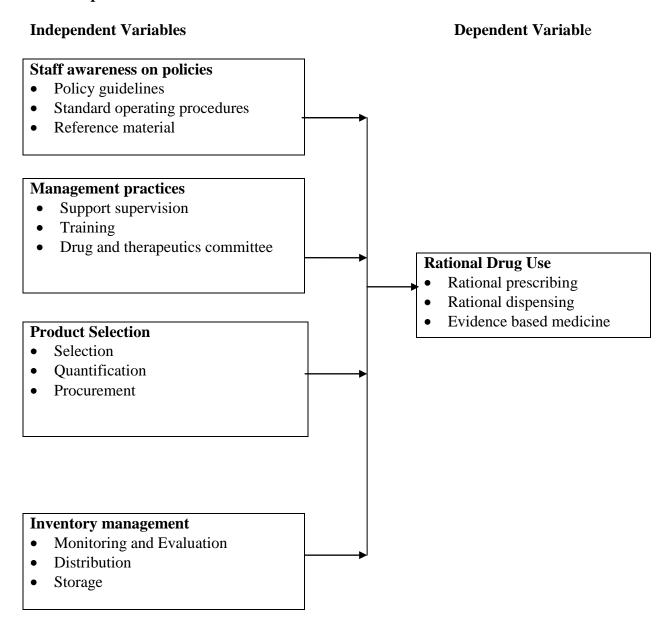


Figure 2.1 Conceptual Framework

Conceptual framework has independent and dependent variables. The independent variables which influence rational use of drugs are staff awareness, management practices, product selection and inventory management. The indicators on Staff awareness are policy guidelines, standard operating

procedures and Reference materials. The indicators in Management practices are support supervision, training and Drugs and Therapeutics Committee. The indicators on product selection are: Selection, Quantification and Procurement. The indicators on inventory management are monitoring and evaluation, distribution and storage. Rational Drug Use as the dependent variable was measured using three indicators namely Rational prescribing, Rational Dispensing and Evidence Based Medicine.

#### **CHAPTER THREE**

#### RESEARCH METHODOLOGY

#### 3.1 Introduction

This chapter describes the methods and procedures that were used to collect and analyze data on the factors that influence rational drug use among doctors and pharmacists in public hospitals in Meru County. This chapter focuses on research design, study site, target population, sample size, sampling method, sampling procedures, data collection methods and procedures, data analysis and results presentation.

### 3.2 Research Design

Ogula (2005) describes a research design as a plan, structure and strategy of investigation to obtain answers to research questions and control variance. Additionally, a study design is the plan of action the researcher adopts for answering the research questions and it sets up the framework for study or is the blueprint of the researcher. This study was aimed at establishing factors that influence rational drug use among doctors and pharmacists working in public hospitals in Meru County. To achieve this, the study employed research design that incorporated quantitative, descriptive and correlational designs. The study was also cross-sectional and Likert scale psychometric construct was used to collect data from the field. Correlational design was able to correlate the independent variables against the dependent variable while the quantitative was used to get the inferential information required for the purpose of this study.

### 3.3 Target Population

Mugenda and Mugenda (2003) define target population as a group of individuals, objects or items from which samples are taken for measurement. Population refers to the entire group of people, events or things of interest that the researcher wishes to investigate (Sekaran & Bougie, 2016). The population of this study were the doctors and pharmacists working in the sub county hospitals and the Meru Teaching and referral hospital in Meru County. The target population for this study was 138, both doctors and Pharmacists.

# 3.4 Study Location

The study was done in eight Sub County hospitals and the Referral hospital, MeTRH, in Meru County. In total, nine facilities participated in the study. Meru County is one of the 47 Counties of Kenya, located in the former Eastern province. It has an estimated population of 1.4million people as of 2017 Kenya Bureau of Statistics. Meru borders Isiolo County to the North, Laikipia County to the North West, Nyeri County to the South-West, Tharaka-Nithi County to the South, and Kitui County to the South-East. The county comprises of nine (9) administrative sub-counties which are equivalent to the constituencies namely, Tigania East, Tigania West, Igembe North, Igembe South, North Imenti, South Imenti, Buuri, Igembe Central and Central Imenti constituencies.

### 3.5. Sampling procedures

This covers the sample size Determination and sampling technique

### 3.5.1 Sample Size Determination

Some populations are too large to use in totality for research. In such cases, a sample is used.

A sample can be defined as the subset of a population (Hair, 2011). Sampling is the process

of selecting a small number of individuals from the population size. This selection is intended to be a representation of the larger group.

According to Fischer (2012) formula, at permissible error of 5% and prevalence of 50% the sample size will be:

$$n = \frac{Z^2 pq}{d^2}$$

Where

 $\mathbf{n} =$  sample size

 $Z^2$ = Standard error from mean corresponds to 95% confidence interval =1.96,

p = proportion of the population with the desired characteristics

$$q = 1-p = 1-0.5 = 0.5$$

d(0.05) = Permissible error in the estimate of P

Thus, with permissible error of 5%, the sample size is:

$$n = (1.96)^{2} \times .5 \times .5$$

$$(0.05)^{2}$$

$$n = 384.16$$

 $n \approx 384$  Thus, the sample size is 384.

The total of healthcare professionals at the Sub county hospitals is 138 as tabulated in Table 3.1

**Table 3:1 Distribution in the Sub Counties** 

SubCounty	Doctors	Pharmacists
Tigania East	7	2
Tigania West	8	2
Igembe North	9	4
Igembe South	9	3
Igembe Central	9	3
Imenti North	42	12
Imenti South	8	2
Imenti Central	5	3
Buuri	7	3
Total	104	34

Sample size calculation was based on Daniel's formula (1999) for estimating a population proportion for a finite population;

$$n \ge \frac{NZ_{\alpha/2}^2 P(1-P)}{d^2(N-1) + Z_{\alpha/2}^2 P(1-P)}$$

Where:

n= minimum sample size required

N=Total estimated population of doctors & pharmacists (N=138)

 $Z_{\alpha/2}$ = Standard normal distribution critical value at  $\alpha$ -level of significance ( $\alpha$ =0.05,

$$Z_{\alpha/2} = 1.96$$
)

P=Estimated proportion of doctors/pharmacists with say good knowledge of drugs and therapeutics policies (P was set at 0.5 because there's no available information from literature)

d=Desired margin of error (d=0.05)

The minimum sample size required is; n=102

# 3.5.2 Sampling technique

The sampling technique describes the sampling unit, sampling frame, sampling procedures and the sample size of the study. The sampling frame describes the list of all population units from which the sample will be selected (Cooper & Schindler, 2011). Sampling refers to the selection of elements of the population to be included in the study. A sample is a part of the entire population that can be used for the study and has all the characteristics of the entire population.

