POLYPHARMACY AND QUALITY PRESCRIBING IN GERIATRIC PATIENTS – A CASE STUDY OF NYERI PROVINCIAL GENERAL HOSPITAL

BY

DR. ANNIE WAMAITHA MWANIKI

REG NO: U51/60276/2013

Department of Pharmacology and Pharmacognosy

School of Pharmacy, University of Nairobi

A Thesis Submitted in Partial fulfilment of the Requirements for Degree of Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance in the School of Pharmacy of the University of Nairobi

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 for publication.

Signature: ....………………….   Date: ....

Dr. Annie Wamaitha Mwaniki

SUPERVISORS APPROVAL

This thesis has been submitted for examination with our approval as University supervisors.

1. **Dr. Eric M. Guantai**

    Department of Pharmacology and Pharmacognosy

    School of Pharmacy, University of Nairobi

Signature: ……………………………   Date: ……………………………………

2. **Dr. Kipruto A. Sinei**

    Department of Pharmacology and Pharmacognosy

    School of Pharmacy, University of Nairobi

Signature: ……………………………   Date:…………………………………….

UNIVERSITY OF NAIROBI DECLARATION OF ORIGINALITY FORM

Name of student: DR.ANNIE WAMAITHA MWANIKI

Registration number: U51/60276/2013

College: COLLEGE OF HEALTH SCIENCES

School: SCHOOL OF PHARMACY

Department: DEPARTMENT OF PHARMACOLOGY AND PHARMACOGNOSY

Course name: MASTER OF PHARMACY IN PHARMACOEPIDEMIOLOGY AND PHARMACOVIGILANCE

Title of the work: POLYPHARMACY AND PRESCRIBING QUALITY IN GERIATRIC PATIENTS – A CASE STUDY OF NYERI PROVINCIAL GENERAL HOSPITAL

DECLARATION

1. I understand what plagiarism is and I am aware of the University's policy in this regard.

2. I declare that this THESIS is my original work and has not been submitted elsewhere for examination, award of a degree or for publication. Where other peoples work or my own has been used, this has properly been acknowledged and referenced in accordance with The University of Nairobi requirements.

3. I have not sought or used the services of any professional agencies to produce this work.

4. I have not allowed, and shall not allow anyone to copy my work with the intention of passing it off as his/her own work.

5. I understand that any false claim in respect of this work shall result in disciplinary action, in accordance with University Plagiarism Policy.

Signature: …………………………………….Date:..…………………………………...

DEDICATION

To my husband Kimathi and my son Adrian.

ACKNOWLEDGEMENTS

LIST OF ABBREVIATIONS AND ACRONYMS

ADEs	Adverse drug event (s)
AOU	Assessment of Under-utilization of Medication (AOU)
ARMOR tool	Assess, Review, Minimize, Optimize, Reassess tool
CNS	Central nervous system
IPs	Inappropriate Prescription (s)
MOPC	Medical Outpatient Clinic
OTC	Over The Counter
START criteria	Screening Tool to Alert doctors to the right Treatment
STOPP criteria	Screening Tool of Older Person's Potentially inappropriate Prescriptions
NSAIDs	Non-steroidal anti-inflammatory drugs

TABLE OF CONTENTS

LIST OF FIGURES TABLES

DEFINITIONS

Adverse Drug Event (ADE): This is an injury or harm resulting from the use of a drug but not necessarily causally related.

Adverse Drug Reaction (ADR): This is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function. The drug at normal doses, directly causes this reaction during normal use, that is, there is a causal link between a drug and an adverse drug reaction.

Contra-therapeutic Polypharmacy: This type occurs when an individual experiences unanticipated or unintentional adverse effects while he or she is on a regimen of multiple drugs and is not adequately monitored.

Geriatric patient: A geriatric patient in the context of this research is any person who is 65 years old and above.

Inappropriate Prescription: It is a prescription that is unnecessary, ineffective, and potentially dangerous and can lead to adverse drug reactions.

Pharmacodynamics: Pharmacodynamics refers to the relationship between drug concentration at the site of action and the resulting effect, including the time course and intensity of therapeutic and adverse effects.

Pharmacokinetics: This is the study of drug absorption, distribution, metabolism, and excretion in the body over time. The principles of pharmacokinetics are applied to ensure the safe and effective therapeutic management of drugs in an individual patient.

Polypharmacy: This is the use of multiple medicines (at least five types of medicines) to treat a single patient.

Therapeutic Polypharmacy: This type occurs when multiple drug regimens are carefully monitored by clinicians and are necessary for the treatment of conditions and for achieving a therapeutic goal.

Unsafe medicine: A medicine that is noxious, causes harm or side effect. In this context it is also amedicine that should be avoided in the elderly according to the Beers criteria.

ABSTRACT

Introduction:

Polypharmacy is the use of multiple medicines (at least five types of medicines) to treat a single patient. Polypharmacy can have positive and negative consequences. Therefore, it is important to distinguish between rational and irrational polypharmacy. Prescription quality, good prescribing practices as well as good dispensing practices are important in avoiding irrational polypharmacy. The elderly are at a risk of negative consequences of polypharmacy because of the pharmacokinetic and pharmacodynamic changes that occur as people age. In addition, such patients tend to present with different disease patterns, often including two or more concurrent diseases, and have altered, usually slower response to treatment.

Objective:

The objective of this study was to establish the frequency and characteristics of irrational polypharmacy and inappropriate medication use among geriatric patients at the Nyeri Provincial General Hospital.

Methodology:

This study was a cross-sectional study that involved the collection and analysis of demographic and treatment data from medical records and interviews of patients aged 65 years and older and who attended the medical outpatient clinic (MOPC) or were admitted to the medical inpatient wards at Nyeri Provincial General Hospital between 1st January and 31st December 2013.

Results:

The prevalence of polypharmacy among patients in Nyeri PGH was found to be 5.15% (N=22). Of all the prescriptions that exhibited polypharmacy (N=22) the proportion of those with inappropriate medicines was 50% (n=11) and those with underused medications was 13.63% (n=3). On the other hand the prevalence of inappropriate prescriptions in patients who did not experience polypharmacy (N=405) was 15.8% (n= 64) and the prescriptions with underused medicines was 3.7% (n=15).

After logistic regression, sex, polypharmacy and the number of drugs per prescription were found to be independent predictors of inappropriate prescribing among these geriatric patients.

This study established that males had lower odds than females of having inappropriate medication in their prescription. Also, the presence of polypharmacy raises the odds of inappropriate prescribing, as does an increase in the number of drugs prescribed. Pain medications (NSAIDS) were the most inappropriately prescribed medicines, followed by anticholinergics, central nervous system drugs and cardiovascular system drugs.

Twenty five patients were interviewed so as to qualitatively explore the possible outcomes of polypharmacy. One patient had difficulty in keeping track of their medicines, 7 had trouble taking their medicines, 19 patients could not describe the purpose of their medicines, 21 had difficulty in understanding the instructions on their medications, 1 patient reported that they experienced an ADR, 3 patients saw more than one doctor and 12 patients visited more than one pharmacy.

Discussion:

The results were consistent with findings from other studies, though the frequency of polypharmacy in Nyeri Provincial hospital was quite low compared to those found in other studies. Polypharmacy is common problem especially in non-government medical institutions and hospitals compared to Government hospitals. The main reason for this is the limited number of available drugs in the Government hospital formularies compared to the larger number of drugs that are available in the private sector and that most of these geriatric patients are retired with no source of income making them have financial restraints.

Most patients in general strive to take their medications as prescribed, but some may not be able to adhere to medication regimens due to lack of understanding, forgetfulness or confusion. Also poor vision and poor manual agility may further reduce adherence as was observed with patients on insulin in this study.

Conclusion:

Awareness of polypharmacy is needed so as to promote routine evaluation of medicines for efficacy, reduce ADRs and make medical practitioners aware of the principals of geriatric medicine. All medicines without therapeutic indication or gain should be eliminated so as to prevent unnecessary ADRs

CHAPTER ONE

INTRODUCTION

1.1 Background

According to the Royal College of Physicians (London), Geriatric medicine deals with the preventive, clinical, remedial and social aspects of illnesses in old age (Hits, 2010). A geriatric patient is classified as one who is 65 years old and over. This is a special group of people because they come with an array of challenges such as comorbidities, disabilities and frailty.

Polypharmacy is the concurrent use of multiple medications. It can be associated with the use of too many or unnecessary medicines at dosages or frequencies higher than therapeutically essential. However, multiple medications can also be necessary and can constitute best care for patients (National Prescribing Service, 2000).

The elderly are at a risk of negative consequences of polypharmacy because of the pharmacokinetic and pharmacodynamic changes that occur as people grow old. Therefore, such patients tend to present with different disease patterns and have altered and often slower response to treatment. In addition, geriatric patients often take several medications at the same time due to several existing comorbidities, and are therefore at risk of having medicine related problems especially because of being exposed to inappropriate prescriptions.

An inappropriate prescription (IP) encompasses the use of medicines that pose more risk than benefit, particularly where safer alternatives exist. IP also includes the misuse of medicines (inappropriate dose or duration), the prescription of medicines with clinically significant drug-drug and drug-disease interactions, and importantly, the under-use of potentially beneficial medications. Hamilton (2009) describes an inappropriate prescription as one that is unnecessary, ineffective, and potentially dangerous and can lead to adverse drug reactions.

The Beers criteria is the most widely cited criteria used to assess inappropriate drug prescribing (Beers & Ouslander, 1991). It is a list of medications considered inappropriate for older patients, either because of ineffectiveness or high risk for adverse events.

There are other factors that contribute to polypharmacy among patients over age 65. Clinicians may be prescribing more drugs for their elderly patients than they have in the past simply because there are more drugs available for treating these patients. This follows the continued discovery and development of a broad range of pharmaceuticals and their generics for a wide variety of conditions, including conditions affecting elderly patients. Unfortunately, this new development has also led to both overuse and inappropriate use of prescription medications. An example is Vildagliptin, a new drug that provides an alternative for people with type 2 diabetes whose blood glucose cannot be controlled effectively with other drugs. Vildagliptin is prescribed in addition to the other diabetic medications that the patient is taking (National prescribing Service Limited (NPS, 2010), and can lead to an (rational or, sometimes, irrational) increase in pill count.

