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CORE INDICATORS OF APPROPRIATE DRUG USE AT PUBLIC PRIMARY HEALTHCARE CENTERS IN KISII COUNTY, KENYA

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A Thesis submitted in partial fulfillment of the requirements for the award of the Degree of Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance of the University of Nairobi

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DEDICATION

I wholeheartedly dedicate this work to my wife, Catherine and my supervisors for their inspiration, encouragement, and support during my studies.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND ACRONYMS

ADRs	Adverse Drug Reactions
AEs	Adverse Events
AL	Artemether - Lumefantrine
CHMT	County Health Management Team
CME	Continuous Medical Education
COs	Clinical Officers
DUR	Drug Utilization Review
EML	Essential Medicines List
FBFs	Faith-based Facilities
FDC	Fixed-Dose Combination
HCW	Health – care worker
INN	International Non-proprietary Name
INRUD	International Network for the Rational Use of Drugs
KEML	Kenya Essential Medicines List
KTRH	Kisii Teaching and Referral Hospital
MOs	Medical Officers
OPD	Out-patient Department
ORS	Oral Rehydration Salt
PHFs	Public Health Facilities
PHC	Primary Health Care
PHCC	Primary Health Care Center
PPHCC	Public Primary Health Care Center
RFV	Reason for Visit
RUD	Rational Use of Drug
SD	Standard Deviation
STG	Standard Treatment Guideline
UHC	Universal Health Coverage
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Antibiotics: Are substances derived from some micro-organisms such as bacteria and fungi that can destroy or inhibit the growth of other micro-organisms. In this study, the term antibiotic will be used as a synonym for drugs used to treat bacterial infections in both human beings and animals.

Dispenser: A pharmacy staff allowed to process the medical prescriptions, i.e., a pharmacist or a pharmaceutical technologist.

Essential Medicines List (EML): It is a compilation of essential drugs that satisfies the priority healthcare needs of populations. They are selected with due regard to the public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

Encounter or patient encounter: Refers to the interaction between a prescriber and a patient that results in the issuance of a prescription.

Fixed-dose combinations (FDCs): More than one drug in a single dosage formulation, either a capsule or tablet, packaged, prescribed and dispensed together for a given health problem or a fixed-dose combination of drugs. For example, the triple therapy for *H.pylori* infection. In this study, such a combination will be considered as one drug.

Generic name: This is the chemical name of a drug rather than its advertised brand name. Also referred to as the international non-proprietary name (INN) of a drug.

Irrational prescribing: Refers to prescribing drugs in a manner that does not conform to the standards of evidence-based healthcare in the treatment of an illness. It includes polypharmacy, use of proprietary brand or trade names of drugs while prescribing, over-prescription of antibiotics and injections as well as prescribing expensive drugs when cheaper equally effective alternatives are available.

Polypharmacy: Prescribing above 1.6-1.8 number of drugs for an out-patient during an encounter in a primary health center.

Prescriber: Anyone in the medical profession allowed to prescribe drugs i.e., a medical officer, a clinical officer or a nurse.

Prescription: A written order from a prescriber to a dispenser for the preparation and dispensing of a drug to a patient.

ABSTRACT

Background: Rational drug use requires that patients receive medications appropriate to their clinical needs, in doses that meet their requirements, for an adequate period, and at the lowest cost to them and their community. It is a complex matter which involves the; patient, prescriber, dispenser, and healthcare facilities. Budgets on drugs usually account for about 25-50% of the total health expenditure in most of the developing countries. Irrational drug use is a global problem; however, the extent of the matter is much higher in low-income countries like Kenya. Drug information gap, weak drug regulation measures, the heavy workload on the healthcare service providers and patient beliefs and preferences contribute to the irrational use of drugs. Since the inception of devolution in 2010, it is most likely that the Kisii County Government was wasting its resources on irrational drug use. This study was thus meant to examine the core indicators of appropriate drug use using the World Health Organization/ International Network for Rational Use of Drugs (WHO/INRUD) methodology at the public primary healthcare (PPHCCs) in Kisii County, Kenya

Objective: The general objective of this study was to assess the patterns of drug use and the prevalence of irrational drug use at the public primary healthcare centers (PPHCCs) in Kisii County, Kenya in reference to the WHO/INRUD core drug use indicators methodology.

Methods: The study was a hospital-based cross-sectional survey. Ten PPHCCs were selected by simple random sampling method. From each PPHCC, ninety prescription encounters, generated from 1st October to 31st December 2018, were systematically randomly sampled. Three-hundred (30/PPHCC) conveniently sampled patients and ten (1/PPHCC) dispensers were also observed and interviewed on the survey visit days. Data entry and analysis were conducted using Epi - infor™ version 7.2.2.16 and STATA version 14.2. Descriptive and inferential statistics were used in data analysis. Graphs and tables were used to represent the results.

Results: Prescribing indicators deviated from the WHO/ INRUD optimal values except for encounters with injections prescribed. The findings were; average number of drugs prescribed per patient encounter = 2.9 (SD 0.5), percentage of prescribing drugs by generic names = 27.7% (SD 21.0), percentage of prescriptions with an antibiotic = 84.8% (SD 26.8), percentage of

prescriptions with an injection = 24.9% (SD 20.5) and percentage prescribing from KEML = 96.7% (SD 4.2) Regarding patient-care practices, average consultation time was short of the optimal time but dispensing time was in line with the WHO/ INRUD recommended time. Drug labeling was poor. Patients' knowledge of dispensed drugs was average. The findings were; average consultation time = 4.1 min (SD 1.7), average dispensing time = 131 sec (SD 41.5), percentage of drugs actually dispensed = 76.3% (SD 10.9), percentage of drugs adequately labeled = 22.6% (SD 27.5) and percentage patients' knowledge of dispensed drugs = 54.7% (SD 8.0).The facility-specific indicators deviated from the WHO/ INRUD optimal values especially the availability of copies of KEML where only two facilities had copies. Almost all essential drugs were available at the facilities. The results were; percentage availability of copies of KEML = 20% (SD 42.2) and percentage availability of essential drugs = 80.0% (SD 16.8). The differences among PPHCCs were statistically significant ($p < 0.05$) for all the indicators.

Conclusion: The survey shows a trend toward irrational practices particularly; polypharmacy, non-generic prescribing, overuse of antibiotics, short consultation time, the inadequacy of drug labeling, and unavailability of KEML copies at most of the facilities.

CHAPTER ONE

1.0 INTRODUCTION

1.1. Background

Primary healthcare (PHC) is a very crucial part of any healthcare system in a country. It is responsible for providing basic healthcare services; from prevention to management of health conditions (1). The initial and close point of contact patients have with a healthcare system is a PHC. It provides accessible, community-based and comprehensive care that meets 80 - 90% health needs of patients (2). There are six levels of health facilities hierarchy in the Kenyan health system, namely: Level I (Community Services), Level II (Dispensaries and Clinics), Level III (Health Centers and Nursing and Maternity Homes), Level IV (Sub-county Hospitals), Level V (County Referral Hospitals) and Level VI (National Referral Hospitals and large Private Teaching Hospitals). PHC services are mainly provided at Levels II and III 3 (3).

Drugs are very significant components of any healthcare system. PHC would be a dream without drugs. The irrational use of drugs has led to serious consequences, both in health and economics, as far as the healthcare system is concerned in developing countries (4).

Drugs are "double-edged swords" thus they should be used rationally. Inappropriate use of drugs is an issue of concern with so many undesirable consequences such as the increased incidences of drug resistance, adverse drug reactions, cost of drug therapy, wastage of resources and reduced quality of drug therapy (5). Irrational drug use may take many different forms; poly-pharmacy, inappropriate use of injections and antibiotics, failure in the use of the standard treatment guidelines (STGs) when prescribing and inappropriate self-medication (6).

Improvements in the manner in which drugs are used are very crucial in minimizing the morbidity and mortality associated with irrational drug use (7). The 'Wise List 2015' in Stockholm, Sweden is a good case on how rational drug use can be attained. It includes an Essential Medicine List (EML) with just about 200 drugs on the list. The EML improves the prescribers' familiarity with drugs and helps in reducing drug expenditure in the country (8).

Rational drug use means patients get medications suitable to their medical needs, in the right doses, for a suitable period, at the cheapest cost (9). Drug use is a complex matter. Despite the complexity, indicators have been established, evaluated and standardized by the World Health Organization and the International Network for rational use of drugs (WHO/INRUD) (10). These pointers are usually used in measuring drug use in out-patient facilities. They provide measures of the optimal use of resources in the facilities as well as identify areas of deviations from the expected standards and in planning (11).

These indicators can further be used to define drug use in any given health facility or geographical region. The WHO/ INRUD champions the practice of drug use documentation. This has led to the emergence of the core drug use indicators namely the; prescribing, patient-care and facility-specific indicators (10).

1.2. Problem statement

Drugs play a crucial role in saving lives. That is in the diagnosing, prophylaxis and therapeutic services using the criteria of risk-benefit analysis, cost-effectiveness, easy administration as well as patient acceptance and compliance (12). Drugs should be taken appropriately to improve therapeutic effect while reducing the risk of toxicity and adverse drug reactions (13). Examples of incorrect use of drugs include; poly-pharmacy, irrational use of antibiotics and injections, failure to use standard treatment guidelines (STGs) while prescribing; self-treatment and not adhering to the dosing schedules (9).

Inappropriate drug use is a worldwide problem, more so in developing countries compared to developed countries (14). Roughly 50% of patients do not take their drugs as prescribed. Poor prescribing practices contribute to irrational drug use. Practices such as polypharmacy with excessive use of antibiotics and injections have been reported locally (15).

Irrational use of drugs can result in wastage of the resources, reduced quality of therapy, increased morbidity and mortality, bacterial resistance, adverse drug reactions (ADRs) and widespread health hazards. A survey carried out at the health facilities of Southern Malawi showed that the country wasted its financial resources in the purchase of excessive drugs which ended up being used irrationally and quite a number expiring at the health facilities' stores (16).

Generally, due to the complexity of drug use, it is important that the overall situation is assessed so that problems may be realized and intervention strategies are implemented to keep on the check the unsafe trends in drug utilization before the planned universal health coverage (UHC) rollout to the counties. Different studies done in parts of the world show that there are different drug use patterns (17), and few such surveys have been carried out in Kenya.

Since no study of this kind has ever been conducted in Kisii County since the inception of devolution in 2010 (18), it is was likely that the Kisii County Government could be wasting its resources on irrational drug use. This study was thus meant to examine the core indicators of appropriate drug use using the WHO/INRUD methodology at the public primary healthcare (PPHCCs) in Kisii County, Kenya. This study was needed to inform policy formulation on optimal drug use in the County and the Country at large.

1.3. Research questions

The survey intended to answer the following questions:

i. What is the prevalence of various types of irrational prescribing practices in Kisii County's PPHCCs in reference to the WHO/INRUD prescribing indicator methodology?

ii. What is the status of the patient-care practices and patient knowledge of drugs in Kisii County's PPHCCs based on the WHO/INRUD patient - care indicator methodology?

iii. What is the status of the availability of essential drugs and KEML copies at the public primary healthcare centers?

1.4. Objectives

1.4.1. General objective

To examine the patterns of drug use and the prevalence of irrational drug use at the PPHCCs in Kisii County, Kenya using the WHO/INRUD core drug use indicators methodology.

1.4.2. Specific objectives

The survey aimed to:

i. Assess the prescribing practices in accordance with established prescribing indicators.

ii. Evaluate the key indicators of patient-care practices and patient knowledge on the drugs prescribed and dispensed to them.

iii. Examine the availability of essential drugs and KEML copies at the public primary healthcare centers.

1.5. Study justification

Periodic monitoring and evaluation of drug use is one way of avoiding irrational drug use. The core drug use indicators need to be evaluated from time to time to provide feedback to the prescribers, dispensers and hospital managers. This would ensure proper drug therapy, reduced wastage of resources, reduced treatment costs, reduced morbidity and mortality, and increased patients outcome as well as lowered risks of adverse drug reactions (ADRs) (10). The WHO/INRUD has established core drug use indicators used as a tool for improving the performance of health facilities with regards to the rational use of drugs (13).

This study sought to determine the patterns of the prescribing practices, patient-care and facility-specific indicator status in Kisii County's PPHCCs. The PHCCs offer health services at the community level before transferring them, if needed, to a more advanced hospital-based care like the referral hospitals. The PHCCs play a vital role in providing comprehensive health care to populations within their locality (19). From the literature review, no survey on drug use patterns had ever been conducted in Kisii County's PHCCs. It was, therefore, an appropriate site for the study (20).

The findings of the current study were intended to enable identify any gaps in the drug use process and recommend the best practices that can be put in place to address them. Identification of risk factors for inappropriate prescribing, inappropriate patient-care practices and facility-specific gaps would help in addressing the root cause of the problem.

The research findings were to be disseminated to the managers of the PHCCs, the County Pharmacist, Director of Health and the Chief Officer of Health for further action. The findings were also published at Hindawi's advances in pharmacological and pharmaceutical sciences journal.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1. Drug utilization research and review

The growth of the twin concepts (therapeutic formularies and essential medicines list (EML)) is one of the chief reasons for drug utilization studies. Drug utilization encompasses the marketing, supply, distribution, and consumption of medicines in a given community. It focuses on the consequential medical, economic and social outcomes. Research on drug utilization promotes the rational use of drugs in human populations. It is also useful for educational, clinical and economic purposes (21).

Drug utilization review (DUR) is a structured on-going review of the prescribing, dispensing and consumption of drugs. It involves a thorough evaluation of patients' medical records before, during and after dispensing, hence ensuring proper treatment decision-making process and desired patient outcomes. DUR activities provide corrective action, prescriber feedback, and further evaluations as a quality assurance measure (22).

Drug utilization research can be grouped into two parts; descriptive and analytical research. Descriptive studies establish drug utilization patterns and enable in identifying challenges that require more comprehensive studies. Analytical studies assess the rationality of drug therapy by correlating drug utilization data to morbidity data, treatment outcomes data and quality of care (22).

Determinants of drug use include patient characteristics (such as sociodemographic traits and knowledge on drugs), prescriber characteristics (specialization, level of education and years of experience) and drug characteristics (cost and drug interactions). Outcomes of drug use include beneficial effects as well as adverse effects (21). Drug utilization reviews can be used as early indicators of inappropriate drug use.

Drug utilization studies can be performed using the anatomical therapeutic chemical/ defined daily dose (ATC/DDD) system. These kinds of studies need to be encouraged at the health facilities and

carried out on an ongoing basis. DUR is significant for the rational use of drugs. Its relevance to policymaking and resource allocation should be emphasized (23).

2.2. Stages of drug use process

Drug use a complex process that entails almost twenty steps thus, twenty opportunities of making a medication error. The multistage process in which a drug moves from the pharmacy to the patient comprises; prescribing, transcribing and documenting, dispensing, administering, and monitoring (24). These stages are described in Figure 2.1.

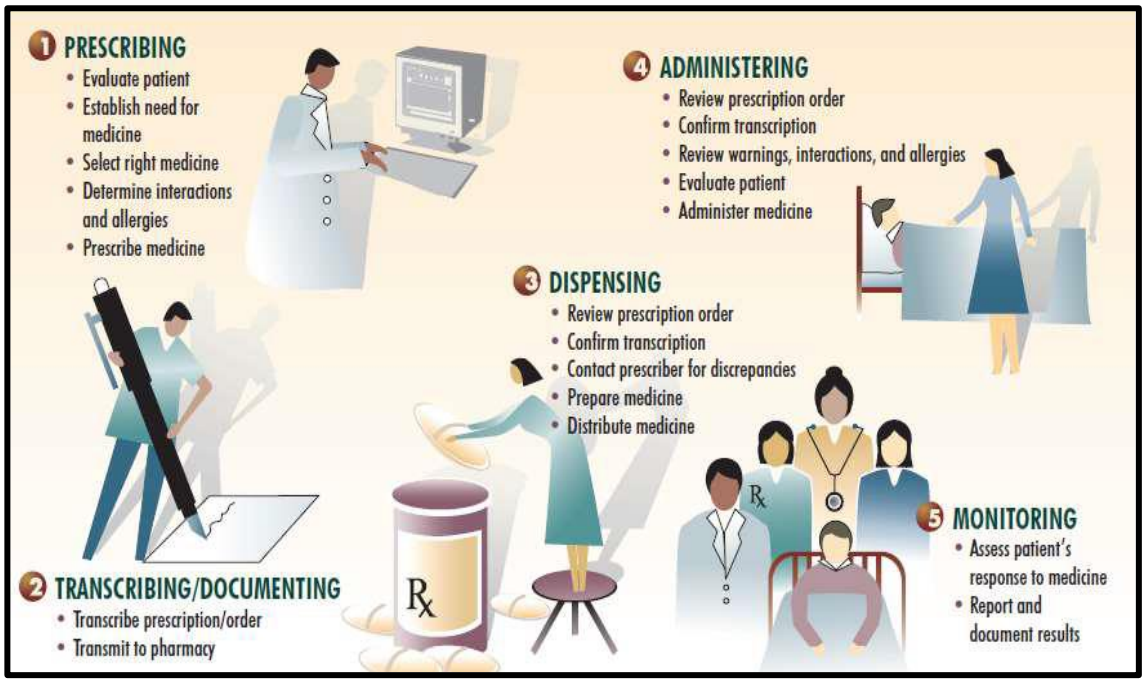

Figure 2. 1 Drug use process (27)

2.3. Impact of irrational drug use

Globally, the unreasonable use of drugs is a major issue of concern that faces most healthcare systems, particularly in developing countries. It can lead to increased; incidences of ADRs, morbidity, mortality, resistance to antibiotics, cost of therapy and drug stock-outs (25).

A study done at Kapiri Mposhi District Hospital, Zambia, found that of the 682 patient records reviewed, more than half showed some form of irrational use of drugs. Excessive prescribing and dispensing of antibiotics and polypharmacy were of great concern. Antibiotics were prescribed 65% of the time and patients had a 52% chance of being prescribed more than two medicines (26).

WHO/INRUD recommends antibiotics prescribing not be more than 30% of the drugs prescribed while the average number of drugs per prescription should not exceed 2 at any single health facility. The average number of prescribed drugs per encounter (2.5 drugs) was above the optimal value (26).

The issue of irrational drug use is poorer in developing countries that have poor and weak healthcare systems, where routine monitoring of drug use is usually not well established or is at times non-existent (27).

The WHO estimates that the rational use of drugs can result in about 50–70% cost reduction in drug expenditure (28). The likely outcomes of irrational drug use are summarized in Figure 2.2.

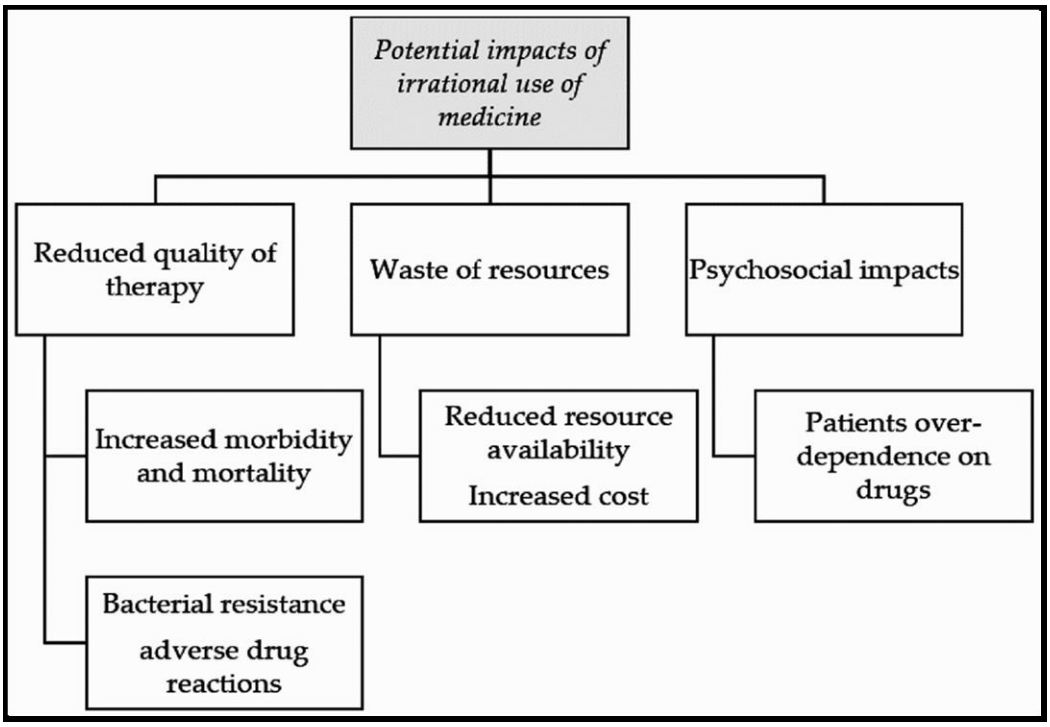

Figure 2. 2 Consequences of irrational use of drugs (30)

2.4. Methods of addressing irrational drug use

Promoting rational drug use requires efficient policies, healthcare professionals, patients and the entire community collaboration. A good understanding of the relevant aspects of drug use by all stakeholders is crucial in driving collaborative efforts towards addressing the irrational drug use (24). Managing irrational drug use improves healthcare delivery in ensuring patient safety and

optimal use of resources. Regular monitoring of the prescribing, dispensing and patient drug use is important in addressing irrational drug use (11).