The study used stratified sampling whereby the population was put on different strata based o the cadre. The sample size was then divided proportionately by percentage of the total population. That is, the total population per cadre over the general population multiplied by the determinant sample size. Out of the sample size in each stratum, simple random sampling was used to get the respondents. Sample size distribution is presented in Table 3.2

**Table 3:2 Sample Size** 

Cadre	Population	Sampling Frame	Sample Size
Doctors	104	76.8	77
Pharmacists	34	25.2	25
Total	138	100%	102

### 3.6 Instrumentation

#### **3.6.1 Tools**

The study used Likert scale questionnaire containing closed ended questions (see appendix II).

The Likert scale ranges between 1 and 5. Strongly Disagree - 5, Disagree - 4, Not Sure - 3,

Agree - 2 and Strongly Agree - 1 respectively.

## 3.6.2 Pre-testing

Pretesting is an activity that assists the researcher in determining if there are flaws, limitations, or other weaknesses within the design and allows researcher to make necessary revisions prior to carrying out the study (Kvale, 2007). Pre-test is conducted to detect weaknesses in design and instrumentation. Pretesting was done at Isiolo Level 5 Hospital where 30 respondents were used to test reliability and validity of the questionnaire. According to Mugenda and Mugenda (2003), 1% to 10% of the actual sample size is adequate for pre-test. The study took 30% of the sample.

#### 3.6.3 Reliability

Reliability is the ability of the test instrument to give same results in repeated trials. In order to ensure the same questionnaire produces the similar results in repeated trials, the reliability of questionnaires was tested for reliability using Cronbach alpha. According to Cronbach (1951), a reliable coefficient ranges between 0.7 and 1.0. Any question or groups falling into this range is deemed to be reliable according to Cronbach. The reliability results for all the variables in the study are presented in Table 3.3

**Table 3:3 Reliability Results** 

	Cronbach's Alpha	N of items	
Staff awareness	.722	8	
Management practices	.735	10	
Product selection	.325	8	
Inventory management	.719	8	

Rational prescribing	.178	3
Rational dispensing	.532	3
Evidence based medicine	.171	3

## 3.6.4 Validity

Validity is the ability of an instrument to measure what it is intended to measure. In order to ensure the questionnaires are valid, the accuracy was tested during the pre-test among the respondents randomly.

## 3.7 Data Collection Methods

This study used drop and pick later method in data collection. The respondents were given two weeks to respond to the questionnaire. The questionnaire had close ended with Likert psychometric instruments of all variables.

### 3.8 Methods of data Analysis

Quantitative data analysis was done with the use of SPSS Version 23 and qualitative data was analyzed using the computer aided content analysis. The Mean Score and standard deviations were used to analyze the descriptive variables in this study. The results were then presented in tables, frequencies and percentages. The test statistics used were P-values, Pearson's Rho (r), mean scores, standard deviations.

The research questions in this study were tested using Pearson's Rho (r) and its corresponding P-Value. Where P-values were less than 0.05, the study concluded that statistical evidence is available for each variable whose p-value was 0.05 and below while insignificant relationships were for those with P-values above 0.05. Likert based questions were analyzed using mean scores for each question asked. A mean score above 3.4 indicates

agreement while those below 3.4 indicated disagreements, where 1 was strongly disagree and 5 was strongly agree.

Correlational analysis was done to establish the significance of each variable on the dependent variable. This was shown by the value of (r) and its corresponding P-value. The Rho lies between 0.0 and 1.0. The more closely the value of r is to 1.0, the stronger the relationship and vice versa. The following functional relationship was used to obtain the model used in this study:

$$Y = f(X_1, X_2, X_3 X_4) + \varepsilon$$

Where Y stands for Rational drug use

 $X_1$ = Staff awareness

X<sub>2</sub>=Management practices

X<sub>3</sub>=Product selection

X<sub>4</sub>=Inventory Management

 $\varepsilon$  = Stochastic disturbance error term

Then univariate and multiple linear regression model was derived;

$$Y = \beta_0 + \beta_i X_i + \varepsilon$$
 .....(1a)

$$Y = \beta_0 + \beta_i X_1 + \beta_{ii} X_2 + \beta_{iii} X_3 + \beta_{iv} X_4 + \epsilon_{...}$$
 (1b)

Where:

 $\beta_0$  is the constant,  $\beta_1$  (i=1,2,3,4) is the slope coefficients of  $X_1$ ,  $X_2$ ,  $X_3$  and  $X_4$  which gives the regression weight for each variable.

# 3.9 Ethical and Logistic Considerations

The research proposal was submitted to Kenya Methodist University, Scientific Ethics and Research Committee (KeMU, SERC), National Commission for Science, Technology and

Innovation (NACOSTI) and Meru County Health department for ethical clearance prior to data collection. The researcher upheld dignity of the participants and confidentiality of information obtained

#### CHAPTER FOUR

#### RESULTS AND DISCUSSION

#### 4.1 Introduction

This section presents the findings and discussions. The first part covers the demographics of the respondents: the second part outlines the descriptive characteristics of both the dependent and independent variables according to the study objectives. The third part covers Bivariate Linear analysis of all the variables. The last part covers the Inferential Statistical analysis. The study had 100% response rate based on the sampled population of 102. Mugenda and Mugenda (2003) posited that a response rate of 50% is adequate, 60% and above is good, and above 70% very good. Thus a response rate of 100%, cognizant of the sensitive nature of the study, is adequate.

# **4.2** Demographic Characteristics of respondents

The study sought to find out the demographic characteristics of the respondents in terms of gender, age, education level, years of service and number of patients served per day. Results of the demographic characteristics are presented in Table 4.4.

The analysis as indicated in Table 4.0 revealed that 61 (59.8%) of the respondents were between age of 31-40 years. Those below 30 years were 31 (30.4). Those with ages 41-50 and 51-60 accounted for 5(4.9%).

**Table 4:4: Characteristics of Respondents** 

Characteristic	Respondents N (%)
Age of respondents (years)	
Below 30 years	31 (30.4)
31-40 years	61 (59.8)
41-50 years	5 (4.9)
51-60 years	5 (4.9)
Total	102(100.0)
Gender	
Male	76(74.5)
Female	26 (25 .5)
Total	102(100.0)
Highest academic qualification	, ,
Bachelor's degree	83 (81.4)
Master's degree	19 (18.6)
Total	102(100.0)
Cadre	
Medical officer	69 (67.7)
Pharmacist	33 (32.3)
Total	102(100
Duration of experience in prescribing/dispensing	
Less than 1 year	45 (44.1)
1-5 years	25 (24.5)
6-10 years	16 (15.7)
More than 10 years	16 (15.7)
Total	102(100.0)
Number of patients served per day	
Less than 50 patients	44 (43.1)
50-100 patients	49 (48.0)
101-200 patients	6 (5.9)
More than 200 patients	3 (2.9)
Total	102(100.0)

The findings on gender showed that there were more males 76(74.5%) than females 26(25.5%). This implies that the bulk of the doctors and pharmacists are of the male gender. Among the respondents, the findings as indicated in Table 4.4 shows that majority of the respondents were degree holders and they accounted for 83 (81.4%). Masters holders were

19 (18.6%). The implication is that all the respondents were literate and were able to fill in the questionnaire appropriately and they were qualified for the positions.