Many drugs that were once obtainable only with a prescription, such as antihistamines, are now readily available over the counter, and their use is on the rise. In addition, complementary and alternative medicines, such as herbal therapies, are becoming increasingly popular among all patients, especially the elderly (Jorgensen, Johansson, & Kennerfalk, 2001).

Compared to the general population, a patient over 65 is more likely to have several chronic disorders, each requiring at least one medication. Elderly patients with more than one health condition are likely to receive care from several healthcare providers, each of whom may prescribe a different medication to treat the same symptoms (Kaufman, 2011).

Additionally, patients may purchase medications from more than one pharmacy, and each pharmacy checks for potential problems only on those medications that its pharmacist knows the patient is, or is supposed to be, taking. Drug-related problems are less likely to occur when one physician, pharmacist or nurse practitioner oversees the patient's medication regimen.

Another factor that may contribute to polypharmacy in geriatric (and other) patients is referred to as the "prescribing cascade", which can be illustrated as follows: An elderly patient develops side effects from a medication he's taking; however, his healthcare provider interprets the symptoms not as side effects of the drug but as symptoms of a disease. The healthcare provider

then prescribes yet another drug, creating the potential for even more side effects and drug interactions.

1.2 Statement of the Problem

Because individuals are living longer, there is a growing ageing population who are acquiring chronic diseases, such as arthritis, hypertension, cancer, heart disease and diabetes mellitus. Strategies to improve prescribing are essential so as to ensure that the many medications available to manage concurrent disease states are prescribed appropriately (Denison, 2010). Because the elderly population has a higher prevalence of chronic diseases, multiple drug use is very common (Jorgensen, Johansson, & Kennerfalk, 2001).

Geriatric patients are particularly vulnerable to the adverse effects of inappropriate use of medicines. Many medications need to be used with special caution in this population due to age related changes in pharmacokinetics (that is, absorption, distribution, metabolism, and excretion) and the pharmacodynamics (the physiological effects of the medicine).

Several studies have been carried out to assess the incidence of polypharmacy as well as prescribing quality in geriatrics. According to a study by Steinman (2006), inappropriate medication use and underuse were common in older people taking five or more medications, with both simultaneously present in more than 40% of patients.

Figure 1: Conceptual framework

Increase in age ⟶ Chronic illnesses ⟶ Polypharmacy

Inapproprite prescriptions

Adverse drug effects   Poor adherence
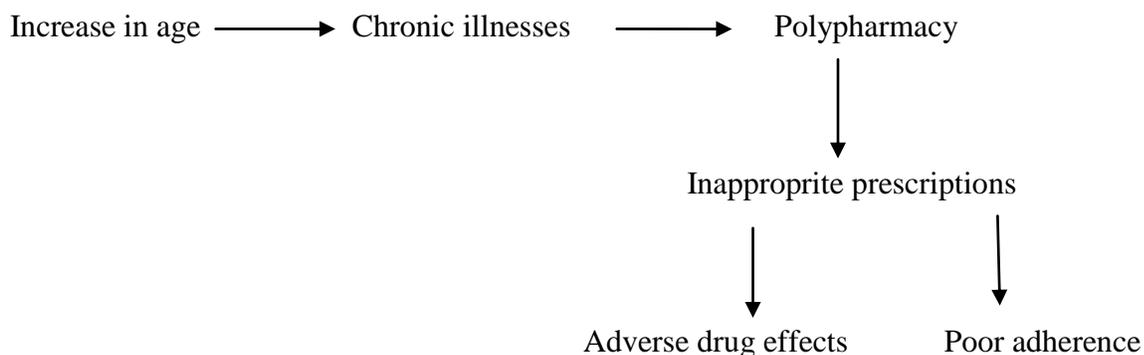
1.3 Objectives of the Study

1.3.1 General Objective

The general objective of the study was to establish the frequency, characteristics and predictors of irrational polypharmacy and inappropriate medication use among geriatric patients at the Nyeri Provincial General Hospital.

Based on this, the specific objectives were:

1. To determine the frequency of polypharmacy in geriatric patients.
2. To establish the frequency and characteristics of inappropriate prescription among geriatric patients using Beers criteria 2012.
3. To explore selected outcomes of polypharmacy among geriatric patients.

1.4 Importance and Justification of the Study

Three per cent of the total Kenyan population is accounted for by persons with the age of over 65 years of age (KNBS, 2010). Older patients often have several co-morbidities for which they are prescribed multiple medications, thereby increasing the risk of adverse drug events (ADEs). Evidence suggests that suboptimal or inappropriate prescribing (IP) is highly prevalent in older people and is associated with an increased risk of ADEs (Hamilton, 2009). Such studies are lacking in Kenya and information on quality of prescribing is inadequate.

It is also conceivable that, in addition to causing adverse drug events and the resultant morbidity and mortality, inappropriate prescribing could be responsible for the significant wastage of billions of Kenya shillings, which is barely affordable as many patients pay for their own prescriptions. In America, for example, tens of billions of dollars are wasted on inappropriate prescriptions, 1.5 million people are hospitalized and more than 100,000 die each year from largely preventable adverse reactions from drugs that should not have been prescribed as they were in the first place (Lazarou, 1998).

The study is therefore both necessary and important as it sets out to explore several facets of polypharmacy and inappropriate medication use in the elderly that have not been adequately explored in the Kenyan setting.

The study findings will facilitate the identification of specific issues that could require attention from healthcare providers in terms of improving quality of care to the elderly, while also providing an evidence-base for practice and policy recommendations. This study set out to establish the prescribing quality, the extent and frequency of polypharmacy among geriatric patients in a Kenyan context. This will hopefully lead to the reduction in expenditure on unnecessary and potentially unsafe medicines.

CHAPTER TWO

LITERATURE REVIEW

2.1 Overview of Polypharmacy

Elderly patients are particularly susceptible to polypharmacy issues not only because aging affects how their body handles medications, but because they take more medications than younger patients. According to Wooten & Galavis (2005), in the United States, people over 65 make up approximately 13% of the population but use about 30% of all prescriptions written. At any given time, an elderly patient takes, on average, four or five prescription drugs and two over-the-counter (OTC) medications.

Elderly patients may be taking medications that have been prescribed inappropriately, that is, medications that are unnecessary, ineffective, or potentially dangerous and could cause adverse drug events (ADEs). Most ADEs are the result of drug interactions; the more drugs a patient takes, the higher the risk of interactions. The estimated incidence of drug interactions rises from 6% in patients taking two medications a day to as high as 50% in patients taking five a day (Wooten & Galavis, 2005). For this reason, elderly patients tend to have a relatively higher risk of experiencing ADEs. Furthermore, a recent study by Maher et al (2013) showed that nearly 50% of elderly patients take one or two medications that are not medically necessary.

According to the Kenya National Bureau of statistics (2010), 3% of the total Kenyan population is accounted for by persons with the age of over 65 years of age. It is important to consider the prescribing and medication use patterns among this demographic. This is because, as the elderly population in Kenya continues to grow, so will the incidence of ADEs, hospitalization and mortality due to the fact that these age group tends to have comorbidities that need to be managed by several drugs at the same time.

Optimizing medication therapy is an important part of caring for geriatric patients. The process of prescribing a medication is complex and includes: deciding that a drug is indicated, choosing the best drug, determining a dose and schedule appropriate for the patient's physiologic status, monitoring for effectiveness and toxicity, educating the patient about expected side effects, and indications for seeking consultation.

2.2 Types of Polypharmacy

Yvette and Terrie (2004) describes polypharmacy as having a negative connotation, but sometimes it is necessary and can be beneficial in treating certain medical conditions. Furthermore, polypharmacy can be categorized into 2 major classes.

Therapeutic Polypharmacy

This type occurs when multiple drug regimens are carefully monitored by clinicians and are necessary for the treatment of conditions and for achieving a therapeutic goal. An example of therapeutic polypharmacy is the combination therapy of isoniazid, rifampin, ethambutol, pyrazinamide, and pyridoxine in the initial treatment of tuberculosis. Therapeutic polypharmacy is also demonstrated in the multiple agents used in the management of congestive heart failure, such as digoxin, angiotensin-converting enzyme inhibitors, and a diuretic (Gurwitz, 1995).

Therapeutic polypharmacy in such cases turns out to be beneficial as it not only prolongs the life of the patient, but also helps to combat increasingly antibiotic resistant bacteria like in the case of multiple drug resistant tuberculosis bacteria.

Contra-therapeutic Polypharmacy

This type occurs when an individual experiences unanticipated or unintentional adverse effects while he or she is on a regimen of multiple drugs and is not adequately monitored. Polypharmacy is particularly detrimental when an individual takes multiple pharmacologic agents for an extended period of time, particularly at high doses, without being monitored (Yvette & Terrie, 2004). This irrational combination of drugs is undesirable regardless of whether ADEs are experienced or not as it leads to increased pill burden, which can cause non-adherence and result in poor therapeutic outcomes.

2.3 Factors Contributing To Polypharmacy and Inappropriate Medicines Use

Several factors contribute to polypharmacy among patients over the age 65. Due to the advance in age, elderly patients have several chronic disorders, each requiring at least one medication. Connected to this, elderly patients seek treatment from more than one healthcare provider

addressing each of the chronic conditions each of whom may prescribe a different medication to treat the same symptoms (Denison, 2010). For example multiple doctors treating one patient can lead to one doctor prescribing a brand name drug for example Panadol® and the second doctor prescribes a generic paracetamol. The patient continues to take both not realizing that they are the same medicines.

Polypharmacy also occurs when the doctor changes from one medicine to another which is in the same therapeutic class, but the patient continues to take the first medicine in addition to the newly prescribed one (Wilson, 2009). For example a patient is taking pantoprazole 20mg then the doctor prescribes esomeprazole 40mg and the patient continues to take the two despite both being proton pump inhibitors. This situation is worsened by the lack of patient education where doctors do not inform their patients and patients do not ask questions.

Clinicians are prescribing more drugs for their elderly patients than they have in the past simply because there are more drugs available for treating these patients. The discovery of a broad range of pharmaceuticals for a wide variety of conditions has helped many patients. Unfortunately, this new development has also led to both overuse and inappropriate use of prescription medications (Wooten & Galavis, 2005). Drug companies contribute to this by using a loop hole in the law not requiring superiority over existing drugs for approval thus more drugs are approved that offer no significant benefit over drugs that are already in the market, also known as "me too" drugs (Public Citizen's Health Research Group, 2003). In addition, the industry spends money in advertising and promotional tricks that may be false and misleading (Stryer, 1996). Thus clinicians are bombarded with misleading information on drugs and very wide varieties of "me too" generic drugs which can be confusing to the clinicians and pharmacists.

