PATTERNS OF PRESCRIBING PRACTICES IN MAKUENI COUNTY REFERRAL HOSPITAL, KENYA

BY,

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U51/81601/2012

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A Thesis Submitted in Partial Fulfillment of the Requirements for the Award of

Master's Degree of the University of Nairobi

(Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance)

November, 2014

DECLARATION

I declare that this thesis is my original work, and to the best of my knowledge, has not been submitted elsewhere for examination, award of a degree or publication.

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DEDICATION

I dedicate this work to my dear wife, Purity and our beloved children, Emmanuel and Jennifer, for their love, encouragement and support during my studies.

ACKNOWLEDGEMENTS

I am grateful to The Almighty God for His grace and favour, without which, I would not have made it this far.

I acknowledge my supervisors, Dr. G. O. Osanjo, Dr. S. N. Ndwigah and Professor G. Muriuki, for their guidance, positive criticism and encouragement throughout my research.

I am thankful to Dr. F.A. Okalebo, the Course Coordinator, for her support and guidance during my entire studies.

I recognize the Medical Superintendent and entire staff of Makueni County Referral Hospital for their support during data collection.

I appreciate my classmates, Albert Ndwiga, Lucy Mecca, Jones Makori, Susan Njogo, Evans Imbuki, Margaret Ambetsa, Seth Jomo, Christabel Khaemba, Kiogora Gatimbu and Annie Wamaitha for their encouragement and comradeship throughout our studies.

Lastly, I appreciate the University of Nairobi, Board of Postgraduate Studies, for offering me a scholarship to pursue my Masters studies.

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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immuno-Deficiency Syndrome
ATC	Anatomical Therapeutic Classification
CCC	Comprehensive Care Clinic
CI	Confidence Interval
COI	Clinical Officer Intern
DDD	Defined Daily Dose
EDL	Essential Drug List
EML	Essential Medicines List
HIV	Human Immunodeficiency Virus
INN	International Non-proprietary Name
INRUD	International Network for the Rational Use of Drugs
KAP	Knowledge, Attitude and Practices
KEML	Kenya Essential Medicines List
MO	Medical Officer
MOI	Medical Officer Intern
MS	Medical Specialist
MTC	Medicines and Therapeutics Committee
OPD	Out-Patient Department
OR	Odds Ratio
PI	Principal Investigator
RCO	Registered Clinical Officer
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Antibiotics: Are substances produced by or derived from certain fungi, bacteria, and other organisms, that can destroy or inhibit the growth of other microorganisms. In this study, the term antibiotic is used as a synonym for drugs used to treat bacterial infections in both people and animals.

Clinical officer: A clinician who holds a Diploma in clinical medicine and surgery from a recognized institution and is registered by the Clinical officers' council of Kenya. In this study, the term includes a registered clinical officer as well as a clinical officer intern.

Combination of drugs: Two or more drugs that are usually packaged, prescribed and dispensed together for a given health condition or a fixed-dose combination of drugs. For example, triple therapy for *Helicobacter pylori* induced peptic ulcer. In our study, such a combination was counted as one drug.

Essential Medicines List: It is a compilation of essential medicines, that is, medicines that satisfy the priority healthcare needs of the population. In this study, it was used interchangeably with the term 'essential drug list.'

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

Generic name: This is the International Non-proprietary Name (INN) of a drug. The Kenya Essential Medicines List 2010 was used as a basis to determine drugs names as generic or brand.

Generic substitution: This is the statutorily permitted substitution of a prescription medicine as prescribed by an authorized (registered) medical, dental or veterinary practitioner using a trade or brand name with a therapeutically equivalent generic medicine. This may only be done by an authorized (registered) pharmacist within the context of dispensing practice.

Irrational/ inappropriate prescribing: Prescribing that does not conform to good standards of treatment. It includes polypharmacy, prescribing using proprietary brand or trade names of drugs, over prescription of antibiotics and injections as well as prescribing too expensive drugs when cheaper equally effective alternatives are available.

Medical practitioner: In this study, the term includes a medical officer intern, a registered medical officer and a medical specialist (consultant).

Parsimonious model: It is a regression model that contains the most important predictor variables for the outcome of interest; hence, it has the highest value of R-squared (coefficient of determination).

Polypharmacy: Prescribing many/ multiple drugs for a patient during a specific patient encounter.

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

ABSTRACT

Introduction: Irrational prescribing is widespread across the globe and is a major problem in many healthcare facilities, especially in developing countries. According to the World Health Organization (WHO), statistics indicate that more than half of all drugs are prescribed, dispensed or sold improperly across the globe. Many studies carried out in different countries have documented various forms of irrational prescribing. It is advisable to describe and quantify the current situation of prescribing practices before mechanisms are put in place to promote rational drug use. Prescribing surveys, using WHO core prescribing indicators, have been employed to describe prescribing patterns in healthcare facilities.

Objective: The study objective was to determine patterns of prescribing practices in Makueni County Referral Hospital.

Methodology: The study was a hospital based cross-sectional survey divided into two parts: a retrospective prescription survey and a questionnaire-based knowledge, attitudes and practices (KAP) survey. In the prescription survey, 824 patient encounters were sampled from outpatient and inpatient departments between 1st January and 31st December, 2013. Data was abstracted using a pre-tested data collection form, entered into and analyzed using Epi info version 7.0 and Stata version 10.0 software. The KAP survey involved administering questionnaires to fifty one prescribers.

Results: The mean number of drugs per patient encounter was 2.7. Only 45.5% of the total drugs were prescribed using international non-proprietary names (generic names). Antibiotics were prescribed in 74% while injections were prescribed in 13.2% of the total prescriptions surveyed. The percentage of drugs prescribed from the Kenya Essential Medicines List was 89.1%. The

percentage of complete prescriptions was 49%. Clinical setting, comorbidities, chronic conditions and prescriber cadre were all found to be significantly associated with both polypharmacy and antibiotic prescribing. Patient age was positively correlated to the number of drugs prescribed per patient encounter. The KAP survey revealed gaps in prescribers' knowledge of prescribing guidelines.

Conclusion: The results show a trend towards inappropriate prescribing, particularly polypharmacy, underuse of generic names when prescribing, over prescription of antibiotics and incomplete prescription writing. Frequent continuous medical education forums (CMEs), seminars and trainings on prescribing are recommended to address irrational prescribing in the hospital. Periodic prescription surveys and drug utilization studies are also recommended to identify any forms of irrational prescribing. The findings of such studies should be disseminated to all healthcare workers and particularly the prescribers, followed by relevant interventions to remedy any problems identified.

CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION

Medicines are important weapons in the fight against diseases. Modern healthcare would be a dream without medicines. However, medicines are 'double-edged swords' and therefore, they should be used rationally. According to World Health Organization (WHO), rational use of drugs requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, at the lowest cost to them and their community" (1). Irrational drug use is an enormous problem with several undesirable consequences such as increased cost of drug therapy, increased risk for adverse drug reactions, emergence of drug resistance, wastage of resources and reduction in the quality of drug therapy (2). In 1985, WHO convened an international conference in Nairobi, Kenya, to develop guidelines for curbing irrational drug use.

Prescribing is a crucial step in the drug use cycle. Prescribing should be rational in order to benefit the patient. However, various forms of irrational prescribing still exist in many healthcare facilities. Irrational prescribing is perpetuated through drug promotion by medical representatives, patient pressure and expectations, and copying bad examples from fellow prescribers (2). It is advisable to describe and quantify the current situation before mechanisms are put in place to promote rational drug use. Survey methods have been used for this purpose. For instance, prescription surveys using WHO core prescribing indicators have been employed to describe prescribing patterns in healthcare facilities (3). These indicators have been accepted globally and have been used in over thirty developing countries (3). Prescribing indicators

measure the performance of healthcare providers in several key dimensions related to the appropriate use of drugs and are useful tools to promote rational prescribing.

A number of factors influence prescribing practices. These include prescriber-related factors, patient-related factors, industry-related factors and disease-related factors. Prescribing practices should be evaluated periodically so as to provide feedback to prescribers which in turn increases the quality of drug therapy, reduces wastage of resources and lowers risk for adverse drug reactions among other benefits (4). This study was conducted in order to assess the patterns of drug prescribing practices in Makueni County Referral Hospital.

1.2 LITERATURE REVIEW

1.2.1 Drug utilization research

In 1977, the WHO defined drug utilization research as "the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences (5)." Drug utilization studies are useful for educational, clinical and economic purposes. The main aim of drug utilization research is to assess if drug use is rational. Methods for auditing drug therapy are thus required to achieve this goal. Drug utilization studies can be divided into descriptive and analytical. Descriptive studies determine patterns of drug utilization and assist in identifying problems deserving more detailed studies. On the other hand, analytical studies assess rationality of drug therapy by linking data on drug utilization to morbidity data, treatment outcomes data and quality of care (6).

Drug utilization studies highlight the key areas of drug use such as patterns of drug use, quality, determinants and the outcomes of drug use (6). Patterns of drug use include the extent, profiles,

trends and costs of drug use over time. Quality of drug use entails comparing actual drug use in terms of the choice of drug, its dosage and cost against prescription guidelines or formulary. Determinants of drug use encompass patient characteristics (such as biodata and attitudes towards drugs), prescriber characteristics (such as biodata, speciality, education and years in service) and drug characteristics (such as cost and drug interactions). Outcomes of drug use include the beneficial effects as well as the adverse effects associated with the drug (5).

Other than describing the drug use patterns, drug utilization studies can be used as early signals for irrational drug use (7). This is achieved by comparing actual drug use against set standards to identify any discrepancies. Afterwards interventions can be put in place to correct any irrational drug use. Further drug utilization studies can be done to assess whether interventions intended to improve drug use have achieved the desired impact. A quality control cycle with continuous quality improvement is required for assessing drug use. This quality control cycle can be applied at different levels ranging from local to international and it can serve as a basis for benchmarking (5).

1.2.2 Irrational use of drugs

Irrational drug use entails practices that do not conform to the ideals of good treatment as outlined in rational drug use. Irrational use, coupled with lack of access to medicines results in increased morbidity and mortality, especially for chronic disease conditions, such as HIV/AIDS, cancer, hypertension and diabetes (4). It also wastes resources, causes significant patient harm through adverse effects and poor patient outcomes. Inappropriate use of antimicrobials leads to antimicrobial resistance while non-sterile injections are a major contributor to the transmission of blood borne-diseases. Moreover, irrational overuse of medicines can cause drug stock outs and

loss of patient confidence in the healthcare system (8). Regular monitoring of prescribing, dispensing and patient use is vital to address irrational drug use.

1.2.3 Prevalence of irrational drug use

Irrational prescribing is widespread and occurs in various forms. Many studies carried out in different countries have documented various forms of irrational prescribing. For instance, polypharmacy has been documented in numerous studies done in Ghana (9), Brazil (10), Sri Lanka (11) and United Kingdom (12). The use of drugs that are not related to the diagnosis has been documented in studies done in Seychelles (13). Prescribing of unnecessarily expensive drugs has been reported by studies done in Tanzania (14), Swaziland (15) and Zaire (16). Inappropriate use of antibiotics has been documented in studies done in Canada (17), Indonesia (18) and Thailand (19).

Over prescription of antibiotics was reported by studies conducted in Thailand (19) and South Africa (20). In a Nigerian study, 74.3% of all paediatric prescriptions were considered inappropriate, mostly because of polypharmacy, the use of unnecessary drugs and sub-optimal dosage schedules (21). In a study conducted in Ethiopia, irrational prescribing was prevalent as shown by high average number of drugs prescribed per encounter, high percentage of injections and high percentage of antibiotic use in the studied region (22).

1.2.4 Methods of measuring irrational drug use

The type and extent of irrational drug use can be measured through several methods such as aggregate drug consumption method, anatomical therapeutic classification (ATC)/ defined daily dose (DDD) methodology, use of WHO drug use indicators, performing drug utilization reviews,

use of Beer's indicators and employing qualitative methods such as in-depth interviews and structured questionnaires (5). Aggregate drug consumption data methods can be used to compare actual consumption versus expected consumption from morbidity data. Anatomical therapeutic classification (ATC)/ defined daily dose (DDD) methodology can be employed to compare drug consumption among facilities, regions and countries (5).

The WHO drug use indicators are useful for identifying general prescribing and quality of care problems at primary healthcare facilities. These indicators are also useful for measuring the impact of an intervention, to make comparisons between facilities, districts or regions, and for supervisory purposes (23). Drug utilization reviews are helpful in establishing problems concerning the use of specific medicines or the treatment of specific diseases. The motives underlying irrational drug use can be investigated by undertaking knowledge, attitudes and practices (KAP) surveys (24). Data obtained through the various methods above is then used to design appropriate interventions and to measure the impact of those interventions on drug use.

1.2.5 Strategies to promote rational prescribing

There are various strategies that have been put forward. These strategies can be classified into three broad classes, namely, educational, managerial and regulatory (25). Bulletins, seminars, printed materials and face-to-face interventions are examples of educational strategies. Managerial strategies are generally restrictions on prescribing and they include cost restrictions, endorsement by higher qualified consultants, a maximum number of drugs per prescription and structured prescription forms. Scheduling drugs in different categories of sale, specifying the minimum level of prescriber or health facility to handle certain drugs and procedures to critically

evaluate drugs and product information before market approval is given, form the bulk of regulatory strategies.

Essential drug lists (EDL) have also helped a lot in promoting irrational prescribing. WHO established the first Model List of Essential Medicines in 1977. This was a key step towards promoting rational drug use. This model list was aimed at assisting countries in formulating their own national essential drug lists. WHO defines essential drugs as "those that satisfy the health care needs of the majority of the population and they should therefore be available at all times, in adequate amounts and in the appropriate dosage forms (26)." Essential drugs are necessary to fight ill health and increasing access and rational use of these drugs will improve health status of the society especially in developing countries (27).