Rational drug use should occur in all settings of healthcare, right from hospitals to the patients' homes. It involves prescribing when there is a need to, and ineffective drugs are not prescribed or dispensed (29). Drugs should be dispensed to the patient safely and hygienically, making sure that patients understand the dosage and course of therapy well; then the patient takes the drug(s) as required. Adherence occurs if the patients comprehend and appreciate the worth of using a particular drug for a specific indication (24).

2.5. Factors that contribute to irrational drug use

Many different factors can promote inappropriate drug use. The main factors can be classified as those originating from the patients, prescribers, workplace, drug supply system including industry influences, regulation, drug information and misinformation, and combinations of these factors as shown in Table 2.1 (30).

Table 2.1 Factors that promote irrational use of drugs (30)

Type of factor	Root cause	Examples
Patients	Drug misinformation	Misleading beliefs
		Patient demands/expectations
Prescribers	Lack of education and training	Inappropriate role models
		Lack of objective drug information
		Generalization of limited experience
Workplace	Heavy patient load	Lack of adequate laboratory capacity
		Insufficient staffing
Drug Supply System	Unreliable suppliers	Drug shortages
		Expired drugs supplied
Drug Regulation	Non-essential drugs available	Non-formal prescribers
		Lack of regulation enforcement
Industry	Promotional activities	Misleading claims

These aspects are influenced by politics together with national and universal healthcare practice changes. For example, the numerous injection use is decreasing in most of African countries because of the fear of HIV/AIDS transmission. However, the use of injections remain high in some countries due to the false perception of some clinicians that injections improve patient satisfaction (30).

2.6. Promoting rational drug use

Several approaches exist for promoting rational drug use practices. These strategies can be grouped as educational, managerial, economic and regulatory as shown in Table 2.2.

Table 2.2 Intervention strategies to improve drug use (21)

Strategies for promoting rational drug use	
1. Educational strategies	***Selection, procurement and distribution***
Training of prescribers	Drug use review and feedback
Formal education (preservice)	Cost information
Continuing education (in-service)	Limited procurement lists
Supervisory visits	Hospital and County drug committees
Group lectures, seminars and workshops	***Prescribing and dispensing approaches***
Printed materials	Structured drug order forms
Newsletters	STGs
STGs and formularies	A course of therapy packaging
Flyers, leaflets	**3. Economic strategies**
Approaches based on face to face contact	Price setting
Educational outreach	Reimbursement and user fees
Patient education	Insurance
Influencing optimum leaders	Capitation based budgeting
2. Managerial strategies	**3. Regulatory strategies**
Monitoring supervising and feedback	Drug registration
Hospital drug and therapeutic committees	Limited drug list
County health teams	Prescribing restrictions
Self - assessment	Dispensing restrictions

Whichever strategy is employed, interventions should focus on a specific problem and target prescribers, dispensers, facilities, or the community, depending on where the assessment indicates the problem lies (29).

2.7. WHO/ INRUD core drug use indicators

Key pointers have been established, standardized and evaluated by the WHO/ INRUD aimed at assisting in the assessment of drug use in PHCCs. These indicators have been broadly divided into core and complementary indicators. The core indicators have been pre-tested and standardized while the complementary indicators are less standardized and are more difficult to measure. These indicators are grouped into three major categories namely; prescribing, patient-care and facility-specific indicators. They serve as tools for assessing key aspects of drug use in PHCCs (31). Table 2.3 shows the WHO/INRUD major drug use indicators and their optimal values (10).

Table 2.3 The WHO core drug use indicators and their optimal values (11)

WHO/INRUD Core Drug Use Indicators	**Optimal value**
Prescribing indicators	
The average number of medicines prescribed per patient encounter	1.6 - 1.8
Percent of medicines prescribed by generic name	100
Percent of encounters with an antibiotic prescribed	20.0 - 26.8
Percent of encounters with an injection prescribed	13.4 - 24.1
Percent of medicines prescribed from essential medicines list or formulary	100
Patient-care indicators	
Average consultation time (minutes)	≥ 10
Average dispensing time (seconds)	≥ 90
Percent of medicines actually dispensed	100
Percent of medicines adequately labeled	100
Percent of patients with knowledge of correct doses	100
Facility-specific indicators	
Availability of essential medicines list or formulary to practitioners	100
Percent of key medicines available	100

Whereas core drug use indicators are well pre-tested, more standardized and easy to measure, complementary indicators are less standardized and difficult to measure. Examples of complementary indicators are; the number of patients treated without drugs, the number of patients treated with drugs, the cost of injections prescribed and the ratio of drugs prescribed versus drugs dispensed at the health facilities (32).

2.7.1. WHO/ INRUD core prescribing indicators

Prescribing indicators assess the performance of prescribers in important areas involving rational drug use. They can be used in dispensaries, health centers and hospitals in both the public and private sectors. There are five core prescribing indicators as presented in Table 2.3. They assess prescribing practices based on clinical encounters at health facilities for the treatment of different diseases. Most suited in measuring aspects of out-patient care, hence less useful for in-patient care (6).

Prescription surveys describing current prescribing practices using the WHO/INRUD prescribing indicators are required to have a minimum of 600 prescriptions included in a cross-sectional study, with a greater number if possible (31).

The following are the five sub-indicators of quality of prescribing:

2.7.1.1. Number of drugs per prescription

This indicator evaluates the level of polypharmacy in prescriptions (33). A Fixed-dose combination of drugs is counted as one. It is not relevant whether the patient actually received the drugs or not (31).

Average values greater than the standard value indicate polypharmacy. Polypharmacy may occur as a result of financial incentives to prescribers by drug industries or inadequate training of prescribers. Polypharmacy should be discouraged since it is a risk factor for drug interactions. The standard value for this indicator is 1.6 to 1.8 as per the WHO/INRUD criteria. Low values might reflect low availability of drugs or properly trained prescribers (34).

Studies done in different countries reported varying results on the mean number of drugs prescribed per encounter/ prescription (35). Low values were reported in the studies done in Zimbabwe, Bangladesh and Sudan while acceptable values were documented in Lebanon and Ethiopia. Several studies conducted in the United Arab Emirates, Jordan, India, Kenya, Nigeria, Uganda, Nepal and Ghana reported a higher average value compared to the standard recommended by WHO/INRUD (15). Table 2.4 shows the results from different countries.

Table 2.4 Average number of drugs per prescription (27)

Study site	Mean number of drugs per encounter
Zimbabwe (30)	1.3
Bangladesh (31)	1.4
Sudan (30)	1.4
Lebanon (32)	1.6
Ethiopia (29, 33-36)	1.9, 1.6, 1.8, 1.8, 1.9
United Arab Emirates (37-38)	2.2, 2,2
Jordan (39)	2.3
India (2, 45-47)	2.8, 2.7, 3.1, 4.2
Kenya, National survey of 2003 (48)	2.8
Kenya, National survey of 2009 (49)	2.8 (public facilities), 2.9 (faith-based facilities)
Nigeria (50)	2.8 (private hospital), 3.9 (public hospital)
Uganda (51)	2.9
Nepal (52)	2.9
Nigeria (53)	3.2 (outpatients), 9.7 (inpatients)
Nigeria (30)	3.8
Ghana (54)	4.8

2.7.1.2. Prescribing by generic name

This indicator assesses the tendency of prescribers to prescribe using the international non-proprietary names (INN) as opposed to using proprietary brand names. The WHO/ INRUD recommended value for the indicator is 100% (31).

Investigators observe and note the actual names of the drugs written in the prescription rather than noting the names of the drugs dispensed. Since these may be different; a list must be available of specific drug names to be counted as generic drugs (31).

Prescribing using generic names helps reduce cost and rationalize drug use. It is encouraged because it allows patients to get the most cost-effective drug available without considering the brands or manufacturers (36). A high percentage of prescribing by brand names can be attributed to drug promotion by the medical representatives and lack of emphasis on generic prescribing during the training of prescribers. It may also indicate that prescribers are not conversant with documents such as EDL and STGs in which drugs are always written in their generic names (15).

The percentages of drugs prescribed using generic names were very low in studies conducted in Lebanon, Jordan and the United Arab Emirates (Table 2.5). High percentages were obtained by studies carried out in Ethiopia, Tanzania, Zimbabwe, Iran, and Cambodia.

Table 2.5 Percentage of drugs prescribed by generic name (27)

Study site	% of drugs prescribed by generic name
Lebanon (32)	2.9
United Arab Emirates (37-38)	4.4, 19.4
India (2, 45-47, 56-58)	48.6, 16, 27.1, 5, 8, 27.3, 73.4
Jordan (39)	5.1
Kenya, National survey of 2003 (48)	48
Uganda (51)	62
Ethiopia (29, 33-34, 36)	98.7, 75.2, 99.2, 87
Tanzania (30)	82
Zimbabwe (30)	94
Iran (64)	96
Cambodia (65)	99.8

2.7.1.3. Antibiotic prescribing encounter

This indicator determines the overall use of antibiotics. The WHO/ INRUD value for this indicator is 20 - 26.8% (31). A high prevalence of antibiotic prescribing may be due to the pressure from patients to receive antibiotics and over-estimation of the severity of diseases by prescribers to substantiate antibiotic prescribing. Overuse of antibiotics could lead to the occurrence of resistance and an unjustified increase in the cost of drugs to the patients (37).

Most prescription studies conducted in various countries reported the overuse of antibiotics (15). In comparison to other countries, Kenya had the highest prevalence of antibiotic prescribing (Table 2.6) (35). This was also reflected in other African countries.

Table 2.6 Percentage of prescriptions with an antibiotic prescribed

Study site	% of prescriptions with an antibiotic
Pakistan (44), (61)	20.4, 78
United Arab Emirates (37)	21.4
Ethiopia (29), (34), (68)	58.1, 29.1, 34.4
Saudi Arabia (41)	32.2
Tanzania (69)	35.4
India (2), (58)	60.9, 39.6
China (42), (43)	48, 44
Nigeria (30)	48
Norway (70)	48
Nigeria (53)	50.3 (outpatients), 96.7 (inpatients)
Yemen (71)	51
Nigeria (50)	55 (private hospital), 75 (public hospital)
Uganda (30)	56
England (72)	60.7
Iran (64)	61.9
Sudan (30)	63
Kenya, National survey of 2009 (49)	68.4 (FBFs), 76.7 (public facilities)
Kenya, National survey of 2003 (48)	78.4

2.7.1.4. Injection prescribing encounter

The indicator assesses the overall use of injections. The WHO/ INRUD recommended value for the indicator is 13.4 to 24.1% (31). Values above this standard value indicate the over-prescribing of injections.

Over-prescription of injections may arise from patients' pressure to receive injections and prescribers' attitude that injections are more efficacious compared to oral medication. High injections use is discouraged because they are relatively more costly compared to other dosage forms and need trained health workers to administer (34).

In a survey carried out in Kenya in 2009, it showed that faith-based facilities performed worse than the public health facilities concerning the prevalence of injections prescribing (37).

Studies carried out in different countries reported the overuse of injections at the outpatient health facilities as shown in Table 2.7 (35). Low-income countries tended to perform better than high-income countries concerning this indicator.

Table 2.7 Percentage of prescriptions with an injection prescribed (35)

Study site	% prescriptions with an injection
India (2), (58), (56)	13.5, 0.2, 5.2
Bangladesh (4)	6.7
Kenya, National survey of 2009 (49)	13 (PHFs), 27 (FBFs)
Ecuador (30)	17
Mali (30)	19
Tanzania (69)	19
Ethiopia (29), (34), (36), (68)	38.1, 28.5, 23, 19
Burkina Faso (73)	24.6
Kenya, National survey of 2003 (48)	28.4
China (43)	34
Sudan (30)	36
Uganda (30)	48
Norway (70)	51

2.7.1.5. Drugs prescribed from the EML or formulary

This indicator evaluates the extent to which the clinicians' prescribing practices conform to the national EML or formulary. The WHO/ INRUD value for this indicator is 100% (31).

Inadequate supply of drugs at health facilities and unavailability of EML copies have been blamed for non-compliance with EML when prescribing (5).

Out of the 10 countries, 80% of the facilities survey, the prevalence of adherence to the EML was very high at above 80%, Table 2.8 (35). Bangladesh and India were the countries with significant deviations. In Kenya, faith-based facilities performed worse than the private facilities.

Table 2.8 Percentage of drugs prescribed from EML or formulary

Study site	% of drugs prescribed from EML
Bangladesh (4), (31)	26.1, 85
India (2)	66.9
Pakistan (44), (61)	80, 70
Kenya, National survey of 2009 (49)	79 (FBFs), 93 (PHFs)
Burkina Faso (73)	88
Uganda (51)	94
Ethiopia (29), (34), (36)	96.6, 98.9, 99
Ghana (54)	97
Saudi Arabia (41)	99.2
Nigeria (50)	100

2.7.2. WHO core patient-care indicators

These address key aspects of what patients experience at the health facilities, and how well they have been prepared to deal with the drugs that have been prescribed and dispensed. (31).

The time that health professionals spend with each patient sets important limits on the quality of diagnosis and treatment. Patient consulting and dispensing times measure the time that healthcare providers spend with patients in the process of consulting, prescribing and dispensing drugs (38). Data for patient-care indicators for each facility can be entered and summarized in the patient care form (Appendix B).

2.7.2.1 Consultation time

This indicator determines the average time the prescriber spends with patients while consulting and prescribing. The WHO/ INRUD recommended time for this indicator is 10 or more minutes. It is the actual time spent during the consultation process, that is, the time between entering and leaving the consultation room by the patient. It is recorded using a stopwatch. Waiting time is not included (31).

Most of the studies conducted around the world reported relatively lower consultation time. Patients in Sweden spent more time with the prescribers as shown in Table 2.9 (35).

Table 2.9 Average consultation time

Study site	Average consultation time (min)
Bangladesh (17)	1.0
Nepal (37)	3.5
India (35)	7.0
China (44)	8.5
Central African Republic (54)	8.3
Ethiopia (56)	6.2
Niger (62)	6.1
Nigeria (65)	5.0
Egypt (15)	7.1
Sweden (90)	22.5

2.7.2.2 Dispensing time

This measures the average time that the dispenser spends with patients while dispensing the drugs. The standard time for this indicator is 90 or more seconds as per the WHO/INRUD criteria (31).

This is the difference of the time when a patient submits the prescription to the dispenser on the pharmacy counter and the time the patient leaves the counter with a drug(s).

In the studies conducted in different parts of the world, The Central African Republic and Saudi Arabia reported the average dispensing time greater than 90 secs while the other countries reported lower dispensing time with Nigeria the least as shown in the Table 2.10 (35).

Table 2.10 Average dispensing time

Study site	Average dispensing time (sec)
China (44)	25.6
Nepal (37)	86.1
India (35)	240
Central African Republic (54)	300
Mozambique (61)	37.0
Tanzania (69)	77.8
Egypt (15)	47.7
Kuwait (78)	54.6
Saudi Arabia (22)	100
Brazil (85)	17.0
Serbia (90)	24.0
Ethiopia (56)	78.0
Nigeria (65)	18.1

2.7.2.3 Drugs actually dispensed

This indicator evaluates the degree to which health facilities can provide the drugs which were prescribed. Drugs dispensed should be 100% as per the WHO/INRUD criteria (31). In the surveys conducted globally, its only China and Niger where all the drugs prescribed were dispensed, most countries did not dispense all the drugs with Serbia dispensing the least as shown in Table 2.11 (35).

Table 2.11 Percentage of drugs actually dispensed

Study site	Percentage of drugs actually dispensed
Bangladesh (17)	81.0
India (35)	96.1
China (44)	100.0
Ethiopia (56)	83.4
Niger (62)	100.0
Nigeria (63)	70.0
Swaziland (65)	99.1
Tanzania (70)	91.6
Egypt (15)	95.9
Kuwaiti (78)	97.9
Brazil (85)	66.0
Serbia (89)	53.5

2.7.2.4 Drugs adequately labeled

This indicator measures the degree to which dispensers write crucial drug information on the drug packages/ labels as they dispense them to patients. The information required on the labels includes; patient name, dosage, strength, frequency, precautions and the total units of the drug dispensed (31).

Studies carried around the world indicated different drug labeling results with China and India accurately labeling all the drugs dispensed with the necessary information. Dispensers in Cambodia and Nigeria failed to label all the drugs correctly as shown in Table 2.12 (35).

Table 2.12 Percentage of drugs adequately labeled

Study site	Percentage of drugs adequately labeled
India (36)	99.4
Pakistan (38)	10.8
Cambodia (42)	0.0
China (44)	100.0
Central African Republic (54)	78.5
Ethiopia (56)	70.1
Nigeria (65)	0.0
Tanzania (70)	87.6
Egypt (15)	0.0
Brazil (85)	63.0
Saudi Arabia (22)	10.0
Swaziland (65)	55.9

2.7.2.5 Patients' knowledge of dispensed drugs

This indicator assesses how well the patient understands and retains the provided information on the dosage and therapy schedules of the drugs dispensed to them. Here, the investigator assesses the dispensed drugs together with patients' knowledge on the dosage schedule or accesses to standards for how each common drug is supposed to be used (31).

Studies around the world have shown patients have varying levels of knowledge about the drugs dispensed to them. Most patients in Tanzania and Egypt understood their medications, indications, and contraindications. In Pakistan, patients had very limited knowledge about the medications that were given as shown in Table 2.13 (35).

Table 2.13 Percentage of patients with adequate drug knowledge

Study site	% of patients with drug Knowledge
Bangladesh (17)	82.0
India (35)	89.9
Nepal (37)	56.0
Pakistan (39)	24.0
Cambodia (42)	55.0
China (45)	85.0
Central African Republic (54)	69.6
Ethiopia (57)	77.3
Mozambique (61)	81.7
Tanzania (70)	96.1
Egypt (15)	94.0
Kuwait (78)	26.9
Brazil (85)	54.0
Sweden (90)	70.0

2.7.3 Facility-specific indicators

Many factors within the healthcare working environment determine the ability of drugs being prescribed rationally. These factors include; the presence of qualified healthcare workers, availability of essential drugs and access to essential medicines list (EML). Without these factors, it would be difficult for health professionals to offer healthcare services effectively (31). The data for the facility-specific indicators are usually captured on the facility summary form (Appendix C)

2.7.3.1. Availability of copies of EML or formulary

This assesses the availability of copies of the national essential EML/ facility formulary at health facilities. The WHO/ INRUD sets this indicator at 100% (31). The availability of EML or formulary copies is checked in the prescriber-patient consulting rooms, dispensing areas and drugstores.

Facilities in India, Cambodia, Nigeria, Niger, and Mozambique had the national EML in place. Most facilities in Brazil and Tanzania had very few copies in place as shown in Table 2.14 (35).