Many drugs that were once obtainable only with a prescription, such as Losec ® (omeprazole) and Claritin® (loratidine), are now readily available over the counter, and their use is on the rise. In addition, complementary and alternative medicines, such as herbal therapies, are becoming increasingly popular among all patients, including the elderly. These products are unregistered and can be sourced without a prescription and sometimes, unqualified persons issue them. Thus a patient can end up with a cocktail of drugs from different sources, which has a higher risk of drug-drug interactions and ADEs (Public Citizen's Health Research Group, 2003).

Additionally, patients may purchase medications from more than one pharmacy, and each pharmacy may check for potential problems only on those medications that the resident pharmacist knows the patient is, or is supposed to be, taking. Drug-related problems are less likely to occur when one physician, nurse practitioner or pharmacist oversees the patient's medication regimen (Wooten & Galavis, 2005).

Another factor that contributes to polypharmacy occurs when the "disease" for which the drug is prescribed is actually an adverse reaction to another drug masquerading as a disease that is not recognized by the healthcare provider (Public Citizen's Health Research Group, 2003). Instead of lowering the dose or replacing the offending drug, another drug is added to treat the adverse drug reaction, which has been mistaken for a disease. This creates potential for more side effects. This is illustrated by an increased use of antihypertensive drugs in people with high blood pressure that was caused by very high doses of non-steroidal anti-inflammatory drugs (Gurwitz, 1995).

Another form of inappropriate prescriptions is observed when a medical problem is self-limiting, unresponsive to treatment with drugs or does not justify treatment with some drugs. For example, the prescribing of antibiotics to "treat" viral infections such as colds in healthy people (Up To Date, 2013).

In some cases a drug is used to treat a problem that should first be treated with sensible lifestyle changes (Public Citizen's Health Research Group, 2003). Problems such as insomnia and abdominal pain often have causes that respond very well to non-pharmacological interventions, and often the physician can uncover these causes by taking a careful history. Other examples include medical problems such as high blood pressure, mild adult-onset diabetes, obesity, anxiety, and situational depression. Doctors should recommend lifestyle changes as the first approach for these conditions, before resorting to prescribing drugs (Public Citizen's Health Research Group, 2003).

Clinicians are often reluctant to stop medications, especially if they did not initiate the treatment and the patient seems to be tolerating the therapy. This can expose the patient to the risks for an adverse event with limited therapeutic benefit.
A common example is the use of digoxin in older adults, often prescribed for indications that have not been well documented. Renal impairment or temporary dehydration may predispose

older adults to digoxin toxicity (Forman, Coletta, & Kenny, 1991).

2.4 Polypharmacy and Adverse Drug Reactions

Adverse drug reactions and serious drug-drug interactions are the major concern for all cases of polypharmacy. In some instances, however, it is therapeutically necessary to use multiple agents to treat certain conditions. It is therefore the responsibility of pharmacists to assess patients with multiple medication regimens and to make recommendations when necessary.

Researchers have shown that more than 75% of adverse drug reactions that result in hospitalization are related to known pharmacologic agents and are partly due to inadequate monitoring, inappropriate prescribing, and lack of patient education and compliance (Yvette & Terrie, 2004). Research also suggests that the potential for an adverse drug reaction to occur is 6% when an individual takes 2 medications. It increases to 50% when 5 medications are taken concomitantly, and it rises to 100% when 8 medications are prescribed (Wooten & Galavis, 2005).

Screening of cases of polypharmacy, particularly in the elderly patient population, is crucial because adverse drug events can often imitate other geriatric syndromes or precipitate confusion, falls, incontinence, urinary retention, and malaise. These side effects in turn may cause a physician to prescribe another agent to treat them (Steinman, 2006).

2.5 Ageing and Drug Sensitivity

The increased risk of ADEs in elderly patients is largely due to of the physiologic changes that occur with aging, which makes the body more sensitive to the effects of medications. These changes affect both pharmacokinetics and pharmacodynamics.

Absorption, distribution, and clearance, which are the three components of pharmacokinetics, are affected by aging. Of the three, absorption, particularly after oral administration, is least affected. In elderly patients, absorption is generally slower but complete. Absorption through the skin after topical administration may actually increase in the elderly as the aging skin becomes thin and frail (Wooten & Galavis, 2005). The more medications a patient takes, however, the greater the chance that one drug will interfere with the absorption of another. This is a possible

consequence of polypharmacy and is not unique to geriatric patients. This is worsened in cases where a drug on its own may be safe and effective, but when combined with another, they interact and can cause injury or death or reduce the efficacy of a drug. This can be demonstrated with the concomitant use of antacid suspensions with digoxin, whereby antacids that contain aluminum, magnesium or simethicone may decrease the absorption and therefore the bioavailability of digoxin, making it less effective in treating heart conditions (McElnay, Harron, D'arcy, & Eagle, 1978).

Distribution of drugs throughout the body also changes with age. Medications get distributed into either fat or water, depending on their physicochemical characteristics. Thus, as a patient's percentage of body fat increases with age, a drug that is lipid-soluble (such as diazepam, a commonly used sedative hypnotic) may stay in the body longer because there are more fat stores into which it can be distributed. Older patients have proportionally less body water than younger people; therefore blood levels of a drug that is water-soluble may be higher than expected. It is difficult, though, to anticipate the effect that changes in fat stores or body water will have on drug distribution because other body functions, such as protein binding, can also complicate drug distribution (Up To Date, 2013).

Aging significantly affects clearance because it produces changes in the liver, where drugs are metabolized, and in the kidneys, through which drugs and their metabolites are excreted. As the body ages, blood flow through the liver decreases, which can reduce the clearance of certain drugs by 30% – 40% (Wooten & Galavis, 2005). Also, the major enzyme system by which the liver metabolizes drugs (cytochrome P450 enzyme system) becomes easily overwhelmed in older patients, so certain medications are not metabolized as well as they are in younger populations or the medicine is metabolized more slowly. Renal clearance of medications can be reduced by up to 50% as a patient reaches age 75 (Beers & Ouslander, 1991).

Aging also affects pharmacodynamics. Changes to drug receptors can make a patient more or less sensitive to certain medications. Drugs that act on the CNS may have far greater impact in an elderly patient than in a younger one as a result of changes in the blood-brain barrier (Yvette & Terrie, 2004).

Altered pharmacokinetics and pharmacodynamics increase an elderly patient's risk for both drug-drug and drug-disease interactions. Drug-drug interactions typically occur when an elderly patient takes two medications that have different indications but additive pharmacologic effects. For example, an elderly patient might experience problems if he is prescribed a narcotic analgesic and an antidiarrheal agent; each is used for a different reason, but each can cause constipation. The risk of an ADE due to drug-drug interactions is substantially increased when multiple drugs are taken (Up To Date, 2013). Geriatric persons are more vulnerable to drug-drug interactions because they often have several medical conditions each needing different drug therapies. When multiple medications are required, greater regimen complexity will increase the likelihood of poor compliance or confusion with dosing. Older adults, and particularly those with low health literacy, are not able to efficiently consolidate prescription regimens to optimize a dosing schedule (Wolf, 2011).

Drug-disease interactions, in which a medication exacerbates a disease process, are also common among elderly patients, because of the prevalence of disease in this population (Up To Date, 2013). Anticholinergic drugs, for example, can exacerbate glaucoma, Alzheimer's disease, and benign prostatic hyperplasia, conditions common among the elderly.

2.6 Underuse of Appropriate Medicines

Clinicians are often challenged with the need to match the complex needs of their older patients with those of disease-specific clinical practice guidelines (Up To Date, 2013).

A lot of attention is usually paid to overprescribing, yet under prescribing is also a cause of concern. Prescribing strategies that seek to simply limit the number of drugs prescribed to older patients in the name of improving quality of care may be seriously misdirected. Sufficient emphasis must therefore be paid to the avoidance of both under- and over-prescribing.

There are several factors that can lead to under prescribing and underuse of medications. These include:

- Clinicians not recognizing the benefit of medications. This is especially so because clinical trials often do not include older adults therefore it is difficult to establish or recognize if there are benefits to treatment in this population. As an example, in a study of statin use for secondary prevention of atherosclerosis in patients over age 66, the

likelihood of being prescribed statin therapy declined 6.4% for every year of age; overall, only 19% of patients in this high risk population had been prescribed a statin (Ko, Mamdani, & Alter, 2004).

- Affordability: Due to the high cost of medicines, some patients may not be able to purchase all the medications in their prescription. Some may be able to fill their prescriptions but not on a regular basis due to financial constraints.

- Dose availability: Older individuals often require lower than usual doses of medications, especially at initiation. If medications are not readily available in prescribed doses, the need to split tablets may make it more difficult for patients to take beneficial drug therapy (Anderson, 1999).

2.7 Criteria Used To Assess Inappropriate Prescriptions

2.7.1 Beers Criteria

The Beers criteria were developed by a panel of experts in 1991 for use in nursing homes. This is the most widely cited criteria used to assess inappropriate drug prescribing (Beers & Ouslander, 1991). The panel produced a list of medications considered inappropriate for older patients, either because of ineffectiveness or high risk for adverse events.

The 2012 revised Beers criteria are available through the American Geriatrics Society website. The criteria include 53 medications designated in one of three categories: those that should always be avoided (e.g., barbiturates, chlorpropamide); those that are potentially inappropriate in older adults with particular health conditions or syndromes; and those that should be used with caution. New additions to the 34 potentially inappropriate medications include sliding scale insulin, glyburide, and megestrol. Thiazolidinediones should be avoided in patients with heart failure, and selective serotonin reuptake inhibitors (SSRIs) in patients with falls and fractures (The American Geriatrics Association, 2012).

Some of the inappropriate drug therapies identified on the Beers list are available as over-the-counter products (Rochon, Lane, & Bronskill, 2004). This reinforces the need to always consider over-the-counter drug therapies when reviewing a patient's medications and to educate individuals on potential problems that can arise from the use of over-the-counter preparations.

The Beer's criteria are increasingly being used to monitor quality of care for older adults. This study will adapt the use of the Beers criteria.

Other criteria used to assess for inappropriate prescriptions are highlighted below.