Medical officers were the majority in the study accounted for 69 (67.7%). The Pharmacists were a paltry 33 (32.3%). Further, the study sought to find out the years of service of the respondents. The results in Table 4.0 indicates that the majority of the participants 45(44.1%) had served for less than one year and this may have attributed to the recent increase in the HCWs. Respondents who had served 1-5 years accounted for 25 (24.5%) whereas those who had served 6-10 years and over 10 years accounted for 16 (15.7%) respectively. According to the findings, majority of the respondents were interns or newly posted to the facilities.

In terms of the number of patients served per day, 49(48.0%) reported serving between 50-100 patients, 44 (43.1%) served less than 50 patients and 3(2.9%) served more than 100 patients per day and this was due to the rural settings of most healthcare settings.

### 4.3 Responses on the Dependent Variable: Rational Drug Use

Table 4.5 shows the respondents agreed that they prescribe drugs from the Essential Drug List (Mean Score 3.84) and most of the prescriptions are clear and legible (Mean Score 3.65) though they disagreed that most of the prescriptions were appropriate for the diagnosis (Mean Score 2.73). It was established that drugs dispensed were well packed and labelled with clear instructions (Mean Score 3.43) and this was in agreement by majority of the respondents and this led to proper prescription and further the patients are given drug information and counselled during dispensing (Mean Score 3.70) though there wasn't a follow up program in place to track patients (Mean Score 2.92). It was established that relevant investigations were carried out prior to making a diagnosis (Mean Score 3.68) and the patient complaints and

adverse drug reactions were reported, and appropriate remedy actions taken as established by the mean responses (Mean Score 3.63) and the doctors and pharmacists were updated on new trends in treatment through workshops and Continuous Medical Education as established from the mean (Mean Score 3.53) and that CME is necessary for updates on the recent trends in prescriptions. This agreed with Syed (2012) who indicated that rrational use of drugs requires patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (Syed, 2012).

**Table 4.5: Descriptive Statistics on Rational Drug Use** 

Statement	N	Mean	SD
We prescribe drugs from the essential drug list	102	3.84	0.95
Most of prescriptions are appropriate for the diagnosis	102	2.73	1.05
Most of the prescriptions are clear and legible	102	3.65	1.06
The drugs dispensed are well packed and labelled with clear instructions	102	3.43	0.88
The patients are given drug information and counselled during	102	3.70	1.07
dispensing  There is follow up program in place to track patients and	102	2.92	0.97
follow up  We are updated on new trends in treatment through workshops and continuous medical education	102	3.52	1.02
Patient complaints and adverse drug reactions are reported and appropriate remedy actions taken	102	3.63	0.86
Relevant investigations are carried out prior to making a diagnosis	102	3.68	0.86

# 4.4 Influence of Staff Awareness on Guidelines

Table 4.6 shows the outcome of responses given by the respondents about various issues of Staff awareness on Rational Drug Use Guidelines and Policies. The respondents were asked questions on three main indicators; Policies, Standard Operating Procedures and Reference materials.

Table 4.6: Descriptive statistics on Staff awareness on guidelines

Statement	N	Mean	SD
I am aware of rational drug use policies that are in place	102	3.28	1.11
The policies are helpful in my work	102	2.16	1.41
Policies are clear, unambiguous and concise	102	3.57	1.32
Standard operating procedures displayed	102	2.94	1.28
Majority of the staff implement the standard operating procedures	102	3.02	1.15
I have a copy of the standard treatment guidelines and essential drug list	102	2.97	1.25
I often use the Standard Treatment Guidelines for reference	102	3.83	1.23
The Standard Treatment Guidelines are helpful source of information	102	3.84	1.15

## 4.4.1 Policies on Rational Drug Use

The respondents were asked various queries/questions related to staff awareness on policy guidelines and the results are as follows: majority of the respondents disagreed that they were aware of the RDU policies in their work place (Mean Score 3.28) and this might be due to lack of displaying policies and awareness of their existence. They also disagreed that the policies were helpful (Mean Score 2.18). From the above results it shows that lack of awareness on policies related to Rational Drug Use is a key problem. The study shows similar results to those done by WHO (2010) that less than 40% of patients are treated according to STGs in the public sector, a figure that drops even lower in private sector settings. The findings of this study are similar to that of a study done that demonstrated among the reasons for irrational drug use include lack of knowledge and skills on policy guidelines (Green, 2012).

### **4.4.2** Standard Operating Procedures

Standard operating procedures serve as a reference for the day to day medical practice, having them displayed is very important. From Table 4.2 respondents in this study disagreed that Standard operating procedures (SOPs) were well displayed at the work station and they

also disagreed that staff were implementing the Standard operating procedures (Mean Score 3.02) and this was in contrast to WHO (2011) which indicated that major SOP areas include receipt and validation of the prescription, understanding and interpreting the prescription, preparing and labeling items for issue, making a final check, recording action taken and issuing medicines to the patient with clear instructions and advice (WHO, 2011).

### **4.4.3** Reference Materials on drugs

Majority of the respondents agreed to using the standard treatment guidelines for reference as presented by the (Mean score 3.83) and they further accounted that guidelines were helpful source of information (Mean Score 3.84) and in this regard, all healthcare facilities should implement them as the yardstick for treatment. They however disagreed that they had copies of the STGs and EDL (Mean Score 2.97) and this was in line with Green (2012) who indicated that STG helps health professionals to use the drugs which are from EDL. Furthermore, based on guideline, patient will receive the optimal treatment with the lowest cost (Green, 2012).

### 4.5 Influence of Management related practices on Rational Drug Use

Management practices play a role in Rational Drug Use through offering leadership and direction. The researcher studied three indicators; support supervision, training and drugs and therapeutics committee. Table 4.7 presents the results on Management practices.