Table 2.14 Percentage with copies of EML

Study site	% of facilities with copies of EML
Bangladesh (34)	16.0
India (35)	100.0
Pakistan (39)	95.0
Cambodia (42)	100.0
Egypt (15)	80.0
Ethiopia (56)	50.0
Nigeria (65)	100.0
Tanzania (68)	15.0
Kuwait (78)	90.0
Brazil (85)	50.0
Niger (62)	100.0
Saudi Arabia (22)	90.0
Mozambique (61)	100.0

2.7.3.2. Availability of essential drugs

This measures the availability of critical drugs at the health institutions recommended for the management of common ailments. The WHO/INRUD sets this indicator at 100% (31).

This information is collected from the drugstore. Results from different surveys worldwide showed that most facilities in India, Nepal, Cambodia, Mozambique and Niger had essential drugs stocked in their drug stores. The others showed more than the average availability of the key drugs as shown in Table 2.15 (35).

Table 2.15 Percentage availability of key drugs (35)

Study site	Percentage availability of key drugs
Bangladesh (17)	54.0
India (35)	89.4
Nepal (37)	90.0
Pakistan (39)	74.2
Cambodia (42)	86.6
Ethiopia (56)	65.0
Mozambique (61)	86.5
Niger (62)	85.6
Malawi (60)	67.0
Tanzania (69)	72.0
Egypt (15)	78.3
Jordan (91)	80.0
Brazil (85)	55.0
Saudi Arabia (22)	59.2

2.8. Conceptual framework

Performance of PHCCs with regards to WHO/INRUD core drug use indicators is based on the prescriber, patient, facility, quality of dispensing and other enabling factors. The contribution of various facets and reasons for non-adherence to the WHO/ INRUD guideline is illustrated in the conceptual framework shown in Figure 2.3 (39).

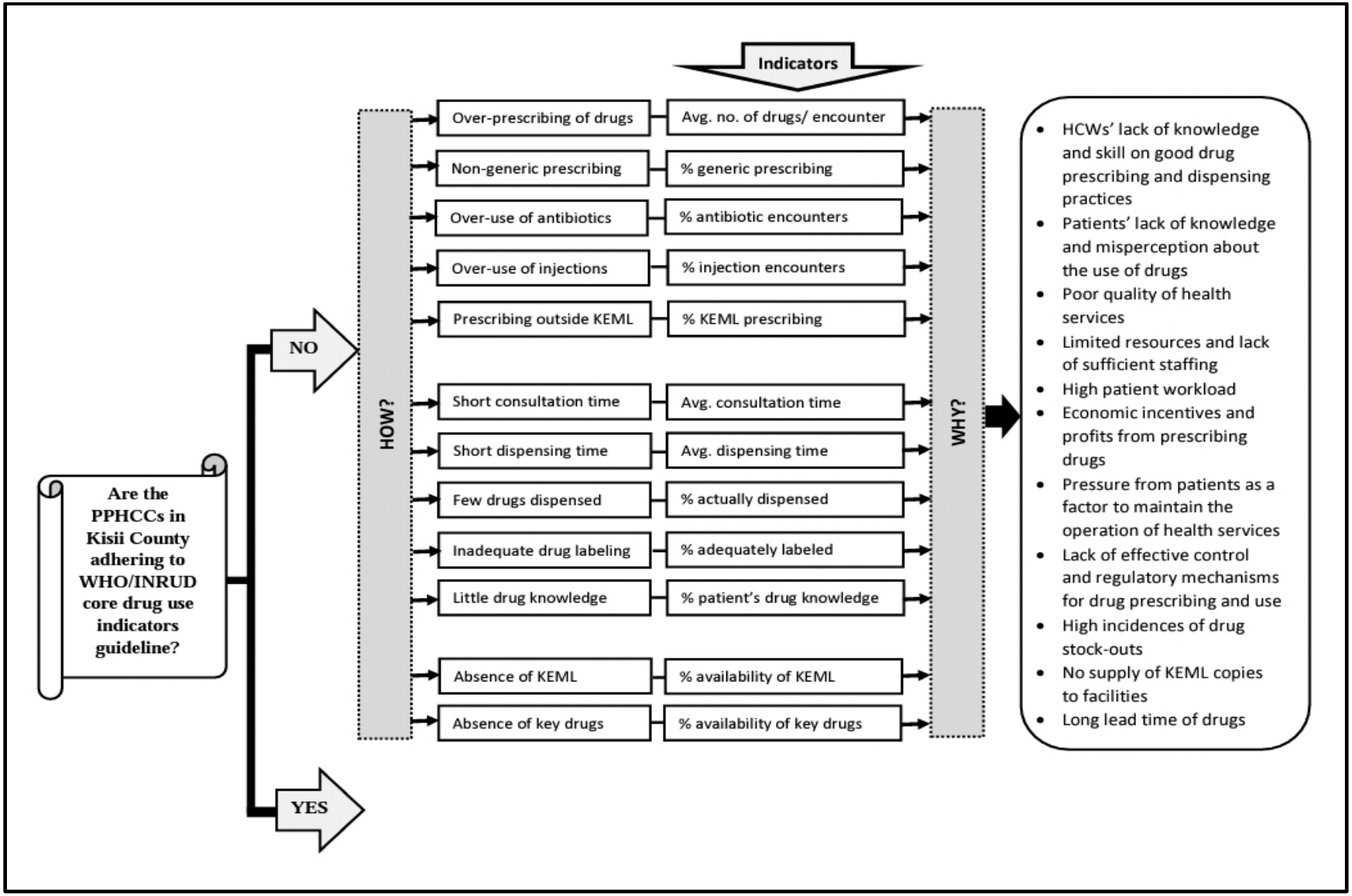

Figure 2. 3 Conceptual framework for rational use of drugs (39)

CHAPTER THREE

3.0 MATERIALS AND METHODS

The study was divided into three parts; prescription survey, patient - care survey and facility-specific survey.

3.1. Study area

The study was conducted at public primary health-care centers (PPHCCs) in Kisii County. The county had a total of 104 operational PPHCCs comprised of levels II (81) and III (23) only. Levels II are dispensaries and clinics while Levels III are health centers, nursing and maternity homes. These facilities provide basic healthcare services such as prevention and management of health conditions. The clientele of these centers is drawn from a population of about 1.2 million (605,784 males, 661,038 females and 38 intersexes) Kisii county residents. The county has a total of 308,054 households and covers an area of 1,323 square kilometers (40).

3.2. Study design

The study design was a hospital-based cross-sectional survey. The design was chosen because data on the indicator variables were to be collected only once from each health facility. A retrospective prescription survey was performed to abstract data from the stored patient prescriptions for the last quarter of 2018 (1st October – 31st December 2018). The WHO/INRUD recommends at least 600 prescriptions to be used in this kind of survey, thus the selection of the three months prescription period to achieve the over the recommended 600 prescriptions. Patient-care and facility-specific surveys were conducted concurrently by direct observation and administration of interviews to outpatients and dispensers on the survey visit days.

3.3. Study population and eligibility criteria

3.3.1. Health facilities

The survey was conducted at the public primary healthcare centers (PPHCCs) in Kisii County. Only levels II and III PPHCCs were used in this study. Private and mission hospitals were excluded because the facilities' management objected to the principal investigator's request letter to have them included.

Inclusion criteria

i. PPHCCs.
ii. Levels II and III facilities.

Exclusion criteria

i. Private, Missionary facilities.
ii. Non-operational facilities

3.3.2. Prescription survey

Prescriptions for the three months (1st October - 31st December 2018) were used to collect the prescribing indicator data at each of the selected facilities.

Inclusion criteria

i. Generated and processed at the study facilities.
ii. Written from 1st October – 31st December 2018.

3.3.3. Patient - care survey

Outpatients who attended the PPHCCs on the survey visit day for diagnosis and treatment were included in the cross-sectional survey. They were observed and interviewed to collect data on the required variables. Younger patients were excluded because they were assumed not to be able to reply to the data collectors' interview questions.

Inclusion criteria

i. Adults (Aged 18 years and above).
ii. Outpatients.
iii. Consented to participate in the study

iv. Received treatment.
v. Conversant with English, Swahili or Ekegusii languages.

3.3.4. Facility-specific survey

Drug dispensers, from each of the study PPHCC, were interviewed on the survey visit day to collect data on the availability of key essential drugs and the KEML copies.

Inclusion criteria

i. Dispensers working at the study PPHCC.
ii. Consented to participate in the study.

3.4. Sampling

3.4.1. Sampling of PPHCCs

According to the WHO/INRUD, at least ten facilities should be sampled for a cross-sectional survey to describe the drug use practices in any geographical region (31). The PPHCCs within the county were selected by simple random sampling method. All the 104 operational PPHCCs were listed (Appendix E), using the code numbers assigned to them, in a Microsoft Excel 2016 spreadsheet to obtain a sampling frame. The 'RAND' function was then used to generate a random number sequence which was used to randomly sample ten PPHCCs from the total 104 PPHCCs.

3.4.2. Sampling of prescriptions

According to the WHO/INRUD, at least six hundred prescriptions should be sampled for a cross-sectional survey to describe the prescribing practices in any region (31). Based on this criterion, a total of 900 (90 per PPHCC) retrospective prescription encounters were sampled by systematic random sampling method at each of the selected PPHCCs.

The prescriptions were obtained from the record rooms, where they are usually archived for 2 years before destruction. The facilities' record officers assisted the investigators on request in sorting out the prescriptions. Ninety prescriptions from each of the selected PPHCCs were used. The prescriptions surveyed were those which had been written from 1st October - 31st December 2018.

On average, between 100 and 150 outpatient prescriptions are issued every month in each PPHCC. The prescriptions were sampled by systematic random sampling method. At each PPHCC, prescriptions for each month were arranged chronologically by date. An appropriate sampling interval (between 2 to 3 encounters) was used to pick up the prescriptions until a batch of between 30 - 35 prescriptions were obtained for October 2018. This was repeated for the remaining two months to obtain a total of between 90 - 100 prescriptions at every PPHCC. The sampled prescriptions were perused to exclude those which did not meet the inclusion criteria. The sampling was either done at the record offices or the pharmacy office based on convenience.

3.4.3. Sampling of patients and dispensers

Based on the WHO/INRUD, at least 300 patients should be sampled and for a cross-sectional survey to describe the patient-care practices at any geographical region (31). Based on this, a total of 300 (30 per PPHCC) patients were recruited into the survey.

The patients were recruited, by convenient sampling, as they waited to see the prescribing officer. They were invited into a private room where the purpose, benefits and risks of the study were explained to them by the research assistants as they got consented.

Also, one dispenser from each PPHCC and available at the time of the survey visit day was interviewed to capture key data aspects on the facility-specific indicators after consenting.

3.5. Data collection

Data on the core indicators was collected and presented on the specific indicator forms (Appendices A, B and C).

Prescription survey data were retrospectively abstracted for the three months (1st October to 31st December 2018) by the research assistants and entered in the Individual Patient Data Forms (Appendix A).

Patient-care survey data were also collected prospectively by the research assistants, using the Individual patient-care Indicator Guide Form (Appendix B). Both observation and interviewing processes were employed concurrently right from the prescribing area to the dispensing area. At the prescribing area, research assistants closely observed from a distance the time the patient entered and exited the consultation rooms. At the dispensing area, patients' prescriptions were

counter-checked with the actual drugs dispensed to them and the labeling information noted by the research assistants. The same patients were interviewed by research assistants as they exited the dispensing area on the knowledge of the drugs dispensed to them, i.e., whether they comprehended their indication, how and when to take the medication and the side effects.

One dispenser from each of the selected PPHCC was interviewed by the principal investigator using the Facility-specific Indicator Interview Form (Appendix C) to collect data on the key aspects of facility-specific indicators such as availability of KEML copies and availability of key drugs at the facility. This data was obtained at the facilities' pharmacy department.

3.6. Quality assurance

The pre-designed data abstraction forms (Appendices A, B, and C) were pre-tested on five subjects a week earlier before the scheduled data collection period. The findings were used to adjust the data collection instruments to be able to collect data accurately. Research assistants were trained on the use of all the indicator forms. There were ten research assistants (pharmaceutical technologists) deployed for the survey, one for each PPHCC. To minimize information bias, no research assistant was assigned to collect data from his/ her routine place of work. They were trained by the principal investigator on how to sample the prescriptions and the outpatients and the use of the data collection tools. Privacy and confidentiality about the patient information on the prescriptions were emphasized during the training.

3.7. Data analysis and management

Data collected in the prescribed forms (Appendices A, B and C) was entered into the – Epi Info™ version 7.2.2.16 (Centers for Disease Control and Prevention, US) software. The entered data was then exported into Microsoft Excel (2016) and then subsequently imported into STATA version 14.2 (StataCorp, USA) software for analysis.

The main study variables were analyzed using descriptive statistics (means, standard deviations, proportions, percentages and ranges) and inferential statistics (confidence intervals, t-test, z-test, Pearson's correlation and ANOVA). An ANOVA test was used to test for statistically significant differences in the selected variables across the PPHCCs. The level of significance of $\alpha = 0.05$ was used to test the level of significance across all the indicator variables. The indicator variables were

also checked for normal distribution using the Shapiro-Wilk (S-W) test by comparing the data to a normal distribution with the same mean and standard deviation of the samples. Both tables and graphs were used to present the results.

The summary of the analyzed data was finally consolidated by the principal investigator in the Consolidation Form (Appendix D).

Data loaded in the STATA (version 14.2) software for the entire survey was used to calculate the various aspects of the three core drug use indicators as shown in Tables 3.1.

Table 3.1 Core indicators of appropriate drug use determination

Prescribing indicators	**Determination**
The average number of drugs per prescription	Dividing the total number of drugs prescribed by the total number of prescriptions
Percentage of drugs prescribed by generic name	Dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100
Percentage of prescriptions with an antibiotic	Dividing the number of prescriptions with an antibiotic by the total number of prescriptions, multiplied by 100
Percentage of prescriptions with an injection	Dividing the number of prescription with injection by the total number of prescription, multiplied by 100
Percentage of drugs prescribed from KEML	Dividing the number of drugs prescribed from the KEML by the total number of drugs prescribed, multiplied by 100
Patient-care indicators	
Average consultation time	Dividing the total time for consultation for a series of consultations, by the number of consultations
Average dispensing time	Dividing the total time for dispensing for a series of prescriptions, by the number of prescriptions
Percentage of drugs actually dispensed	Dividing the number of drugs actually dispensed by the total number of drugs prescribed, multiplied by 100
Percentage of drugs adequately labeled	Dividing the number of drug packages with; patient name, drug name, and frequency by the total number of drug packages dispensed, multiplied by 100

Patients' knowledge of dispensed drugs	Dividing the number of patients who could adequately respond to the six areas (Appendix B, Part 2), by the total number of patients interviewed, multiplied by 100
Facility-specific indicators	
Percentage availability of KEML/ formulary copies	Dividing the total number of health facilities that have the KEML by the total number of facilities surveyed, multiplied by 100
Percentage availability of key drugs	Dividing the number of available key drugs from the checklist by the total number of drugs on the checklist multiplied by 100

3.8. Ethical considerations

Ethical approval to carry out the study was sought from the Kenyatta National Hospital - University of Nairobi (KNH – UoN) Ethics and Research Committee Reference number: KNH – ERC/A/50 (Appendix I). Permission to conduct the survey was also sought from the Kisii County - Director for Health's office (Appendix J).

For the prescription survey, informed consent from patients was not required because data were obtained from the record offices. However, for the patient-care and facility-specific surveys, informed consent was obtained in writing from the patients, prescribers, and dispensers (Appendices F, G, and H respectively) before conducting the interviews.

Confidentiality was ensured while handling patients' prescriptions. Prescription data abstraction was done at either the records office or the office of the facility pharmacy in-charge. The patient exit interview was done at the dispensing area where the patients were invited to the empty waiting dispensing bench and interviewed. Data collection instruments did not bear participants' names or patient numbers, study codes were used instead.

CHAPTER FOUR

4.0 RESULTS

4.1. Characteristics of the selected PPHCCs

The study was carried out at ten randomly sampled public primary healthcare centers (PPHCCs) in Kisii County. These were only Levels II (5) and III health facilities (5). Table 4.1 shows the level, sub-counties, distance from the County health headquarters and rural/ urban settings of the selected PPHCCs. Oresi is the only facility located in an urban setting, about 1.3 km from the Couty Health headquarters while the other facilities are located in rural settings.

Table 4. 1 Type and location of the selected PPHCCs (n = 10 PPHCCs)

PPHCCs	Level	Sub – county	Distance (km)	Setting
Oresi	III	Kitutu Chache South	1.3	Urban
Kegogi	III	Kitutu Chache North	39	Rural
Masimba	III	Nyaribari Masaba	37	Rural
Entanda	II	Kitutu Chache North	25	Rural
Magena	II	Bomachoge Borabu	34	Rural
Nyamagundo	II	Bonchari	9.9	Rural
Isecha	III	Kitutu Chache North	25	Rural
Egetuki	II	Bomachoge Chache	20	Rural
Kionyo	III	Bobasi	23	Rural
Mosocho	II	Kitutu Chache South	13	Rural

4.2. General outpatient (Filter clinic) attendance at selected PPHCCs

The total attendance of patients at the outpatient department (OPD) at the selected PPHCCs in the last quarter of 2018 (1st October to December 2018) was 39,222 patients (40). These comprised of new clients and revisits. Masimba recorded the highest attendance of patients (9,846) while Kionyo registered the least (1,602) as shown in Table 4.2.

Table 4. 2 Outpatient department attendance at PPHCCs (n = 39,222 Outpatients)

PPHCCs	New clients	Revisits	Total
Oresi	4,807	1,128	5,935
Kegogi	3,248	926	4,174
Masimba	6,890	2,956	9,846
Entanda	1,640	1,124	2,764
Magena	3,027	967	3,994
Nyamagundo	1,124	697	1,821
Isecha	1,804	409	2,213
Egetuki	2,156	305	2,461
Kionyo	1,077	525	1,602
Mosocho	3,209	1,203	4,412
Overall	**28,982**	**10,240**	**39,222**

4.3. Distribution of prescribers and dispensers at the selected PPHCCs

The prescribers were grouped into medical officers (MOs), clinical officers (COs) and nurses while the dispensers were grouped into pharmacists and pharmaceutical technologists (Table 4.3). Entanda, Nyamagundo and Egetuki Hospitals had neither a pharmacist nor a pharmaceutical technologist as the qualified dispensers at the facilities. Those who were dispensing were the nurses.

The highest qualified prescribers and dispensers were a medical officer (Oresi) and a pharmacist (Masimba). However, on the survey visit day, the two were not involved in the prescribing and dispensing activities. This is because they (the Medical officer and pharmacist) were involved in the facilities' managerial activities.

Table 4. 3 Distribution of the prescribers and dispensers at the selected PPHCCs

	Prescribers			Dispensers		
PPHCCs	**MOs**	**COs**	**Nurses**	**Pharmacists**	**Pharm Techs**	**Total**
1	1	6	12	0	3	**22**
2	0	2	4	0	1	**7**
3	0	7	13	1	2	**23**
4	0	1	4	0	0	**5**
5	0	3	6	0	1	**10**
6	0	4	7	0	0	**11**
7	0	2	4	0	1	**7**
8	0	0	2	0	0	**2**
9	0	1	4	0	1	**6**
10	0	2	5	0	1	**8**
Overall	**1**	**28**	**61**	**1**	**10**	**101**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

The general outpatient attendance had a strong positive correlation (r = 0.8249) with the total number of healthcare workers at the selected PPHCCs as shown in Figure 4.1.