2.7.2 "START" Criteria

START (Screening Tool to Alert doctors to the right Treatment) is an effort to help prevent omission of important appropriate medications and is organized by organ system (Raza, 2009). The START criteria highlights under prescribing or omission of clinically indicated, evidence-based medications, thereby addressing more domains of prescribing appropriateness (Hilary, Paul F, & O'Mahoney, 2009)

2.7.3 "STOP" Criteria

STOPP (Screening Tool of Older Person's potentially inappropriate Prescriptions) criteria are a useful guide to identify potentially inappropriate medications particularly in the hospital (Raza, 2009). The STOPP criteria are arranged according to physiological systems for ease of use and include reference to drug class duplication, drug-drug and drug-disease interactions. They are uniquely designed for use alongside the START criteria (Hilary, Paul F, & O'Mahoney, 2009).

2.7.4 The ARMOR Tool

The ARMOR tool (Assess, Review, Minimize, Optimize, and Reassess) is an attempt to consolidate these recommendations into a functional and interactive tool. It takes into account the patient's clinical profile and functional status, and tries to balance evidence-based practice with altered physiological reserves (Raza, 2009). The primary outcome goal of this tool is to restore and maintain functional status of the patient. This tool also emphasizes quality of life as a key factor for making decisions on changing or discontinuing medications. Use of a certain medication is weighed against its impact on primary biological functions such as bladder, bowel, and appetite. Functional status and mobility is held up as the essential final outcome measure for any medication change using ARMOR.

2.7.5 The Medication Appropriateness Index (MAI)

The Medication Appropriateness Index (MAI) is an implicit tool which measures prescribing

appropriateness according to ten criteria including indication, effectiveness, administration, drug-drug and drug-disease interactions and cost (Hanlon, et al., 1992). It does not address under-prescribing. Clinical expertise is required to apply some of the criteria. Consequently, the MAI is predominantly used as a research tool (Hilary, Paul F, & O'Mahoney, 2009).

2.8 Monitoring Medicine Use in the Elderly

It should be noted that any of the above mentioned tools are not meant to establish any causal relationships between a drug and an adverse effect. They are instead useful as guides for health care practitioners to prescribe safe medicines and identify medicines whose risks outweigh the benefits. A drug's inclusion in the Beers criteria should not be used as an absolute prohibition in using it, instead, providing patient based care, prognosis, comorbidities and sound clinical judgment should be used together with the tool while prescribing (Molony, 2009).

According to Bergman-Evans (2006) patients prescriptions should be assessed once every six months especially so for long term medications and during acute illness or Medication assessment should be done at least every six months, and more often during an acute illness or exacerbation of a chronic illness.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter highlights the methodology that was adopted to meet the objectives of the study. It covers the type of design that was used, the study population, sampling design and sample size, data collection methods, procedures and data analysis approaches that was utilized by the researcher.

3.2 Research Design

This study was a descriptive hospital-based cross-sectional study of geriatric patients.

3.3 Study Setting

The study was carried out at in Nyeri Provincial General Hospital. The hospital is located in Nyeri county in Kenya. It is a government public hospital that serves a population of 234, 528 Kenyans (Integrate, 2012). The hospital has been earmarked to be converted into a county referral hospital. Nyeri County is a rural town and most people move out of the cities to settle in their rural homes as they age or retire. Therfore the population of the elderly was expected to be high in this site.

3.4 Target Population

The study targeted patients over 65 years of age at the medical outpatient clinic (MOPC) and the medical inpatient wards.

3.4.1 Eligibility Criteria for Objectives 1 and 2

Inclusion Criteria

- Patients who are 65 years old and above who were attended to at the MOPC or admitted to the medical in-patient wards between 1st January 2013 to 31st December 2013

Exclusion Criteria

- Patients with herbal preparations did not have the herbal preparations included in the analysis.

3.4.2 Eligibility Criteria for Objective 3

Inclusion Criteria

- Patients who are 65 years and above and who attended the MOPC during the study period (June –July 2014)
- Patients with prescriptions with five or more medicines

Exclusion Criteria

- Patients who declined to give informed consent
- Patients with herbal preparations did not have the herbal preparations included in the analysis.

3.5 Sample Size Calculation

According to Steinman & Landefield, (2006), inappropriate medication use and underuse were common in older people taking five or more medications, with both simultaneously present in more than 40% of patients.

The number of subjects required for the semi quantitative part of this study needed to determine the frequency of polypharmacy and to establish inappropriate medication use (objectives 1 and 2) was calculated using Fisher's formula (Weisstein, 1999):

$$N=Z^{\alpha}P\ (1\text{-}P) \div \delta^2$$

Where

- N is the sample size required for the study
- $Z^{\alpha} = \mathbf{1.96}$, which is the standard normal deviate for the desired 95% confidence interval

- δ is the desired level of precision of 5%

- P is the estimated proportion of an attribute that is present in the population

The number of patients required was thus:

N= {1.96^2 x 0.4(1-0.4)}/0.05^2

=369

In anticipation of files with missing data, the calculated sample size was adjusted upwards by 15%, giving a target minimum sample size of 425. A total of 427 files were sampled in this study.

The third objective was qualitative in nature. The sample size was obtained through point of theme saturation, whereby patient recruitment was stopped when new themes or explanations stopped emerging from the data, i.e. when there was no more variation in the answers given by different study participants and repetition of answers given by the participants was observed during the interviews.

3.6 Sampling Technique

The MOPC and inpatient booking list was used to get file numbers for patients who attended clinics between January to December 2013 so as to achieve objective 1 and 2. Convenience sampling was applied to obtain a total of 427 files for eligible patients over the age of 65 years. Starting with files from January 2013, each file was perused and the first 427 files that meet the eligibility criteria were used to obtain data.

Purposeful sampling was used to identify participants who were required to meet objective 3, that is, to explore potential outcomes of polypharmacy. Trained Pharmacy personnel were involved in participant recruitment. Recruitment of study participants took place at the MOPC between 1st June 2014 and 31st July 2014. The potential participants were approached and given a brief summary of the research study to be undertaken. Written informed consent was then sought. Upon giving written consent, the participant was recruited into the study and underwent an interviewer-administered questionnaire.

3.7 Data Collection

This involved the collection of demographic and treatment data from medical records and interviews of patients meeting the eligibility criteria and who attend the medical outpatient clinic (MOPC) or were admitted to the medical inpatient wards at Nyeri Provincial General Hospital.

Data on the number of drugs per prescription, sex, and age was extracted from the 427 eligible files and entered into the data collection form (Appendix C) and this information was used to determine the frequency of polypharmacy.

All 427 prescriptions were then evaluated for inappropriate prescription of medication with the aid of the Beers criteria tool (Appendix D). This was done by checking all the drugs that had been prescribed against the Beers criteria checklist. Any drug that had been prescribed and indicated to be avoided according to the Beers criteria was recorded.

In order to explore potential outcomes of polypharmacy through patient interview (objective 3), the recruited subjects were subjected to a brief interviewer-administered questionnaire to obtain information on: education level, the number of prescription and over the counter medications being taken, difficulty in keeping track of their medication, trouble in taking their medication, ability to describe the purpose of their medication, ability to describe the instructions for their medications, any reports of ADRs, number of pharmacies, doctors or/and specialists that are visited and if the patient has any other sources of drugs. This information was used to supplement information obtained from patient medical records. The data collection and questionnaire form that was used is attached (Appendix E). The questionnaire was available for administration in any of the following three languages: English, Kiswahili and Kikuyu, so as to overcome any potential communication barriers since these are the predominant languages in the area. The translations were done by certified tranlators.

3.8 Quality Assurance

A pilot study was done before initiating data collection. The findings were used to improve the design of the data collection tools. Adjustments to the tools were made accordingly so as to correct any limitations and improve the quality of the data that was collected.

The collected data was keyed into a database using MS Office Excel (2010) and exported to IBM SPSS version 20 for analysis. All data entries were double checked against the source documents for completeness and accuracy by the investigator.

3.9 Data Analysis

Descriptive data analysis was carried out for the following variables: age, sex, level of education and number of drugs per prescription. This data is presented in tables.

To evaluate the association between number of medications taken and number of problem medications, simple linear regression was used. An assessment of the influence of the various possible predictors of inappropriate medication use was carried out using multivariate logistic regression. The total number of medications was the primary independent variable while age, sex, education level and medication and disease diagnoses were some of the secondary independent variables.

3.10 Data Management

All study participants were allocated a unique identifier that was used throughout the study. The participant's confidentiality was maintained by not recording their name or clinic number in the data collection forms. Any document linking the patient's name, file number and data collection number was kept by the principal investigator under lock and key. Reviewing of patient files and data abstraction was carried out within Nyeri provincial hospitals MOPC and in patient clinics. All raw data was filed and kept under lock and key by the principal investigator.

3.11 Ethical Considerations

Ethical approval was sort from the Kenyatta National Hospital / University of Nairobi Ethics and Research Committee and The Nyeri Provincial Hospital training committee (Appendix I and J).

Potential participants were informed about the study through an oral presentation regarding the purpose, procedure to be carried out, potential hazards and rights of the participant. They were required to understand and sign a consent form summarizing the exercise (Appendix D). The consent forms were availed in English, Kiswahili and Kikuyu. One copy of the signed informed statement consent form was given to the participant and the investigator retained another copy.

Participants were not compensated for their participation in the study.

3.12 Study Limitations

Some of the health records were inaccurate or incomplete. All incomplete records were excluded from the study. Possible unrecorded non-prescription use of medicines was also a limitation to the study. Some patients may have felt uncomfortable with the face to face interview, therefore making them reluctant to give truthful answers and instead give answers that they may have perceived as acceptable to the interviewer. Some patients were wrongfully suspicious of signing the informed consent form and therefore declined in participating in the interview.

The corresponding diagnoses of the 427 prescriptions were not available from the records that were used in this study thus it was not possible to establish any relationship between specific diseases and polypharmacy. This was acknowledged as a limitation.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.0 Introduction

This chapter gives an account of the findings of the study in regards to the respondents' age, sex, education level, descriptive statistics of the variables and regression results based on the variables used in the study.

4.1 Socio-demographic characteristics of the study cohort

Prescription records for 427 patients who were 65 years old and above, who were attended at the in-patient and MOPC departments in Nyeri Provincial Hospital between January and December 2013 were sampled from the records department as described in Section 3.6. Out of these 236 belonged to females (55.3%) and 191 (44.7%) belonged to males. The overall mean age was 72.4 years (range 65 - 85 years). The females had a mean age of 73.0 years and the mean age of the males was 71.9 years.