**Table 4:7: Descriptive statistics on Management related practices** 

Statement	N	Mean	SD
I have a supervisor whom I report to in the course of my work	102	3.52	1.16
The supervisor is always available for consultation	102	3.51	1.19
The supervisor often gives valuable feedback	102	3.04	1.23
Majority of the staff feel that the supervision is adequate and builds capacity	102	2.93	1.08
I have attended training(s) and or workshop(s) on Rational Drug Use	102	3.01	1.08
The training was informative and educative	102	2.44	1.05
New staff are taken through an induction training on rational drug use as part of orientation process	102	2.75	1.30
We have an active drug and therapeutics committee	102	2.68	1.26
I have participated in drug and therapeutic committee Meetings	102	2.86	1.16
The drug and therapeutics committee has developed a hospital formulary which is reviewed periodically	102	2.87	1.02

# 4.5.1 Support Supervision

The study sought to examine the management practices as a means of identifying the best practices and areas that need improvement. The respondents agreed with the statements that; they had a supervisor whom they reported to in the course of their work (Mean Score 3.52) and that the supervisor was available for consultation (Mean Score 3.50). However they disagreed that supervision was adequate and built capacity (Mean Score 2.93) and thus more supervisors are needed to oversee healthcare provision and any guidance that should be needed as motivated staffs are more likely to deliver a higher quality of healthcare service (MSH, 2010)

# 4.5.2 Training on rational drug use

Training is essential to gain new knowledge and improve on skills requisite to carry out relevant task in the field of medicine. The respondents disagreed that they had attended trainings on Rational Drug Use (Mean Score 3.01) and in this regard, more training that are mandatory should be implemented. They also disagreed that new staff were taken through

induction training on RDU as part of the orientation process (Mean Score 2.75) and induction training should also be implemented as part of the orientation and induction process of new and existing employees. The study agreed with a similar study that majority of inventory management staff did not have adequate training on supply chain management (Shadrack, 2015).

### 4.5.3 Drug and therapeutics committees

The respondents disagreed that they had an active Drugs and Therapeutics Committee (Mean Score 2.67). They also disagreed to have participated in Drugs and Therapeutics Committee meetings (Mean Score 2.86). They disagreed that the drug and therapeutics committee had developed a hospital formulary which is reviewed periodically (Mean Score 2.87). The results concur with similar study that less than half of all countries have medicine information centre for prescribers or drug (medicine) and therapeutics committees in most of their hospitals or regions and this was corroborated by the WHO (2003) and MOH [2013] which indicated that committees may not be as active as they are required to be. It may be worthwhile for these committees to actively undertake their various roles which include guiding and monitoring drug use in the hospital by way of conducting prescription audits, monitoring adverse drug reactions, monitoring drug dispensing practices, formulating antibiotic policy with the active participation of the clinician as well as the laboratory and effecting course corrections whenever required.

### 4.6 Product / Drug selection

Product selection is important to ensure availability of essential drugs because it is not possible to stock all the drugs due to financial constraints. The products selected must be of good quality. All the stakeholders must be consulted in product selection and this is the mandate of the Drugs and Therapeutics Committee. The respondents were asked questions on

three main indicators: Selection, Quantification and Procurement. The results are presented in

Table 4.8

**Table 4:8: Descriptive statistics on Product selection** 

Statement	N	Mean	SD
I have participated in medicines/product selection in Consultation with other stakeholders	102	3.96	1.01
Quality of products is considered in when carrying out product selection	102	3.73	1.19
The products selected are from the essential drug list	102	3.69	1.03
I am engaged in the quantification of drugs to enable planning and budgeting	102	3.98	1.03
We use consumption data to forecast drugs to procure	102	3.59	1.13
Past performance, quality and ability to meet delivery schedules are factors we consider prior to procuring	102	3.91	1.06
The procurement period from one to the next is well defined such that we do not experience stock outs	102	2.93	0.98
We have a procurement committee to carry out prequalification of suppliers	102	3.09	0.97

### 4.6.1 Selection of Essential drugs

The respondents agreed to have participated in medicines/product selection in consultation with other stakeholders (Mean Score 3.96). They also agreed that products selected were from the Essential Drug List (Mean Score 3.69) and this was important as it is necessary for the drugs to be stocked from the Essential drugs list. Similar studies have shown that in Kenya in 2008, drugs accounted for 14% of the health budget and one of the areas targeted was to improve essential drug supply particularly in selection and quantification (MOH, 2017).

### 4.6.2 Quantification of drugs

The respondents according to Table 4.4 agreed that consumption data is used to forecast drugs to procure (Mean Score 3.59) and MoH 643 tool should be used in quantification and

procurement of drugs in relation to consumption data. They also agreed that they were actively engaged in the quantification of drugs to enable planning and budgeting (Mean Score 3.98). Similar studies have shown that there is need to improve essential drug supply particularly in selection and quantification (MSH, 2010).

## 4.6.3 Procurement of drugs

The respondents agreed that past performance, quality and ability to meet delivery schedules were factors to consider prior to procuring supplies (Mean Score 3.91). They disagreed that there was a procurement committee to carry out prequalification of suppliers (Mean Score 3.08). They also disagreed that the procurement period was well defined and there were no stock outs (Mean Score 2.93). This study agrees with a similar study done in Meru County whereby there were delays in receiving supplies and stock outs of essential drugs in public hospitals was a common occurrence (Shadrack, 2015). The findings of the study also agree with a similar study by Wangu (2014) that showed shortage of essential drugs is a major challenge in public hospitals in Nakuru County.

### 4.7 Inventory Management of drugs

Availability of essential medicines is commonly cited as the most important element of quality by health care consumers, and the absence of medicines is a key factor in the underuse of government health services. Improving pharmaceutical supply management is one of the elements among many health sector reform efforts. Promising improvements in pharmaceutical supply systems have been made in some countries. However, many continue to struggle with a mix of inefficient public and private health sector supply systems. Decentralization of health sectors has in some cases intensified the problem, establishing logistics systems in the absence of trained human resources, infrastructure, and management

systems at the decentralized levels (Aronovich, 2001). Results on Inventory management are presented in the Table 4.9 below.

Table 4:9: Descriptive statistics on Inventory Management

Statement	N	Mean	SD
The drug store is secure and locked to prevent theft and	102	3.98	0.93
Unauthorized access			
We have cold storage for commodities that are required	102	2.80	1.14
There is enough storage space for drugs	102	3.42	1.10
Most staff know the rules of disposing expired and damaged	102	3.97	1.06
drugs			
Staff verify orders received against the orders placed	102	2.93	0.97
We carry out monthly stock counts	102	3.45	0.95
We have stock/bin cards for the control of stocks	102	3.76	0.96
The bin cards are up to date and correctly filled	102	2.89	1.02

# 4.7.1 Storage and Distribution of drugs

The respondents agreed that there was enough storage space for drugs Mean Score (3.42). They also agreed that the stores were secure and locked to prevent theft and unauthorized access (Mean Score 3.98). They however disagreed that the stock control cards were up to date and correctly filled (Mean Score 2.89). There was also a challenge in the storage of cold chain drugs as the respondents disagreed that there was cold storage for commodities (Mean Score 2.80). The results agreed with a similar study done in Meru County that inventory management challenges included inadequate storage space (Shadrack, 2015)

# 4.7.2 Monitoring and Evaluation of drug use

The respondents agreed that they carried out monthly stock counts (Mean Score 3.45). They also disagreed that bin cards were up to date and correctly filled (Mean Score 2.89). This

study concurs with another study by Mungu (2013) that associates shortage of essential drugs in public health facilities in Bungoma County with poor inventory management practices.