According to WHO, statistics indicate that more than half of all drugs are prescribed, dispensed, or sold improperly across the globe, and 50% of patients fail to take them correctly (8). In addition, about 33% of the world's population lacks access to essential medicines (8). Individual countries have developed their own essential medicines list. For instance, the Kenya Essential Medicines List (KEML) 2010 is the current EDL for Kenya. Moreover, certain healthcare facilities have compiled their own hospital formularies based on the specific hospital needs. Most of these hospital formularies borrow a lot from the country's EDL. These strategies have helped in promoting rational drug use.

1.2.6 WHO drug use indicators

The drug use indicators were developed by WHO in conjunction with the International Network for the Rational Use of Drugs (INRUD) to assist in investigating drug use in primary health care facilities. The indicators are broadly divided into core and complementary indicators. The core

indicators have been pre-tested and are highly standardized whereas the complementary indicators are less standardized and are more difficult to measure (23). Table 1 presents the WHO core drug use indicators.

Table 1: The WHO core drug use indicators (23)

Prescribing indicators

1. Average number of drugs per encounter
2. Percentage of drugs prescribed by generic name
3. Percentage of encounters with an antibiotic prescribed
4. Percentage of encounters with an injection prescribed
5. Percentage of drugs prescribed from essential drugs list or formulary

Patient care indicators

6. Average consultation time
7. Average dispensing time
8. Percentage of drugs actually dispensed
9. Percentage of drugs adequately labeled
10. Patients' knowledge of correct dosage

Facility indicators

11. Availability of copy of essential drugs list or formulary
12. Availability of key drugs

The core drug use indicators were developed to measure performance in three general areas related to the rational use of drugs. These areas include prescribing practices, patient care and facility-specific factors that support rational drug use. Therefore, these core indicators are divided into prescribing indicators, patient care indicators and facility indicators (23). These

indicators serve as tools for assessing key aspects of pharmaceutical use in primary healthcare and the results obtained highlight drug use problems that need remedial interventions. Cross-sectional surveys can be carried out using these drug use indicators whereby data is collected only once, or else data on the indicators can be collected at different periods to assess change in performance.

1.2.7 WHO core prescribing indicators

There are five core prescribing indicators as presented in Table 1. These indicators measure the performance of prescribers in key areas concerning rational drug use. The indicators assess prescribing practices based on clinical encounters at healthcare facilities for the treatment of different illnesses (23). The WHO core prescribing indicators are most suited to measure aspects of outpatient treatment. Therefore, they are less useful when used for inpatient care. These indicators can be used in dispensaries, health centers and hospitals in both public and private sector.

Prescription surveys describing current prescribing practices using the WHO prescribing indicators should have at least 600 encounters/ prescriptions included in a cross-sectional survey, with a greater number if possible (23). Since the clinical encounters cover a wide range of illnesses, the core prescribing indicators assess general prescribing practices independent of specific diagnoses. After a baseline study with prescribing indicators to determine overall prescribing practices, it is advisable to carry out disease-specific or drug-specific studies to assess the quality of diagnosis and treatment.

1.2.8 Use and application of the five core WHO prescribing indicators

1.2.8.1 Average number of drugs per encounter

The indicator is used to assess the degree of polypharmacy. The WHO standard value for this indicator is 1.6 to 1.8 (28). Studies done in different countries across the world reported varying results on the average number of drugs prescribed per prescription. Low mean values were reported by studies done in Zimbabwe, Bangladesh and Sudan while acceptable values were documented in Lebanon and Ethiopia. Several studies conducted in Dubai, United Arab Emirates, Jordan, Brazil, Saudi Arabia, China, Pakistan, India, Kenya, Nigeria, Uganda, Nepal and Ghana reported a higher average value compared to the standard recommended by WHO. Table 2 presents some of the results obtained in various studies.

Average values greater than the standard value indicate polypharmacy. Polypharmacy may occur as a result of financial incentives to prescribers by drug industry or inadequate training of prescribers. Polypharmacy should be discouraged since it is a risk factor for drug interactions and increased incidence of adverse drug reactions (29). Low values of average number of medicines prescribed per patient encounter might reflect low availability of drugs or properly trained prescribers.

Table 2: Average number of drugs per encounter

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
Brazil (40)	2.4
Saudi Arabia (41)	2.4
China (42-43)	2.4, 2.6
Pakistan (44)	2.4 (outpatients), 3.3 (inpatients)
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)
Bangladesh (4)	3.2
Nigeria (30)	3.8
Ghana (54)	4.8

1.2.8.2 Percentage of drugs prescribed by generic name

This indicator assesses the propensity of prescribers to prescribe using international non-proprietary names as opposed to use of proprietary brand names. The WHO standard value for the indicator is 100% (28). Varying percentages ranging from 2.9 to 99.8% were reported by studies done in different countries across the world (Table 3). The percentage of drugs prescribed using generic names was very low in studies conducted in Lebanon, Dubai, Jordan, United Arab Emirates and Nepal. However, high percentages were documented by studies carried out in Ethiopia, Tanzania, Zimbabwe, Iran and Cambodia.

Prescribing using generic names is encouraged because it allows the patient to get the most cost-effective drug available without consideration of brand or manufacturer. Therefore, prescribing using generic name helps to reduce drug cost and rationalize drug use (55). Low percentage of generic prescribing is usually attributed to drug promotion by medical representatives as well as lack of emphasis on generic prescribing during training of prescribers. Brand name prescribing may indicate that prescribers are not conversant with documents like EDL and clinical guidelines in which drugs are always written in their generic names.

Table 3: Percentage of drugs prescribed by generic name

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
Nigeria (50)	16 (private hospital), 54 (public hospital)
Sudan (30), (59)	63, 19.5
Nepal (60)	21.3
Pakistan (44), (61)	23.6, 38
Kenya, National survey of 2009 (49)	31.8 (public facilities), 34.7 (faith-based facilities)
Uzbekistan (62)	38
Kenya, National survey of 2003 (48)	48
Nigeria (30)	58
Saudi Arabia (41)	61.2
Uganda (51)	62
China (42), (63)	64.1, 73.4
Ghana (54)	65
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

1.2.8.3 Percentage of encounters with an antibiotic prescribed

The indicator is used to assess the overall use of antibiotics. The WHO standard value for this indicator is 20 to 26.8% (28). Percentages above this standard value indicate over prescription of antibiotics. Most prescription surveys conducted in different countries reported over prescription of antibiotics. Among the 22 studies reviewed, Kenya had the highest prevalence of antibiotic prescribing (Table 4).

High prevalence of antibiotic prescribing may be due to pressure from patients to receive antibiotics. Overestimation of the severity of illness by prescribers to justify antibiotic prescribing is another reason. Overuse of antibiotics could facilitate emergence of resistance and unnecessarily increases the cost of drugs to the patient (49).

Table 4: Percentage of encounters with an antibiotic prescribed

Study site	% of encounters with an antibiotic prescribed
Pakistan (44), (61)	20.4, 78
United Arab Emirates (37)	21.4
Malaysia (66)	23.2
Bangladesh (4), (31)	48.7, 25
Nepal (67)	28.3
Zimbabwe (30)	29
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 (faith-based facilities), 76.7 (public facilities)
Kenya, National survey of 2003 (48)	78.4

1.2.8.4 Percentage of encounters with an injection prescribed

This indicator is used to assess the overall use of injections. The WHO standard value for the indicator is 13.4 to 24.1% (28). Percentages above this standard value indicate over prescription of injections. A number of studies carried out in different countries reported overuse of injections as shown in Table 5.

Table 5: Percentage of encounters with an injection prescribed

Study site	% of encounters with an injection prescribed
India (2), (58), (56)	13.5, 0.2, 5.2
Bangladesh (4)	6.7
Kenya, National survey of 2009 (49)	13 (public facilities), 27 (faith-based facilities)
Ecuador (30)	17
Indonesia (30)	17
Pakistan (44), (61)	17.1, 73
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

In a survey conducted in Kenya in 2009, faith-based facilities performed worse than public facilities on the prevalence of antibiotic prescribing (49). Over prescription of injections could arise as a result of patients' pressure to receive injections or prescribers' attitude that injections are more efficacious compared to oral medication. High injections use is discouraged because injections are relatively more expensive compared to other dosage forms and require trained personnel for administration. In addition, unsafe use of injections can increase the risk of transmission of blood-borne diseases (29).

1.2.8.5 Percentage of drugs prescribed from essential drug list or formulary

This indicator is used to assess the extent to which prescribing practices conform to the national EDL or formulary. The WHO standard value for the indicator is 100% (28). Most of the surveys done in several countries reported relatively high percentages, however a few studies documented low percentages of drugs prescribed from EDL (Table 6).

Availability of copies of EDL at health facilities has been cited as a major reason for exemplary high percentages of drugs prescribed from the EDL (62). On the other hand, inadequate supply of drugs at health facilities and unavailability of copies of EDL have been blamed for non-compliance with EDL when prescribing (74).

Table 6: Percentage of drugs prescribed from essential drug list or formulary

Study site	% of drugs prescribed from essential drug list
Bangladesh (4), (31)	26.1, 85
India (2)	66.9
China (42)	67.7
Pakistan (44), (61)	80, 70
Kenya, National survey of 2009 (49)	79 (faith-based facilities), 93 (public facilities)
Kenya, National survey of 2003 (48)	81.3
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

1.3 PROBLEM STATEMENT

Irrational prescribing is a major problem in many healthcare facilities around the world, especially in developing countries. The problem includes prescribing using proprietary brand names, polypharmacy, over prescription of antibiotics and overuse of injections among other practices. Prescribing using proprietary brand names poses a great challenge during dispensing since the pharmacy personnel have to confirm the respective active ingredients in the brands before dispensing. Sometimes, the dispenser has to liaise with the prescriber before substituting the innovator brand for a generic. This contributes to an increase in waiting time at the pharmacy. It could also lead to unwarranted drug stock out situations especially if the branded product is new in the market. Brand name prescribing also increases drug costs since most of the innovator branded drugs are more expensive compared to the generic products (49).

Polypharmacy is associated with increased risk of drug-drug interactions which may result in adverse drug reactions, diminished adherence due to pill burden and unnecessary high drug costs (41). Over prescription of antibiotics increases the risk of drug resistance as well as increasing drug costs unnecessarily while injections overuse increases the risk of transmission of blood-borne diseases such as HIV/AIDS and Hepatitis B (75). Moreover, injections are relatively more expensive compared to oral medications and therefore their overuse increases drug costs unnecessarily. Inappropriate prescribing habits lead to higher treatment costs, ineffective therapy, unsafe treatment and exacerbation of illness (29). Analysis of prescriptions and drug utilization studies can identify the problems and provide feedback to prescribers so as to create awareness about irrational prescribing and put mechanisms in place to curb the problem.

1.4 JUSTIFICATION OF THE STUDY

Drugs should be prescribed rationally for optimal benefit to patients. However, studies done in various countries have reported a remarkable degree of irrational prescribing of drugs in healthcare facilities (50). Patterns of prescribing practices have not been studied extensively in Kenya hence there is limited data on the extent of irrational prescribing in healthcare facilities in the country.

The types of irrational prescribing should be characterized so that strategies can be targeted towards solving specific problems. The amount of irrational prescribing should be quantified so that the magnitude of the problem is known and the impact of the various strategies can be assessed (23). The reasons underlying irrational drug prescribing should be explored so that appropriate and feasible strategies can be chosen. This study sought to determine the patterns of prescribing practices in Makueni County Referral Hospital so that mechanisms can be put in place to address any gaps found. Identification of risk factors for inappropriate prescribing as well as the prescribers' knowledge, attitudes and practices, would help in addressing the root cause of the problem.

Prescribing practices should be evaluated periodically so as to provide feedback to prescribers which in turn increases the quality of drug therapy, reduces wastage of resources and lowers risk for adverse drug reactions among other benefits (23). From the literature reviewed, no drug prescribing survey had been conducted before in Makueni County Referral Hospital. The hospital was not included in the national survey on access to essential medicines in Kenya (2009), neither was it included in the baseline survey to assess the pharmaceutical situation in Kenya (2003). It was therefore an appropriate site for the study.

1.5 RESEARCH QUESTIONS

1. What are the patterns of prescribing practices in Makueni County Referral Hospital?
2. What are the risk factors for inappropriate prescribing in Makueni County Referral Hospital?
3. What are the prescribers' knowledge, attitudes and practices (KAP) concerning prescribing in Makueni County Referral Hospital?

1.6 OBJECTIVES

Broad objective

To determine patterns of prescribing practices in Makueni County Referral Hospital

Specific objectives

1. To determine patterns of prescribing practices using the WHO core prescribing indicators
2. To determine risk factors for inappropriate prescribing using polypharmacy and antibiotic prescribing as the outcomes of interest
3. To assess prescribers' knowledge, attitudes and practices (KAP) concerning prescribing

CHAPTER TWO: METHODOLOGY

The study was divided into two parts: a prescription survey and a questionnaire-based knowledge, attitudes and practices survey.

2.1 ETHICAL CONSIDERATIONS

Ethical approval to carry out the study was sought from the Kenyatta National Hospital – University of Nairobi (KNH – UoN) Ethics and Ethics Committee, Approval Reference Number: KNH-ERC/A/82 (Appendix 1). For the prescription survey, informed consent from patients was not required because data was abstracted from stored patient records (prescriptions, patient files and computerized records). However, in the KAP survey, informed consent was obtained in writing from prescribers before administering the questionnaire (Appendix 5).

Confidentiality was ensured when handling patients' records. Prescription data abstraction was done in the office of the hospital pharmacist in-charge while questionnaires were administered in the office of the prescriber. Data collection instruments did not bear participants' names or patient numbers; instead study numbers were used. The signed consent forms that had prescriber identifier information were stored away from the filled questionnaires to ensure confidentiality. All filled up data collection instruments were stored under lock and key in cabinets only accessible to the investigators. All electronic data were stored in password protected computer files.