Table 1 summarizes the socio-demographic characteristics of the study subjects.

Table 1: Table depicting the gender and age of the patients

Gender	Frequency	Percent (%)	Mean Age
Female	236	55.3	73.0
Male	191	44.7	71.9
Total / Overall	427	100	72.4

4.2 Polypharmacy

The prescription records for the sampled 427 patients were evaluated for polypharmacy.

4.2.1 Frequency of polypharmacy

The largest proportion (143, 33.5%) of the patients had 2 drugs on their prescription. A significant proportion (135, 31.6%) of the patients had 3 drugs while only one respondent had more than 6 drugs in their prescription. The highest number of drugs that the respondents had in

the prescription was 7 while the lowest number of medicines was 1. The average number of drugs prescribed was 2.56.

Figure 1 shows the frequency distribution of the different number of drugs per prescription.

Figure 2: Frequency polygon depicting number of medicines per prescription
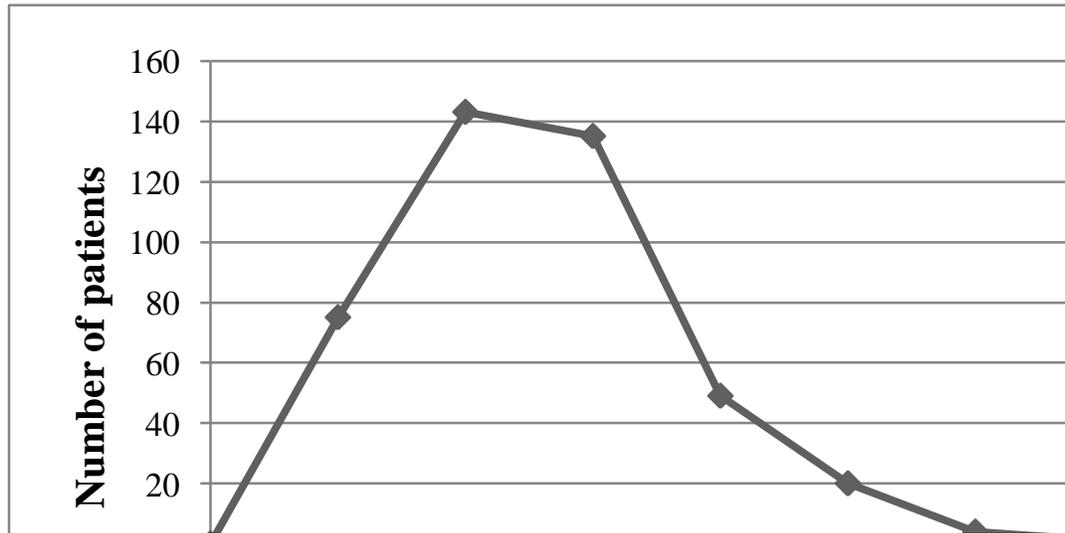
Twenty two prescriptions out of the sample of 427 prescriptions had more than 5 drugs in their prescription while 405 prescriptions did not exhibit polypharmacy. This gives an overall frequency of polypharmacy of 5.15%, where polypharmacy refers to the use of at least five types of medicines to treat a single patient.

The majority of the 22 patients with prescriptions exhibiting polypharmacy were female (13, 59.09%). The proportion of females with polypharmacy is not significantly higher than the equivalent proportion for the males (p = 0.20).

4.2.2 Relationship between number of drugs per prescription and sex among patients with polypharmacy (bivariate analysis)

To determine the relationship between presence or absence of inappropriate medication, sex, age, and polypharmacy, a Pearson correlation analysis was carried out using data from all the 427 patients.

Table 2: Correlation of number of drugs per prescription, age and sex among the 427 patients

Pearson Correlation coefficients

	Presence of inappropriate medication	Sex	Age	Polypharmacy
Presence of inappropriate medication	1.000	-0.133	-0.023	0.171
Sex		1.000	-0.100	-0.005
Age			1.000	0.052
Polypharmacy				1.000

Table 2 presents the matrix of Pearson correlation coefficients. It can be observed that there is a fairly weak negative correlation between presence of inappropriate medicines and sex (–0.133) implying that male patients are likely to have less inappropriate medication in their prescription compared to female patients. There is a weak negative correlation between age and presence of inappropriate medication (-0.23) thus one can conclude that the presence of inappropriate medication tends to reduce as one ages. There is a weak positive correlation between presence of inappropriate medication and polypharmacy (0.171) implying that as number of drugs in one's prescription increases the higher the chance of having inappropriate medication in their prescription. However, there isn't enough evidence that the observed correlations were statistically significant as all had accompanying p-values greater than 0.05.

A sub-analysis was also carried out to determine the relationship between number of inappropriate medications per prescription, age and sex among patients with polypharmacy.

Table 3: Correlation of number of drugs per prescription age and sex among the 22 patients with polypharmacy

Pearson Correlation coefficients

	Sex	Number of in appropriate medication	Age
Sex	1	-0.157	0.062
Number of inappropriate medication		1	-0.002
Age			1

Table 3 shows the matrix of Pearson correlation coefficients between number of inappropriate medications per prescription, age and sex for the 22 patients who had polypharmacy.

The results show that there is a fairly negative correlation between sex and number of inappropriate medication in one's prescription (-0.157) implying that male patients are less likely to have inappropriate medication than female patients. There is a weak negative correlation between age and presence of inappropriate medication (-0.02) implying that presence of inappropriate medication tends to reduce as one ages.

The findings from the sub-analysis reveal statistically non-significant correlations between the number of inappropriate medications, age and sex that are consistent with those observed from the analysis of the entire cohort.

4.2.3 Discussion

The frequency of polypharmacy in Nyeri Provincial General Hospital was found to be 5.15%. This is quite low compared to other studies. For example a study on the prevalence and predictors of polypharmacy among Korean elderly by Kim, Shin, Kim & Park (2014) found that 86.4% of their study population experienced polypharmacy. Another study by Maheshkumar & Dhanapal (2014) on the prevalence of polypharmacy in a rural hospital in India, found that 88.26% of the patients under study had polypharmacy. One can speculate that the reason as to

why the prevalence of polypharmacy in this study is quite low compared to other studies is due to the limited variety of medicines in the formulary at Nyeri Provincial General Hospital. Most of the people in Nyeri are subsistence farmers and the per capita income in Kenya is 994 US dollars per annum (World bank, 2014). Most of the geriatric patient are retirees and have no steady source of income and most do not have pensions. Thus they are limited as to the quantity and variety of medicines that they can afford. This may cause these patients to opt for as few medicines as possible so as to reduce the cost of their prescriptions. Prescribers in such settings may also take the financial situations of such patients into consideration and reduce the number of drugs where possible so as to get maximum compliance, since there is no point of prescribing many medicines that the patient will not likely buy.

Majority of the patients with prescriptions exhibiting polypharmacy were female (59.09%). This was also observed in a study by Venturini et al (2011) where they found that women used more drugs than men in the same age group, and that female patients go to hospitals and consult doctors more often than men. In fact, records from Nyeri PGH showed that females outnumbered male patients during the study period. This is a possible explanation as to why females with polypharmacy outnumbered their male counterparts.

4.3 Inappropriate Prescriptions

Out of the 427 prescriptions, 22 were identified as prescriptions with 5 or more medicines. These 22 prescriptions were examined for inappropriate medications using the Beers criteria.

4.3.1 Frequency of inappropriate prescribing

The analysis of the 22 prescriptions that had 5 or more drugs for inappropriate medications is summarized in Table 4.

The remaining 405 prescriptions that had less than five medications were also analyzed for inappropriate medications, as summarized in Table 5.

Table 4: Summary of Inappropriate Medications and Underused Medications for the 22 prescriptions that had 5 or more drugs

Drug class	Frequency (n)	Individual drugs	Description/Recommendation
Inappropriate (n=12)			
1. Anti infectives	1	Nitrofurantoin	This should be avoided for long term suppression
2. Cardiovascular system (CVS) drugs	1	Digoxin	Doses >0.125mg/day should be avoided
3. Central nervous system (CNS) drugs	5	Amitryptyline (3)	This should be avoided
		Haloperidol (1)	It should be avoided for behavioral problems of dementia unless non-pharmacological options have failed
		Chlorpromazine (1)	Same as for haloperidol
4. Gastrointestinal system	2	Metoclopramide (2)	Avoid unless for gastroparesis
5. Nonsteroidal anti-inflammatory drugs	3	Diclofenac (2)	Avoid chronic use unless other alternatives are not effective
Underused (n=3)			
1. Proton pump inhibitors	3	--------	This is beneficial for patients on long-term use of non-cyclooxygenase selective NSAIDs

Table 5: Summary of Inappropriate Medications and Underused Medications for the 405 prescriptions that had less than 5 drugs

Drug class	Frequency(n)	Individual drugs	Description / Recommendation	Gender	
Inappropriate (n=64)				Women	Men
1. Anticholinergics (excludes antidepressants)	18	Chlopheniramine (14)	Should be avoided	7	7
		Hyoscyamine (4)	Avoid except in short term palliative care to decrease oral secretions	3	1
2. Anti-infectives	1	Nitrofurantoin (1)	Avoid for long term suppression	0	1
3.CVS drugs	4	Digoxin (4)	Avoid doses >0.25mg/day	2	2
4. CNS drugs	15	Amitriptyline (13)	Avoid	10	3
		Chlopromazine (1)	Avoid use for behavioral problems of dementia unless non-pharmacological options have failed	1	0
		Fluphenazine	Same as for chlorpromazine	1	0
5. Gastrointestinal system	3	Metoclopramide	Avoid, unless for gastroparesis	1	2
6. Pain medication	23	Diclofenac (9)	Avoid chronic use unless other alternatives are not effective and patient can take gastroprotective agents	6	3
		Meloxicam (14)	Same as for diclofenac	8	6
Underused drugs (n=15)					
1. Proton pump inhibitors	15	--------	Beneficial for patients on long-term NSAIDS	7	8

Out of the 22 prescriptions that had 5 or more drugs, 12 (54.5%) of them exhibited inappropriate medication and there were 3 (13.6%) prescriptions that had underuse of medication (i.e. did not have a potentially useful medication prescribed).