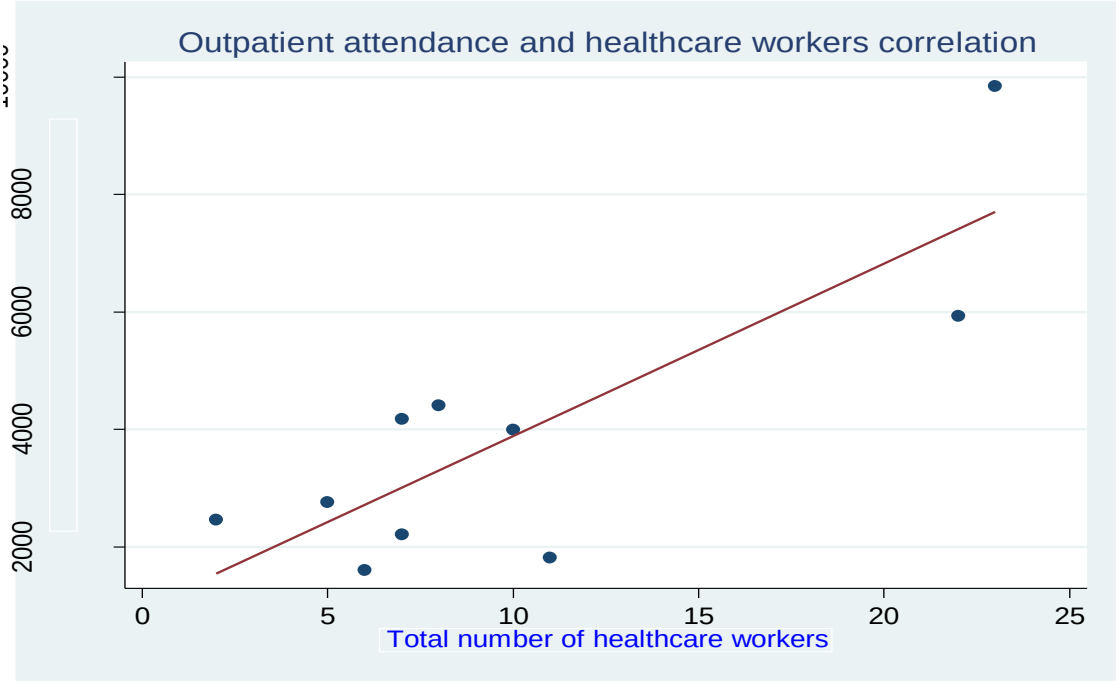

Figure 4. 1 Correlation of total number of patient attendance and healthcare workers

4.4. Core drug use indicators at selected PPHCCs

A total of 900 (90 per PPHCC) systematically sampled prescriptions for the 4th quarter of 2018 (1st October to 31st December 2018) were used to extract data. A total of 300 (30 per PPHCC) conveniently sampled outpatients who were served at the PPHCCs on the survey visit day were recruited to the study. They were observed and interviewed to obtain data on the patient – care indicators. Finally, a total of ten dispensers (one per PPHCC) available on the very day of data collection were interviewed to capture the data on the facility-specific indicators.

4.5. Prescribing indicators

4.5.1. Prescription selection

Overall, 2623 outpatient prescriptions were written from 1st October to 31st December 2018. They were retrieved from the record offices for sampling. On sampling, 973 prescriptions were obtained. Seventy-three (8.0%) of these were excluded because they were not generated at the PPHCCs (3.2%) or were not written within the three month study period (4.8%). (Figure 4.2).

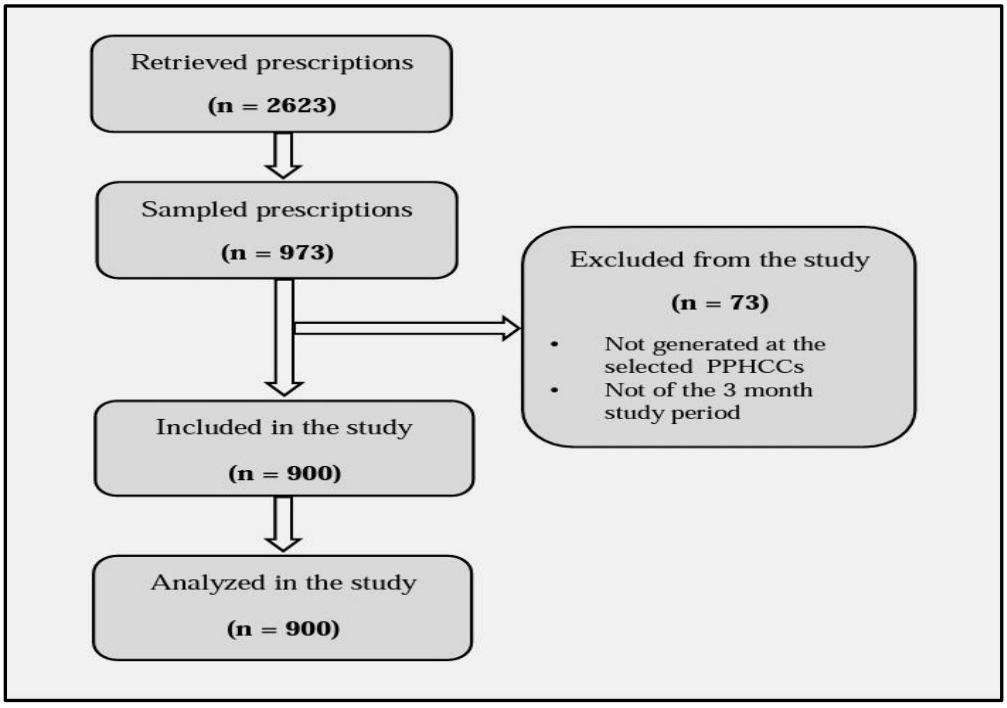

Figure 4. 2 CONSORT diagram for prescription selection

Therefore, a total of 900 (34.3%) prescriptions were included in the survey for prescribing indicators' analysis leaving out 1,723 of the sampling frame. These sampled prescriptions were a good representative of the total retrieved prescriptions and were above the WHO/ INRUD recommended number (at least 600 prescriptions) needed for the survey.

Oresi had the highest number (321) of prescriptions retrieved. Kegogi and Nyamagundo had a large number of prescriptions excluded, 12 and 11 respectively. Table 4.4 shows the; retrieved, sampled, excluded and included prescriptions per PPHCC for the three-month study period.

Table 4. 4 Prescription encounter inclusion at PPHCCs (n = 900)

	Prescriptions			
Facility	**Retrieved**	**Sampled**	**Excluded**	**Included**
1	321	97	7	90
2	307	102	12	90
3	277	94	4	90
4	255	98	8	90
5	269	99	9	90
6	314	101	11	90
7	199	95	5	90
8	247	96	6	90
9	201	93	3	90
10	233	95	8	90
Overall	**2623**	**973**	**73**	**900**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

4.5.2. Gender of participants in the prescription survey

Among the 900 prescriptions encounters, 534 (59.3%) were prescribed for females and the remaining 366 (40.7%) for male out-patients. The distribution of out-patients prescriptions served at the PPHCCs with regard to gender is shown in Table 4.5. In all the PPHCCs, the number of the females served was greater than those for the males except at Isecha Hospital where males were more (at 55.6%) than females.

Table 4. 5 Gender distribution of participants in prescription survey (n = 900 encounters)

Facility	Males	Females	Total
1	39 (43.3%)	51 (56.7%)	90 (10.0%)
2	41 (45.6%)	49 (54.4%)	90 (10.0%)
3	30 (33.3%)	60 (66.7%)	90 (10.0%)
4	31 (34.4%)	59 (65.6%)	90 (10.0%)
5	32 (35.6%)	58 (64.4%)	90 (10.0%)
6	36 (40.0%)	54 (60.0%)	90 (10.0%)
7	50 (55.6%)	40 (44.4%)	90 (10.0%)
8	36 (40.0%)	54 (60.0%)	90 (10.0%)
9	33 (36.7%)	57 (63.3%)	90 (10.0%)
10	38 (42.2%)	52 (57.8%)	90 (10.0%)
Overall	**366 (40.7%)**	**534 9.3%)**	**900 (100.0%)**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

4.5.3. Presenting complaints and diagnosis

Symptoms related to; the respiratory (33.4%), GIT (14.9%), urological (14.7%) and skin (12.6%) systems among others were the most common reasons for the visit (RFV) to the facilities by the patients. Symptoms related to the neurological and endocrine systems were the least RFV at 0.3% and 0.4% respectively. Upper respiratory tract infection (URTI) was the most (66.8%) commonly diagnosed disease found to affect the respiratory system. Complaints of fever and headache were in most cases (59.3%) associated with malaria (Figure 4.3).

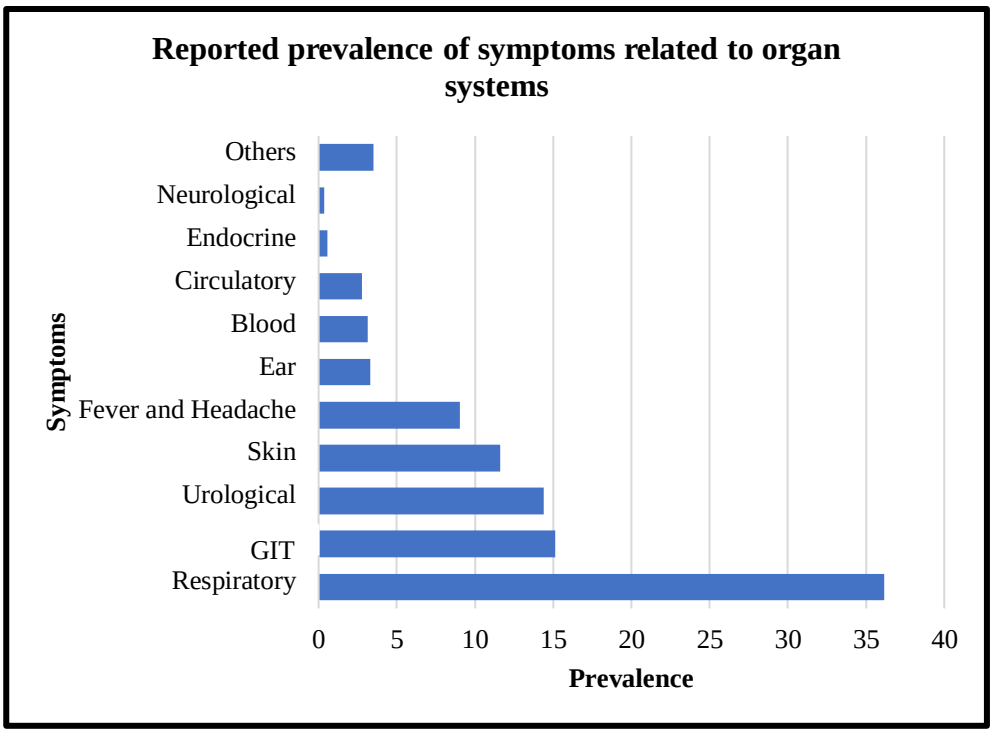

Figure 4. 3 Reported prevalence of symptoms related to organ systems at the PPHCCs

Note: 'Other systems' were those rarely encountered such as the reproductive, musculoskeletal and immunological systems.

4.5.4. Classes of drugs prescribed to outpatients

Cumulatively, 2636 drugs were prescribed to the out-patients in all the 900 sampled prescription encounters. The majority of the prescribed drugs were analgesics/antipyretics 970 (36.8%) and antibiotics 795 (30.2%). The least prescribed drugs were antivirals (0.2%). The commonly prescribed analgesics were; paracetamol (43.7%), ibuprofen (19.4%), diclofenac (8.9%), and tramadol (5.2%). Table 4.6 shows the various classes of drugs prescribed at the PPHCCs in the study period.

Table 4. 6 Percentage of commonly prescribed drugs at the PPHCCs (n = 2636 drugs)

Class of Drugs	Frequency	Percentage
Analgesics/antipyretics	970	36.8%
Antibiotics	795	30.2%
Antimalarials	178	6.8%
Antihistaminics	151	5.7%
Antihelminthics	89	3.4%
Drugs for GIT	82	3.1%
Dermatological preparations	78	3.0%
Tetanus Toxoid	48	1.8%
Antifungals	37	1.4%
Antivirals	4	0.2%
Others e.g., antihypertensives	204	7.7%
Overall	**2,636**	**100.0%**

Note: 'Other classes of drugs' comprised of the rarely prescribed classes of drugs at the PPHCCs which included; antihypertensives, antidiabetics, anaesthetics, anticonvulsants/ antiepileptics, antineoplastics, and immunosuppressants.

4.5.5. Number of drugs prescribed per prescription

The overall average number of drugs prescribed per patient encounter was 2.9 (prescribing indicator 1). Kegogi and Magena had the highest average number of drugs prescribed per prescription of 3.6 while Egetuki had the least (2.1). The highest number of drugs prescribed in all the 900 encounters was 8 drugs (Magena) (Table 4.7).

Table 4. 7 Average number of drugs prescribed per encounter (n = 900 encounters)

PPHCC	Mean ± SD	Range	P-value
1	2.6 ± 0.9	1,5	0.042
2	3.6 ± 1.0	2,6	0.053
3	3.0 ± 1.0	1,6	0.042
4	2.8 ± 0.9	1,6	0.061
5	3.6 ± 1.2	1,8	0.043
6	3.3 ± 1.1	1,6	0.035
7	3.0 ± 0.8	1,5	0.060
8	2.1 ± 0.0	1,4	0.003
9	2.6 ± 0.7	1,4	0.048
10	2.6 ± 0.8	1,5	0.050
Overall	**2.9 ± 0.5**	**1,8**	**0.043**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

Regarding the overall number of drugs prescribed per encounter, 5.0%, 30.8%, 38.2% and 20.1% of the prescriptions had; one, two, three and four drugs, respectively. The rest of the prescriptions (5.8%) had more than four drugs as shown in Figure 4.4.

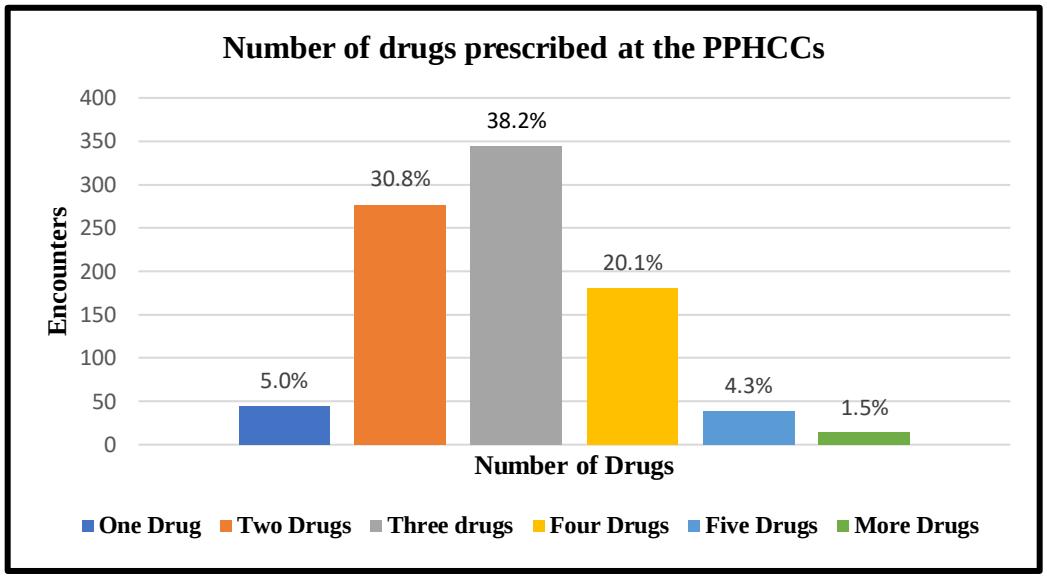

Figure 4. 4 Number of drugs prescribed per encounter at PPHCCs (n = 900 encounters)

Kegogi had no prescription with one drug. Oresi, Isecha, Egetuki, Kionyo, and Mosocho had no prescriptions with more than five drugs.

Table 4.8 shows the distribution of the number of drugs prescribed per encounter at each of the PPHCC.

Table 4. 8 Number of drugs prescribed per prescription at PPHCCs (n = 900 encounters)

PPHCC	One Drug	Two Drugs	Three Drugs	Four Drugs	Five Drugs	More Drugs
1	7 (7.8%)	37(41.1%)	30 (33.3%)	14 (15.6%)	2 (2.2%)	-
2	-	12 (13.3%)	32 (35.6%)	32 (35.6%)	10 (11.1%)	4 (4.4%)
3	1 (1.1%)	29 (32.2%)	37 (41.1%)	16 (17.8%)	5 (5.6%)	2 (2.2%)
4	5 (5.6%)	27 (30.0%)	41 (45.6%)	15 (16.7%)	1 (1.1%)	1 (1.1%)
5	4 (4.4%)	9 (10.0%)	25 (27.8%)	38 (42.2%)	10 (11.1%)	4 (4.4%)
6	3 (3.3%)	19 (21.1%)	28 (31.1%)	29 (32.2%)	8 (8.9%)	3 (3.3&)
7	4 (4.4%)	15 (16.7%)	51 (56.7%)	18 (20.0%)	2 (2.2%)	-
8	8 (8.9%)	58 (64.4%)	23 (25.6%)	1 (1.1%)	-	-
9	5 (5.6%)	35 (38.9%)	42 (46.7%)	8 (8.9%)	-	-
10	8 (8.9%)	36 (40.0%)	35 (38.9%)	10 (11.1%)	1 (1.1%)	-
Overall	**45**	**277**	**344**	**181**	**39**	**14**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

In three PPHCCs, the median number of drugs per prescription was 3. These facilities were Masimba, Entanda, and Isecha. In Egetuki, the median was 2 with 64.4% of the prescriptions having only 2 drugs.

4.5.6. Prevalence of generic prescribing

Out of the 2636 prescribed drugs, 706 (27.7%) were written in their generic names (prescribing indicator 2). The rest, 1,930 (72.3%), of the drugs were not written in their generic names. Of the drugs not prescribed by generic names, 1677 (86.9%) were prescribed by brand names and the remaining 253 (13.1%) had their generic names abbreviated. Isecha had the least number (7.8%) of the drugs prescribed by generic names while Kionyo had the highest (69.1%). Table 4.9 shows the prevalence of generic prescribing at the selected PPHCCs.

Table 4. 9 Number of drugs prescribed by generic name at PPHCCs (n = 2636 drugs)

PPHCC	Frequency	Prescribed by generic name	Percentage
1	237	30	12.7%
2	322	56	17.4%
3	271	125	46.1%
4	253	49	19.4%
5	325	48	14.8%
6	299	64	21.4%
7	269	21	7.8%
8	197	27	13.7%
9	233	161	69.1%
10	230	125	54.3%
Overall	**2,636**	**706**	**27.7%**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

The following drugs were prescribed using abbreviated names; tetanus toxoid – TT (91.2%), cotrimoxazole – CTX (62.7%), paracetamol – PCM (59.6%), artemether/ lumefantrine – AL (58.3%), ceftriaxone – CEF (27.1%), albendazole – ABZ (11.7%) and hydrochlorothiazide – HCTZ (10.9%).

4.5.7. Prevalence of antibiotic prescribing

Out of the 900 prescription encounters, 795 (84.8%) had antibiotics (prescribing indicator 3). Amoxicillin was the most widely (26.5%) prescribed antibiotic per encounter followed by cotrimoxazole (17.7%) and metronidazole (16.0%). Erythromycin was the least frequently (1.7%) prescribed antibiotic. Table 4.10 shows the main antibiotics prescribed at the PPHCCs' out-patient pharmacies.

Table 4. 10 Antibiotics commonly prescribed at PPHCCs (n = 795 encounters)

Antibiotics	Frequency	Percentage
Amoxicillin	211	26.5%
Cotrimoxazole	141	17.7%
Metronidazole	127	16.0%
Flucloxacillin	67	8.4%
Amoxicillin-clavulanic acid	62	7.8%
Ceftriaxone	56	7.0%
Ampicillin – cloxacillin	17	2.1%
Doxycyclline	15	1.9%
Erythromycin	14	1.7%
Others	85	10.7%
Overall	**795**	**100.0%**

Note: 'Other antibiotics' comprised of the rarely prescribed antibiotics at the PPHCCs which included; antituberculosis drugs, chloramphenicol, clarithromycin, and gentamycin.