### 4.8 Bivariaite Linear correlation analysis: All variables

This analysis is set to determine whether each of the independent variables in the study that is, staff awareness  $(X_1)$ , Management practices  $(X_2)$ , Product selection  $(X_3)$  and Inventory management  $(X_4)$  influences Rational Drug Use (Y). The results for each variable in this study are given by the Spearman's Rho (r) and its corresponding *p-value*. If the *p-value* is less than 0.05, then the relationship/influence is statistically significant.

**Table 4:10: Bivariate Linear Correlation: All Variables** 

		RDU	staff awareness	management practices	Product Selection	Inventory Mgt
RDU	Pearson			1		U
	Correlation					
	Sig. (2-					
	tailed)	ate.				
staff awareness	Pearson	.232*				
	Correlation					
	Sig. (2-	.019				
	tailed)					
Management	Pearson	.136	.045			
practices	Correlation					
	Sig. (2-	.173	.654			
	tailed)			str.		
Product	Pearson	.134	.014	.236*		
Selection	Correlation					
	Sig. (2-	.179	.893	.017		
	tailed)					
Inventory Mgt	Pearson	<b>ታ</b> ታ	.092	.145	.067	
	Correlation	.324**				
	Sig. (2-	.001	.359	.147	.505	
* Camalatian is	tailed)					

<sup>\*.</sup> Correlation is significant at the 0.05 level (2-tailed).

Table 4.10 presents the results of the Pearson's product moment correlation analysis show varied degrees of interrelationships. The results suggested that staff awareness and inventory

<sup>\*\*.</sup> Correlation is significant at the 0.01 level (2-tailed).

management influence rational drug use. Staff awareness (X1) was statistically significantly correlated with rational drug use (r=.232, p=0.019). This implies that any improvement in staff awareness results in improvement of rational drug use. The null hypothesis that there was no influence of staff awareness on rational drug use was rejected. Results showed there was a statistically significant relationship between staff awareness and rational use of drugs.

Similarly, inventory management factors (X4), are statistically significantly correlated with rational drug use (r=.324\*\*, p=0.01). This means that adherence to inventory management requirements enhances rational drug use. The null hypothesis that there was no influence of inventory management on rational drug use was rejected. Results showed there was a statistically significant relationship between inventory management and product selection on rational use of drugs by doctors and pharmacists in Meru County was not rejected.

#### 4.9 Inferential Statistical Analysis

This model sought to establish the influence of four independent variables in a combined relationship (staff awareness, management practices, product selection and inventory management on the rational drug use among doctors and pharmacists in public hospitals in Meru County. The linear model based on the output is as follows;

$$Y = \beta_0 + \beta_i X_1 + \beta_{ii} X_2 + \beta_{iii} X_3 + \beta_{iv} X_4 + \varepsilon$$

Where: Y = Rational drug use,  $\beta_0 = intercept$  (constant),  $\beta_1$ ,  $\beta_2$ ,  $\beta_3 = slope$  coefficients representing the influence of independent variables with the dependent variable  $X_1 = Staff$  awareness,  $X_2 = management$  practices,  $X_3 = Product$  selection,  $X_4 = Inventory$  Management and  $\varepsilon = error$  term, the basis under which the three specific objectives were set.

**Table 4.11: Rational Drug Use: ANOVA** 

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	253.857	4	63.464	4.684	.002 <sup>b</sup>
	Residual	1314.143	97	13.548		
	Total	1568.000	101			

a. Dependent Variable: Y

A multiple regression analysis was performed on the four principal factors (Staff awareness, Management practices, Product selection and Inventory management) to test their combined influence on rational drug use among doctors and Pharmacists working in Public Hospitals in Meru County. The regression output was varied as indicated in Table 4.11 (F <sub>(4,97)</sub>=4.68, p=0.002) shows that there is correlation between the predictors variables (Staff awareness, management practices, product selection and inventory management) and the dependent variable Rational drug use.

**Table 4.12: Rational Drug Use Model Summary** 

				Std. Error of the
Model	R	R Square	Adjusted R Square	Estimate
1	$.402^{a}$	.162	.127	3.68074
a. Predictors	: (Constant), X	$X_1, X_2, X_3, X_4$		

The results of the regression analysis in Table 4.12 above indicates significant influences of the factors that affect rational drug use as presented in the model summary, within the variables, coefficient of determination (R) of 0.402 was obtained compared to overall R<sup>2</sup> of 0.162 and this explains that 40.2% of total variations that explained factors that influence rational drug use among the healthcare workers in Meru County. The standard error of estimate (3.68074) shows the average deviation of the independent variables from the line of best fit.

b. Predictors: (Constant), X<sub>1</sub> X<sub>2</sub>, X<sub>3</sub>, X<sub>4</sub>

**Table 4.13: Rational Drug Use: Regression Coefficients** 

		Unstand Coeffi		Standardized Coefficients		
Model		В	Std. Error	Beta	t	Sig.
1	(Constant)	8.524	3.994		2.134	.035
	Staff awareness	.144	.067	.201	2.151	.034
	Management practices	.056	.086	.062	.644	.521
	Product selection	.109	.107	.097	1.019	.311
	Inventory Management	.358	.117	.290	3.072	.003

a. Dependent Variable: RDU

The Multiple Linear Regression model used to present the relationship between factors influencing rational drug use among doctors and pharmacists in Meru County was:

$$Y = \beta_0 + \beta_i X_1 + \beta_{ii} X_2 + \beta_{iii} X_3 + \beta_{iv} X_4 + \varepsilon$$

Where Y stands for Rational drug use

 $X_1$ = Staff awareness

X<sub>2</sub>=Management practices

 $X_3$ = Product selection

X<sub>4</sub>= Inventory management

 $\varepsilon$  = Stochastic disturbance error term

Substituting the beta coefficients in the equation  $Y = \beta_0 + \beta_i X_1 + \beta_{ii} X_2 + \beta_{iii} X_3 + \beta_{iv} X_4 + \epsilon$ We get:-

$$RDU = 8.5 + 0.144X_1 + 0.056X_2 + 0.109X_3 + 0.358X_4$$

From the equation, holding other factors constant, rational drug use is 8.5. A unit change in Staff awareness leads to an increase in RDU index by .144 compared to .056 index increase for a unit change in Management practices and a unit change in Product selection led to an increase in RDU index by .109 while unit change in Inventory management led to an increase in RDU index by .358 which is statistically significant.