Table 6: Summary of the number of inappropriate prescriptions

Cohort	Prescriptions with IP	Prescriptions with underuse of medication	Number of males with IP	Number of females withIP
22 prescriptions with PP	12 (54.5%)	3 (13.6%)	4	8
405 prescriptions without PP	64 (15.8%)	15 (3.7%)	39	25

Out of the 9 males who had prescriptions that exhibited polypharmacy 4 (44.4%) patients had inappropriate medicines prescribed. Out of the 13 females who had prescriptions that exhibited polypharmacy 7 patients (53.8%) had 8 inappropriate medicines prescribed as demonstrated in table 5.

Out of the eight categories of drugs in the Beers criteria, the following five classes of drugs were identified as inappropriately prescribed in this study: anti-invectives (8.33%), cardiovascular system drugs (8.33%), central nervous system drugs (41.67%), gastrointestinal acting drugs (16.67%) and NSAIDs (25.00%). The proton pump inhibitors were the most commonly underused drug.

On the other hand, out of the 405 prescriptions that did not exhibit polypharmacy, 64 prescriptions (15.8%) had inappropriate medications prescribed. The proportion of patients with polypharmacy that exhibited inappropriate prescriptionS (54.5%) is significantly higher than among those patients with no polypharmacy (p =0.03). It was also noted that there were more women (60.94%) than men (39.06%) among the 64 prescriptions with inappropriate medications prescribed. Six classes of drugs were identified as inappropriately prescribed. These included anticholinergics (28%), anti-infectives (1.56%), cardiovascular system drugs (6.25%), central nervous system drugs (23.44%), gastrointestinal drugs (4.69%) and pain medication (35.94%).

Seven women and 8 men had prescriptions that did not have a potentially beneficial proton pump inhibitors.

4.3.2 Logistic regression of presence of inappropriate medication with sex, age and polypharmacy

A logistic regression analysis was done on all the 427 prescriptions. The dependent variable in this analysis was presence of inappropriate prescribing while the independent variables were sex, age and polypharmacy.

After logistic regression, sex, polypharmacy and the number of drugs per prescription were found to be independent predictors of inappropriate prescribing among these geriatric patients.

Males had lower odds than females of having inappropriate medication in their prescription [OR 0.50 (0.3 - 0.84)] p=0.009. Also, the presence of polypharmacy raises the odds of inappropriate prescribing [OR 2.03 (1.65 – 2.86)] p=0.04.

As expected, the probability of inappropriate prescribing rises with the number of medicines prescribed. For this set of geriatric patients, the odds of finding inappropriate medication almost triple with every increase in the number of drugs prescribed [OR 2.89 (2.12 – 3.94)] p<0.0001.

4.3.3 Discussion

It is known that the prevalence of chronic diseases for which one or more medications will be used increases as one ages, and as the number of medicines taken increases, the incidence of inappropriate medicines increases as well. Sex, polypharmacy and the number of drugs per prescription are independent predictors of inappropriate prescribing.

The more drugs a patient is exposed to, the more likely they are to be prescribed inappropriately (Steinman, 2006). One of the causes for an increase in the number of prescription drugs are new medication that are prescribed to 'treat' a side effect that has been misdiagnosed as a new illness. According to Fick et al (2003), potentially inappropriate medications in the elderly include those with sedative or anticholinergic effects and long-acting non-steroidal anti-inflammatory drugs. This was also observed in this study, with pain medications (NSAIDS) being the most inappropriately prescribed medicines, followed by anticholinergics, central nervous system drugs and cardiovascular system drugs. The most common anticholinergic drug

that was prescribed was chlorpheniramine. This is most likely because its popularity due to its sedative effects. A lot of people abuse chlorpheniramine, commonly known as Piriton® due to its sedative effects. This could be a reason why it was so commonly prescribed in addition to it being available without a prescription and it is easily affordable, going for a little as 50 cents a tablet.

On the other hand adding more medications can be beneficial when a patient has been found to be genuinely having multiple chronic conditions, each with its appropriate medicines and also taking considerations that there are no drug-drug interactions. For example, a 69 year old patient who was sampled in this study had 7 medications to manage his diabetes, arthritis, hypertension, and asthma.

Females are at higher risk of having inappropriate prescriptions than males. This is most likely because majority of the patients with prescriptions exhibiting polypharmacy were female (59.09%) and the more medicines that one has, the more likely one can get an inappropriate medicine prescribed.

4.4 Exploring potential outcomes of polypharmacy in geriatric patients.

Qualitative analysis was used to explore any relationships between the number of drugs in the prescriptions and difficulty in keeping track of medication, trouble in taking medication, ability to describe purpose of medication, ability to understand instruction of taking medication and self-reported adverse reactions.

Geriatric patients from the MOPC were selected as described in Section 3.6, and interviewed. The interview records were reviewed during the interviewing period so as to get general scopes and perspectives of the central themes. Themes from each interview were reviewed and identified after every interview and codes were assigned to the themes so as to help catalogue the themes. The codes were used to update a code structure, which helped in determination of the point of theme saturation and give a sample size of 25 patients.

4.4.1 Socio- demographic characteristics of the 25 patients interviewed

A total of 25 patients were interviewed. They were chosen based on their availability and willingness at the time of the study. Of the 25 subjects recruited for interview, 10 were females

and 15 were males. The age of respondents ranged from 65-85 years. The mean age of participants was 72.5 years. Out of these 4% of the respondents didn't have any formal educational background, 48% of them had primary school level of education, while 48% of them had secondary school level of education. These socio demographic characteristics are represented further in Table 8. All the prescriptions belonging to these participants exhibited polypharmacy

Table 7: Table of socio-demographic characteristics

AGE (Years)		GENDER		EDUCATION		
	Frequency	**Male**	**Female**	**No education**	**Primary education**	**Secondary education and above**
65-75	10	6	4	0	3	7
71-75	6	3	3	0	4	2
76-80	5	3	2	1	3	1
81-85	4	2	2	0	2	2
TOTAL	**25**	**14**	**11**	**1**	**12**	**12**

4.4.2 Qualitative findings of the possible outcomes of polypharmacy

Table 8: Summary of the findings form the interviews on the possible outcomes of polypharmacy

Outcome	Tally of patients
Difficulty in keeping track of medicine	1
Trouble in taking medicines	7
Inability to describe purpose of medicines	19
Difficulty in understanding the instructions of medicines	21
Patients who reported ADRs	1
Number of patients who saw > 1 doctor	3
Number of patients who visited > 1 pharmacy	12

Difficulty in keeping track of medication

All the 25 interviewees were asked if they experienced any difficulty in keeping track of medication, their responses varied from *strongly disagree* to *agree*. Twenty four interviewees reported that they didn't experience any difficulty in keeping track of medication, 13 of them were female while 11 were male. It was just one female interviewee aged 77 who agreed that she experienced difficulty in keeping track of medications.

"*Sometimes I forget to take my 'pressure' medications especially in the mornings" [Interviewee 3]*

Two patients reported that they finished some of their medicines before the others and they would not go for a refill to keep them going until their next appointment. This implies that these patients could be either missing doses of some of their drugs or taking double doses of others. Therefore, despite being given adequate medications to last till their next appointment, they end up with excess drugs or run out of drugs before their next due date at the clinic. Patients with financial problems may decide not to fill a prescription, or may take lower than prescribed dosages to extend their supply.

Ignorance could contribute to this because some of the patients do not know that the medications such as anti-hypertensive medicines are supposed to be taken continuously until they are either changed or stopped by the prescriber.

Trouble in taking medication

All the 25 interviewees were asked if they experienced any trouble while taking medication, responses varied from strongly disagree to agree. 18 of them *strongly disagreed* that they experienced any sort of trouble in taking medication, 6 of them were females while 12 of them were males. Out of the other 7 who had trouble in taking their medicine, the most common problem experienced was withdrawing insulin for injection. The 6 patients who had trouble with this had said it was because they could not clearly see the graduations on the syringe making it difficult at best to draw out the correct dose of the insulin. One patient of 83 years relied on his niece to give him his injections.

"My eyesight is not what it used to be. I cannot be able to see the lines on the syringe to show me where I am supposed to pull the insulin to." [Interviewee 9]

One male patient had difficulty in swallowing his glucosamine/chondroitin tablets. He said that they were too big and they made him gag when he tried to swallow them.

Ability to describe purpose of medication

Interviewees were asked if they were able to describe purpose of medication, their responses varied from *strongly agree* to *strongly disagree*.

Fourteen (56%) respondents strongly disagreed that they were able to describe the purpose of their medication. 5 (20%) of the interviewees disagreed that they were able to describe the purpose of their medication, while 6 (24%) of them strongly agreed that they were able to describe the purpose of their prescribed medication. Those who were not able to describe the purpose of their medication said that they took the medicines because it was prescribed to them, without knowing what it is for. The six patients, who were able to describe the purpose of their medicines, gave answers that were consistent with the information in their files.

The probable reasons as to why these patients do not know what their medicines are for include; feeling intimidated to ask their doctor, poor memory due to old age, and confusion due to the many drugs. Sometimes the prescriber, due to lack of time and having many patients to attend to, may not explain the purpose of the medicines they prescribe. This also leads to poor compliance to the drug regimen since these patients do not know that some of their medicines, in particular the anti-hypertensives are long term medications that should not be stopped unless under the advice of their doctor. So, when their medicines run out before their next appointment, the patients do not get refills to bridge the gap between appointments. This is common among patients who come for appointments after three months yet they are supposed to pick their drugs from the pharmacy on a monthly basis, yet this was not clearly explained to them. Another possible reason as to why patients were not able to describe the purpose of their medications is that some of the medications are repacked from large tins of 1000 tablets into smaller quantities in medical envelopes with no medical/patient information leaflets inside for the patient to read up on their medicines. The other group of patients who were not able to describe the purpose of

their medicines were the ones with no formal education. Language barrier was also an issue as the labels and inserts are written in English, which the patient was not able to read. Such patients rely on verbal explanations together with the use of symbols like "1 X 3" which means one tablet to be taken three times a day (every eight hours).

Ability to understand instructions of medication

The 25 interviewees were further asked if they were able to understand the instruction of their medication, their responses varied from *strongly agree* to *strongly disagree.*

17 (68%) respondents *strongly disagreed* that they were able to understand the instructions of their medication 5 of them were male while 12 of them were female. Four (16%) of the interviewees *disagreed* that they were able to understand the instruction of their medication. Four (16%) of them strongly agreed that they were able to understand the instruction of their prescribed.