Kegogi and Isecha had the highest proportion of encounters with antibiotics; 91.1%, and 90.0% respectively while Masimba had the least (77.8%). Figure 4.5 shows the distribution of antibiotic encounters at all the PPHCCs;

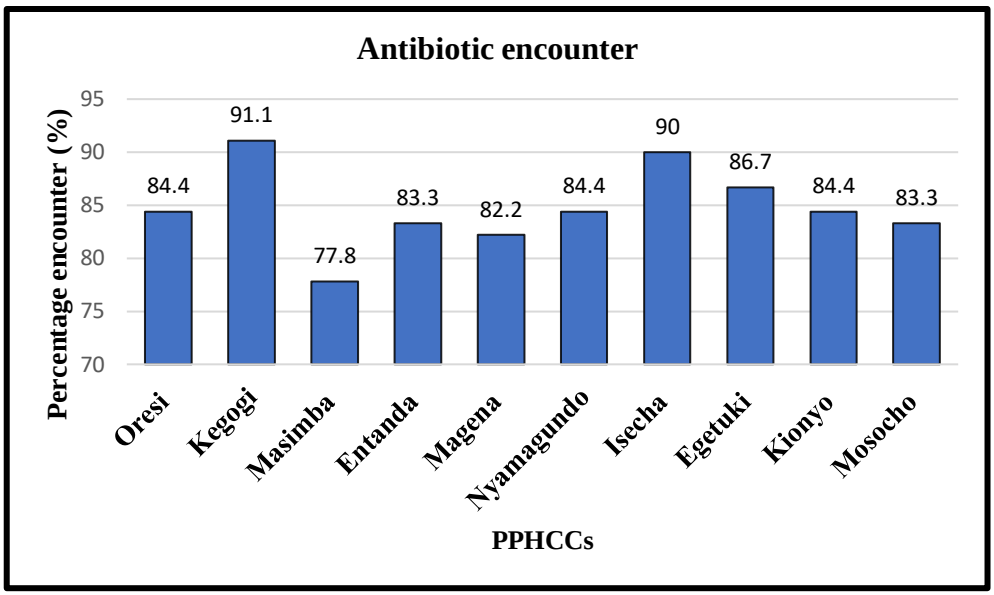

Figure 4. 5 Percentage antibiotic encounters at PPHCCs (n = 90 encounters/ PPHCC)

4.5.8. Prevalence of Injection prescribing

Out of the 900 encounters, 224 (24.9%) included injections (prescribing indicator 4).

Diclofenac injection was the most widely (38.2%) prescribed injection per encounter while the artesunate injection was the least frequently (0.7%) prescribed drug, (Table 4.11).

Table 4. 11 Injections commonly prescribed at PPHCCs (n = 267 injection encounters)

Injections	Frequency	Percentage
Diclofenac	102	38.2%
Ceftriaxone	65	24.4%
Tetanus toxoid	36	13.5%
Tramadol	21	7.9%
Hydrocortisone	15	5.6%
Aminophylline	6	2.2%
Artesunate	2	0.7%
Others	20	7.5%
Overall	**267**	**100.0%**

Note: 'Other injections' comprised of the rarely prescribed injections at the PPHCCs which included; medroxyprogesterone acetate, insulin, triamcinolone acetate, and tranexamic acid injections.

Based on the individual PPHCCs, Magena had the highest proportion of injection encounters (67.8%) while Oresi had the least (3.3%). In Kegogi, one out of every two adults received an

injection. In Magena, nearly 70% of the encounters resulted in an injection. Figure 4.6 shows the distribution of injection encounters at all the PPHCCs.

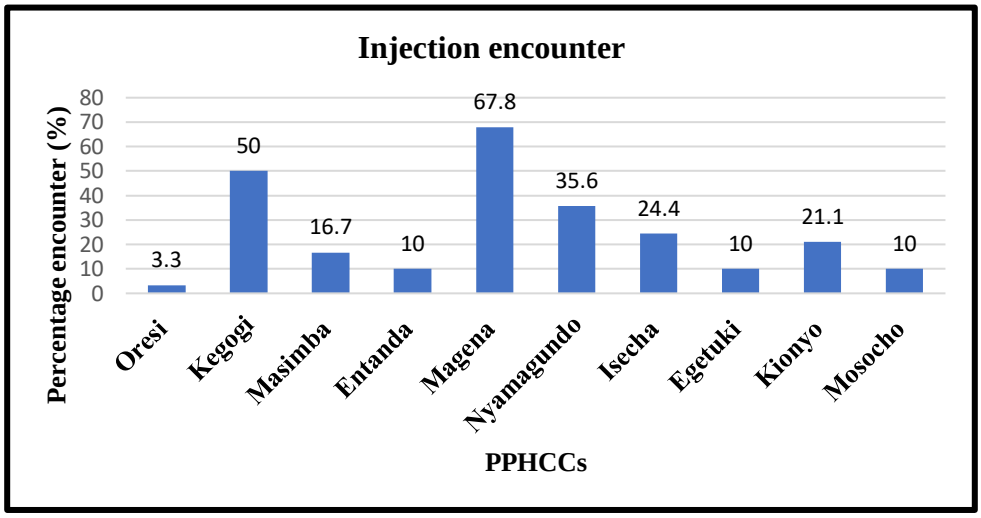

Figure 4. 6 Percentage Injection encounters at PPHCCs (n = 90 encounters/ PPHCC)

4.5.9. Compliance with KEML while prescribing

Out of the 2636 drugs prescribed, 2550 (96.7%) were prescribed from the KEML 2016 (prescribing indicator 5). All the facilities had almost all the drugs prescribed from the KEML. In Kionyo, all drugs prescribed were listed the KEML (Table 4.12).

Table 4. 12 Percentage of drugs prescribed that are in the KEML (n = 2636 drugs)

PPHCC	Frequency	Prescribed from KEML	Percentage
1	237	206	86.9%
2	322	318	98.8%
3	271	268	98.9%
4	253	234	92.5%
5	325	308	94.8%
6	299	297	99.3%
7	269	263	97.8%
8	197	195	99.0%
9	233	233	100.0%
10	230	228	99.1%
Overall	**2,636**	**2,550**	**96.7%**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

Only two drugs were found to be still being prescribed and yet they had been deleted from the KEML 2016. These drugs were; diclofenac injection in 124 encounters (13.8%) and chlorpheniramine oral liquid in 7 encounters (0.8%).

4.5.10. Overall comparison of prescribing indicators across facilities

Generally, the facilities performed poorly with regard to antibiotic prescribing, prescribing by generic names and the number of drugs prescribed. However, they fairly performed well in prescribing of injections and adhering to the KEML while prescribing. Table 4.13 demonstrates the summary performance of the findings of the five prescribing indicators at the selected PPHCCs in Kisii County.

Table 4. 13 Summary of the prescribing indicators at PPHCCs (n = 900 prescriptions)

PPHCCs	Core prescribing indicators				
	Average number of drugs prescribed per patient encounter	**Percentage of drugs prescribed by generic name**	**Percentage encounters with an antibiotic prescribed**	**Percentage encounters with an injection prescribed**	**Percentage of drugs prescribed from KEML 2016**
1	2.6 (1,5)	12.7	84.4	3.3	86.9
2	3.6 (2,6)	17.4	91.1	50.0	98.8
3	3.0 (1,6)	46.1	77.8	16.7	98.9
4	2.8 (1,6)	19.4	83.3	10.0	92.5
5	3.6 (1,8)	14.8	82.2	67.8	94.8
6	3.3 (1,6)	21.4	84.4	35.6	99.3
7	3.0 (1,5)	7.8	90.0	24.4	97.8
8	2.1 (1,4)	13.7	86.7	10.0	99.0
9	2.6 (1,4)	69.1	84.4	21.1	100.0
10	2.6 (1,5)	54.3	83.3	10.0	99.1
Mean (SD)	**2.9 (0.5)**	**27.7 (21.0)**	**84.8 (3.8)**	**24.9 (20.5)**	**96.7 (4.2)**
Optimal	**1.6 – 1.8**	**100**	**20 – 26.8**	**13.4 – 24.1**	**100**
ANOVA	***p* = 0.043**	***p* = 0.005**	***p* = 0.033**	***p* = 0.002**	***p* = 0.008**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

Performed well Moderately performed well Poorly performed

4.6. Patient – care Indicators

4.6.1. Consultation time

On the survey visit, between one to two prescribers were available at the selected facilities. The overall average consultation time at the PPHCCs was 4.1 (range 1, 14) minutes (patient – care indicator 1). Kegogi had the highest average consultation time of 6.8 (range 3, 11) minutes followed by Egetuki at 6.0 (range 2, 11) minutes. Oresi had the least 2.0 (range 1, 4) minutes as shown in Table 4.14.

Table 4. 14 Average consultation time at selected PPHCCs (n = 300 patients)

PPHCCs	Number of Prescribers	Number of patients	Average consultation time Min (Range)
1	2	30	2.0 (1, 4)
2	1	30	6.8 (3, 11)
3	2	30	3.3 (1, 9)
4	1	30	5.7 (2, 10)
5	1	30	3.0 (1, 5)
6	2	30	5.0 (3, 14)
7	1	30	4.5 (2, 10)
8	1	30	6.0 (2, 11)
9	1	30	2.4 (1, 4)
10	1	30	2.6 (1, 5)
Overall	**14**	**300**	**4.1 (1, 14)**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

4.6.2. Dispensing time

On the survey visit, only one dispenser was available at each facility. The average dispensing time in the PPHCCs was 131.5 (range 45, 360) seconds (patient – care indicator 2). Based on individual PPHCCs, Isecha had the highest average dispensing time of 200.2 (range 60, 360) seconds followed closely by Entanda at 190.0 (range 120, 360) seconds. Magena had the least average dispensing time of 88.0 (60, 180) seconds as shown in Table 4.15.

Table 4. 15 Average dispensing time at selected PPHCCs (n = 300 patients)

PPHCCs	Number of dispensers	Number of patients	Average dispensing Sec (Range)
1	1	30	115.5 (60, 240)
2	1	30	171.6 (60, 300)
3	1	30	104.3 (60, 300)
4	1	30	190.0 (120, 360)
5	1	30	88.0 (60, 180)
6	1	30	124.0 (60, 300)
7	1	30	200.2 (60, 360)
8	1	30	132.4 (45, 321)
9	1	30	92.9 (45, 180)
10	1	30	95.6 (57, 147)
Overall	**10**	**300**	**131.5 (45, 360)**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

4.6.3. Drugs actually dispensed

Out of 872 drugs prescribed to the outpatients, 656 (76.3%) drugs were dispensed to the patients (patient – care indicator 3). Oresi had the highest proportion (86.7%) of the drugs prescribed getting dispensed followed closely by Egetuki Hospital (86.2%). Kegogi Hospital had the least proportion (55.0%) (Table 4.16).

Table 4. 16 Percentage of drugs actually dispensed at PPHCCs (n = 872 drugs)

PPHCC	Number of drugs prescribed	Number of drugs dispensed	Percentage
1	75	65	86.7%
2	80	44	55.0%
3	108	79	73.1%
4	79	62	78.5%
5	123	76	61.8%
6	84	71	84.5%
7	87	69	79.3%
8	65	56	86.2%
9	93	67	72.0%
10	78	67	85.9%
Overall	**872**	**656**	**76.3%**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

4.6.4. Drugs adequately labeled

Out of the 656 drugs dispensed to the outpatients, 148 (22.6%) were adequately labeled (prescribing indicator 4). A drug was adequately labeled if the information found on the label of the dispensed drug observed during patient exit interview had the following details; the drug name, strength, dose, quantity dispensed and frequency of administration.

Entanda Hospital was the only PPHCC which recorded the highest percentage (93.5%) of the drugs dispensed adequately labeled. This was surprising because, on the day of the survey visit, the facility (Entanda) did not have a pharmacist or a pharmaceutical technologist as the dispenser. Actually, it was a nurse dispensing. Isecha Hospital performed worse (1.4%) (Table 4.17).

Table 4. 17 Percentage of dispensed drugs adequately labeled at PPHCCs (n = 656 dugs)

PPHCC	Number of drugs dispensed	Number of drugs adequately labeled	Percentage
1	65	7	10.8%
2	44	13	29.5%
3	79	29	36.7%
4	62	58	93.5%
5	76	19	25.0%
6	71	6	8.5%
7	69	1	1.4%
8	56	10	17.9%
9	67	3	4.5%
10	67	2	3.0%
Overall	**656**	**148**	**22.6%**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

In all the encounters, the following aspects of labeling were missing; patient name, storage conditions and any other special precaution concerning the drugs.

4.6.5. Patient knowledge of drugs dispensed

Three hundred (30/ PPHCC) outpatients were also interviewed to collect data on their level of knowledge concerning the drugs dispensed to them. They were assessed in the following areas; drug interactions, dosage, and side effects as shown in Table 4.18.

The overall score on patients' knowledge of drugs dispensed to them was 54.7%. Isecha had the highest score (71.1%) while Oresi had the least (44.7%). Patients' percentage knowledge on drug indications and dosage was good; 77.0% and 75.7% respectively. However, very few patients (11.3%) were aware of the side effects of the drugs issued to them.

Table 4. 18 Percentage patient knowledge of dispensed drugs at PPHCCs (n = 300 outpatients)

	Percentage patient knowledge of:			
PPHCC	**Drug indications**	**Drug dose and use**	**Drug side effects**	**Average**
1	63.3%	76.7%	0.0%	44.7%
2	73.3%	93.3%	13.3%	60.0%
3	83.3%	63.3%	20.0%	55.5%
4	80.0%	56.7%	3.3%	46.7%
5	63.3%	93.3%	3.3%	53.3%
6	90.0%	80.0%	10.0%	60.0%
7	96.7%	90.0%	26.7%	71.1%
8	70.0%	73.3%	26.7%	56.7%
9	83.3%	56.7%	10.0%	50.0%
10	66.7%	73.3%	0.0%	46.7%
Overall	**77.0%**	**75.7%**	**11.3%**	**54.7%**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

Kegogi and Magena had the highest fraction of patients who understood the correct drug dose and use, at 93.3%. The good score (93.3%) can be attributed to the presence of pharmaceutical technologists as dispensers at the two facilities. Entanda and Kionyo had the least score of 56.7% each. The score (56.7%) was understandable for Entanda since it did not have a pharmaceutical technologist, but surprising for Kionyo yet it had a pharmaceutical technologist available on the survey visit day.

4.6.6. Overall comparison of patient-care indicators across facilities

Generally, the facilities performed poorly with regard to patient consultation time and adequate labeling of drugs. However, they performed well in the time they took to dispense drugs to the patients. Table 4.19 demonstrates the summary performance of the findings of the five patient-care indicators at the selected PPHCCs in Kisii County.

Table 4. 19 Summary of the patient - care indicators PPHCCs (n = 300 patients)

PPHCCs	Core patient - care indicators				
	Average consultation time (minutes)	**Average dispensing time (seconds)**	**Percentage of drugs actually dispensed (%)**	**Percentage of drugs adequately labeled (%)**	**Patients' knowledge of dispensed drugs (%)**
1	2.0 (1, 4)	115.5 (60, 240)	86.7	10.8	44.7%
2	6.8 (3, 11)	171.6 (60, 300)	55.0	29.5	60.0%
3	3.3 (1, 9)	104.3 (60, 300)	73.1	36.7	55.5%
4	5.7 (2, 10)	190.0 (120, 360)	78.5	93.5	46.7%
5	3.0 (1, 5)	88.0 (60, 180)	61.8	25.0	53.3%
6	5.0 (3, 14)	124.0 (60, 300)	84.5	8.5	60.0%
7	4.5 (2, 10)	200.2 (60, 360)	79.3	1.4	71.1%
8	6.0 (2, 11)	132.4 (45, 321)	86.2	17.9	56.7%
9	2.4 (1, 4)	92.9 (45, 180)	72.0	4.5	50.0%
10	2.6 (1, 5)	95.6 (57, 147)	85.9	3.0	46.7%
Mean (SD)	**4.1 (1.7)**	**131.5 (41.5)**	**76.3 (10.9)**	**22.6 (27.5)**	**54.7 (8.0)**
Optimal	**≥ 10**	**≥ 90**	**100**	**100**	**100**
ANOVA	***p* = 0.046**	***p* = 0.004**	***p* =0.001**	***p* = 0.002**	***p* = 0.005**

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosocho

Performed well Moderately performed well Poorly performed

4.7. Facility-specific indicators

4.7.1. Availability of copies of KEML

Out of the 10 PPHCCs, only 2 (20%) were reported to have hard copies of the KEML 2016 booklets both at the prescribing and dispensing areas. The two were Oresi Hospital and Masimba. There were no drug formularies available at all the PPHCCs.

4.7.2. Availability of key essential drugs

Overall, 80.0% of the selected essential drugs assessed were available at the PPHCCs during the survey visit. Oresi, Kegogi, and Masimba had the highest percentage (94.4%) of the essential drugs in stock while Magena and Entanda had the least, i.e. 50.0% and 55.6% respectively as shown in Table 4.20.

Artemether/lumefantrine tablets, amoxicillin capsules, metronidazole tablets, and zinc sulfate tablets were all available in all the PPHCCs. Fluconazole tablets were the least likely to be in stock (40.0%) across all the PPHCCs as shown in Table 4.20.

Table 4. 20 Availability of essential drugs at the selected PPHCCs (n = 18 essential drugs)

		Availability of key essential drugs at the PPHCCs										
Essential drugs	**Strength**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**%**
Artemether + Lumefantrine (AL)	20mg + 120mg	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100.0
Artesunate vials	60mg vials	✓	✓	✓	×	×	✓	✓	×	×	✓	60.0
Paracetamol tablets	125mg/5ml, 500mg	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	90.0
NSAIDS(Ibuprofen)	100mg/5ml, 200mg	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	90.0
Aspirin	300mg	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	90.0
Amoxicillin capsules	250mg, 500mg	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100.0
Amoxicillin–clavulanic acid tabs	875mg + 125mg (1g)	✓	×	✓	×	×	✓	✓	×	×	✓	50.0
Benzathine-benzyl penicillin vials	900mg (1.2MU) vial	×	✓	✓	✓	✓	✓	✓	×	✓	✓	80.0
Metronidazole/ Tinidazole tablets	400mg/ 500mg	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100.0
Fluconazole tablets	200mg	✓	✓	×	×	×	×	✓	✓	×	×	40.0
Griseofulvin tablets	125mg	✓	✓	✓	×	×	×	✓	✓	✓	×	60.0
Nystatin	100,000 IU/ml	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	90.0
Clotrimazole vaginal pessaries	500mg	✓	✓	✓	×	×	✓	✓	✓	✓	✓	80.0
Acyclovir tablets	200mg	✓	✓	✓	✓	×	✓	✓	✓	×	×	70.0
Albendazole	400mg	✓	✓	✓	×	×	✓	×	✓	×	✓	60.0
ORS	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	90.0
Loperamide	2mg	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	90.0
Zinc Sulphate	20mg	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100.0
Percentage essential drugs availability at the PPHCCs		**94.4**	**94.4**	**94.4**	**55.6**	**50.0**	**88.9**	**94.4**	**83.3**	**72.2**	**72.2**	**80.0**

Note: - "✓": Available, "×": Not available

1 = Oresi, 2 = Kegogi, 3 = Masimba, 4 = Entanda, 5 = Magena, 6 = Nyamagundo, 7 = Isecha, 8 = Egetuki, 9 = Kionyo, 10 = Mosoho

CHAPTER FIVE

5.0 DISCUSSION

Worldwide, irrational drug use causes harm to patients (41). Core drug use indicators, as explained by the WHO/ INRUD, have provided simple and suitable measures used to assess the optimal use of drugs at healthcare centers (31). In the current study, the core indicators were used to describe the current patient management practices as well as the facilities' status; whether they were exceeding or underperforming with regards to the WHO/ INRUD set standard of practice.