The prescription survey used stored patients' records; hence there were no direct benefits or risks to the patients whose records were sampled. Likewise, in the KAP survey, there were no direct benefits or risks to the prescribers administered questionnaires. However, the study findings shall

be communicated to the hospital management. It is envisaged that these findings will help in improving the quality of prescribing in the hospital.

2.2 STUDY AREA

The study was carried out in Makueni County Referral Hospital. This is the largest hospital in Makueni County and it serves as the county referral hospital. The hospital clientele are drawn from the entire county as well as from the neighbouring counties. The hospital is located in Wote Town where the county headquarters are. It offers both inpatient and outpatient services. The hospital has two pharmacies; a comprehensive care clinic (CCC) pharmacy and an outpatient pharmacy which has a wing for serving inpatients. All prescriptions from outpatient departments are stored in the outpatient pharmacy store, whereas all inpatient files are stored in the records department. At the time of study, the hospital had 58 prescribers who included 4 consultants/medical specialists (MS), 5 medical officers (MO), 8 medical officer interns (MOI), 11 registered clinical officers (RCO), 25 clinical officer interns (COI), 2 dental officers and 3 nurses.

2.3 STUDY DESIGN

The study design was a hospital-based cross-sectional survey. A prescription survey was carried out by abstracting data retrospectively from stored copies of patient records while a KAP survey on drug prescribing was conducted by administering questionnaires to prescribers.

2.4 QUALITY ASSURANCE

The pre-designed prescription data abstraction form and the KAP questionnaire were pre-tested using a pilot study. The findings of the study were used to modify the data collection instruments to be able to collect data accurately. Research assistants were trained to achieve a degree of inter-

data collector agreement of 90%. The research progress was monitored at least once a week by the supervisors.

2.5 PART ONE: PRESCRIPTION SURVEY

The prescription survey entailed the use of the five core WHO prescribing indicators which were calculated as follows:

Average number of drugs per encounter

It was calculated by dividing the total number of drugs prescribed by the number of encounters/prescriptions sampled. Combination drugs and fixed-dose drug combinations were counted as one drug. This indicator was used to assess the degree of polypharmacy.

Percentage of drugs prescribed by generic name

The indicator was calculated by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100. In our study, the KEML 2010 (76) and the WHO Model List of Essential Drugs (77) were used to classify drug names as generic or not. This indicator was used to assess the propensity of prescribers to prescribe using international non-proprietary names (generic names) as opposed to use of proprietary brand names.

Percentage of encounters with an antibiotic prescribed

It was achieved by dividing the number of prescriptions/encounters with an antibiotic prescribed, by the total number of prescriptions sampled, multiplied by 100. Classes of drugs to be regarded as antibiotics were identified as per the WHO recommendation (23). The indicator was used to assess the overall use of antibiotics.

Percentage of encounters with an injection prescribed

It was derived by dividing the number of patient encounters during which an injection was prescribed, by the total number of encounters sampled, multiplied by 100. The indicator was used to assess the overall use of injections.

Percentage of drugs prescribed from essential drug list (EDL) or formulary

The indicator was calculated by dividing the number of drugs prescribed from the KEML by the total number of drugs prescribed. Drugs prescribed using proprietary brand names were regarded equivalent to their counterparts written by generic name in the KEML. The indicator was used to assess prescribers' compliance with KEML when prescribing.

2.5.1 Study population

The study population included all prescriptions/ patient encounters from outpatient (OPD) and inpatient departments written between 1st January and 31st December 2013 which were received, processed and stored at the hospital's outpatient pharmacy and records department.

Inclusion and exclusion criteria

Prescriptions/ patient encounters were included in the study if they originated from Makueni County Referral Hospital and were written between 1st January and 31st December 2013. Prescriptions/ patient encounters were excluded from the study if they were illegible/ faded, from CCC or written before 1st January 2013 or after 31st December 2013.

2.5.2 Sample size determination

The sampling unit was a patient encounter/ prescription. The sample size calculation was based on the proportion of encounters/prescriptions with an antibiotic prescribed. In a survey on access to essential medicines in Kenya in 2009 (49), the percentage of encounters with an antibiotic prescribed was 76.7% in public health facilities. The prevalence of antibiotic prescribing in Makueni County Referral Hospital was estimated to be 76.7%. Based on this prevalence, the sample size was calculated using the formula below (78).

$$\mathbf{N = \{Z^2P(1-P)\} / S^2}$$

Where:

N = Estimated sample size

P = Estimated proportion of outcome of interest (in this case, 76.7%)

S = Standard error (in this case, set at 5%)

Z = Z-score value corresponding to 95% Confidence Interval, which is 1.96

$$\mathbf{N = \{1.96^2 x\ 0.767(1-0.767)\} / 0.05^2}$$

$$\mathbf{N = 275}$$

Applying the formula above, the minimum sample size was 275. However, according to the WHO, at least 600 patient encounters/ prescriptions should be included in a cross-sectional survey to describe the current prescribing practices in one facility, with a greater number, if possible (23). Based on this WHO criterion, a total of 960 patient encounters/ prescriptions were sampled. Out of the 960 patient encounters sampled, only 824 met the inclusion criteria. All

excluded patient encounters plus reasons for exclusion were recorded in the prescription exclusion form (Appendix 3).

2.5.3 Sampling technique

All prescriptions/ patient encounters issued between 1st January 2013 and 31st December 2013 which met the inclusion criteria were considered for sampling. In the year 2013, the pharmacy records showed that a total of 25,320 prescriptions were received from outpatient department, processed and copies stored in the pharmacy store. The records further showed that the total number of prescriptions received per month did not change significantly across the 12 months, with an average of 2,110 prescriptions per month. All prescriptions were serialized using outpatient numbers and were stored in separate files for each month. The filing was done chronologically as per the date the prescription was written. From the records department, a total of 3,700 inpatients were seen between 1st January and 31st December 2013. The total number of inpatients seen per month did not change significantly across the 12 months, with an average of 308 inpatients per month. All inpatients had files which were serialized using inpatient numbers.

All outpatient numbers for the 25,320 outpatient prescriptions stored at pharmacy were listed together with their respective date of issue. The same was done for the 3,700 inpatient files stored at records department. The two set of numbers were compiled into one list and arranged chronologically as per the date of issue. The list of 29,020 patient numbers was used for sampling. Sampling of prescriptions was distributed across the 12 months of year 2013 so as to achieve some degree of sample representation and minimize seasonal variations. Eighty patient encounters were sampled every month from January to December 2013 so as to obtain a sample size of 960 encounters.

Quasi-random sampling technique was employed whereby; every 30th patient encounter from the list of 29,020 patient numbers was sampled to get a sample size of 960 encounters. So as to minimize bias, sampling was done by a non-healthcare worker from the facility, who was appropriately trained on non-biased sampling. The Principal Investigator did not do sampling. The 960 sampled patient numbers were then given to the pharmacist in-charge and records officer in-charge for retrieval of prescriptions and patient files.

2.5.4 Data collection procedures and instruments

Data collection took place between 15th April and 15th July 2014. A pre-designed prescription data abstraction form was used to collect the relevant data on patient demographics, source of prescription, disease information, drug information and prescriber information (Appendix 2). Data was abstracted retrospectively from stored copies of prescriptions, patient files, registers, cards and computerized patient records. Prescription sampling and data abstraction took place within the pharmacy premises in the office of the hospital pharmacist.

In the records department, the relevant patient records were accessed by getting permission from the hospital administration and the hospital records officer in-charge. A list of the sampled patient numbers was provided to the records department who maintained a computerized record of all outpatient and inpatient visits as well as manual registers, patient cards and patient files. The relevant patient records were retrieved for use in data abstraction. The computerized records had details such as patient's age, sex and place of residence therefore the patient demographic information was abstracted from these records as well as from the prescription. The following information was abstracted from the prescription or patient file: prescribed drugs, particulars of

the prescriber, source of prescription and disease information. Any information lacking from the prescriptions such as diagnosis was obtained from the patient cards and the patient registers.

After prescription data abstraction, the prescriptions were re-filed back into their respective files as they were placed as per their OPD serial numbers. The files were then taken back to their respective storage areas in the outpatient pharmacy store. The manual patient files and other patient records retrieved from the records department were also re-arranged as they were originally placed in their respective storage areas.

2.5.5 Variables

There were two main outcomes of interest: prevalence of polypharmacy and prevalence of antibiotic prescribing. Predictor variables were patient sex, patient age, patient residence, comorbidities, chronic conditions, prescriber sex and prescriber cadre.

2.6 PART TWO: QUESTIONNAIRE-BASED KAP SURVEY

2.6.1 Study population and selection criteria

The study population was all prescribers working in Makueni County Referral Hospital at the time of the study. The inclusion and exclusion criteria listed below were considered during selection of prescribers to be administered questionnaires.

Inclusion Criteria

Prescribers were included in the study if:

1. They were working at Makueni County Referral Hospital during the time of the study
2. They gave consent to be administered the questionnaire

Exclusion criteria

Prescribers were excluded from the study if:

1. They declined to be administered the questionnaire
2. They were not working at Makueni County Referral Hospital during the time of the study

2.6.2 Sample size determination and sampling technique

The sampling unit was a prescriber. Since the total population of prescribers in the study site was small (fifty eight), universal sampling method was used, whereby the entire population of prescribers in the hospital was sampled. All prescribers who met the inclusion criteria were administered questionnaires.

2.6.3 Data collection procedures and instruments

A pre-tested questionnaire (Appendix 4) was used to collect data from prescribers. The questionnaires were administered between 15th April and 15th July 2014. The data collected included prescriber demographics, number of years of practice as well as their knowledge, attitude and practices concerning prescribing. In Makueni County Referral Hospital, prescribers reported for morning duty at around 8.00 a.m. but usually the clinics became busy from about 10.00 a.m. Prescribers were therefore approached between 8.00 a.m. and 10.00 a.m. when patient flow was very low. The questionnaire was relatively short and had been designed to take a maximum of 10 minutes to complete. This ensured minimum or no interruption of services.

Administration of the questionnaire was done in the absence of patients and fellow healthcare workers. Informed consent was obtained before administering the questionnaire. Prescribers who

preferred to fill the questionnaire by themselves were left with the questionnaire and it was collected later.

2.7 DATA MANAGEMENT AND ANALYSIS

Data management

All filled up data collection instruments were stored securely. Data was coded to ensure confidentiality and blind the data analyst. Data from the surveys was entered into a MS-Access database. Data cleaning and validation was performed to achieve a clean dataset which was then exported into Epi info software (version 7.0) and Stata software (version 10.0) for data analysis. Daily back up was done using a compact disk (CD) and a flash disk to avoid loss of information. The back-ups were stored away from the original data.

Data analysis

Data analysis was done using Epi info software (version 7.0) and Stata software (version 10.0). All variables were subjected to descriptive data analysis. Continuous variables that were normally distributed were expressed as mean and standard deviation (SD) of the mean. For those continuous variables that were not normally distributed, the median and interquartile range (IQR) were reported. Categorical variables were reported as proportions and their corresponding 95% confidence intervals (95% CI). Data from the KAP survey was analyzed and reported as proportions and their corresponding 95% confidence intervals (95% CI).

Bivariable analysis was done to show the distribution of the outcome of interest across the different arms of the predictor variables. Inferential methods such as the Chi Square test, Mann-Whitney test, t-test and Kruskal-Wallis test were used. Logistic regression modeling was conducted to determine the most important risk factors for inappropriate prescribing and to

control for confounding. Both bivariable and multivariable analyses were conducted. Model building was done using a manual stepwise forward approach to achieve a parsimonious model. The results of the logistic regression analysis were reported using odds ratios (OR).

For all analyses, p values less than 0.05% were considered statistically significant.

CHAPTER THREE: RESULTS AND DISCUSSION

3.1 PART ONE: PRESCRIPTION SURVEY

3.1.1 Baseline characteristics of the study participants

Among the 824 encounters, 720 were from outpatient and 104 from inpatient department. The baseline characteristics of the study participants are described in Table 7. There were more female participants (53.9%) compared to males (46.1%). There was no significant difference (p = 0.827) in the proportion of males and females across the two arms of the clinical setting (outpatient and inpatient departments). The patient age ranged from 0.1 to 95 years. The median age was 29 (IQR: 15 – 43) years. Outpatients had a higher median age of 30 (IQR: 15 – 43) years compared to inpatients' 24 (IQR: 6.5 – 45) years, though not statistically significant (p = 0.155).

Most of the patients were rural/village dwellers (78.5%) as opposed to town/market dwellers (21.5%). This was expected since the hospital is situated in a rural county. The place of residence did not differ significantly between outpatients and inpatients (p = 0.173). About a fifth of the study participants had comorbidities (20.8%). This did not differ significantly across the clinical settings (p = 0.914). About 14% of the participants had chronic conditions. These chronic conditions were significantly more prevalent among inpatients (21.2%) compared to outpatients (12.9%), p = 0.023. The median length of hospitalization for inpatients was 5 (IQR: 3 – 8) days. The length of hospitalization ranged from 1 to 17 days.

Clinical officers generated most of the prescriptions (63.1%). However, comparing the two clinical settings, medical practitioners generated a majority of the prescriptions for inpatients (79.8%) whereas clinical officers generated the highest percentage of prescriptions for

outpatients (70.4%), $p < 0.001$. The reason for this is due to the fact that clinical officers are the first line clinicians in most public hospitals in Kenya; hence they form a bigger percentage of prescribers in outpatient departments. On the other hand, medical practitioners usually deal with more complex medical conditions that require hospital admissions. Other cadres were involved in generating about 6.6% of the prescriptions. These cadres included nurses and dental officers.