This lack of understanding of the instructions could stem from having poorly labeled drugs and lack of verbal instructions when dispensing from the pharmacy, the labels are usually done in English and most patients in this age group are not conversant with written English. These four patients rely on relatives to guide them on how to take their medicines. They also rely on symbols, for example "1 X 2" which means take one tablet to be taken two times a day (every 12 hours).

Adverse drug reactions

The 25 interviewees' were further probed as to whether they had experienced any adverse drug reaction, side effect or problem after taking their medications.

One of the respondents reported that he had indeed experienced adverse drug reaction from their medication. He also complained of flatulence and nausea after taking his glucosamine and chondroitin tablets.

24 of the interviewees were not sure if they have ever had any adverse drug reaction from their medication. A patient may not know if they are experiencing an adverse effect. This is especially so if the effect does not cause great discomfort. Some patients believe that good medicine is

"very strong" and working well when it is in fact causing a side effect, or that the side effect is an indication that the medicine is working. In a prescribing cascade, an adverse reaction to one drug goes unrecognized or misinterpreted, causing the healthcare provider to inappropriately prescribe other medicines to treat the signs and symptoms of the ADR.

4.4.3 Number of doctors and pharmacies visited by respondents

The study also sought to find out the number of specialists or doctors the 25 interviewees had visited. Twenty two (88%) of the respondents reported that they had one specialist while 3 (22%) of them reported that they had more than one doctor. The interviewees were further probed on the number of pharmacies they had visited the results are summarized in table 7.

Table 9: Summary of interviewees responses on number of pharmacies they visit

Number of Pharmacies	Frequency	Percentage	Gender	
			Male	Female
1	13	52%	6	7
2	10	40%	3	7
3	1	4%	1	0
4	1	4%	1	0
Total	25%	100%	11	14

52% of the respondents had visited one pharmacy while 40% of them had visited two pharmacies while 2 (8%) had visited more than 2 pharmacies.

The reasons they gave for visiting more than one pharmacy was because of the differences of prices and the lack of availability of some drugs in one pharmacy over the other.

The 3 patients who visited other doctors said that they sometimes go to the satellite clinics that are near their homes, but they go to Nyeri PGH when they felt exceptionally ill or for major

clinics and lab tests. When probed further, it was found that these 3 patients had indeed travelled quite a large distance to come for the clinic on that day.

It should be noted that these outcomes of polypharmacy could be as a result of other age-related variables like reduced cognitive function which for example can lead to a patient having difficulty in keeping track of their medications. The study of such variables was beyond the scope of this study.

4.5 GENERAL DISCUSSION

Polypharmacy is common problem especially in non-government medical institutions and hospitals compared to Government hospitals. The main reason for this is the limited number of available drugs in the Government hospital formularies compared to the larger number of drugs that are available in the private sector.

Patients may also contribute to polypharmacy and taking of inappropriate medicines when they self-medicate, fail to follow the directions of their prescriptions and to report all the over the counter medicines and herbal preparations they may be using. This study established that more than 50% of the patients that were interviewed were not able to describe the purpose of their medicines and understand instructions on their medicines. Such patients are at risk of having inappropriate medicines prescribed. It also becomes difficult to take accurate medication history in such patients especially when they are taking many medicines. The number of ADRs that were reported was very low compared to other studies. This is probably because most patients do not report ADRs if the effects are mild. Patients who went to more than one pharmacy or saw more than one doctor put themselves at risk of duplicating drug therapy.

Awareness of polypharmacy is needed so as to promote routine evaluation of medicines for efficacy, reduce ADRs and make medical practitioners aware of the principals of geriatric medicine. All medicines without therapeutic indication or gain should be eliminated so as to prevent unnecessary ADRs. Most patients in general strive to take their medications as prescribes but some may not be able to adhere to medication regimens due to lack of understanding, forgetfulness or confusion. Also poor vision and poor manual agility may further reduce adherence   as   was   observed   with   patients   on   insulin   in   this   study.

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSION

The prevalence of polypharmacy among patients in Nyeri PGH was found to be 5.15% (N=22).

Of all the prescriptions that exhibited polypharmacy (N=22) the prevalence of patients taking inappropriate medicines was 50% (N=11) and the prevalence of patients who had underused medications was 13.63% (N=3).

On the other hand the prevalence of inappropriate prescriptions in patients who did not experience polypharmacy (N=405) was 15.8% (N= 64) and the prescriptions with underused medicines was 3.7% (N=15).

This study established that males had lower odds than females of having inappropriate medication in their prescription. Also, the presence of polypharmacy raises the odds of inappropriate prescribing, as does an increase in the number of drugs prescribed. Pain medications (NSAIDS) were the most inappropriately prescribed medicines, followed by anticholinergics, central nervous system drugs and cardiovascular system drugs. Females are at higher risk of having inappropriate prescriptions than males.

Twenty five patients were interviewed so as to get qualitative findings of the possible outcomes of polypharmacy. 1 patient had difficulty in keeping track of their medicines, 7 had trouble taking their medicines, 19 patients could not describe the purpose of their medicines, 21 had difficulty in understanding the instructions on their medications, 1 patient reported that they experienced an ADR, 3 patients saw more than one doctor and 12 patients visited more than one pharmacy.

The study was successful in determining the frequency of polypharmacy in geriatric patients, establishing the frequency, characteristics and predictors of inappropriate prescription among geriatric patients using Beers criteria 2012 and exploring selected outcomes of polypharmacy among geriatric patients.

5.2 RECOMMENDATIONS

Steps need to be taken to reduce the prevalence of polypharmacy or to ensure maximum benefits to the patient where polypharmacy is absolutely necessary. Therefore programs like continuing medical educations (CMEs) should be attended by medical practitioners on a regular basis. Tools should also be made readily available in hard and soft copy like the Beers criteria booklet, East African Drug Index so that one can always refer to the frequency of dosing, safety profile, total number of medicines a patient has to take and other factors.

Patient education and one on one patient/care giver counseling should be carried out by the pharmacist so that they know that they should report all adverse effects they may experience and let their prescriber know all the medicines they are taking irrespective of where they get them from.

The following steps can be employed to reduce polypharmacy in the elderly:

Recomendations for healthcare workers (Pharmacists, prescribers and nurses):

1. One should get and maintain accurate medication history including over the counter medications and herbal preparations during every clinic visit. This will greatly reduce duplication of therapies. Knowledge of the pharmacology medication being used is also important as it can explain patient specific symptoms. For example a patient on tramadol may explain why he/she is experiencing nausea and vomiting.
2. Each medication should match the patient's disease state or diagnosis.
3. Drug reconciliation of patients drugs upon discharge or transfer from hospital to hospital. This will reduce duplication of medicines, unnecessary and inappropriate medications.
4. The appropriateness of any medicine and potential side effects should be evaluated during prescribing so as to take preventive measures to avoid unnecessary, inappropriate drugs, or medicines with a high likelihood for causing side effects that would require additional therapy.
5. Medicines that are used to treat side effects should be identified. This is because use of many medicines increases the risk of side effects and these side effects more often than not lead to the addition of more medicines to treat the side effects. More often than not, discontinuing one drug that causes a side effect leads to the discontinuation of several

other medicines. Pharmacovigilance should be emphasized and practiced by all healthcare workers in the hospital so as to prevent and to catch any ADRs at an early stage.

6. It should be noted that the more drugs a patient takes, the harder it may be to obtain an accurate medication history, which impedes informed medication review and prescribing, therefore time should be taken to get a thorough medication history from both the patient and their relatives or care takers.

7. Extra attention should be given to patients who have trouble in taking their medicines especially those who inject insulin as this medicine is very dose sensitive and wrong doses can be potentially fatal.

8. Instructions on the patients label should be written in a way that the patient can read and understand clearly, for example in Kiswahili. Verbal instructions and information should be given to the patients and the patient should be aided in organizing their medicines.

9. Multidisciplinary teams involving the prescribers and the pharmacists should be involved in patient management.

Recommendations for the hospital administration and policy makers

10. The hospital administration should encourage and sponsor more members of staff for courses in geriatric medicine and patient care.

11. In the wake of free maternal and child healthcare, a policy that would offer free medical care for geriatric patients would be appropriate. This will encourage patients to be consistent with the medical facilities they visit thus reducing the number of pharmacies and doctors that a patient sees.

Recommendations affecting the patients

12. Patients should be encouraged to carry the balance of their medications on every appointment so as to assist in accurate medication history and reconciliation.

This study can be carried out in private hospitals and pharmacies so as to get a picture of the status of polypharmacy in this sector. Other possible factors that can contribute to polypharmacy can be explored, like impact of advertising of drugs on the consumer.

The findings and recommendations of this study will be disseminated to the pharmacists and prescribers at Nyeri PGH for further action so as to improve the quality of prescribing and geriatric patient care in the hospital

BIBLIOGRAPHY

World bank. (2014). Retrieved 11 2, 2014, from CDP Per Capita (Current US$): http://www.data.worldbank.org/indicator/NY.GDP.PCAP.CD

Anderson, R. P. (1999). Age and gender-related use of low-dose drug therapy:the need to manufacture low-dose therapy and evaluate the minimum effect dose. *J Am Geriatric Society*.176: 88-92

Beers, M., & Ouslander, J. R. (1991). *Explicit criteria for determining inappropriate medication use in nursing home residents.* UCLA Division of Geriatric medicine, Arch Intern Med. 31: 52-53

Bergman-Evans, B. (2006). *Evidence-based guideline. Improving medication management for older adult clients.* Retrieved September 19, 2014, from www.nursingcenter.com: http://www.nursingcenter.com/Inc/cearticle?tid=836277#P143

Denison, s. M. (2010). Interventions to improve prescribing quality in care homes: a systematic review. *Epidemiol community health*, 64: 43-44.

Fick, D., Cooper, J., Waller, J., Maclean, J., & Beers, M. (2003). Updating the Beers criteria for potentially inappropriateb medication use in older adults: results of a US consensus panel of experts. *ARCH Intern Med*, 163:2716-24.

Forman, D., Coletta, D., & Kenny, D. e. (1991). Clinical issues related to discontinuing digoxin therapy in elderly nursing home patoents. *Arch Intern Med, 151*, 2194.

Gurwitz, R. (1995, July 1). Drug Therapy. *Lancet, 346*, 32-36.

Gwenno, & Robert G, R. A. (2003). Using prescribing indicators to measure the quality of prescribing to elderly medical inpatients. *Age and Ageing-British Geriatrics Society*, 32: 292–298.