5.1. Prescribing indicators

Prescribing practices impacts on patients' compliance and therapeutic success or failure. For prescribing practices to be of high quality, they should be safe, effective, cost-effective and patient-centered (42).

In the current study, there were more females than males; 59.3%, 40.7% respectively which corresponded to the study conducted in Makueni County (15) where the proportions for both females and males were 54.0% and 46.0% respectively. In both studies, it can be noted that females sought healthcare services more than males.

The average number of drugs prescribed per prescription was 2.9 (Table 4.4). The difference among the PPHCCs was statistically significant, $p = 0.043$, (Table 4.13). This figure was above the optimal range of 1.6 – 1.8 recommended by the WHO/ INRUD (31); hence indicating polypharmacy. Kegogi and Magena recorded the highest average number of drugs per prescription (3.6 drugs). No facility had an average number of drugs prescribed that were within the WHO/ INRUD recommended optimal range. In studies done in other countries, the average number of drugs per prescription was also higher and ranged between 2.5 and 4.8. The findings in the literature were; 2.5 in Egypt (43), 3.4 in Bahawalpur, Pakistan (44), 3.0 in Sri Lanka (45) and 4.8 in Ghana (46). However, a lower value is 1.4 in Sudan (47).

Incompetent prescribers, unavailability of STGs, lack of continuous medical education (CME) programs and the unavailability of therapeutically potent drugs at the PPHCCs could be the reasons

for the observed polypharmacy (44). Polypharmacy adversely influences patient treatment outcomes since they are likely to be non-compliant hence at higher risk of experiencing ADRs (43). Rational prescribing is encouraged by the WHO/ INRUD to avoid unnecessary excessive use (hence, wastage) of drugs and probable adverse effects on the patients (44). The recommended maximum of two drugs per prescription may not apply to patients with chronic illnesses. However, in this setting, this was appropriate as it was at primary health care facilities that were not expected to handle chronic illnesses. Also, under-prescribing has a risk of leading to poor patient management and worse outcomes.

That percentage of drugs prescribed by their generic name was 27.7% (Table 4.9). The difference among the PPHCCs was statistically significant, p = 0.005 (Table 4.13). Isecha had the least number (7.8%) of the drugs prescribed by generic names while Kionyo had the highest (69.1%) (Table 4.9). In studies carried out in other countries, the percentage of drugs prescribed by generic name was found to be less than 50%. For example, 6% in Andorra (48) and 38.3% in Uzbekistan (49). However, higher values were reported in other studies; 71.6% Nigeria (1), 95.4% at Alexandria in Egypt (43) and 99.4% in Malawi (16). In studies done in Kenya, the findings were; 25.6% at Mbagathi District Hospital (50) and 45.5% at Makueni County Referral Hospital (15). Based on the present study, the PPHCCs' clinicians in Kisii County rarely prescribe drugs by their generic names.

The WHO/ INRUD optimal percentage of drugs prescribed by the generic name is 100% (Table 2.3) (31). The findings of this study were way below the recommended value. This might be attributed to the belief of prescribers in branded drugs over generic products, extensive promotional activities by drug companies' medical representatives to the prescribers or absence of a policy of generic prescribing. The WHO/ INRUD recommends prescribing drugs by their generic names. It gives clear identification, allows easy information exchange and allows improved communication among health professionals (44).

The percentage of encounters with antibiotics prescribed was 84.8% (Figure 4.3). The difference among the PPHCCs was statistically significant, p = 0.033 (Table 4.13). Kegogi and Isecha had the highest proportion of encounters with antibiotics prescribed, 91.1% and 90.0% respectively while Masimba had the least (77.8%) (Figure 4.3). The percentage was found to be higher compared to other studies. For instance, at Arba Minch and Chencha Hospitals in Ethiopia, the

prevalence was 48.7% and 60.2% respectively (38). In India's PHCCs, it was 60.9% (5). Other studies had the following results; 35.4% Tanzania (51), 43.0% Nepal (52), 33.1% Burkina Faso (53), 50.0% Burundi (54) and 28.8% Brazil (54).

The WHO/ INRUD standard value for percentage encounter with an antibiotic prescribed is 20 - 26.8% (31). The prescribers at the PPHCCs in Kisii County might be overusing and misusing the antibiotics. The overuse and misuse of antibiotics, especially in developing countries, is a threat to the human population health. It can lead to increased antibiotic resistance, adverse effects/ ADRs and frequent hospital admissions of patients. It leads to wastage of scarce resources. A high prevalence of upper respiratory tract infections (URTIs) as was noted in most of the prescription diagnoses could be the reason for the unreasonable overuse of antibiotics (44).

The percentage of encounters with an injection prescribed was 24.9% (Figure 4.4). The difference among the PPHCCs was statistically significant, $p = 0.002$ (Table 4.13). Magena had the highest proportion of prescriptions with injections (67.8%) while Oresi had the least (3.3%) (Figure 4.4). In other studies, the prevalence of injection prescribing was 27.6% at the PHCCs in Malawi (16), 23.8% at Mbeya Health Center in Tanzania (51), 3.0% at the PHCCs at Kaski District in Nepal (52), 11.4% at PHCCs in Pakistan (44), 9% in Botswana (55) and 10.1% in Burundi (54). Other studies reported higher values such as 80.3% in Ghana (46) and 57.6% in Cambodia (54).

The WHO/ INRUD standard value for percentage encounters with an injection prescribed is 13.4% to 24.1% (31). The results of this study are slightly above the standard range. In most PPHCCs, Injections were rationally prescribed. Excessive use of injections, when oral dosage forms are readily available, is an example of irrational use of the injections. Injections are more expensive than orally taken drugs. Limited availability of alternative modes of therapy, attitudes, and beliefs of prescribers are some of the reasons for the excessive use of injections as reported in other studies. In Pakistan's rural areas, patients compel the prescribers to prescribe injections because of the belief of a quick and complete relief associated with injections (44).

The percentage of drugs prescribed from the KEML 2016 was 96.7% (Table 4.12). The difference among the PPHCCs was statistically significant, $p = 0.008$ (Table 4.13). All the PPHCCs had almost all the drugs prescribed from the KEML. In Kionyo Hospital, all the drugs (100.0%) were prescribed from the KEML (Table 4.12). However, it was notable that though many PPHCCs did not have copies of KEML, they prescribed from the list. It was noted that the electronic Kenya

Medical Supplies Agency (KeMSA) drug ordering tools, usually filled by the sub-county pharmacists, have only drugs listed in the KEML, hence the high adherence to the available drugs at the facilities by the prescribers while prescribing. In other studies conducted in Kenya, the percentage of drugs prescribed from the KEML was 72.2% at Mbagathi District Hospital (50) and 89.1% at Makueni County Referral Hospital (15). In studies done in other African countries, it was 95.4% at the PHCCs at Alexandria in Egypt (43), 100.0% at both Arba Minch and Chencha Hospitals in Ethiopia (38), 96.7% at the health facilities in Tanzania (51) and 86.1% in Nepal (52).

Prescribing drugs from the EML is one way of rational prescribing. Drugs listed in EML have been tested for safety and efficacy for a specific clinical setting/ country, with proven evidence-based clinical use, and are of lower cost. However, prescribers may not choose drugs not in the EML due to the inadequate supply of EML copies (44).

5.2. Patient – care indicators

The time that health – care providers devote to patients, majorly at the prescribing and dispensing areas, determines the quality of disease diagnosis and management (38). The average consultation time was 4.1 min (Table 4.14). The difference among the PPHCCs was statistically significant, $p = 0.046$ (Table 4.19). Kegogi and Egetuki had the highest average consultation time of 6.8 min and 6.0 min respectively. Oresi Hospital recorded the least (2.0 min). The optimum WHO/ INRUD value for average consultation time is $\geq$ 10 min (31). The time taken by the prescribers at the PPHCCs in the current study was too short, to conduct a thorough patient assessment and prescribe drugs appropriately. The little consultation time corresponded with findings reported in other countries (2.0 to 7.5 min). These were; 7.1 min at Alexandria's PHCCs in Egypt (43), 2.2 min at PHCCs in Bahawalpur, Pakistan (44), 3.8 min in Ethiopia's PHCCs (38) and 2.0 min at the PHCCs of Kaski District, Western Nepal (52). However, the study conducted in Nigeria reported a better consultation time of 11.3 min (56).

Insufficient consultation time can lead to an incomplete examination of patients and subsequently irrational therapy (41). Prescribers need to take sufficient time with patients to carry out comprehensive history taking, patient examination, provide suitable health education and ensure good clinician-patient rapport. This is significant as it ensures good patient-care. The increased

workload of the prescriber and religious, ethnic or socioeconomic barriers between HCWs and patients could be the reasons for the short consultation time (44).

The average dispensing time was 131.5 s (Table 4.15). The difference among the PPHCCs was statistically significant, $p = 0.004$ (Table 4.19). Isecha had the highest average dispensing time of 200.2 s followed closely by Entanda (190.0 s). Magena had the least (88.0 s).
The optimum value set by the WHO/ INRUD for average dispensing time is ≥ 90 s (31). In comparison to the WHO/ INRUD minimum time, the dispensers at the PPHCCs took sufficient time in processing the prescriptions and ultimately dispensing the prescribed drugs to the patients. In most studies conducted around the world, the average dispensing time was lower than that of the current study. The findings were; 47.4 s at Alexandria's PHCCs in Egypt (43), 38.0 s at PHCCs in Bahawalpur, Pakistan (44), 42.5 s at the PHCCs of Kaski District, Western Nepal (52), 12.5 s in Nigeria (56) and 78 s in Ethiopia (38). A study carried out at public hospitals in Ethiopia found more time taken by the dispensers at an average of 219.6 s (17).

Short dispensing time, as was noted in other studies, is not adequate to explain key information about the drug(s) (dosage, adverse effects, and precautions) to the patient(s) as well as label the drug(s) adequately and dispense them to patients. Adherence of patients to drug use instructions directly depends on his/her knowledge about the drug(s). Prolonging the dispensing time is important in improving patient care. Little dispensing time may be linked to a high patient load and non-qualified personnel as dispensers, thus limited time to counsel patients (44).

The percentage of drugs actually dispensed was 76.3% (Table 4.16). The difference among the PPHCCs was statistically significant, $p = 0.005$. Oresi had the highest proportion (86.7%) of the drugs prescribed dispensed followed closely by Egetuki (86.2%) while Kegogi had the least (55.0%). The recommended optimal value of drugs actually dispensed by the WHO/ INRUD is 100% (31). The finding of this study was less than those found in other places such as; 95.9% at PHCCs in Egypt (43), 83.4% Ethiopia (38), 85.3% Nigeria (56) and 89.6% at PHCCs of Kaski District, Western Nepal (52). However, the percentage was higher compared to that reported at the public health facilities of Tanzania (56.2%) (51). This could because drugs were out-of-stock. Hence, the drug supply chain needed strengthening.

Drugs at the PPHCCs are usually dispensed free of charge to the patients. The findings of this study could be an indication that some drugs were out of stock, hence not dispensed. An inadequate

supply of drugs to the PHCCs has effects on the patients' health outcomes, convenience, and trust in a healthcare system (44).

Drug labeling practice was very poor at the selected PPHCCs. The percentage of drugs dispensed adequately labeled was 22.6% (Table 4.17). The difference among the PPHCCs was significant, $p = 0.002$. Entanda recorded the highest percentage (93.5%) of the drugs adequately labeled. Isecha performed worse (1.4%). The majority of the dispensers only wrote the frequency of administration of drugs on the drug package or envelop/ bag. WHO/ INRUD recommends that each drug label should contain; patient name, dose regimen, dose, frequency of administration and quantity of the drug. (31). Poor labeling of dispensed drugs could be due to lack of enough time to dispense well to large patient numbers or poor training of the dispensing personnel.

The poor labeling practices noted in this survey was similar to the findings of the survey performed at PHCCs in Eastern Province of Saudi Arabia (10.4%) (6) and Tanzania (20.1%) (51) where patient names and other vital details about the drug dosage regimen were not written in the labels (57). However, all drugs dispensed were adequately labeled (100.0%) in the Tertiary Care Hospital of India (58). The findings in Cambodia were worse (0.0%) compared to the current study (59).

Poor drug labeling can be attributed to a lack of appropriate labeling systems in place at the PPHCCs. The omission of patient name, storage conditions and any other special precaution concerns on the drug label is a serious matter. This can lead to serious consequences such as drug misuse, and abuse by patients (44).

Patients' percentage knowledge on dispensed drugs was average, at 54.7% (Table 4.18). The difference among the PPHCCs was statistically significant, $p = 0.005$. Kegogi and Magena had the highest proportion of patients who knew the correct drug dose and use (93.3%). Entanda and Kionyo had the lowest score of, 56.7 and 65.0% respectively (Table 4.18). The patients' knowledge of the drugs' side effects was very poor (11.3%) and fairly good (77.0%) on drug interactions. Poor patient knowledge of the drugs dispensed to them could be due to dispensers' negligence while assuming that the patients understood well of the drugs dispensed to them or the patients' lack of interest in understanding the drugs information well.

The optimal WHO/ INRUD value for patients' percentage knowledge on correct drug dosage is 100% (31). The findings of this study (54.7%) were a bit higher than those obtained from the

Tertiary Care Hospital in India (46%) (58), Tanzania (37.9%) (51) and Malawi (27.1%) (16). However, the study findings were much lower than those reported at the PHCCs at Alexandria, in Egypt (94.1%) (43), and Nigeria (93.2%) (56).

The patient's knowledge of drug dosage is important. It helps in improving patient care by; avoiding overuse and abuse of drugs; and preventing ADRs/ adverse effects that can cause harm to the patient's health. The increased workload of the dispensers, unavailability of qualified pharmacy personnel in all facilities and poor patient understanding skills could be the reason for the poor drug-related knowledge of the patients.

5.3. Facility-specific indicators

In any health - care center, availability of qualified prescribers and dispensers, adequate supply of key drugs and information access about drugs, such as EMLs/ formulary, influences the ability to prescribe and dispense drugs rationally. Without these factors, it is difficult for HCWs to provide health services efficiently (31).

Out of the 10 PPHCCs, only 2 (20.0%) (Oresi and Masimba) had copies of the KEML 2016 booklets available both at the prescribing and dispensing areas. The findings (20.0%) were not consistent with the study carried out at Alexandria's PHCCs in Egypt where 8 (80.0%) out of 10 PHCCs had copies of the EML (43), (62.3%) in Nigeria (56) and (67.4%) in Malawi (16). The surveys performed at the PHCCs of Kaski District's in Western Nepal (52) and those at Bahawalpur, Pakistan (44) found that all the facilities (100.0%) had copies of EML.

The WHO/ INRUD requires that all health facilities have copies of EML (31). This is aimed at ensuring adherence of prescribers to the medicines listed in the EML when prescribing to promote the efficient provision of healthcare to patients (44).

Eighty percent (80.0%) of the selected essential drugs assessed were available at the PPHCCs at the time of the survey visit (Table 4.20). Oresi, Kegogi, and Masimba had the highest (94.4%) percentage of the key drugs in stock while Magena and Entanda had the least; 50.0 and 55.6% respectively. The findings (80.0%) of this study were higher than those found at the PHCCs in Kragujevac in Serbia (38.7%) (60) and Chencha Hospital (63.3%) in Ethiopia (17). Other studies had better findings; 100.0% in Tanzania (51), 90.9% in Nigeria (56) and 86.6% in Cambodia (59).

WHO/ INRUD recommends 100% availability of essential drugs at the health facilities (31). The shortage of key drugs is detrimental to patients with regard to their health status and out-of-pocket expenses (44).

5.4. Study strengths

The use of WHO/INRUD guidelines on the three core drug use indicators and adherence to the WHO methodology offers more strength to the study. Also, adding to the study strength was; the use of a large sample size of 900 prescriptions and 300 outpatients (observations and interviews).

5.5. Study limitations

The reasons for the irrational use of drugs could not be revealed in this study because it was limited. Further studies are necessary to disclose these reasons. Also, being a cross-sectional and retrospective study, there could have been an information bias and desirability.

The WHO/ INRUD threshold mainly applies to the out-patient setting and would be inappropriate for the in-patient setting where there is a greater prevalence of use of injectable formulations.

Given that there are seasonal differences in disease patterns, the findings may not apply to other parts of the year. Also, in the last quarter of the year, there happens to be a lot of rural-urban migration and therefore the findings may not apply over the whole year.

The prescribers and hospital managers were not interviewed. The prescription audit was retrospective and this could have affected data quality.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1. Conclusion

With regards to the prescribing indicators, most of the results in this survey greatly deviated from the WHO/ INRUD recommended optimal values except that of the percentage encounter with an injection prescribed and percentage prescribing from the KEML. Percentage encounter with an injection prescribed (24.9%) was slightly above the recommended range of 13.4% - 24.1% while percentage prescribing from the KEML (96.7%) was slightly below the recommended percentage of 100%. The average number of drugs prescribed per encounter (2.9 drugs) was greater than the recommended range of 1.6 – 1.8 drugs, thus indicating the practice of polypharmacy. The percentage of drugs prescribed by generic names (27.7%) was way less than the proposed one of 100%. The percentage encounters with antibiotic prescribed (84.8%) was also way above the recommended 20.0% – 26.8%, indicating the irrational use of antibiotics.

Concerning the patient care indicators, the findings were far from the optimal values except that of the average dispensing time (131.5 s) which was above the recommended ≥ 90 s, confirming one of the good dispensing practices in place. The average consultation time (4.1 min) was less than the proposed ≥10 min, suggesting an incomplete assessment of patients for diagnosis and subsequent irrational therapy. The percentage of prescribed drugs actually dispensed (76.3%) was lower than the recommended 100%, indicating some degree of drug stock-outs. The percentage of drugs adequately labeled (22.6%) was greatly below the recommended 100%, indicating a lack of appropriate labeling systems in place. Patients' percentage knowledge of drugs dispensed to them (54.7%) was average but still lower than the proposed 100%, suggesting drug misuse and abuse by patients.

Finally, for the facility-specific indicators, the findings deviated from the optimal value especially on percentage availability of KEML copies (20%), far below the recommended 100%. This could partially explain the non-adherence of prescribers to the drugs listed in the KEML when prescribing, hence irrational prescribing. The percentage availability of key drugs (80.0%) was also slightly below the recommended 100%, depicting, to some extent, drug stock-outs.

6.2. Recommendations

6.2.1. Policy and practice

The County Health Management Team (CHMT) together with other stakeholders should design/ strengthen the periodic CMEs, workshops, and seminars on good prescribing and patient-care practices for the county's HCWs.

The programs will help the prescribers to; prescribe an effective minimum number of drugs to patients and encourage the use of fixed-dose combinations (FDCs), prescribe drugs by their generic names, promote rational prescribing of antibiotics and injections, adhere to the KEML when prescribing and prolong consultation time. The dispensers need to be encouraged to educate patients on drug dosage and use. The County Pharmacist should develop and adopt a drug labeling system to enhance adequate drug labeling at the health facilities. The CHMT should establish antimicrobial stewardship committees in all facilities, equip all health facilities with enough copies of the KEML, improve the availability of essential drugs.

6.2.2. Future studies

The CHMT should conduct periodic prescription surveys and drug utilization studies at the health facilities to assist in finding any forms of irrational prescribing and dispensing practices. The findings of such studies should be disseminated to the HCWs, followed by relevant interventions to remedy any problems identified.

The WHO/INRUD methodology should not be used alone to provide conclusions on rational drug use. This survey was just a baseline for examining core indicators of appropriate drug use, further studies at the county and countrywide should be carried out for ongoing evaluation and measuring the drug use patterns.

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APPENDICES

Appendix A: Individual patient prescription data form

PPHCC Code…….