Table 7: Baseline characteristics of study participants in the prescription survey

Baseline characteristic	Outpatient (N=720)	Inpatient (N=104)	Total (N=824)	p value*
Patient demographics:				
Sex:				
Male	331 (46%)	49 (47.1%)	380 (46.1%)	0.827**
Female	389 (54%)	55 (52.9%)	444 (53.9%)	
Age in years, Median (IQR)	30 (15 – 43)	24 (6.5 – 45)	29 (15 – 43)	0.155***
Residence:				
Town/Market	160 (22.2%)	17 (16.4%)	177 (21.5%)	0.173**
Village/Rural	560 (77.8%)	87 (83.7%)	647 (78.5%)	
Disease information:				
Comorbidities:				
Yes	149 (20.7%)	22 (21.2%)	171 (20.8%)	0.914**
No	571 (79.3%)	82 (78.9%)	653 (79.3%)	
Chronic conditions:				
Yes	93 (12.9%)	22 (21.2%)	115 (14%)	**0.023****
No	627 (87.1%)	82 (78.9%)	709 (86%)	
Length of hospital admission in days, Mean (SD)	-	5.96 (4.24)	-	-
Prescriber characteristics:				
Sex:				
Male	469 (65.1%)	69 (66.4%)	538 (65.3%)	0.809**
Female	251 (34.9%)	35 (33.7%)	286 (34.7%)	
Cadre:				
Clinical Officers	507 (70.4%)	13 (12.5%)	520 (63.1%)	
Medical Practitioners	167 (23.2%)	83 (79.8%)	250 (30.3%)	**< 0.001****
Others (nurses & dental officers)	46 (6.4%)	8 (7.7%)	54 (6.6%)	**< 0.001****

***Significant p values are bolded, **Pearson Chi-square test, ***Mann-Whitney test*

3.1.2 WHO core prescribing indicators

Table 8: WHO core prescribing indicators in the prescription survey

Indicator, % (95% CI)	Outpatient (N=720)	Inpatient (N=104)	Total (N=824)	Reference values (KENYA)[a]	Standard values (WHO)[b]	p value*
Average number of drugs per encounter, (SD)	2.48 (1.34)	4.18 (1.99)	2.70 (1.54)	< 2	1.6 – 1.9	**<0.001*** **
Percentage of drugs prescribed by generic name	45 (40.9-48.3)	47.6 (43.5-51.7)	45.5 (41.2-49.6)	100	100	0.095**
Percentage of encounters with an antibiotic prescribed	72.9 (69.7-76.2)	81.7 (74.2-89.3)	74 (72-77)	< 30	20 – 26.8	0.055**
Percentage of encounters with an injection prescribed	1.5 (0.6-2.4)	94.2 (89.7-98.8)	13.2 (10.9-15.6)	< 20	13.4 – 24.1	**<0.001** **
Percentage of drugs prescribed from essential drugs list or formulary	90.6 (84.8-95.4)	82.8 (77.5-87.7)	89.1 (84.4-94.3)	100	100	0.098**

***Significant p values are bolded, ****Pearson Chi-square test, *****Mann-Whitney test,* **a**=*Adapted from "Access to Essential Medicines in Kenya. A Health Facility Survey (December 2009)"* (49), **b**=*Adapted from "The development of standard values for the WHO drug use prescribing indicators," (Geneva WHO, 2008)* (28)

3.1.2.1 Average number of drugs per encounter

As presented in Table 8, the mean number of drugs prescribed per patient encounter was 2.7. This meant that on average, a patient got 2 to 3 drugs. The mean number of drugs prescribed per patient encounter was higher than the country's reference value (49) of less than 2 and the WHO standard value (1.6 – 1.9) (28). This indicated some degree of polypharmacy. Table 9 gives a breakdown of the number of drugs prescribed per encounter which ranged from 1 to 8. About a

third (30.6%) of all outpatient prescriptions had one drug prescribed compared to only 11.5% of inpatient prescriptions. Only two (0.3%) outpatient prescriptions had 7 to 8 drugs prescribed compared to 23 (22.1%) inpatient prescriptions.

Table 9: Number of drugs prescribed per patient encounter

Number of drugs prescribed	Outpatient	Inpatient	Total
1	220 (30.6%)	12 (11.5%)	232 (28.2%)
2	171 (23.8%)	5 (4.8%)	176 (21.4%)
3	170 (23.6%)	25 (24%)	195 (23.7%)
4	91 (12.6%)	26 (25%)	117 (14.2%)
5	60 (8.3%)	9 (8.7%)	69 (8.4%)
6	6 (0.8%)	4 (3.9%)	10 (1.2%)
7	1 (0.1%)	19 (18.3%)	20 (2.4%)
8	1 (0.1%)	4 (3.9%)	5 (0.6%)
Total	**720 (100%)**	**104 (100%)**	**824 (100%)**

As shown in Figure 1, the prevalence of polypharmacy was higher for inpatients compared to outpatients. Two or more drugs were prescribed in 83.7% of all inpatient prescriptions compared to 45.7% of outpatient prescriptions.

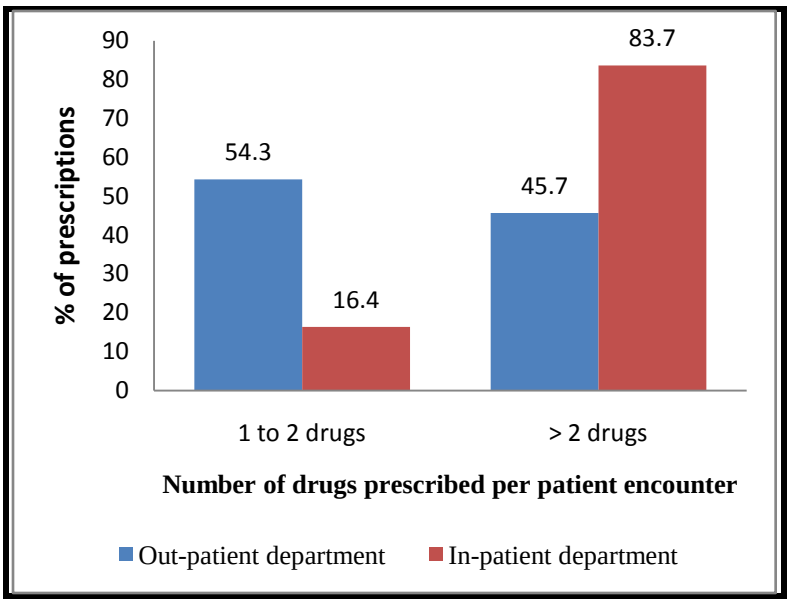


Figure 1: Comparison of prevalence of polypharmacy between outpatient and inpatient departments

Inpatients (4.18) received significantly a higher average number of drugs per encounter compared to outpatients (2.48), $p < 0.001$. This indicated a higher degree of polypharmacy in inpatient compared to outpatient department. This could be explained by the fact that inpatients usually have severe disease than outpatients which may require more drugs in order to manage successfully. This finding was consistent with results obtained from prescription surveys conducted in Pakistan (44) and Nigeria (53).

In this study, the mean number of drugs prescribed per encounter for outpatients (2.48) was similar to that reported by earlier surveys done in Saudi Arabia (41), China (43) and Brazil (40) as can be seen in Table 2. This average was lower compared to that reported in a survey on access to essential medicines in Kenya in 2009 (49). Other studies that reported a higher average number of drugs per encounter compared to our study include prescription surveys conducted in Bangladesh (4), India (46), Ghana (54) and Uganda (51). Compared to the study results, lower

averages have been reported by studies done in Lebanon (32), Ethiopia (34), Sudan (30) and Zimbabwe (30), as presented in Table 2.

Inadequate training and financial incentives to prescribers by drug industry have been documented as major contributors to polypharmacy. These two factors may have contributed to the polypharmacy seen in the study site since most of the prescribers did not attend frequent trainings/seminars on prescribing. Also, most prescribers had frequent visits by medical representatives as shown by results of the KAP survey. Polypharmacy should be discouraged because it is increases the incidence of drug interactions and adverse drug reactions.

3.1.2.2 Percentage of drugs prescribed by generic name

Prescribing using international non-proprietary (generic) names was not widely practiced in the hospital. Less than half (45.5%) of all drugs were prescribed using generic name. Prescribing using generic names was slightly higher in inpatient (47.6%) compared to outpatient (45%) department, though the difference was not statistically significant, $p = 0.095$. Prescribing using proprietary brand names was very common with combination drugs such as ophthalmological preparations and cardiovascular agents. This may be attributed to the lengthy names of such combinations as shown by results of the KAP survey.

Other reasons that might have contributed to the low prevalence of prescribing using generic names in the study site include prescribers' perception that most generics are of poor quality and are less effective compared to innovator brands as shown by results of the KAP survey. Low prevalence of generic prescribing is also attributed to drug promotion since most medical representatives emphasize on their specific brand name as opposed to the generic name of the drug. This might have been a contributing factor since most of the prescribers reported frequent

visits by medical representatives as per the KAP survey results. Moreover, most of the prescribers interviewed rated drug information given by medical representatives as excellent. Also, the poor knowledge of prescribing guidelines among the interviewed prescribers in the KAP survey may have contributed to the low prevalence of generic prescribing since some of the interviewed prescribers thought that all drugs should ideally be prescribed using brand names.

As presented in Table 8, the percentage of drugs prescribed using generic name was very low compared to the country's reference value (49) and the WHO standard value (28) of 100%. However, the results show an improvement compared to those of a survey on access to essential medicines in Kenya in 2009 (49) where the percentage of drugs prescribed by generic name was 31.8% in public health facilities. The results on prevalence of generic prescribing were similar to those reported by studies done in India (2) and Kenya (48). However several studies conducted in different countries reported lower or higher prevalence compared to our results (Table 3).

3.1.2.3 Percentage of encounters with an antibiotic prescribed

As presented in Table 8, 72.9% of all prescriptions sampled had at least one antibiotic prescribed, which shows a high prevalence of antibiotic prescribing. The prevalence was higher for inpatients (81.7%) compared to outpatients (72.9%), though the difference was not statistically significant, $p = 0.055$ (Figure 2). This may be explained by the fact that inpatients usually have severe disease than outpatients which may require empirical treatment with antibiotics even before confirmatory diagnosis. Overestimation of the disease severity could also have led to over prescription of antibiotics. The higher antibiotic prescribing in inpatients was consistent with results obtained from a survey done at a general hospital in Nigeria (53) which reported a prevalence of 96.7% for inpatients compared to 50.3% for outpatients.

The prevalence of antibiotic prescribing in outpatient department (72.9%) was similar compared to that reported in a survey on access to essential medicines in Kenya in 2009 (49), where the percentage of prescriptions with an antibiotic prescribed was 76.7% in public health facilities. This was very high compared to the country's reference value (49) of less than 30% and the standard value (28) derived by WHO to serve as ideal (20 - 26.8%). This indicated over prescription of antibiotics. The results were also similar compared to those of a baseline survey to assess the pharmaceutical situation in Kenya in 2003 (48), where the percentage of prescriptions with an antibiotic prescribed was 78.4% in public health facilities. Studies conducted in different countries reported varying percentages of antibiotic prescribing as shown in Table 4.

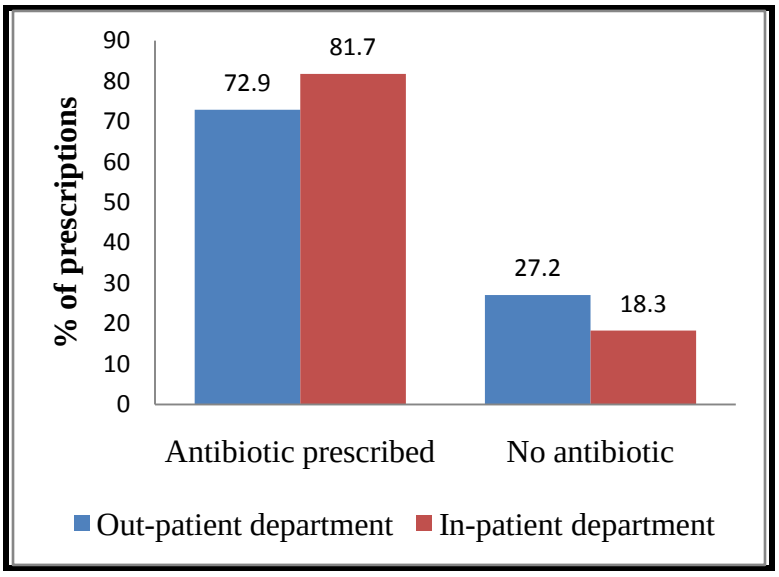


Figure 2: Comparison of prevalence of antibiotic prescribing between outpatient and inpatient departments

In encounters where an antibiotic was prescribed, 82% of the prescriptions had one antibiotic, 15.5% had two antibiotics and 2.5% had three or more antibiotics prescribed. Prescriptions with three or more antibiotics were almost exclusively prescribed for inpatients (99.5%). The

commonly prescribed antibiotics differed between outpatients and inpatients (Table 10). In the outpatient department, the top four commonly prescribed antibiotics were amoxicillin (47.6%), cotrimoxazole (23.2%), ciprofloxacin (13.1%) and flucloxacillin (10.5%). The top four commonly prescribed antibiotics for inpatients were benzyl penicillin (52.9%), gentamicin (45.9%), ceftriaxone (37.7%) and chloramphenicol (17.7%). Most inpatient prescriptions had injectable antibiotics as opposed to oral formulations, while most outpatient prescriptions had oral antibiotics.