In summary, it therefore follows that, this study found statistical and significant evidence that the coefficient of Staff awareness on policies (P=0.034) and the coefficient of inventory management (P=0.003) in a combined relationship, positively and significantly influence rational drug use among doctors and pharmacists in public hospitals in Meru County since their P value is less than 0.05, while on the other hand management practices (P=0.521) and product selection (P=0.311) are not statistically significant because their P value is greater than 0.05.

#### **CHAPTER FIVE**

# SUMMARY OF FINDINGS, CONCLUSION AND RECOMMENDATIONS

#### 5.1 Introduction

This chapter presents summary of the study findings in relation to the specific objectives in chapter one. Conclusions and recommendations are also drawn for action.

# 5.2 Summary and Discussion

Majority of the respondents were more than 30 years and most were male. Majority 83(81.4%) had bachelor's degree compared to 19(18.6%) with master's degree. The study established that most of the respondents had experience of more than one year and those with less than one year were a third of the respondents. Most of the respondents were medical officers 69(67.7%) and the rest were pharmacists 33(32.3%). The study also probed the duration in which the respondents were prescribing drugs and number of patients served daily and it was determined those who prescribed for more than one year and slightly less than half served between 50-100 patients daily while a quarter served less than 50 patients on daily basis.

#### **5.2.1 Staff Awareness**

Majority disagreed that they were aware of the RDU policies in their workplace (Mean Score 3.28). Most disagreed that policies helped them at workplace (Mean Score 2.16). They also disagreed that Standard operating procedures were well displayed at work station (Mean Score 2.94) and staff were not involved in the SOPs implementation (Mean Score 3.02). The respondents agreed to use the guidelines for references (Mean Score 3.83) and they further accounted that guidelines are helpful source of information (Mean Score 3.84). In general, the interpretation follows that there is need to communicate the RDU policies through the Drugs

and Therapeutic committees and also ensure that SOPs are available and involve the stakeholders in their implementation.

# **5.2.2 Management Practices**

The respondents agreed with the statement that they had a supervisor whom they reported to in the course of their work (Mean Score 3.52) and further these supervisors were available for consultation (Mean Score 3.51). They disagreed that supervisors often gave valuable feedback (Mean Score 3.04). They also disagreed that supervision was adequate and built capacity (Mean Score 2.93) and that they had attended trainings and or workshops on Rational drug use (Mean Score 3.02). Due to lack of attendance to training/workshops, they further disagreed that trainings were educative and informative (Mean Score 2.44). The respondents further disagreed that there was an active Drug and therapeutics committee (Mean Score 2.68). In addition they disagreed to the statement that Drug and therapeutics committee had developed a hospital formulary which was reviewed periodically (Mean Score 2.87). There are significant gaps seen in relation to management practices in place. While supervision is there, it is not adequate and doctors and pharmacists felt that it did not build capacity. There were challenges related to training on RDU. It was not available and this hinders the implementation of rational drug use. In addition, Drug and therapeutic committees were not in place. This therefore means that there is no framework agreed upon on medicines use that guides selection, use and therapeutic outcomes. This definitely compromises quality assurance on medicines use and thus impedes rational drug use.

### **5.2.3 Product Selection**

The respondents agreed that they participated in medicines/product selection in consultation with other stakeholders/departments (Mean Score 3.96) and Quality of products was

considered when carrying out product selection (Mean Scorer 3.73). Further, they agreed that products were selected from the Essential Drug List (Mean Score 3.67)

The respondents agreed to having used consumption data to forecast drugs to procure and past performance, quality and ability to meet delivery schedules were factors considered prior to procuring (Mean Score 3.91). They disagreed that procurement period from one to the next was well defined such that they did not experience stock outs (Mean Score 2.93) and that there was a procurement committee to carry out prequalification and procurement in the hospitals (Mean Score 3.09). It is important to have a procurement cycle/calendar to ensure that there are no stock outs of essential drugs and thus a non interrupted supply of commodities in the facilities. Also, a procurement committee which is lacking is important so that it can implement recommendation of the DTC through procuring as per their guidelines.

#### **5.2.4 Inventory management**

The respondents agreed that the drug stores were secure and locked to prevent theft and unauthorized access (Mean Score 3.98) and the various facilities had enough room/space for storage of drugs (Mean Score 3.43). They further agreed that most staff knew the rules of disposing expired and damaged drugs (Mean Score 3.97). The respondents disagreed that there were cold storage for commodities that are required (Mean Score 2.80) and they also disagreed to the statement that bin cards were up to date and correctly filled (Mean Score 2.89). It is therefore incumbent upon the facility in charges to ensure that staffs are well trained on inventory management to ensure that commodities are well stored, to check the supplies for quality and that bin cards are updated. This will ensure that there are no losses through pilferage and enhance accountability.

# **5.2.5** Rational drug Use

The respondents agreed that they prescribed drugs from the Essential Drug List (Mean Score 3.84) and most of the prescriptions are clear and legible though (Mean Score 3.65). They however disagreed that most of the prescriptions were appropriate for the diagnosis (Mean Score 2.73). It was established that drugs dispensed were well packed and labeled with clear instructions (Mean Score 3.43) and the patients are given drug information and counseled (Mean Score 3.69.). The respondents disagreed that was a follow up program in place to track patients and follow up (Mean Score 2.92). It was established that there were relevant investigations are carried out prior to making a diagnosis (Mean Score 3.68)

Correlations between the dependent variable Rational drug use and independent variables: Staff awareness, inventory management, product selection and management practices.. There was a significant relationship between RDU and staff awareness (r=.232, p<0.05) and inventory management (significant at the 0.01 level) (r=.324, p<0.05).Coefficient of determination (R) of 0.402 was obtained compared to overall R<sup>2</sup> of 0.162 and this explains 40.2% of total variations that explained factors that influence rational drug use among the healthcare workers in Meru County. The ANOVA findings (F (4,97)=4.68, p<0.05) shows that there is correlation between the predictors variables (Staff awareness, Management practices, Products selection and Inventory Management) and the dependent variable Rational drug use

$$RDU = 8.5 + 0.144X_1 + 0.056X_2 + 0.109X_3 + 0.358IX_4$$

The rational drug use is 8.5. A unity change in Staff awareness leads to an increase in RDU by 0.144 times compared to 0.056 times increase for a unit change in Management practices and a unity change in Product selection led to an increase in RDU by 0.109 times while unity change in Inventory management led to an increase in RDU by 0.358.

#### **5.3 Conclusion**

- i. Gaps were identified among the respondents that they were not aware of the Rational drug use policies in place and that Standard operating procedures were not available or displayed at the respective work stations. However, Standard treatment guidelines were available and they further accounted that guidelines were helpful source of information.
- ii. Regarding the input of Management, supervision was well done as supervisors were available for consultation. However, the respondents cited that supervision was not adequate and it did not build enough capacity.
- iii. The respondents agreed that they participated in product selection and that products were selected from the Essential Drug List. It was also noted that the procurement cycle was not well defined and as such there were frequent stock outs of Essential Drugs and this hampered delivery of quality services.
- iv. There were specific challenges relating to Inventory management. There was lack of enough physical storage space for commodities and also lack of adequate cold chain storage facilities. Also, record keeping was wanting since most of the stock control cards were not correctly filled and therefore not up to date.