Name of research assistant……Date……

<table>
<tr><th colspan="4">INDIVIDUAL PATIENT PRESCRIPTION DATA FORM</th></tr>
<tr><td>Patient Sequence No.</td><td colspan="3"></td></tr>
<tr><td>Gender (M/F)</td><td colspan="3"></td></tr>
<tr><td>Diagnosis</td><td colspan="3"></td></tr>
<tr><td rowspan="12"></td><td colspan="3">Drug(s) prescribed (As written on the prescription form)</td></tr>
<tr><td>No.</td><td>Drug(s)</td><td>Dosage</td></tr>
<tr><td>1</td><td></td><td></td></tr>
<tr><td>2</td><td></td><td></td></tr>
<tr><td>3</td><td></td><td></td></tr>
<tr><td>4</td><td></td><td></td></tr>
<tr><td>5</td><td></td><td></td></tr>
<tr><td>6</td><td></td><td></td></tr>
<tr><td>7</td><td></td><td></td></tr>
<tr><td>8</td><td></td><td></td></tr>
<tr><td>9</td><td></td><td></td></tr>
<tr><td>10</td><td></td><td></td></tr>
<tr><td>Additional information</td><td colspan="3"></td></tr>
</table>

Appendix B: Individual patient - care indicator guide form

PPHCC Code…….

Patient Code……..

Name of research assistant……Date……

PART ONE			
OBSERVATIONS	**Consultation Time**	**Time**	**Time taken (Min)**
	Time in		
	Time Out		
	Dispensing Time	**Time**	**Time taken (Sec)**
	Time in		
	Time out		
	No. of Drugs Prescribed		
	List of drugs prescribed		
	No. of Drugs Dispensed		
	List of drugs NOT Dispensed		
	No. of Drugs labeled correctly		
	List of drugs labeled incorrectly		

PART TWO

	Patient Knowledge on Drugs	**Response**
INTERVIEW	Do you know why you have been given each of the drug(s)? *Unafahamu mbona umepewa kila moja ya dawa hizi?* *Nobe nobomanyi ng'a ninki kwaerwa kera eriogo kwaegwa?*	Yes ◯ No ◯
	Explain what each of your drugs is used for: *Fafanua kuhusu matumizi ya kila dawa:* *Karwe okoera igoro y,emeremo ya kera eriogo:*	Knows ◯ Does not know ◯
	Do you know when to take each of your drug(s)? *Wafahamu wakati wa kutumia kila moja ya dawa hizi?* *Nomanyete chingaki obwenerete konywa kera eriogo kwaegwa?*	Yes ◯ No ◯
	Describe how you will take each of the drugs: *Toa maelezo ya jinsi utakavyo tumia kila moja ya hizi dawa:* *karwe okoera buna ogochia konywa amariogo ayaiga:*	Knows ◯ Does not know ◯
	Have any side effect of the drug(s) been explained to you? *Umeelezwa kuhusu madhara yoyote ya dawa hizi?* *Notebirie eki kerache kobwatekana nobotumeki bw'amariogo ayaiga?*	Yes ◯ No ◯
	Describe any side effects of your drugs that have been explained to you: *Toa maelezo kuhusu madhara yoyote ya dawa hizi yaliyotolewa kwako:* *Karwe okoera igoro y'obobe bonde bwonsi borache kobwatekana n'obotumeki bw'amariogo aya:*	Knows ◯ Does not know ◯
	Other Comments:	

Appendix C: Facility-specific indicator interview guide

PPHCC Code……

Name of Investigator……Date……...

Question		Response	
		YES	**NO**
Does this facility have qualified prescriber(s)?			
Does this facility have qualified dispenser(s)?			
Does the facility have copies of the KEML/ Formulary?			
Does the facility have the following drugs in stock?			
Common Health Problem	**Key Drug(s)**		
Malaria	AL		
	Artesunate vials		
Pain	Paracetamol tablets		
	NSAIDs (Ibuprofen)		
	Aspirin		
Bacterial infections	Amoxicillin capsules		
	Amoxicillin-clavulanic acid tabs		
	Benzathine-benzyl penicillin vials		
Protozoal Infections	Metronidazole/ Tinidazole tablets		
Fungal infections	Fluconazole tablets		
	Griseofulvin tablets		
	Nystatin		
	Clotrimazole vaginal pessaries		
Viral Infections	Acyclovir tablets		
Helminth Infestations	Albendazole/ Mebendazole		
Diarrhea	ORS		
	Loperamide		
	Zinc Sulphate		
Percentage of drugs in stock			

Appendix D: Drug use indicator consolidation form

Name of Investigator…… Date……..

Facility	Average number of drugs prescribed	Percent of by generic name	Percent with an antibiotic	Percent with an injection	Percent from KEML 2016	Average consultation time (Minutes)	Average dispensing time (Seconds)	Percentage of drugs actually dispensed	Percentage of drugs adequately labeled	Percentage with adequate knowledge of dosage	Percent of drugs in stock
Total											
Average											
Percentage											

Appendix E: List of operational PPHCCs in Kisii County

-

No.	Code	Name	Level
1	13502	Bitare health center	Level 2
2	20936	Bobaracho Dispensary	Level 2
3	13505	Boige Health Centre	Level 3
4	16974	Bokimai Dispensary	Level 2
5	13511	Borangi Health Centre	Level 3
6	20112	Bouti Dispensary	Level 2
7	13536	Eberege Health Centre	Level 2
8	13537	Ebiosi Dispensary	Level 2
9	16975	Eburi Dispensary	Level 2
10	13538	Egetonto Health Centre	Level 2
11	19984	Egetuki GOK Dispensary	Level 2
12	16422	Ekerubo Dispensary (Kisii South)	Level 2
13	13541	Ekerubo Health Centre	Level 2
14	17272	Emeroka Dispensary	Level 2
15	13545	Entanda Health Centre	Level 2
16	16424	Entanke Dispensary	Level 2
17	13546	Eramba Health Centre	Level 2
18	22633	Gekonge Dispensary	Level 2
19	13558	Gesabakwa Health Centre	Level 3
20	13560	Gesuguri Dispensary	Level 2
21	13561	Gesure Dispensary (Sameta)	Level 2
22	13568	Geteri Dispensary	Level 2
23	13573	Giatunda Dispensary	Level 2
24	19916	Gionsaria Health Centre (Nyamache)	Level 3
25	13580	GK Prisons Dispensary (Kisii)	Level 2
26	13593	Gotichaki Health Centre	Level 2
27	22629	Ikorongo Dispensary	Level 2
28	13620	Iranda Health Centre	Level 3
29	13621	Irondi Dispensary	Level 2
30	16425	Isamwera Dispensary	Level 2
31	13623	Isecha Health Centre	Level 3
32	16879	Itembu Dispensary	Level 2
33	13627	Itibo Eramani Dispensary	Level 2
34	13630	Itumbe Dispensary	Level 2
35	13631	Iyabe District Hospital (Kisii South)	Level 3
36	17435	Keera Dispensary	Level 2
37	13662	Kegogi Health Centre	Level 3
38	13671	Kenyambi Health Centre	Level 3
39	13675	Kenyerere Health Centre (Masaba S)	Level 2
40	13674	Kenyerere Sub County Hospital	Level 2
41	19996	Kenyoro Dispensary	Level 2
42	18336	Keragia Health Centre	Level 2
43	13681	Kiagware Dispensary	Level 2
44	13683	Kiamokama Sub County Hospital	Level 3
45	13685	Kiaruta Dispensary	Level 2
46	19917	Kiobegi Dispensary (Nyamache)	Level 2
47	20113	Kioge Dispensary	Level 2
48	13696	Kiogoro Dispensary	Level 3
49	13697	Kionyo Sub County Hospital	Level 3
50	21018	Kisii County Beyond Zero Clinic	Level 2
51	13748	Magena Health Centre	Level 2

52	13749	Magenche Health Centre	Level 2
53	21449	Maroba Dispensary	Level 2
54	13786	Masongo Dispensary	Level 2
55	13790	Matongo Dispensary	Level 2
56	13814	Misesi Sub County Hospital	Level 2
57	18447	Moogi Dispensary	Level 2
58	20114	Mosocho Market Disp	Level 2
59	13825	Moticho Health Centre	Level 3
60	16984	Motonto Health Centre	Level 2
61	13847	Nduru Health Centre	Level 3
62	16880	Nyabiosi Health Centre	Level 2
63	16423	Nyabioto Dispensary	Level 2
64	13868	Nyachenge Dispensary	Level 2
65	13869	Nyachogochogo Dispensary	Level 2
66	13872	Nyagiki Dispensary	Level 2
67	13876	Nyagoto Dispensary	Level 2
68	13878	Nyaguta Dispensary	Level 2
69	13882	Nyakegogi Dispensary	Level 2
70	13886	Nyakwana Dispensary	Level 2
71	16265	Nyamagesa Dispensary	Level 2
72	16878	Nyamagiri Dispensary	Level 2
73	13892	Nyamagundo sub-county hospital	Level 2
74	13893	Nyamagwa Health Centre	Level 3
75	13903	Nyamasibi Sub-County Hospital	Level 2
76	13908	Nyamemiso Dispensary	Level 2
77	13983	Nyamogonchoro Health Centre	Level 2
78	20133	Nyamokenye Health Centre(Sameta)	Level 3
79	13931	Nyanko Dispensary	Level 2
80	13933	Nyansakia Health Centre	Level 3
81	13934	Nyansancha Dispensary	Level 2
82	13938	Nyansira Dispensary	Level 2
83	17714	Nyaore Dispensary	Level 2
84	13942	Nyasike Dispensary	Level 2
85	13945	Nyatike Health Centre	Level 3
86	21053	Nyaura Dispensary	Level 2
87	13982	Omobera Dispensary	Level 2
88	13984	Omogwa Dispensary	Level 2
89	13986	Omosaria Dispensary	Level 2
90	16973	Openda Dispensary	Level 2
91	13991	Oresi Health Centre	Level 3
92	13992	Oroche Dispensary	Level 2
93	22483	Otamba Dispensary	Level 2
94	14025	Raganga Health Centre	Level 3
95	14029	Ramasha Health Centre	Level 2
96	14045	Riana Health Centre	Level 3
97	17347	Rikendo Dispensary	Level 2
98	14054	Riotanchi Health Centre	Level 3
99	14062	Rusinga Dispensary	Level 2
100	14083	Sieka Dispensary	Level 2
101	14099	Sosera Health Centre	Level 2
102	22135	Sugubo Dispensary	Level 2
103	14131	Suguta Sub County Hospital	Level 3
104	14142	Taracha Dispensary	Level 2

Appendix F: Patient consent form

Consenting process

You are being invited to participate in a medical research that seeks to assess the core drug use indicators using the WHO/INRUD guideline at the primary healthcare centers within Kisii County. Before you make a decision to participate, it is important for you to understand why the survey is being done and what it will involve. Please take time to read the following information carefully and feel free to ask for more information, especially if there is anything you do not understand. Permission is required from you to enroll in this medical research. You should understand the following general principles which apply to all the participants in a medical research:

1) Your agreement to participate in this study is voluntary
2) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
3) After you have read the explanation, please feel free to ask any questions that will enable you to understand clearly the nature of the study

Title of the study: Examination of Core Indicators of Appropriate Drug Use at Public Primary Healthcare Centers in Kisii County, Kenya

Investigator: Aggrey Orwenyo Nyabuti – student and the principal investigator. P.O. BOX 50-40100 Nyamira. Tel: 0729595818

Introduction to the study

Rational drug use is essential to optimize the quality of healthcare delivery and resource utilization. It is a complex subject involving the prescriber, the dispenser, the patient and the health institutions. It is influenced by factors such as drug availability, prescriber's experience, and knowledge of dispensers, health budget, cultural factors and many more. Inappropriate drug use is a worldwide problem; however, the degree of the problem is higher in developing countries like Kenya. Knowledge gap, loose drug control, loads on healthcare providers and patient beliefs are some of the factors contributing to this problem.

In this survey, I will be collecting information on the prescribing practices, facility-specific information, and patient – care information where you will be needed most. Here I will be collecting information on the consultation time, dispensing time, drugs dispensed and drug labeling and your knowledge about the drugs issued to you.

Purpose of the study: the main objective of this research is to assess the drug use pattern at PPHCCs in Kisii County, Kenya

Patient participation: in this survey, I will not interrupt your treatment process. I will not join you in the consultation room, hence your privacy and confidentiality will be strictly observed. I will just monitor from a distance to capture the time you spend in the consultation room and the time is taken for you to receive drugs from the pharmacy. However, I would request you to allow me to have a look at your prescription and drugs dispensed to you. This is to allow me to note down the number of drugs prescribed, dispensed and how they are labeled. Finally, I will interview you concerning the drugs to note if you understood well on when and how to use them. This will enable in evaluating the key indicators of patient - care practices and patient knowledge on the drugs dispensed to them.

Benefits: there will be no direct benefits to you but the findings of this study will be useful in improving the rational use of drugs, improve the patient – care services and help enhance the facility-specific needs needed for management of patients.

Risks: there will be no risk involved in this study.

Confidentiality: utmost privacy and confidentiality will be ensured. Your name will not be mentioned or used during data handling or resulting publications. Study codes and numbers will be used instead.

Contacts: please feel free to contact me, my academic department or Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee for any clarification or concerns. Use the contacts provided below:

Institution: Department of Pharmacology and Pharmacognosy, School of Pharmacy, University of Nairobi, P.O. BOX 30197-00400, Nairobi.

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PATIENT STATEMENT OF CONSENT

I confirm that I have read and understood the information given above for the study. I have had the opportunity to consider the information, asked questions and I have had them answered satisfactorily. I understand that my participation is voluntary and I am free to leave at any time without giving any reason, without violation of any rights.

I agree to take part in this study.

Patient:

Name…….Signature……Date ……/……./2019

Investigator:

Name…….Signature……..Date ……/……./2019

KIPENGELE CHA F1: FOMU YA KIBALI CHA MGONJWA

Umealikwa kushiriki katika utafiti wa kimatibabu unaokusudia kutathmini viashiria muhimu vya dawa, kuzingatia mwelekezo wa shirika la afya ulimwenguni, WHO/UNRUD katika vituo vya kutoa huduma za afya za msingi katika gatuzi la Kisii.

Kabla uufanye uamuzi wa kushiriki, ni muhimu kuelewa kusudi la utafiti huu na utakachokihusisha. Chukua muda wako kusoma maelezo kwa makini, na uko radhi kuuliza kupewa maelezo zaidi, ikiwa lipo jambo hujaelewa.

Idhini yahitajika kutoka kwako ili kujisajili kama mshiriki katika utafiti huu. Ni heri pia uelewe kanuni zifuatazo zitakazotumika kwa washiriki wote katika utafiti huu wa kimatibabu:

1. Makubaliano ya kushiriki ni kwa hiari.
2. Unaruhusiwa kujiondoa kwenye utafiti huu, muda wowote, pasipo kutoa sababu ya kujiondoa kwako.
3. Baada ya kusoma maelezo, una uhuru kuuliza swali lolote litakalokuwezesha kuelewa bayana jinsi utafiti huu ulivyo.

Mada ya utafiti: Udadizi wa Viashiria Msingi vya Matumizi Mwafaka ya madawa katika vituo vya utoaji Afya Msingi katika Gatuzi la Kisii, Kenya.

Mtafiti: Aggrey Orwenyo Nyabuti**,** Mwanafunzi na mtafiti mkuu**,** Sanduku la posta, 50-40100, Nyamira**,** Nambari ya simu: 0729 595 818.

Utangulizi kwa utafiti huu: Matumizi mema ya dawa, ni mihimu katika kuboresha viwango vya huduma za afya pamoja na matumizi bora ya rasilimali. Ni swala nyeti ambalo umuhusisha anayetoa idhini, ya matumizi, msambazaji dawa, mgonjwa, pamoja na vituo vya afya. Swala hili huchochewa na vigezo vingine kama: upatakanaji rahisi wa dawa, tajriba ya mhudumu anayetoa dawa hizo, ujuzi wa msambazaji wa dawa hizo, makadirio wa afya, tamaduni pamoja na vigezo vingine vingi.

Makadirio ya dawa, yanachukua kati ya asilimia ishirini na asilimia hamsini ya jumla ya makadirio yote ya afya katika nchi zinazostawi kiuchumi. Matumizi yasiyofaa ya dawa ni tatizo sugu ulimwenguni kote. Hata hivyo, viwango vya matumizi hayo vimekidhiri zaidi katika mataifa yanayostawi kiuchumi, kwa mfano, Kenya.

Viwango vya elimu, utepetevu katika kuzuia matumizi yasiyofaa ya dawa, majukumu mengi kwa watoaji wa huduma za afya pamoja na mila na itikadi za mgonjwa, ni baadhi tu ya maswala yanayochangia kuzidi kwa tatizo hili.

Katika utafiti huu, nitakusanya maelezo kuhusu mazoea ya kuidhinisha matumizi ya dawa- hususan maelezo kamili na maelezo ya huduma kwa mgonjwa, ambako utahitajika zaidi. Nitakuwa nikikusanya maelezo kuhusu mambo yafuatayo;

1. Muda unaotumika kutafuta ushauri.
2. Muda unaotumika kusambaziwa dawa.
3. Aina za dawa zinazosambazwa.
4. Maelezo kuhusu dawa iliyosambazwa.
5. Ufahamu wako kuhusu dawa uliyosambaziwa.

Kusudi la utafiti huu: Madhumni makuu ya utafiti huu ni kufikia namna dawa hutumika, kwa kuzingatia viashiria muhimu vya shirika la afya ulimwenguni, WHO/INRUD katika PHCC Kisii , Kenya.

Kushiriki kwa mgonjwa: Katika utafiti huu,sitajaribu kuhitirafiana na matibabu yako. Sitajiunga nawe kwenye chumba cha kutolewa ushauri. Hivyo basi uhuru wako pamoja na siri zako zitalindwa vilivyo. Nitakuwa ninachunguza kwa umbali kidogo ili niweze kutambua muda uliouchukua kwenye chumba cha ushauri na muda uliochukua kupewa dawa kutoka kwa chumba cha madawa.

Hata hivyo, nitakuomba uniruhusu nitazame dawa ulizoandikiwa na aina ya dawa ulizosambaziwa. Hili litaniwezesha kufahamu idadi ya madawa ulizoandikiwa, idadi ya madawa ulizosambaziwa na kama zimeandikwa kwenye pakiti vyema. Mwisho, nitakuhoji kulingana na dawa ulizopewa ili kufahamu ikiwa waelewa muda wa kuzitumia na namna ya kuzitumia. Haya yote yataniwezesha kutathmini namna kituo hiki hufanya utaratibu wake kwa mujibu wa shabaha ya utafiti huu.

Manufaa: Hakutakuwepo na manufaa mahususi kwako, ila ugunduzi utakaotokana na utafiti huu, utafaidi sana katika kuboresha viwango vya matumizi yanayofaa ya dawa, kuboresha viwango vya huduma hizo muhimu pamoja na kufahamu mahitaji ya kimsingi katika kumhudumia mgojwa.

Hatari zilizopo: Hamna hatari zozote zitakazotokana na kushiriki katika utafiti huu.

Siri: Viwango vya juu vya siri vitazingatiwa. Jina lako halitatajwa popote wala halitatumiwa katika nakala zitakazochapishwa. Nambari maalum za kufanyia utafiti ndizo zitazotumika badala ya jina lako.

Mawasiliano: Una uhuru kuwasiliana nami au idara yangu ya elimu, au hospitali ya kitaifa ya Kenyatta au kamati ya madili na utafiti ya chuo kikuu cha Nairobi. Ili kuwasilisha marekebisho yoyote au kuwasilisha malalamishi.

Tumia njia za mawasiliano zifuatazo:

Idara ya Taaluma ya Madawa,

Shule ya Madawa,

Chuo Kikuu cha Nairobi,

S.L.P 30197-00400, Nairobi.

Aggrey Orwenyo Nyabuti –Mtafiti,
Idara ya Taaluma ya Madawa,

Shule ya matumizi ya Madawa,

Chuo Kikuu cha Nairobi.

S.L.P 19672, Nairobi.

Simu: 0729595818.

Prof. Faith A. Okelebo, Shahada ya Uzamilifu – Mhadhiri Mwangalizi,
Idara ya Taaluma ya Madawa,

Shule ya matumizi ya Madawa,

Chuo Kikuu cha Nairobi.

S.L.P 19676 , Nairobi.

Simu:0737434204.