Table 10: Commonly prescribed antibiotics

Name of Antibiotic	**Prescriptions with an antibiotic**	
	Outpatient department (N=525)	
Amoxicillin	250	47.6%
Cotrimoxazole	122	23.2%
Ciprofloxacin	69	13.1%
Flucloxacillin	55	10.5%
	Inpatient department (N=85)	
Benzyl penicillin	45	52.9%
Gentamicin	39	45.9%
Ceftriaxone	32	37.7%
Chloramphenicol	15	17.7%

***Some prescriptions had 2 or more antibiotics; hence the total % may be > 100*

3.1.2.4 Percentage of encounters with an injection prescribed

Injections were prescribed in 13.2% of all prescriptions as shown in Table 8. The prevalence of injection prescribing differed significantly between outpatients and inpatients ($p < 0.001$). As shown in Figure 3, the prevalence was very low for outpatients (1.5%) and extremely high for inpatients (94.2%). The higher prevalence of injection prescribing for inpatients was consistent with results obtained from a survey of prescribing practices in three teaching hospitals in Pakistan (44). This correlates with the severity of illness which is higher for inpatients compared

to outpatients. Injections are preferred for severely ill patients since they have a faster onset of action and also severely ill patients may be unable to take drugs orally.

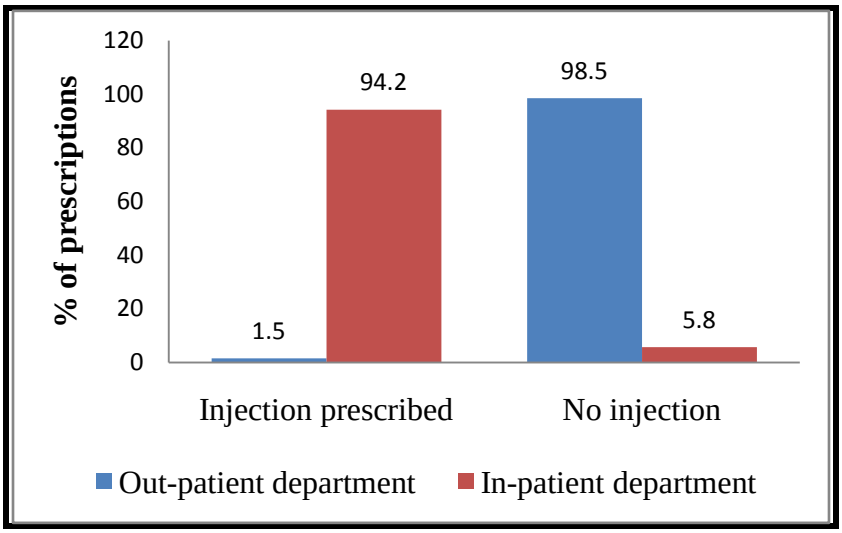


Figure 3: Comparison of prevalence of injection prescribing between outpatient and inpatient departments

The prevalence of injection prescribing in outpatient department (1.5%) was lower compared to that reported in a survey on access to essential medicines in Kenya in 2009 (49), where the percentage of prescriptions with an injection prescribed was 13% in public health facilities. This percentage was within the country's reference value (49) of less than 20% and lower than the standard value (28) derived by WHO to serve as ideal (13.4% - 24.1%). The results showed a significant decrease in injection overuse compared to those of a baseline survey to assess the pharmaceutical situation in Kenya in 2003 (48), where the percentage of outpatient prescriptions with an injection prescribed was 28.4% in public health facilities.

In outpatient department, our results were comparable to those of a study conducted in India (58). Other studies that have reported acceptable percentage of injection prescribing, though higher than our findings include Bangladesh (4), India (56), Mali (30), Indonesia (30) and

Ethiopia (36) (Table 5). Some studies have reported extremely high outpatient injection prescribing. These include surveys conducted in Burkina Faso (73), China (43) and Pakistan (61). In prescriptions where an injection was prescribed, most (90%) had two or more injections prescribed. Outpatient prescriptions accounted for almost all (98.2%) prescriptions with one injection prescribed. Diclofenac (65.6%) was the most frequently prescribed injection in outpatient department followed by insulin (29.5%) and hydrocortisone (25.2%) injection. In the inpatient department, benzyl penicillin (55.7%) was the most frequently prescribed injection followed by gentamicin (48.2%) and ceftriaxone (40.3%) injection.

Our study found that injections were overused in the inpatient department. This may have been as a result of patients' pressure to receive injections or prescribers' attitude that injections are more efficacious compared to oral formulations. This was well demonstrated by results of the KAP survey. Overuse of injections should be avoided because injections are relatively more expensive compared to other dosage forms and require trained personnel for administration. In addition, unsafe use of injections increases the risk of transmission of blood-borne diseases.

3.1.2.5 Percentage of drugs prescribed from the Kenya Essential Medicines List (KEML)

Most (89.1%) of the drugs were prescribed from the KEML, indicating a high compliance with KEML during prescribing (Table 8). This could be attributed to the availability of copies of KEML in the facility. Most of the prescribers understood the role of KEML in prescribing as depicted by results of the KAP survey. Compliance was higher in outpatient (90.6%) compared to inpatient (82.8%) department, though the difference was not statistically significant, $p = 0.098$. Drugs that contributed to non-compliance with KEML were mostly cough preparations and various creams and ointments.

The percentage of drugs prescribed from the KEML in outpatient department (90.6%) was comparable to that of a survey on access to essential medicines in Kenya in 2009 which reported a percentage of 93 in public health facilities (49). This was encouraging but below the country's (49) and WHO's (28) reference values of 100%. The results show a significant improvement in KEML compliance compared to those of a baseline survey to assess the pharmaceutical situation in Kenya in 2003 (48), where the percentage of prescribed medicines on KEML was 81.3% in public health facilities.

Similar to our results, several studies conducted in various countries reported high percentage of Essential Drug List (EDL) compliance. Such studies include surveys conducted in Bangladesh (31), Ghana (54), Uganda (51) and Burkina Faso (73). On the other hand, some studies reported low percentages of EDL compliance compared to our results, such as, surveys conducted in Bangladesh (4), India (2), Pakistan (44), China (42) and Pakistan (61) (Table 6).

3.1.3 Completeness of prescriptions

As presented in Table 11, the percentage of complete prescriptions was 41.7 and 100% for outpatient and inpatient prescriptions respectively. Most of the incomplete prescriptions lacked diagnosis. Incomplete prescriptions were exclusively found in outpatient department. This could be attributed to the frequent stock out of the standard printed prescription books in outpatient department. This led to improvising of prescription books using plain papers which did not have the various sections required to be filled when writing prescriptions.

Table 11: Completeness of prescriptions

	Outpatient (N=720)	**Inpatient (N=104)**	**Total (N=824)**	**p value***
Completeness of prescriptions % (95% CI)				
Patient name indicated	100	100	100	-
Prescription date indicated	94.4 (92.8-96.1)	100	95.2 (93.7-99.6)	**0.014****
Diagnosis indicated	41.7 (38.1-45.3)	100	49 (45.6-52.5)	<**0.001****
Dose, frequency and duration of treatment indicated	98.1 (97-99.1)	100	98.3 (97.4-99.2)	0.151**
Name or signature of prescriber indicated	100	100	100	-
Complete prescriptions considering all 5 criteria[a]	41.7 (38.1-45.3)	100	49 (45.6-52.5)	<**0.001****

***Significant p values are bolded, **Pearson Chi-square test, **a**=the 5 criteria are patient name; date; diagnosis; dose, frequency & duration of treatment; and name or signature of prescriber*

Writing the patient name as well as the patient number on a prescription helps to avoid mix ups during dispensing since several patients may be prescribed similar medication. The date of prescription is equally important so as to differentiate valid and invalid prescriptions. Including diagnosis on the prescription will help the pharmacist to contribute to positive therapeutic outcomes through auditing prescriptions hence avoiding potential drugs interactions and contraindications as well as other medication errors. Making the right diagnosis is the cornerstone for choosing the right type of therapy. Correct drug information (dose, frequency and duration of treatment) is key to the success of therapy. This information should be written clearly in every prescription so as to allow the dispenser to give the patient the correct medication and with correct instructions. Prescriber's name and signature should be indicated on the prescription so as to allow either the patient or the dispenser to contact the prescriber for any clarification or potential problem with the prescription.

3.1.4 Factors associated with polypharmacy

As presented in Figure 4, a linear relationship was found between patient age and number of drugs prescribed per patient encounter. The correlation was positive and the number of drugs prescribed seemed to increase with increasing patient age. The fitted regression line showed a general increase in the number of prescribed drugs as the patient age increased. The correlation was statistically significant ($p < 0.001$) with a correlation coefficient of 0.36. A similar correlation was reported in a study done at Kitovu Hospital in Uganda (51).

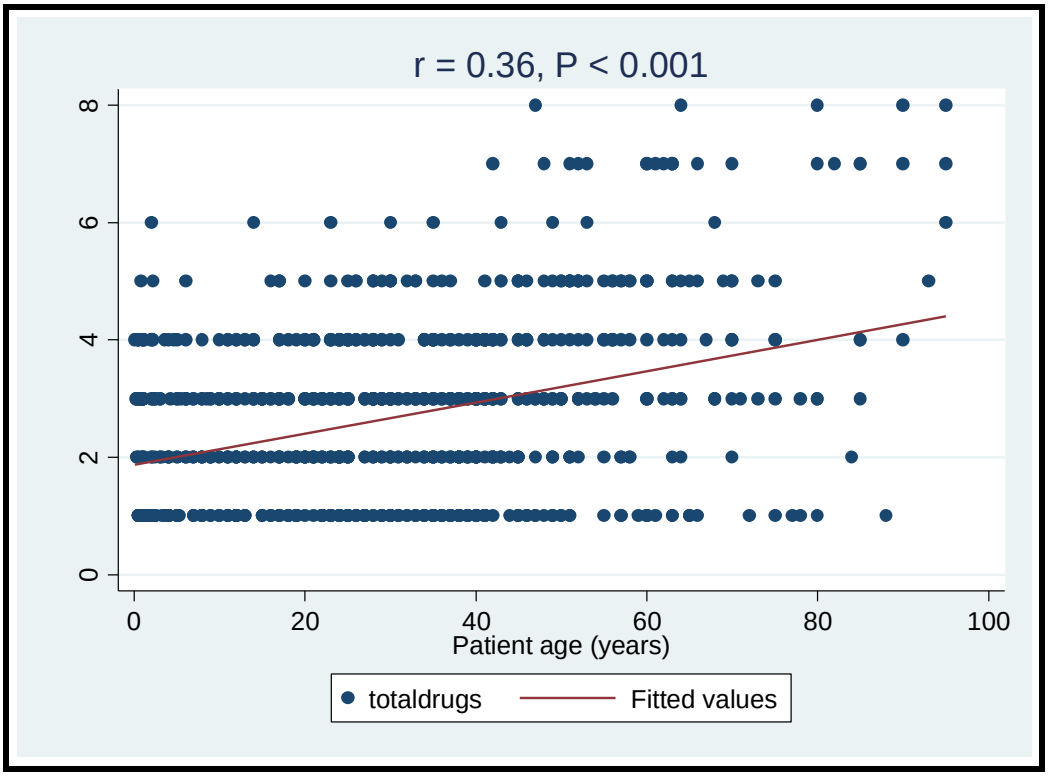


Figure 4: Correlation between patient age and number of drugs prescribed per encounter

Logistic regression modeling was used to determine the most important factors associated with polypharmacy and to control for confounding. The results of the logistic regression analysis are presented in Table 12. For purposes of logistic regression, polypharmacy was defined as

prescription of more than two drugs per encounter. A cut off of two drugs was used because the Kenyan reference value (49) for average number of drugs prescribed per patient encounter is < 2.

On bivariable analysis, patient age, clinical setting, presence of comorbidities, presence of chronic conditions, prescriber sex and cadre were all significantly associated with polypharmacy. After adjusting for confounders and other variables in multivariable analysis, prescriber sex and cadre became insignificant. On the other hand, patient residence became a significant factor after multivariable analysis. Patient age, clinical setting, presence of comorbidities and presence of chronic conditions were still significantly associated with polypharmacy even after multivariable analysis.

Patient age was positively associated with polypharmacy. Polypharmacy was more likely to occur in prescriptions of older patients compared to those of younger patients. For every one year increase in patient age, the odds of polypharmacy occurring increased by 2% (adjusted OR 1.02; 95% CI: 1.01 – 1.03; $p < 0.001$). This could be explained by the fact that older people usually present with several diseases together, hence requiring a greater number of drugs compared to younger people. Indeed 90% of patients aged 60 years or more in our study received three or more drugs. Prescriptions for patients living in town/market setting were associated with higher odds of polypharmacy compared to those of patients living in rural/village settings. Polypharmacy was one and half times more likely to be seen in prescriptions for patients living in town/market settings compared to those living in rural/village settings (adjusted OR 1.55; 95% CI: 1.04 – 2.31; $p = 0.030$).

Clinical setting was strongly associated with polypharmacy. Outpatient prescriptions were associated with a lower prevalence of polypharmacy compared to inpatient prescriptions. Polypharmacy was 86% less likely to be seen in outpatient prescriptions compared to inpatient

prescriptions (adjusted OR 0.14; 95% CI: 0.07 – 0.26); $p < 0.001$). This could be due to the fact that inpatients usually have severe disease than outpatients which may require more drugs in order to manage successfully.

Presence of comorbid conditions was strongly associated with a higher prevalence of polypharmacy. Prescriptions for comorbid conditions were 6.3 times more likely to exhibit polypharmacy compared to the ones with no comorbidities (adjusted OR 6.30; 95% CI: 4.06 – 9.77; $p < 0.001$). This was expected since comorbidities involve several diseases which may require different drugs to manage hence leading to polypharmacy. Likewise, presence of chronic conditions was strongly associated with a higher prevalence of polypharmacy. The prevalence of polypharmacy in prescriptions for chronic conditions was eight-fold that of prescriptions for non-chronic conditions (adjusted OR 8.08; 95% CI: 3.96 – 16.50; $p < 0.001$). This could possibly be due to the observation that most chronic conditions require multiple drugs for effective management. In addition, most of these chronic conditions usually present with additional symptoms which may lead to extra drugs being prescribed.