# **5.4 Recommendations**

The study recommends that:

The hospitals develop training manuals on rational drug use and organize workshops
that will be used to create awareness on importance of rational drug use among
doctors and pharmacists to enhance knowledge and build capacity.

- ii. Departmental heads to offer supportive supervision on a regular basis, quarterly review, assessment and appraisals and offer feedback on areas of Rational Drug use that require improvement.
- iii. While it is a policy to have a Drugs and Therapeutics Committees, most facilities do not have one. The hospital management team should constitute and make operational drugs and therapeutics committee in all the facilities to ensure that hospital formularies are developed from the Essential Drugs List and implementation of the SOPs to enhance uniformity and build capacity.
- iv. The hospitals to constitute procurement committee with all stakeholders including the doctors and pharmacists to ensure they are involved in the budgeting, selection, ordering and monitoring the use of Essential drugs.

# 5.5 Suggested areas for further research

- Carry out a study on factors that influence rational drug use among patients in public hospitals.
- ii. A study on the impact of irrational drug use and its financial implications on the healthcare system

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#### **APPENDICES**

# **Appendix 1: Consent form.**

Kenya Methodist University P. 0 Box 267-60200 Meru, Kenya.

# **Subject: Informed Consent**

Dear Respondent,

My name is Dennis. M. Wahome. I am a Msc.HSM student from Kenya Methodist University. I am conducting a study titled: Factors influencing Rational Drug Use among Healthcare Workers in Meru County. The findings will be utilized to strengthen the health systems in Kenya and other Low-in- come countries in Africa. As a result, countries, communities and individuals will benefit from improved quality of healthcare services. This research proposal is critical to strengthening health systems as it will generate new knowledge in this area that will inform decision makers to make decisions that are research based.

#### Procedure to be followed

Participation in this study will require that I ask you some questions and also access all the hospital's department to address the six pillars of the health system. I will record the information from you in a questionnaire check list.

You have the right to refuse participation in this study. You will not be penalized nor victimized for not joining the study and your decision will not be used against you nor affect you at your place of employment.

Please remember that participation in the study is voluntary. You may ask questions related to the study at any time. You may refuse to respond to any questions and you may stop an interview at any time. You may also stop being in the study at any time without any consequences to the services you are rendering.

# Discomforts and risks.

Some of the questions you will be asked are on intimate subject and may be embarrassing or make you uncomfortable. If this happens; you may refuse to answer if you choose. You may also stop the interview at any time. The interview may take about 40 minutes to complete.

# Benefits

If you participate in this study you will help us to strengthen the health systems in Kenya and other Low-in- come countries in Africa. As a result, countries, communities and individuals will benefit from improved quality of healthcare services. This field attachment is critical to strengthening the health systems as it will generate new knowledge in this area that will inform decision makers to make decisions that are research based.

#### Rewards

There is no reward for anyone who chooses to participate in the study.

# **Confidentiality**

The interviews will be conducted in a private setting within the hospital. Your name will not be recorded on the questionnaire and the questionnaires will be kept in a safe place at the University.

#### **Contact Information**

If you have any questions you may contact the following supervisors:

- 1. Ms. Eunice Muthoni Mwangi: Department of Health Systems Management, Kenya Methodist University: <a href="mailto:eunicelucki@yahoo.co.uk">eunicelucki@yahoo.co.uk</a> Tel: 0722986349
- 2. Mr. Titus Mutwiri: Department of Health Systems Management, Kenya Methodist University: <a href="mailto:titus.mutwiri@kemu.ac.ke">titus.mutwiri@kemu.ac.ke</a> Tel: 0722653089

# **Participant's Statement**

The above statement regarding my participation in the study is clear to me. I have been given a chance to ask questions and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary. I understand that my records will be kept private and that I can leave the study at any time. I understand that I will not be victimized at my place of work whether I decide to leave the study or not and my decision will not affect the way I am treated at my work place.

private and that I can leave the study at any time. I understand that I will not be victimized my place of work whether I decide to leave the study or not and my decision will not affect the way I am treated at my work place.	
Name of Participant	
Signature	
Investigator's Statement	
I, the undersigned, have explained to the volunteer in a language s/he understands procedures to be followed in the study and the risks and the benefits involved.	
Name of Interviewer	•
Interviewer Signature	

# **Appendix II: Rational Drug Use Questionnaire**

More than 10 years

7. How many patients do you serve in a day? Less than 50 patients

Between 50-100 patients

Between 101-200 patients

More than 200 patients

#### **SECTION A: Demographics** Please tick ( $\checkmark$ ) where appropriate 1. What is your age group? Below 30 years 31-40 years ) 41-50 years ) 51-60 Years 60 and above 2. Please indicate your gender Male ) Female ( ) 3. What is your highest academic qualification? Certificate Diploma ( ) Bachelor's degree ( ) Master's degree ) **PHD** ) 4. How long have you been working at this facility? Less than 5 years ( ) ( ) 5-10 years 10-15 years ( ) More than 15 years 5. What is your job title? **Doctors (Medical Officer)** Pharmacist 6. How long have you been prescribing and or dispensing drugs? Less than 1 year ( ) Between 1-5 years ( ) Between 6-10 years ( )

( )

( )

( )

)

# **SECTION B: STUDY VARIABLES**

**INSTRUCTIONS:** On the scale provided below, please indicate the level to which you agree with the description on that factor that influence rational drug use by doctors and pharmacists in Meru County. Tick  $(\checkmark)$  where appropriate