Dktr. Eric M. Gauntai, Shahada ya Uzamilifu - Mhadhiri Mwangalizi,
Idara ya Taaluma ya Madawa,

Shule ya matumizi ya Madawa,

Chuo Kikuu cha Nairobi,

S.L.P 19676, Nairobi.

Simu:0722955883.

Prof. Mark Chindia – Katibu,
Hospitali ya Kitaifa ya Kenyatta – Kamati ya Maadili na Utafiti,

S.L.P 19676 – 00202,Nairobi.

Simu: +254-020-2726300-9.

Hospitali ya Kitaifa ya Kenyatta.
S.L.P 19676-00202, Nairobi.

Simu: 020-2726300.

KIBALI CHA UTAFITI CHA MGONJWA

Nimekubali kushiriki katika utafiti huu baada ya kuelezwa na Mtafiti mkuu. Sahihi yangu ni thibitisho ya kwamba nimeelewa umuhimu wa utafiti huu na kwamba habari yoyote nitakayotoa itawekwa siri.

Pia nathibitisha ya kwamba sijapewa au kuahadiwa pesa au chochote kile, kukubali Kushiriki kwenye utafiti huu.

Mgonjwa:

Jina……Sahihi……Tarehe ……./……./2019

Mtafiti Mkuu

Jina……Sahihi……Tarehe ……./……./2019

ENSEMO YA F1: EFOMU YOGOITABERA GOTUKWA YOMORWAIRE

Kwaariganigwe koba oyomo ase obotuki bw'obochenu, Bw'okomanya ebimanyererio bieng'encho igoro ya Amariogo, kobwatekana nomoroberio orure nekeombe ekenene getenenerete obochenu giense, WHO/INRUD ase ebitaseni biokorwa obokoreri bw'obochenu bw'oboroso, ase ekaunti ya Kisii.

Nyuma otaranacha ekina giokoba oyomo ase obotuki obo, mbuya komanya ekerenga ki'obotuki oboiga, amo na keria obotuki oboiga boraganie. Kwaborigwe oire chingaki chiao gosoma buya kegima naende nobwate obosibore bw'okoboria koegwa koererwa konde ase ing'ana rinde rionsi otaraigwa. Ribaga ndiganirie korwa asore erinde kwerikia buna oyomo ase obotuki oboiga. Mbuya koyamanya amarago akobwatia, aywo agochia gotumeka nabaria bonsi baraunenkigwe ase obounenkia obo bw'obochenu:

1. Ogwancha koba oyomo ase obotuki oboigwa nogochora kwago beene
2. Noancheire kwerusia korwa ase obotuki obo ngaki chinde chionsi otari korwa esababu y'okwerusia okwo.
3. Nyuma kogwasomire amarago onsi, nore nobosibore bw'okoboria ibori rinde rionsi, erio riragokonye komanya buya eng'encho y'obotuki oboiga

Ring'ana rinene ri'obotuki oboiga

Obotuki bw,ebiorokererio bi,obotumeki obuya bwa amariogo ase ebitaseni bikorwa obokoreri bw,ochenu ase ekaonti ya kisii, Kenya.

Omotuki: Erieta riane: Aggrey Orwenyo Nyabuti, oyore omworokigwa naende omotuki omonene**.** Enamba y'esimi: 0729595818**.** Esanduki y'eriuko: 50-40100, Nyamira

Omochakano bw'obotuki oboiga: Obotumeki obuya bw'amariogo, n'obwengecho ase ogokinia ebirengo bi'obokoreri bw'obochenu amo n'obotumeki obuya bw'enibo. Ring'ana eri neri'engencho riganentie abanto bakobwatia kobwaterana: oyokorika amariogo, oyokorwa amariogo, omorwaire, omoroberio bw'obochenu, ebimera ng'amo nayande amange.

Chibesa chikobekwa ensemo ase okogora amariogo nigo chikoira emerongo ebere ogoro y'emia goika emerongo etano igoro y'emia yechibesa chionsi chikobekwa ensemo ase ogotenenera obochenu, ase chinse chiria chikogenderera kiuchumi . obotumeki obobe bw'amariogo

n’omochando omonene ase ense yonsi. Nonya naboigo, ebirengo biobotumeki obwo, nigo bire igoro kegima, mono ase chinse chiria chikogenderera kiuchumi buna ense ya Kenya.Amang’ana akogera obotumeki obobe bw’ariogo bwabucha ng’amo na: ebirengo biechisemi, obworo bw’ogotanga obotumeki obobe bw’amariogo, egurube enene bakoegwa abakoreri bw’obochenu amo nemegiro n’ebimira bi’omorwaire.

Ase obotuki oboiga, nimbe ngosangereria amange igoro y’enaro y’ogwanchera obotumeki bw’amariogo; anene mono okoerwa kwa ime mono kw’oria okorwa obokoreri bw’obochenu nabwe nao ndakoganie mono orwe obokonyi bwago. Nimbe ngosangereria amange igoro ya amang’ana akobwatia:

1. Chingaki chikoirwa ase okorwa obosemia
2. Chingaki chikoirwa ase okorwa amariogo
3. Engencho y’amariogo akorwegwa
4. Okoererwa igoro y’amariogo omorwaire akoegwa
5. Obomanyi igoro y’amariogo akorwegwa

Eganga y’obotuki oboiga: Eganga enene y’obotuki oboiga nogoikera ring’ana ri’obotumeki bw’amariogo, kobwatekana n’omoroberio orure n’ekeombe ekenene k’iobochenu g’iense WHO/INRUD ase PPHCC Kisii, Kenya.

Ensemo y'omorwaire: Ase obotuki oboiga,tinkoba egetango ase oborwari bwago. Tingosoa naye ase enyomba y'okoruerwa obosemia. Ase igo,obosibore bwago amo n'obobisi bwago mbirendwe buya kegima. Nimbe ngotukatuka korwa egeka ake,erinde nyare komanya chingaki kwaira ime y'enyomba y'okoruerwa obosemia,amo ne'chingaki kwaira nyuma otaraegwa amariogo korwa ase enyomba y'amariogo.Nonya naboigo,ningosabe onyanchere indigererie amariogo kwarikerwa ,amo n'amariogo kwaegwa. Eke ng'enkonye komanya omobaro bw'amariogo kwarikerwa,amo n'omobaro bw'amariogo kwaegwa,na komanya norikeire buya igoro y'obotumeki. Omoerio,ninganie komanya korengana n'amariogo aywe,gore nore n'obomanyi bonde igoro y'echingaki chiokoyatumeka,ngamo n'enchera y'obotumeki. Ayaiga onsi nankonye komanya enchera egetaseni eke kegokora emeroberio yaye,korengana n'ekerenga ekenene ki'obotuki oboiga.

Obuya bokonyorwa korwa ase obotuki obo: Buya tiboiyo bonene oranyore korwa ase obotuki obo bwabeene. Korende ayare aratoke korwa obotuki oboiga nakonye mono kegima ase ogokinia ebirengo bi'obotumeki bobwenerete bw'amariogo, boigo gokinia ebirengo bi'obokoreri obwo, naboigo komanya gochia ime mono okogania kwengecho ekero ogokorera omorwaire.

Ing'ana rinde rikong'u: Ing'ana rinde rikong'u tiriyo rirache kobwatekana nokwerwa kwago koba oyomo ase obotuki oboiga.

Obobisi: Nimbwatie ebirengo bi'a igoro mono biokobeka koba obobisi amang'ana onsi. Erieta Riago tirigoatorwa aande onsi, gose tirikorikwa ime yebitabu birarikwe igoro y'obotuki oboiga. Enamba y'obobisi nero eratumeke ribaga ri'erieta riago ase obotuki obo.

Gotoma Amang'ana: Nore nobosibore bw'ogotoma amang'ana gocha asende, gose gochia ase ngosoma, gose enyagitari enene ya Kenya ya Kenyatta, gose ekamati y'etabia n'obotuki y'eyunibasiti ya Nairobi, erinde gokora boonchoreria bonde, gose koboria komanya eng'ana ende yonsi.

Tumeka chinchera chikobwatia chioboererania:

Eyunibasiti
Ensemo y'echisemi igoro y'obochenu
Esukuru y'amariogo
Eyunibasiti ya Nairobi
Esanduku y'eriuko 30197-00400,
Nairobi

Aggrey orwenyo Nyabuti- Omotuki
Ensemo y'echisemi igoro y'obochenu
Esukuru y'amariogo
Eyunibasiti ya Nairobi
Esanduki y'eriuko 19672
Nairobi
Enamba y'esimi: 0729595818

Prof. Faith A. Okalebo (PhD) - Omworoki Omoteneneri

Ensemo y'echisemi igoro y'obochenu

Esukuru y'amariogo

Eyunibasiti ya Nairobi

Esanduki y'eriuko 19676

Nairobi

Enamba y'esimi: 0737434204

OGWANCHERA KW,OBOUNENKIA

Naitaberanire koba oyomo ase obounenkia,nyuma yokoererwa n,omounenkia omonene.esei yane nekemanyererio nga namanyire obuya bwobotuki obo,naende nga,kera engana ndarwe nebekwe koba eyabobisi.

Naende naenekirie nga tindaegwa gose korierwa eira yokoegwa chinusi chinde chionsi gose gento kende gionsi,erinde ngitaberane koba ase obounenkia oboiga.

Omorwaire:

Erieta.....Esei..,..... Chitariki.....

Omounenkia

Erieta.....Esei..... ……Chitariki.....

Appendix G: Prescriber consent form

Consenting process

You are being invited to participate in a medical research that seeks to assess the core drug use indicators using the WHO/INRUD guideline at the primary healthcare centers within Kisii County. Before you make a decision to participate, it is important for you to understand why the survey is being done and what it will involve. Please take time to read the following information carefully and feel free to ask for more information, especially if there is anything you do not understand. Permission is required from you to enroll in this medical research. You should understand the following general principles which apply to all the participants in a medical research:

1) Your agreement to participate in this study is voluntary
2) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
3) After you have read the explanation, please feel free to ask any questions that will enable you to understand clearly the nature of the study

Title of the study: Examination of Core Indicators of Appropriate Drug Use at Public Primary Healthcare Centers in Kisii County, Kenya

Investigator: Aggrey Orwenyo Nyabuti – student and the principal investigator. P.O. BOX 50-40100 Nyamira. Tel: 0729595818

Introduction to the study

Rational drug use is essential to optimize the quality of healthcare delivery and resource utilization. It is a complex subject involving the prescriber, the dispenser, the patient and the health institutions. It is influenced by factors such as drug availability, prescriber's experience, and knowledge of dispensers, health budget, cultural factors and many more. Budgets on drugs account for 20% to 50% of the total health budget in developing countries. Inappropriate drug use is a worldwide problem; however, the degree of the problem is higher in developing countries like

Kenya. Knowledge gap, loose drug control, loads on healthcare providers and patient beliefs are some of the factors contributing to this problem.

In this survey, I will be collecting information on the prescribing practices, facility-specific information, and patient – care information where you will be needed most. Here I will be collecting information on the consultation time, dispensing time, drugs dispensed and drug labeling and your knowledge about the drugs issued to you.

Purpose of the study: the main objective of this research is to assess the drug use pattern using WHO/INRUD core drug use indicators at PHCCs in Kisii County, Kenya

Prescriber participation: you will be indirectly involved in this study. This is because I will be monitoring the time you take to consult with the patients from a distance, hence not joining you together with the patient at the consultation room. That is, the privacy and confidentiality of the patient will be adhered to at all times. I will also request the patient for the prescription to note the number of drugs prescribed as I will tally it together with those dispensed. This will help in assessing the key dimensions of prescribing practices in accordance with good prescribing practices.

Benefits: there will be no direct benefits to you but the findings of this study will be useful in improving the rational use of drugs, improve the patient – care services and help enhance the facility-specific needs needed for management of patients.

Risks: there will be no risk involved in this study.

Confidentiality: utmost confidentiality will be ensured. Your name will not be mentioned or used during data handling or resulting publications. Study codes and numbers will be used instead.

Contacts: please feel free to contact me, my academic department or Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee for any clarification or concerns. Use the contacts provided below:

Institution: Department of Pharmacology and Pharmacognosy, School of Pharmacy, University of Nairobi, P.O. BOX 30197-00400, Nairobi.

Aggrey Orwenyo Nyabuti – Student
Department of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi
P.O. BOX 50-40100 Nyamira. Tel: 0729595818

Prof. Faith A. Okalebo, Ph.D. - Supervisor
Department of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi
P.O. BOX 19676, Nairobi. Tel: 0737434204

Dr. Eric M. Guantai, Ph.D. - Supervisor
Department of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi
P.O. BOX 19676, Nairobi. Tel: 0722955883

Prof. Mark Chindia – The Secretary
KNH – UoN Ethics and Research Committee
P.O. BOX 19676 – 00202, Nairobi. Tel: (254 - 020) 2726300 - 9

KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723 – 00202, Nairobi. Tel: 020 – 2726300

PRESCRIBER STATEMENT OF CONSENT

I confirm that I have read and understood the information given above for the study. I have had the opportunity to consider the information, asked questions and I have had them answered satisfactorily. I understand that my participation is voluntary and I am free to leave at any time without giving any reason, without violation of any rights.

I agree to take part in this study.

Patient:

Name…….Signature……Date ……/……./2019

Investigator:

Name…….Signature……..Date ……/……./2019

Appendix H: Dispenser consent form

Consenting process

You are being invited to participate in a medical research that seeks to assess the core drug use indicators using the WHO/INRUD guideline at the primary healthcare centers within Kisii County. Before you make a decision to participate, it is important for you to understand why the survey is being done and what it will involve. Please take time to read the following information carefully and feel free to ask for more information, especially if there is anything you do not understand. Permission is required from you to enroll in this medical research. You should understand the following general principles which apply to all the participants in a medical research:

1) Your agreement to participate in this study is voluntary
2) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
3) After you have read the explanation, please feel free to ask any questions that will enable you to understand clearly the nature of the study

Title of the study: Examination of Core Indicators of Appropriate Drug Use at Public Primary Healthcare Centers in Kisii County, Kenya

Investigator: Aggrey Orwenyo Nyabuti – student and the principal investigator. P.O. BOX 50-40100 Nyamira. Tel: 0729595818

Introduction to the study

Rational drug use is essential to optimize the quality of healthcare delivery and resource utilization. It is a complex subject involving the prescriber, the dispenser, the patient and the health institutions. It is influenced by factors such as drug availability, prescriber's experience, and knowledge of dispensers, health budget, cultural factors and many more. Budgets on drugs account for 20% to 50% of the total health budget in developing countries. Inappropriate drug use is a worldwide problem; however, the degree of the problem is higher in developing countries like

Kenya. Knowledge gap, loose drug control, loads on healthcare providers and patient beliefs are some of the factors contributing to this problem.

In this survey, I will be collecting information on the prescribing practices, facility-specific information, and patient – care information where you will be needed most. Here I will be collecting information on the consultation time, dispensing time, drugs dispensed and drug labeling and your knowledge about the drugs issued to you.

Purpose of the study: the main objective of this research is to assess the drug use pattern using WHO/INRUD core drug use indicators at PHCCs in Kisii County, Kenya

Dispenser participation: You will be directly involved in this study particularly in assessing the facility-specific indicators. You will be interviewed on the staffing, availability of key documents and drugs at the facility. This will help in evaluating the status of the facility's ability and readiness to prescribe and dispense drugs rationally.

Benefits: there will be no direct benefits to you but the findings of this study will be useful in improving the rational use of drugs, improve the patient – care services and help enhance the facility-specific needs needed for management of patients.

Risks: there will be no risk involved in this study.

Confidentiality: utmost confidentiality will be ensured. Your name will not be mentioned or used during data handling or resulting publications. Study codes and numbers will be used instead.

Contacts: please feel free to contact me, my academic department or Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee for any clarification or concerns. Use the contacts provided below:

Institution: Department of Pharmacology and Pharmacognosy, School of Pharmacy, University of Nairobi, P.O. BOX 30197-00400, Nairobi.

Aggrey Orwenyo Nyabuti – Student
Department of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi
P.O. BOX 50-40100 Nyamira. Tel: 0729595818

Prof. Faith A. Okalebo, Ph.D. - Supervisor
Department of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi
P.O. BOX 19676, Nairobi. Tel: 0737434204

Dr. Eric M. Guantai, Ph.D. - Supervisor
Department of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi
P.O. BOX 19676, Nairobi. Tel: 0722955883

Prof. Mark Chindia – The Secretary
KNH – UoN Ethics and Research Committee
P.O. BOX 19676 – 00202, Nairobi. Tel: (254 - 020) 2726300 - 9

KENYATTA NATIONAL HOSPITAL
P.O. BOX 20723 – 00202, Nairobi. Tel: 020 – 2726300

DISPENSER STATEMENT OF CONSENT

I confirm that I have read and understood the information given above for the study. I have had the opportunity to consider the information, asked questions and I have had them answered satisfactorily. I understand that my participation is voluntary and I am free to leave at any time without giving any reason, without violation of any rights.

I agree to take part in this study.

Patient:

Name…….Signature……Date ……/……./2019

Investigator:

Name…….Signature……..Date ……/……./2019

Appendix I: KNH – UoN ERC approval letter

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

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

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

Ref: KNH-ERC/A/50

12th February, 2019

APPROVED
12 FEB 2019
KNH/UoN-ERC
P. O. BOX 20723 - 00202 NAIROBI

Aggrey Orwenyo Nyabuti
Reg. No.U51/6929/2017
Dept. of Pharmacology and Pharmacognosy
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Aggrey

RESEARCH PROPOSAL – EXAMINATION OF CORE INDICATORS OF APPROPRIATE DRUG USE AT PUBLIC PRIMARY HEALTHCARE CENTERS IN KISII COUNTY, KENYA (P782/11/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 12th February 2019 – 11th February 2020.

This approval is subject to compliance with the following requirements:

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

Protect to discover

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

Yours sincerely,

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

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

Appendix J: Study site approval letter

Dr. Aggrey Orwenyo Nyabuti,
P.O. BOX 50-40500,
NYAMIRA-KENYA.

April, 20th 2019.

The Director for Health,
MINISTRY OF HEALTH
P.O BOX 92-40200,
KISII-KENYA.
KISII COUNTY GOVERNMENT

Cc
The Chairman
Research and Training Committee,

KISII COUNTY GOVERNMENT
COUNTY HEALTH DIRECTOR
P. O. Box 92 - 40200
KISII.

Dear Sir,

RE: PERMISSION TO CONDUCT RESEARCH AT THE PUBLIC PRIMARY HEALTHCARE CENTERS IN KISII COUNTY.

The above subject matter applies. My name is Aggrey Orwenyo Nyabuti, a postgraduate student at the University of Nairobi, School of Pharmacy pursuing a study entitled, **Examination of Core Indicators of Appropriate Drug Use at Public Primary Healthcare Centers in Kisii County, Kenya.** This research will form part of my fulfilment for the award of the Degree in Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance. Please find attached my approval letter from KNH-UON ERC on the same.

The study will be a cross-sectional survey employing both the retrospective and prospective data to be collected from ten Public Primary Healthcare Centers (PPHCCs) in Kisii County selected by simple random sampling method. It will aim at assessing the prescribing patterns, patient – care

practices and the facility – specific pointers using the WHO/INRUD core drug use indicators methodology at public primary healthcare centers in Kisii County.

The survey will be crucial in assessing the performance of Kisii County's PPHCCs' adherence to the WHO/INRUD core drug use indicators guideline. No such study has been conducted in the region. The outcome of the study will provide evidence for the need to formulate policies to promote rational use of drugs in the County.

The study will be carried out at the following ten sampled PPHCCs:

1. Oresi H/C
2. Kegogi H/C
3. Masimba H/C
4. Entanda H/C
5. Magena H/C
6. Nyamagundo Hospital
7. Isecha H/C
8. Egetuki GOK Dispensary
9. Kionyo Hospital
10. Mosocho Market Dispensary

I look forward to your consideration and support.

Thanks in advance.

Yours Sincerely,

Aggrey Orwenyo Nyabuti