In the parsimonious model (Table 13), four predictor variables were identified as the most important variables associated with polypharmacy. These were patient age, clinical setting, comorbid conditions and chronic conditions. The odds ratios in the parsimonious model were almost similar to the adjusted odds ratios in the multivariable logistic regression.

Table 12: Bivariable and multivariable logistic regression analysis of factors associated with polypharmacy

Factors (Independent variables)	Polypharmacy (Yes/No) (Dependent variable)			
	Bivariable logistic regression		**Multivariable logistic regression**	
	Crude OR (95% CI)	**p value***	**Adjusted OR (95% CI)**	**p value***
Patient demographics:				
Sex: Male	0.91 (0.69 – 1.20)	0.498	0.96 (0.69 – 1.33)	0.797
Age in years	1.03 (1.02 – 1.03)	**< 0.001**	1.02 (1.01 – 1.03)	**< 0.001**
Residence: Town/Market	0.93 (0.67 – 1.30)	0.689	1.55 (1.04 – 2.31)	**0.030**
Clinical setting: Outpatient	0.16 (0.10 – 0.28)	**< 0.001**	0.14 (0.07 – 0.26)	**< 0.001**
Disease information:				
Presence of comorbidities	4.58 (3.09 – 6.77)	**< 0.001**	6.30 (4.06 – 9.77)	**< 0.001**
Presence of chronic conditions	12.03 (6.35 – 22.78)	**< 0.001**	8.08 (3.96 – 16.50)	**< 0.001**
Prescriber characteristics:				
Sex: Male	1.77 (0.60 – 1.17)	**< 0.001**	1.35 (0.95 – 1.93)	0.098
Cadre:				
Clinical Officers	1.00 (REF)		1.00 (REF)	
Medical Practitioners	3.70 (2.67 – 5.11)	**< 0.001**	1.46 (0.95 – 2.26)	0.085
Other (nurses & dental officers)	2.40 (13.50 – 4.26)	**0.003**	1.34 (0.66 – 2.70)	0.419

***Significant p values are bolded*

Table 13: Parsimonious logistic regression model for factors associated with polypharmacy

Factors (Independent variables)	Polypharmacy (Yes/No) (Dependent variable)	
	Adjusted OR (95% CI)	**p value***
Patient Age in years	1.02 (1.01 – 1.03)	**< 0.001**
Clinical setting: Outpatient	0.12 (0.06 – 0.21)	**< 0.001**
Presence of comorbidities	5.81 (3.78 – 8.92)	**< 0.001**
Presence of chronic conditions	10.08 (5.17 – 19.66)	**< 0.001**

***Significant p values are bolded*

3.1.5 Factors associated with antibiotic prescribing

Logistic regression modeling was used to determine the most important factors associated with antibiotic prescribing and to control for confounding. The results of the logistic regression analysis are presented in Table 14. On bivariable analysis, patient age, presence of comorbidities, presence of chronic conditions and prescriber cadre were all significantly associated with antibiotic prescribing. Adjusting for confounders and other variables in multivariable analysis, the association between patient age and antibiotic prescribing was abolished. However, presence of comorbidities, presence of chronic conditions and prescriber cadre were still significantly associated with antibiotic prescribing. Clinical setting became a significant factor after multivariable analysis.

Prescriptions from outpatient department were associated with a lower prevalence of antibiotic prescribing compared to inpatient prescriptions. An outpatient prescription was 65% less likely to have an antibiotic prescribed compared to an inpatient prescription (adjusted OR 0.35; 95% CI: 0.19 – 0.64; p = 0.001). This may be explained by the fact that inpatients usually have severe disease than outpatients which may require empirical treatment with antibiotics even before confirmatory diagnosis. Overestimation of the disease severity could also have led to over prescription of antibiotics.

Presence of comorbid conditions was strongly associated with a higher prevalence of antibiotic prescribing. Prescriptions for comorbid conditions were 4.78 times more likely to have an antibiotic prescribed compared to the ones with no comorbidities (adjusted OR 4.78; 95% CI: 2.67 – 8.56; p < 0.001). This may be explained by the fact that comorbidities usually involve several diseases which require different management approaches including antibiotic use. This

could have increased the chances of antibiotic prescribing. On the contrary, presence of chronic conditions was strongly associated with a lower prevalence of antibiotic prescribing. Prescriptions for chronic conditions were 86% less likely to have an antibiotic prescribed compared to prescriptions for non-chronic conditions (adjusted OR 0.14; 95% CI: 0.08 – 0.24; p < 0.001). This may be explained by the observation that, in our study most of the chronic conditions were cardiovascular disorders, asthma and cancers of various types, which did not necessarily require antibiotics for management. This may explain the low prevalence of antibiotic prescribing in this group.

Prescriber cadre was also significantly associated with antibiotic prescribing. Medical practitioners were 43% less likely to issue a prescription with an antibiotic compared to clinical officers (adjusted OR 0.57; 95% CI: 0.36 – 0.91; p = 0.018). This may be explained by the observation that most of the clinical officers were stationed in outpatient department where most of the medical representatives visited. This may have influenced their nature of prescribing leading to high prevalence of antibiotic prescribing. However, further studies are needed to evaluate whether the high antibiotic prescribing was justified or not. Similarly, other cadres (nurses and dental officers) were 71% less likely to issue a prescription with an antibiotic compared to clinical officers (adjusted OR 0.29; 95% CI: 0.14 – 0.55; p < 0.001). Other cadres comprised mostly of nurses in mental health clinic and dental officers in dental clinic. Considering the nature of disease conditions seen in these two departments, they did not generate as much antibiotic prescriptions as general outpatient and inpatient departments.

Table 14: Bivariable and multivariable logistic regression analysis of factors associated with antibiotic prescribing

Factors (Independent variables)	**Antibiotic prescribing (Yes/No) (Dependent variable)**			
	Bivariable logistic regression		**Multivariable logistic regression**	
	Crude OR (95% CI)	**p value***	**Adjusted OR (95% CI)**	**p value***
Patient demographics:				
Sex: Male	0.90 (0.66 – 1.22)	0.492	0.86 (0.61 – 1.21)	0.387
Age in years	0.99 (0.98 – 0.99)	**0.028**	1.00 (0.99 – 1.01)	0.847
Residence: Town/Market	1.04 (0.71 – 1.52)	0.851	0.89 (0.58 – 1.35)	0.572
Clinical setting: Outpatient	0.60 (0.36 – 1.02)	0.057	0.35 (0.19 – 0.64)	**0.001**
Disease information:				
Presence of comorbidities	3.41 (2.05 – 5.65)	**< 0.001**	4.78 (2.67 – 8.56)	**< 0.001**
Presence of chronic conditions	0.16 (0.10 – 0.24)	**< 0.001**	0.14 (0.08 – 0.24)	**< 0.001**
Prescriber characteristics:				
Sex: Male	0.84 (0.60 – 1.17)	0.295	1.37 (0.92 – 2.02)	0.118
Cadre:				
Clinical Officers	1.00 (REF)		1.00 (REF)	
Medical Practitioners	0.46 (0.33 – 0.65)	**< 0.001**	0.57 (0.36 – 0.91)	**0.018**
Others (nurses & dental officers)	0.17 (0.10 – 0.31)	**< 0.001**	0.29 (0.14 – 0.55)	**< 0.001**

***Significant p values are bolded*

In the parsimonious model (Table 15), four predictor variables were identified as the most important variables associated with antibiotic prescribing. These were clinical setting, comorbid conditions, chronic conditions and prescriber cadre. The odds ratios in the parsimonious model were almost similar to the adjusted odds ratios in the multivariable logistic regression.

Table 15: Parsimonious logistic regression model for factors associated with antibiotic prescribing

Factors (Independent variables)	**Antibiotic prescribing (Yes/No) (Dependent variable)**	
	Adjusted OR (95% CI)	**p value***
Clinical setting: Outpatient	0.37 (0.21 – 0.67)	**0.001**
Presence of comorbidities	4.82 (2.71 – 8.59)	**< 0.001**
Presence of chronic conditions	0.14 (0.08 – 0.24)	**< 0.001**
Prescriber cadre:		
Clinical Officers	1.00 (REF)	
Medical Practitioners	0.65 (0.42 – 1.01)	0.053
Others (nurses & dental officers)	0.33 (0.17 – 0.63)	**0.001**

***Significant p values are bolded*

3.2 PART TWO: QUESTIONNAIRE-BASED KNOWLEDGE, ATTITUDES AND PRACTICES SURVEY

3.2.1 Baseline characteristics of the study participants

At the time of the study, the hospital had a total of fifty eight prescribers. Four (2 clinical officers and 2 medical officers) of these prescribers were on leave hence could not be interviewed. Of the remaining fifty four, three (2 clinical officers and 1 medical officer) declined to be interviewed. The baseline characteristics of the fifty one prescribers interviewed are presented in Table 16.

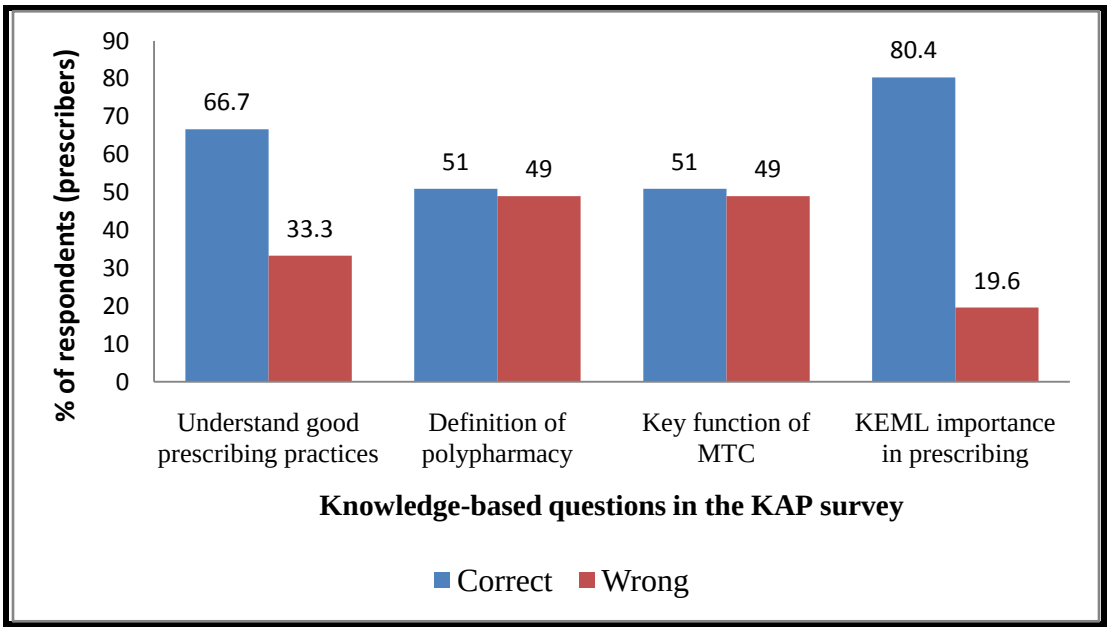
Table 16: Baseline characteristics of study participants in the KAP survey

Baseline characteristic	**Total (N=51)**
Sex:	
Male	21 (41.2%)
Female	30 (58.8%)
Age (years):	
Under 26	11 (21.6%)
26 – 30	20 (39.2%)
31 – 35	9 (17.7%)
36 – 40	3 (5.9%)
41 – 45	4 (7.8%)
Over 45	4 (7.8%)
Highest education level:	
Diploma	24 (47.1%)
Higher diploma	7 (13.7%)
Bachelor's degree	17 (33.3%)
Post-graduate degree	3 (5.9%)
Cadre:	
Clinical Officers	29 (56.9%)
Medical Practitioners	17 (33.3%)
Others (nurses & dental officers)	5 (9.8%)
Years of practice (experience):	
Under 1	18 (35.3%)
1 – 5	16 (31.4%)
6 – 10	8 (15.7%)
Over 10	9 (17.7%)

There were more female (58.8%) than male prescribers (41.2%) interviewed. About a third (39.2%) of the prescribers were aged between 26 and 30 years. Only 7.8% of the prescribers were aged over 45 years. Diploma holders (47.1%) were the majority followed by bachelor degree holders (33.3%), then higher diploma holders (13.7%) and finally post-graduate degree holders (5.9%). Clinical officers accounted for 56.9% of the participants, medical practitioners 33.3% and other cadres (nurses and dental officers) 9.8%. Most (35.3%) of the prescribers had less than 1 year experience, followed by 1 to 5 years (31.4%), then over 10 years (17.7%) and lastly 6 to 10 years (15.7%) of experience.

3.2.2 Knowledge of prescribing guidelines

Figure 5 summarizes the responses to knowledge-based questions in the KAP survey.



KEML=*Kenya Essential Medicines List,* **MTC**=*Medicines and Therapeutics Committee*

Figure 5: Knowledge of prescribing guidelines

Approximately, a third (33.3%) of the respondents did not understand what good prescribing practices entail. Eleven (21.6%) interviewees responded that drugs should ideally be prescribed using brand names. Three (5.9%) respondents said that a standard prescription should have at least four drugs. Another 5.9% responded that a standard prescription should have at least one antibiotic prescribed. Only 66.7% of the prescribers knew that drugs should ideally be prescribed using generic names. This showed a serious knowledge gap on prescribing practices among prescribers. These results may explain why most prescribing indicators were poor in the prescription survey.

Almost, half (49%) of the interviewed prescribers did not understand what polypharmacy was. This may have led to the notable polypharmacy seen during the prescription survey. Likewise, about half (49%) of the respondents did not know that formulation of prescribing guidelines is a key function of medicines and therapeutics committee (MTC). This could mean that such prescribers were not aware of the functions of MTC. It was encouraging to note that most (80.4%) of the prescribers knew the importance of KEML during prescribing. This might have contributed to the high percentage of drugs prescribed from the KEML as shown by results of the prescription survey.