Key: SD= Strongly Disagree, D=Disagree NS =Not Sure A=Agree SA=Strongly Agree

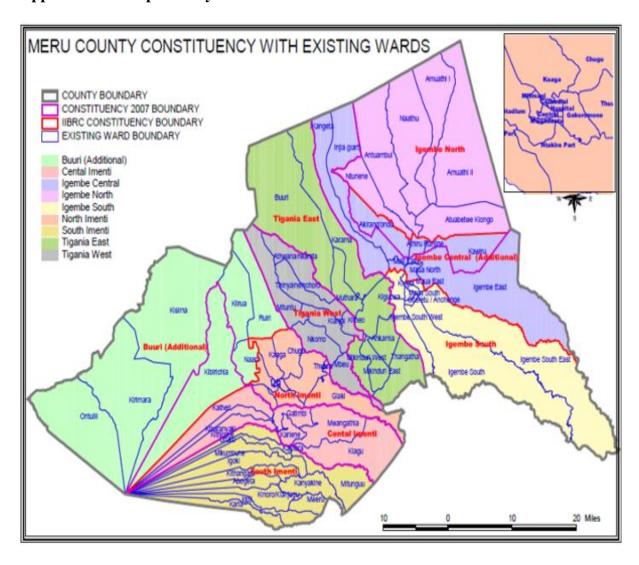
Statement Statement		SD	D	NS	A	SA
<b>a</b> )	Staff awareness on policies					
i.	I am aware of Rational Drug Use policies that are in place					
ii.	The policies are helpful in my work					
iii.	The policies are clear, unambiguous and concise					
iv.	Standard operating procedures are well displayed at work station					
v.	Majority of the staff implement the Standard operating procedures					
vi.	I have a copy of the Standard treatment guidelines and Essential Drugs List					
vii.	I often use the guidelines for reference					
viii.	The guidelines are helpful source of information					
	Management Practices					
i.	I have a supervisor whom I report to in the course of my work					
ii.	The supervisor is always available for consultation					
iii.	The supervisor often gives valuable feedback					
iv.	Majority of the staff feel that the supervision is adequate and builds capacity					
v.	I have attended training(s) and or workshop(s) on Rational drug use					
vi.	The training was educative and informative					
vii.	New staff are taken through an induction training on rational drug use as part of orientation process					
viii.	We have an active Drug and Therapeutics committee					
ix.	I have participated in Drug and Therapeutic committee meetings					
х.	The Drug and therapeutics committee has developed a hospital formulary which is reviewed periodically					
c)	Product selection					
i.	I have participated in medicines/product selection in consultation with other stakeholders/departments					
ii.	Quality of products is considered in when carrying out					
			1		1	1

Statement		SD	D	NS	A	SA
	product selection					
iii.	The products selected are from the Essential Drug List					
iv.	I am engaged in the quantification of drugs to enable planning and budgeting					
v.	We use consumption data to forecast drugs to procure					
vi.	Past performance, quality and ability to meet delivery schedules are factors we consider prior to procuring					
vii.	The procurement period from one to the next is well defined such that we do not experience stock outs					
viii.	We have a procurement committee to carry out prequalification and all procurement in the hospital					
d)	Inventory Management					
	i. The drug store is secure and locked to prevent theft and unauthorized access					
	ii. We have cold storage for commodities that are required					
	iii. There is enough room/space for storage of drugs					
	iv. Most staff know the rules of disposing expired and damaged drugs					
	v. Staff verify orders received against the orders placed					
	vi. We carry out monthly stock counts					
	vii. We have stock/bin cards for the control of stocks					
	viii. The bin cards are up to date and correctly filled					
e)	Rational Prescribing					
i.	We prescribe drugs from the Essential Drug List					
ii.	Most of the prescriptions are appropriate for the diagnosis					
iii.	Most of the prescriptions are clear and legible					
f)	Rational Dispensing					
i.	The drugs dispensed are well packed and labeled with clear instructions					
ii.	The patients are given drug information and counseled during dispensing					
iii.	There is a follow up program in place to track patients and follow up					
g)	Evidence based medicine					
i.	Relevant investigations are carried out prior to making a diagnosis					
ii.	Patient complaints and adverse drug reactions are reported and appropriate remedy actions taken					

Statement	SD	D	NS	A	SA
iii. We are updated on new trends in treatment through					
workshops and Continuous Medical Education.					

# Thank you for participation

**Appendix III: Map of study location** 





# KENYA METHODIST UNIVERSITY

P. O. BOX 267 MERU - 60200, KENYA TEL: 254-064-30301/31229/30367/31171 FAX: 254-64-30162' EMAIL: info@kemu.ac.ke

2ND MAY 2018

Dennis Mwiti Wahome HSM-3-0880-3/2012

Dear Mwiti,

#### RE: ETHICAL CLEARANCE OF A MASTERS' RESEARCH THESIS

Your request for ethical clearance for your Masters' Research Thesis titled "Factors Influencing Rational Drug Use among Doctors and Pharmacists in Meru County" has been provisionally granted to you in accordance with the content of your project proposal subject to tabling it in the full Board of Scientific and Ethics Review Committee (SERC) for ratification.

As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

- 1. All co-investigators must be kept informed of the status of the project.
- Changes, amendments, and addenda to the protocol or the consent form must be submitted to the SERC for re-review and approval <u>prior</u> to the activation of the changes. The Proposal number assigned to the project should be cited in any correspondence.
- 3. Adverse events should be reported to the SERC. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for SERC review. The SERC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.
- 4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The SERC may conduct audits of all study records, and consent documentation may be part of such audits.

5. SERC regulations require review of an approved study not less than once per 12-month period. Therefore, a continuing review application must be submitted to the SERC in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.

Please note that any substantial changes on the scope of your research will require an approval.

Yours sincerely

Chair, SERC

cc: Director, RI & PGS

#### **COUNTY GOVERNMENT OF MERU**



#### **DEPARTMENT OF HEALTH**

Email: merucountyhealth@gmail.com When replying please quote County Government Headquarters P.O. Box 120-60200 MERU

Ref: CGM/COH/1/2/Vol.2(11)

Tuesday, 19 June 2018

Dr. Dennis M. Wahome Kanyakine Sub-County Hospital

# **RESEARCH PROJECT**

Reference is made to your letter dated 16<sup>th</sup> May 2018 requesting to undertake the study on Factors influencing rational drug use among Doctors and Pharmacists in Meru County.

This is therefore to inform you that the approval has been granted.

Thank you

Dr. Kanana Kimonye Chief Officer of Health



# NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

Telephone:+254-20-2213471, 2241349,3310571,2219420 Fax:+254-20-318245,318249 Email: dg@nacosti.go.ke Website: www.nacosti.go.ke When replying please quote NACOSTI, Upper Kabete Off Waiyaki Way P O Box 30623-00100 NAIROBI-KENYA

#### Ref. No. NACOSTI/P/18/94868/22943

Date: 11th July, 2018

Dr. Dennis Mwiti Wahome Kenya Methodist University P.O. Box 267- 60200 MERU.

# **RE: RESEARCH AUTHORIZATION**

Following your application for authority to carry out research on "Factors influencing rational drug use among doctors and pharmacists in Meru County" I am pleased to inform you that you have been authorized to undertake research in Meru County for the period ending 10<sup>th</sup> July, 2019.

You are advised to report to the County Commissioner, the County Director of Education and the County Director of Health Services, Meru County before embarking on the research project.

Kindly note that, as an applicant who has been licensed under the Science, Technology and Innovation Act, 2013 to conduct research in Kenya, you shall deposit a copy of the final research report to the Commission within one year of completion. The soft copy of the same should be submitted through the Online Research Information System.

DR. STEPHEN K, KIBIRU, PhD. FOR: DIRECTOR-GENERAL/CEO

Copy to:

The County Commissioner Meru County.

The County Director of Education Meru County.