3.2.3 Factors considered when prescribing

Table 17 presents the factors considered when prescribing.

Table 17: Factors considered when prescribing

Question and Responses	% of respondents Total (N=51)
MOST important factor to consider with respect to cost of drugs when prescribing:	
Patients of low socio-economic status should always be prescribed cheaper drugs	1 (2%)
Patients of high socio-economic status should always be prescribed expensive drugs	3 (5.9%)
The prescriber should prescribe the best drug for the patient irrespective of its cost	21 (41.2%)
Patient's ability to purchase drugs should always be considered when prescribing	26 (51%)
What factor BEST explains why a prescriber would prescribe using a particular brand name as opposed to using the generic name?	
Most generics are of poor quality compared to innovator brands	26 (51%)
Most generics are less effective compared to innovator brands	17 (33.3%)
Generic names are difficult to remember compared to brand names	4 (7.8%)
Generic names are lengthy to write compared to brand names	4 (7.8%)
What factor BEST explains why a prescriber would prescribe an injection as opposed to the oral formulation of the drug?	
Injections are more effective compared to oral drugs	7 (13.7%)
Patients demand that they be prescribed injections	12 (23.5%)
Injections have a faster onset of action compared to oral drugs	27 (52.9%)
Injections are safer compared to oral drugs	5 (9.8%)

3.2.3.1 Cost considerations when prescribing

Twenty one (41.2%) respondents were of the opinion that the prescriber should prescribe the best drug for the patient irrespective of its cost. This should be discouraged since the patient's ability to purchase drugs should always be considered when prescribing. Cost consideration is a key element in rational prescribing. About half (51%) of the interviewees responded that patient's ability to purchase drugs should always be considered when prescribing, which is commendable. Three (5.9%) prescribers responded that patients of high socio-economic status should always be prescribed expensive drugs while one (2%) responded that patients of low socio-economic status should always be prescribed cheaper drugs. This is not necessarily the case since the concept of cost consideration in prescribing is to ensure that every patient gets an affordable, good quality and effective medicine.

3.2.3.2 Reasons for preference for branded drugs

Prescribers interviewed gave varying reasons for not using generic names when prescribing. Twenty six (51%) interviewees were of the opinion that most generic drugs are of poor quality compared to the innovator brands, while seventeen (33.3%) thought that most generics are less effective. Four (7.8%) respondents chose difficulty to remember generic names and another four (7.8%) chose lengthiness of generic names as the best explanations for using brand names as opposed to generic names when prescribing. These could be the reasons behind the low prevalence of generic prescribing seen during the prescription survey. It is important to emphasize that generic drugs are equally of good quality and as effective as the innovator brands. The importance of prescribing using generic names also needs to be emphasized. Generic prescribing reduces drug costs hence rationalizing drug therapy.

3.2.3.3 Reasons for preference for injections

There were varying reasons, reported in the KAP survey, as to why prescribers prescribe injections as opposed to oral drugs. Twenty seven (52.9%) respondents chose faster onset of action as the best explanation for prescribing an injection as opposed to an oral drug, while twelve (23.5%) cited pressure from patients to get injections. Seven (13.7%) prescribers thought that injections were more effective compared to oral drugs, while five (9.8%) thought that injections are safer compared to oral formulations.

As much as injections have a faster onset of action, there are equally good and safer routes of drug administration that have faster onset of action, for example, the rectal and sublingual routes. Prescribers should not bow to pressure from patients, rather the clinician should advise the patient on the best and safest route of drug administration depending on the desired therapeutic outcome. Clinicians should know that oral drugs are equally effective as injections in treating various disease conditions. Oral drugs are safer to administer compared to injections since unsafe use of injections can increase the risk of transmission of blood-borne diseases.

3.2.4 Sources of information on drugs

Our study explored commercial/ industry sources and continuous medical education (CMEs)/ seminars as sources of drug information for prescribers. As presented in Figure 6, about two thirds (66.7%) of the respondents had monthly visits by medical representatives, 19.6% had quarterly visits, 5.9% had biannual visits, 3.9% had annual visits and another 3.9% had never been visited by medical representatives. Most of the prescribers had monthly visits by medical representatives. This high frequency of visits by drug promoters should be checked because studies have shown that drug information from industry sources is often biased towards certain

drugs and is likely to result in inappropriate prescribing (79). Prescribers should be aware of the fact that drug promoters often emphasize only the positive aspects of drugs and overlook or give little coverage to the negative aspects since their primary goal is to promote a particular drug (79). This may result in various forms of irrational prescribing.

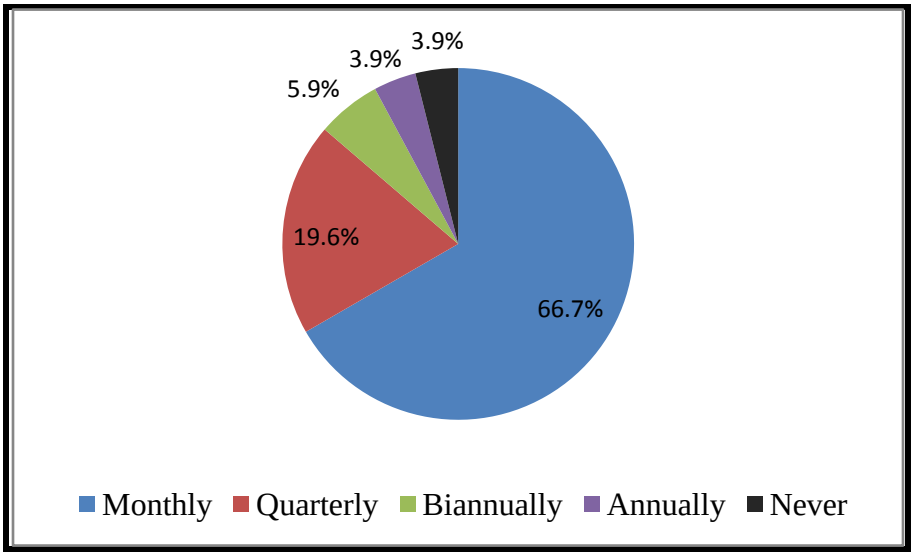


Figure 6: Frequency of prescriber visits by medical representatives

Slightly more than half (52.9%) of the respondents rated the quality of drug information given by medical representatives as excellent, 21.6% rated it as good and 25.5% rated it as poor. It is not good practice to use only industry information to keep up-to-date. Information from medical representatives is helpful in learning new developments about drugs, but it should always be verified and compared with impartial sources (79).

As shown in Figure 7, 11.8% of the respondents had monthly CME attendance, 9.8% had quarterly attendance, 13.7% had biannual attendance, 17.7% had annual attendance and 47.1% had never attended a CME/ seminar on prescribing. The KAP survey results revealed that almost half of the prescribers had never attended a continuous medical education (CME)/ seminar on

prescribing. This meant that prescribers were not frequently updated on prescribing practices. This was evident in the KAP survey since most of the prescribers had poor knowledge on prescribing guidelines. The lack of updates may have led to the poor prescribing indicators seen in the prescription survey.

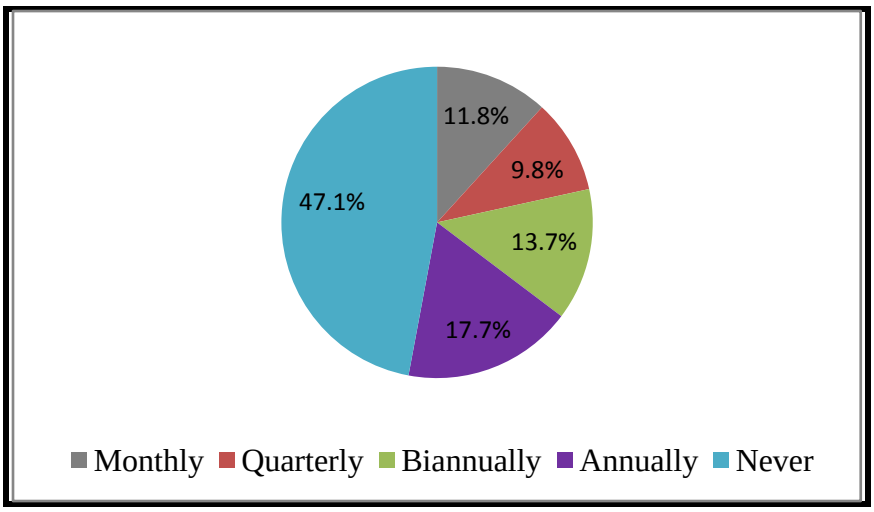


Figure 7: Frequency of prescriber attendance of continuous medical education forums (CMEs)/ seminars on prescribing

CHAPTER FOUR: GENERAL DISCUSSION, CONCLUSION AND RECOMMENDATIONS

4.1 GENERAL DISCUSSION

Based on the WHO prescribing indicators, the study findings showed a remarkable degree of polypharmacy in the study site. Prescribing using proprietary brand names was widely practiced in the hospital. Combination drugs were almost exclusively prescribed using proprietary brand names. There was over prescription of antibiotics in the hospital. Prescriptions with three or more antibiotics were mainly found in inpatient department. In the outpatient department, the top four commonly prescribed antibiotics were amoxicillin, cotrimoxazole, ciprofloxacin and flucloxacillin whereas the top four commonly prescribed antibiotics for inpatients were benzyl penicillin, gentamicin, ceftriaxone and chloramphenicol in that order.

The prevalence of injection prescribing was within the acceptable range for outpatients with overuse noted in inpatient department. In the outpatient department, the commonly prescribed injections were diclofenac, insulin and hydrocortisone whereas the commonly prescribed injections for inpatients were injectable benzyl penicillin, gentamicin and ceftriaxone in that order. There was high compliance with KEML during prescribing, which was encouraging. However, a few drugs were prescribed outside the KEML especially cough preparations and various creams and ointments.

Incomplete prescriptions were exclusively found in outpatient department. Diagnosis was not written in most of the prescriptions. There was a positive correlation between patient age and number of drugs prescribed per patient encounter. Using logistic regression, four variables, that is, patient age, prescription source, comorbid conditions and chronic conditions, were identified

as the most important variables associated with polypharmacy. Prescription source, comorbid conditions, chronic conditions and prescriber cadre were identified as the most important variables associated with antibiotic prescribing.

KAP survey identified gaps in prescribers' knowledge concerning prescribing which included lack of knowledge regarding prescribing guidelines, polypharmacy and functions of MTC. However, most of the prescribers were aware of the usefulness of KEML during prescribing. Majority of the prescribers rated the quality of drug information given by medical representatives as excellent. Moreover, most of the prescribers had monthly visits by medical representatives. Most of the prescribers were of the opinion that generic drugs are of poor quality and less effective compared to branded drugs. Majority of the prescribers were not frequently updated on prescribing practices since most of them had low frequency of attendance or had never attended a CME/seminar on prescribing. These knowledge gaps together with the undesirable attitudes and practices might have contributed to the poor prescribing indicators' results.

4.2 CONCLUSION

Some of the prescribing indicators showed deviation from the standard values recommended by WHO. This indicated some degree of irrational/inappropriate prescribing in the hospital, particularly polypharmacy, underuse of international non-proprietary names (generic names), over prescription of antibiotics and incomplete prescription writing. Some knowledge gaps were identified among prescribers concerning prescribing guidelines as well as undesirable attitudes and practices as depicted by results of the KAP survey.

4.3 RECOMMENDATIONS

Frequent CMEs, seminars and trainings on prescribing are recommended so as to keep prescribers updated on good prescribing practices. Periodic prescription surveys and drug utilization studies are recommended to assist in identifying any forms of irrational prescribing. The findings of such studies should be disseminated to all healthcare workers and particularly the prescribers. This should be followed by relevant interventions to remedy any problems identified.

The high frequency of visits by drug promoters should be checked because studies have shown that drug information from industry sources is often biased towards certain drugs and is likely to result in inappropriate prescribing. Information from medical representatives should always be verified and compared with impartial sources. The baseline data reported by our study can help hospital administrators, policy makers and researchers to improve prescribing practices in health facilities. This being among the first few studies on prescribing practices using WHO prescribing indicators in Makueni County and Kenya in general, further research is required.

4.4 STUDY LIMITATIONS

In the retrospective prescription survey, illegible and faded prescriptions were a challenge. All illegible and faded prescriptions were excluded from the study. This might have introduced bias in the selection of prescriptions. However, the prevalence of illegible/faded prescriptions was very low and it was distributed equally across outpatients and inpatients and also across the different prescriber cadres. Incomplete and missing patient records also posed a challenge. These were also excluded.

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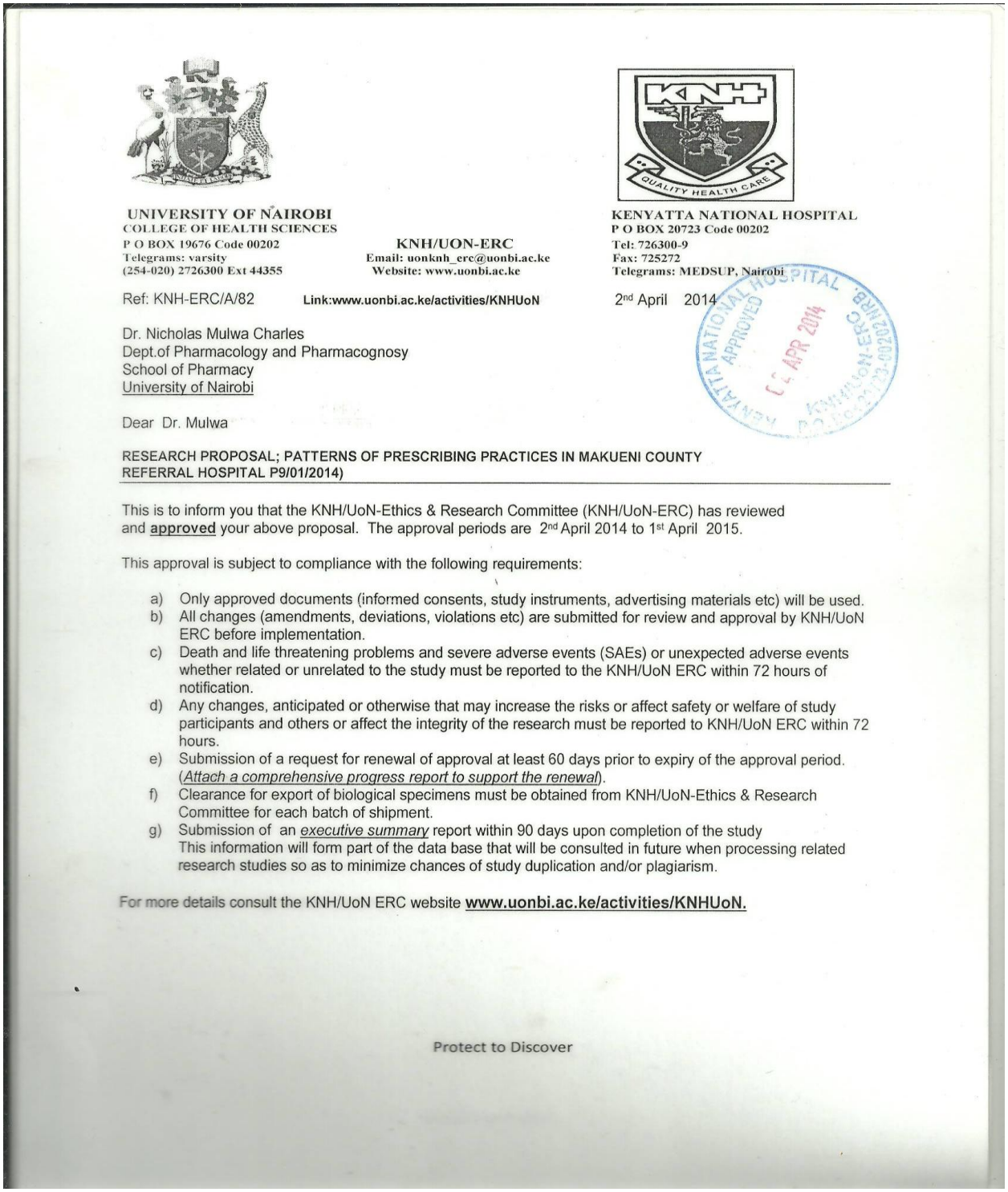
APPENDICES

APPENDIX 1: LETTER OF ETHICAL APPROVAL



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Ref: KNH-ERC/A/82 Link:www.uonbi.ac.ke/activities/KNHUoN

2nd April 2014

KENYATTA NATIONAL HOSPITAL APPROVED 02 APR 2014 KNH/UON-ERC P.O. Box 20723-00202 NRB

Dr. Nicholas Mulwa Charles
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi

Dear Dr. Mulwa

RESEARCH PROPOSAL; PATTERNS OF PRESCRIBING PRACTICES IN MAKUENI COUNTY REFERRAL HOSPITAL P9/01/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 2nd April 2014 to 1st April 2015.

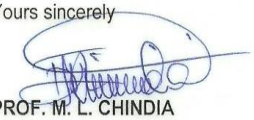
This approval is subject to compliance with the following requirements:

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 severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
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.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

Protect to Discover

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Dean, School of Pharmacy, UoN
The Assistant Director, Health Information, KNH
Supervisors: Dr. George O. Osanjo, Prof. Gichuru Muriuki, Dr.Stanley Ndwigah

APPENDIX 2: PRESCRIPTION DATA ABSTRACTION FORM

STUDY TITLE: PATTERNS OF PRESCRIBING PRACTICES IN MAKUENI COUNTY REFERRAL HOSPITAL, KENYA

Data Collector: _____Date Collected: _____

Date of Prescription: _____ Study Number: _____

A) ELIGIBILITY CHECKLIST

i. Is the prescription/ patient encounter written at Makueni County Referral Hospital?
[ ] Yes [ ] No

ii. Was the prescription/ patient encounter written between 1st January and 31st December 2013? [ ] Yes [ ] No

NOTE: All the two Eligibility criteria above MUST be answered 'YES' before data abstraction.

B) PATIENT DEMOGRAPHIC INFORMATION

1. Sex [ ] 1=Male [ ] 0=Female
2. Age in years _____
3. Place of Residence _____
[ ] 1=Town/Market [ ] 0=Village/Rural

C) SOURCE OF PRESCRIPTION

4. Prescription source
[ ] 1=Out-patient department/clinic (specify) _____
[ ] 0=In-patient department/ward (specify) _____

D) DISEASE INFORMATION

5. Diagnosis (specify) _____
6. Is there a chronic condition?
[ ] 1=Yes [ ] 0=No
7. Are there comorbidities?
[ ] 1=Yes [ ] 0=No

E) DRUGS PRESCRIBED

8. List of ALL drugs prescribed **(as per the names used in the prescription):**

1)	7)
2)	8)
3)	9)
4)	10)
5)	11)
6)	12)

F) PRESCRIBING INDICATORS

9. Total number of drugs prescribed	…….
10. Number of drugs prescribed using generic name	…….
11. Any antibiotic prescribed?	1=Yes 0=No
12. Any injection prescribed?	1=Yes 0=No
13. Number of drugs prescribed from the Kenya Essential Medicines List	…….

G) PRESCRIBER INFORMATION

14. Sex [ ] 1=Male [ ] 0=Female

15. Current job title/designation/cadre:

[ ] 1=Clinical Officer (includes intern)

[ ] 2=Medical Practitioner (includes medical officer, intern, consultant)

[ ] 3=Other (Specify) _____

H) COMPLETENESS OF THE PRESCRIPTION

CRITERION	1=YES	0=NO
i. Is the patient's name indicated?		
ii. Is the date of prescription indicated?		
iii. Is the diagnosis indicated?		
iv. Is the Dose, Frequency & Duration (ALL 3) of therapy indicated?		
v. Is the name or signature of the prescriber indicated?		

16. Is the prescription complete considering ALL the 5 criteria above?

[ ] 1=Yes [ ] 0=No

I) LENGTH OF STAY (FOR IN-PATIENTS ONLY)

17. Length of stay in the hospital/length of admission (days) ……

APPENDIX 3: PRESCRIPTION EXCLUSION FORM

STUDY TITLE: PATTERNS OF PRESCRIBING PRACTICES IN MAKUENI COUNTY REFERRAL HOSPITAL, KENYA

STUDY NUMBER	REASON FOR EXCLUSION

APPENDIX 4: QUESTIONNAIRE TO PRESCRIBERS

STUDY TITLE: PATTERNS OF PRESCRIBING PRACTICES IN MAKUENI COUNTY REFERRAL HOSPITAL, KENYA

Data Collector: _____

Date Collected: _____Questionnaire Number: _____

A) ELIGIBILITY CHECKLIST

i. Has the prescriber signed the voluntary informed consent form? [ ] Yes [ ] No

ii. Is the prescriber currently working at Makueni County Referral Hospital?[ ] Yes [ ] No

NOTE:

1. **The two Eligibility criteria above MUST be answered 'YES' before the questionnaire is administered.**
2. **This questionnaire will be completed ANONYMOUSLY. We would appreciate if you answer all the questions and answer as honestly as possible.**

B) PRECRIBER DEMOGRAPHIC QUESTIONS

Please CIRCLE THE BEST ANSWER for each question. Kindly choose ONLY ONE ANSWER per question.

1. What is your sex? a) 1=Male b) 0=Female

2. How old are you?

1) Under 26 years
2) 26 – 30 years
3) 31 – 35 years
4) 36 – 40 years
5) 41 – 45 years
6) Over 45 years

3. What is your highest level of education?

1) Diploma
2) Higher Diploma
3) Bachelors Degree
4) Post-graduate Degree

4. What is your current job title/designation/cadre?

1) Clinical Officer (includes intern)
2) Medical Practitioner (includes medical officer, intern, consultant)
3) Other (Specify)……

5. How long have you been working as a prescriber (years of practice), including internship?

1) Under 1 year
2) 1 – 5 years
3) 6 – 10 years
4) Over 10 years

C) KNOWLEDGE, ATTITUDE AND PRACTICES (KAP) SURVEY QUESTIONS

Please CIRCLE THE BEST ANSWER for each question. Kindly choose ONLY ONE ANSWER per question.

6. Concerning good prescribing practices:
   1) All drugs should ideally be prescribed using brand names
   2) All drugs should ideally be prescribed using generic names
   3) A standard prescription should have an average of four drugs
   4) A standard prescription should have at least one antibiotic prescribed
   5) Injections should only be used for inpatients

NB: *Generic name is the International Non-Proprietary Name (INN) of a drug e.g. Paracetamol. Brand names are the specific names given by manufacturers to identify their products e.g. Panadol®, Calpol®, Curamol®, Unimol® e.t.c.*

7. What do you understand by the term Polypharmacy?
   1) Dispensing more drugs than prescribed
   2) Prescribing too many drugs in one prescription
   3) Dispensing drugs from different pharmacies
   4) Prescribing the same drug in different prescriptions

8. One of the key functions of Medicines and Therapeutics Committee (MTC) in a hospital is:
   1) To formulate drug disposal guidelines
   2) To formulate procurement guidelines
   3) To formulate prescribing guidelines

9. How does the Kenya Essential Medicines List (KEML) 2010 influence prescribing?
   1) KEML is only used when procuring drugs but it does not influence what is prescribed
   2) Prescribers should try as much as possible to adhere to the drugs in KEML when prescribing
   3) Prescribers should adhere to clinical guidelines and NOT the KEML when prescribing
   4) So long as the prescribed drug is effective, it does not matter whether it is in the KEML or not

10. How do you rate the quality of drug information given by medical representatives?
    1) Excellent (> 80%)
    2) Good (50 – 80%)
    3) Poor (< 50%)

11. In your own opinion, what factor BEST explains why a prescriber would prescribe using a particular brand name as opposed to using the generic name of the drug?
    1) Most generics are of poor quality compared to branded drugs
    2) Most generics are less effective compared to branded drugs
    3) Generic names are very difficult to remember compared to brand names
    4) Generic names are lengthy to write compared to brand names
    5) Other (specify)……..

12. In your own opinion, what factor BEST explains why a prescriber would prescribe an injection as opposed to an oral drug?
    1) Injections are more effective compared to oral drugs
    2) Injections are cheaper compared to oral drugs
    3) Patients demand that they be prescribed injections
    4) Injections have a faster onset of action compared to oral drugs
    5) Injections are safer compared to oral drugs
    6) Other (specify)……..

13. In your own opinion, what is the MOST important factor to consider with respect to cost of drugs when prescribing?
    1) Patients of low socio-economic status should always be prescribed cheaper drugs
    2) Patients of high socio-economic status should always be prescribed expensive drugs
    3) The prescriber should prescribe the best drug for the patient irrespective of its cost
    4) Patient's ability to purchase drugs should always be considered when prescribing
    5) Other (specify)……..

14. On average, how often do medical representatives (drug promoters) visit you?
    1) Monthly
    2) Quarterly (four times in a year)
    3) Biannually (twice in a year)
    4) Yearly
    5) Never visited

15. How often do you attend Continuous Medical Education (CMEs) or seminars on prescribing?
    1) Monthly
    2) Quarterly (four times in a year)
    3) Biannually (twice in a year)
    4) Yearly
    5) Never

THANK YOU FOR YOUR PARTICIPATION

APPENDIX 5: CONSENT FORM FOR QUESTIONNAIRE TO PRESCRIBERS

STUDY TITLE: PATTERNS OF PRESCRIBING PRACTICES IN MAKUENI COUNTY REFERRAL HOSPITAL, KENYA

You are being invited to participate in a survey assessing patterns of prescribing practices in Makueni County Referral Hospital. Before you decide whether to participate, it is important for you to understand why the research 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 that you do not understand. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

Thank you for reading this.

Title of the study: Patterns of prescribing practices in Makueni County Referral Hospital, Kenya

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

Investigator: Dr Nicholas Mulwa Charles, P.O BOX, 30197-00400, Nairobi. Tel: 0720 349 153

Supervisors: Dr G Osanjo, Department of Pharmacology and Pharmacognosy
Prof G Muriuki, Department of Pharmacology and Pharmacognosy
Dr S Ndwigah, Department of Pharmaceutical Chemistry

Ethical Approval: Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee, P.O BOX 20723-00100, Nairobi. Tel. 2726300/2716450 Ext. 44102

Permission is requested from you to enroll in this medical research study. You should understand the following general principles which apply to all 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.

Purpose of the study: The purpose of the study is to assess prescribing practices in the hospital.

Procedure to be followed: With your permission, I will administer a questionnaire to you or leave you with the questionnaire to fill. All information obtained will be handled with confidentiality. It will take a maximum of 10 minutes to administer the questionnaire.

Risks: There will be no risks involved in this study.

Benefits: There will be no direct benefits to you but the findings of this study will be useful in improving prescribing practices in Makueni County Referral Hospital.

Confidentiality: Utmost confidentiality will be ensured. Your name will not be mentioned or used during data handling or in any resulting publications. Study numbers/codes will be used instead.

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

I now request you to sign the consent form below.

CONSENT FORM

I confirm that I have read and understood the information given above for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my rights being affected. I agree to take part in the above study.

Name …… Signature …… Date ……

Witnessed by:

Name …… Signature …… Date ……
(Investigator)