Hamilton, H. J. (2009). Inappropriate prescribing and adverse drug events in older people. *BMC Geriatrics*, 9:5.

Hanlon, KE, S., Samsa GP, W. M., KM, U., IK, L., HJ, C., et al. (1992). A method for assessing drug therapy appropriateness. *Journal of Clinical Epidemiol*, 45:1045-51.

Hilary, J. H., Paul F, G., & O'Mahoney, D. (2009). Inappropriate prescribing and adverse drug reactions in older people. *Biomed Central*. 434: 102-109

Hoffman, S. G. (2011, October). Polypharmacy or Medication Washout : An Old Tool Revisited. *US National Library of Medicine*. 53: 78

Intergrate. (2012). *Nyeri Provincial General Hospital*. Retrieved March 17, 2014, from www.intergratepc.org/hospital/kenya-only/ 23: 38

Jorgensen, T., Johansson, S., & Kennerfalk, A. (2001). Prescription drug use,diagnosis and healthcare utilisation among the elderly. (A. Pharmacother., Ed.) *Pubmed*. 1067: 99-101

Kaufman, G. (2011, May 25). Polypharmacy in older adults. *Nursing standard*, pp. 49-55.

Kim, H.-A., Shin, J.-o., Kim, M.-H., & Park, B.-J. (2014, June 10). *Prevalence and predictors of polypharmacy among Korean elderly.* Retrieved November 2, 2014, from Plosone.org: http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0098043

KNBS. (2010). *Kenya National Bureau of Statistics 2009 Population and Housing Census Results.* NAIROBI: Kenya National Bureau of Statistics .

Ko, Mamdani, & Alter. (2004). Lipid-lowereing therapy with statins in high risk elderly patients; the treatment risk paradox. *JAMA*. 1037; 96-112

Lazarou, P. B. (1998, April 15). Incidence of adverse drug reactions in hospitalised patients: A meta-analysis of prospective studies. *Journal of the American Medical Association*, 279: 78-80.

Maheshkumar, V., & Dhanapal, C. (2014). Prevalence of polypharmacy in geriatric patients in rural teaching hospital. *American Journal of Phytomedicine and Clinical Therapeutics*, 413-419.

McElnay, Harron, D'arcy, & Eagle. (1978, June 10). Interaction of digoxin with antacid constituents. p. 1554: 26

Molony, S. L. (2009). How to try this: Monitoring Medication Use in Older adults. *American Journal of Nursing (AJN)*, Volume 109 Number 1. Pages 68-78.

National Prescribing Service. (2000, December). What is polypharmacy? *National Prescribing Service Newsletter*. 78; 52

National prescribing Service Limited (NPS). (2010, August). *Medicine Update Vildagliptin (Galvus) for type 2 diabetes*. Retrieved March 30, 2014, from NPS Web site: www.nps.org.au/_data/assets/pdf_file/0009/106578/NPS_Medicine_Update_Vildagliptin_August 2010.pdf   923: 45

Patterson S, H. C., & Kerse N, C. C. (2012). Interventions to improve the appropriate use of polypharmacy for older people (Review). *Cochrane Database of Systematic Reviews*, Issue 5. Art. No.: CD008165. DOI:10.1002/14651858.CD008165.pub2.

Public Citizen's Health Research Group. (2003). *Misprescribing and Overprescribing of Drugs*. Retrieved March 12, 2014, from Worst Pills, Best Pills: http://www.worstpills.org/public/page.cfm?op_id=3

Raza, H. M. (2009, June). ARMOR: A Tool to Evaluate Polypharmacy in Elderly Persons. *Annals of Long term Care, 17*(6), 26-30.

Rochon, P., Lane, C., & Bronskill, S. (2004). Potentially inappropriate prescribinb in Canada relative to the US. *Drugs and Aging*(21), 939.

Steinman, L. C. (2006). Polypharmacy and Prescribing Quality in Older People. *The American Geriatrics Society*, 54:1516–1523.

Stryer, D. B. (1996, October). Characteristics of materials distributed by drug companies: An evaluation of appropriateness. *Journal of General Internal Medicine, 277*, 115-121.

The American Geriatrics Association. (2012). Retrieved from www.americangeriatrics .org: www.americangeriatrics.org/files/documents/beers/Printablebeerspocketcard.pdf

Up To Date. (2013, November 6). *Drug prescribing for older adults.* (K. E, & M. schmader, Eds.) Retrieved March 2014, from UpToDate: www.uptodate.com/contents/drug-prescribing-for-older-adults

Venturini, C. D., Engroff, P., Ely, L. S., Zago, F. d., Gulherme, S., Gomes, I., et al. (2011). Gender differences, polypharmacy and potential pharmacological interactions in the elderly. *Clinics (Sao Paolo).*

Weisstein, E. W. (1999). *"Fishers Exact Test." From MathWorld--A Wolfram Web Resource.* Retrieved May 11, 2014, from Mathworld. wolfram.com: http://mathworld.wolfram.com/FishersExactTest.html 78: 23-24

Wilson, K. (2009). *Polypharmacy: Making it all Work.* Retrieved March 11, 2014, from Post Polio: http://www.post-polio.org/net/10thConfPolyPharmacy.pdf

Wolf, C. W. (2011). Helping patients simplify and safely use complex prescription regimens. *Arch Intern Med, 171*, 300.

Wooten, J., & Galavis, J. (2005, August 1). *Polypharmacy: Keeping the elderly safe.* Retrieved January 26, 2014, from Modern Medicine: http://www.modernmedicine.com/modern-medicine/news/polypharmacy-keeping-elderly-safe 65: 76-80

Yvette, & Terrie. (2004, December 1). *Understanding and Managing Polypharmacy in the Elderly.* Retrieved January 26, 2014, from Pharmacy Times: http://www.pharmacytimes.com/publications/issue/2004/2004-12/2004-12-9094#sthash.TGVVlb8J.dpuf 295: 35

APPENDIX A

ETHICS AND RESEARCH COMMITTEE APPROVAL LETTER page 1 of 2

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

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

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

Ref: KNH-ERC/A/223   Link:www.uonbi.ac.ke/activities/KNHUoN   7th July   2014

Dr. Mwaniki Annie Wamaitha
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi

Dear Dr. Mwaniki

RESEARCH PROPOSAL: PRESCRIBING QUALITY AND POLYPHARMACY IN GERIATRIC PATIENTS – A CASE STUDY OF NYERI PROVINCIAL GENERAL HOSPITAL   (P216/04/2014)

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 7th July   2014 to 6th July 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

45

Yours sincerely

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

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

Protect to Discover

46

APPENDIX B

NYERI PROVINCIAL GENERAL HOSPITAL TRAINING AND ETHICS COMMITTEE APPROVAL LETTER

Approved
25|6|14.

TRAINING AND ETHICS COMMITTEE
NYERI - P.G.H.
P. O. Box 27-10100, NYERI

Annie Wamaitha Mwaniki,
P.O. Box 1442-10100
Nyeri
Tel: +254722733192

Date: 3rd June 2014

The Chairperson,
Training committee
Nyeri Provincial General Hospital
P.O. box 27-10100
Nyeri

Dear Sir/Madam,

REF: REQUEST TO CARRY OUT RESEARCH PROJECT AT NYERI PROVINCIAL GENERAL HOSPITAL

I am a student at the University of Nairobi, School of Pharmacy where I am pursuing a Master of Pharmacy degree in Pharmacoepidemiology and Pharmacovigilance.
I am undertaking a research project in partial fulfillment of the requirements for my degree entitled **Prescribing Quality and Polypharmacy in Geriatric Patients – A case study of Nyeri Provincial General Hospital.**
I humbly request you to allow and facilitate me to undertake this research project at your hospital sometime during the months of June, July and August 2014. I will need to collect the data through patient interviews as well as from records form the in-pateint and medical out-patient clinics.
Please find appended, a copy of my research proposal as well as an introduction letter from my supervisor at the University of Nairobi. Please feel at free to contact me in case of any queries.
Your kind consideration will be highly appreciated.
Yours sincerely,

Dr. Annie W. Mwaniki

47

APPENDIX C

DATA COLLECTION TABLE: NUMBER OF PRESCRIPTIONS WITH FIVE OR MORE DRUGS

No-	Number of medicines on prescription	Does the prescription have 5 or more medicines? Tick where appropriate	
		YES	NO

APPENDIX D

DATA COLLECTION TABLE FOR INAPPROPRIATE MEDICATION USE

Determining inappropriate medication use in patients > 65 years using Beer's criteria(2012)					
Organ system/ therapeutic category/ Drugs	Recommendation	Tally of number of patients having inappropriate medication	Total number of patients		
Anticholinergics (excludes TCAs)					
First generation antihistamines (as a single agent or as part of combination product) Brompheniramine Carbinoxamine Chlorpheniramine Clemastine Cyproheptadine Dexbrompheniramine Dexchlorpheniramine Diphenhydramine (oral) Doxylamine Hydroxyzine Promethazine Triprolidine	Avoid				
Antiparkinson agents Benztropine (oral) Trihexyphenidyl	Avoid				
Antispasmodics Belladonna alkaloids Clidinium-chlordiazepoxide	Avoid except in short-term palliative care to decrease oral secretions.				

Dicyclomine Hyoscyamine Propantheline Scopolamine				
Antithrombotics				
Dipyridamole, oral short-acting (does not apply to the extended-release combination with aspirin)	Avoid			
Ticlopidine				
Anti-infectives				
Nitrofurantoin	Avoid for long-term suppression; avoid in patients with CrCl <60 mL/min.			
cardiovascular				
Alpha1 blockers Doxazosin Prazosin Terazosin	Avoid use as an antihypertensive.			
Alpha blockers, central Clonidine Guanabenz Guanfacine Methyldopa Reserpine (>0.1 mg/day)	Avoid clonidine as a first-line antihypertensive. Avoid others as listed.			
Antiarrhythmic drugs (Class Ia,Ic,	Avoid antiarrhythmic			

III) Amiodarone Dofetilide Dronedarone Flecainide Ibutilide Procainamide Propafenone Quinidine Sotalol	drugs as first-line treatment of atrial fibrillation.				
Disopyramide					
Dronedarone	Avoid in patients with permanent atrial fibrillation or heart failure				
Digoxin >0.125 mg/day					
Nifedipine, immediate release					
Spironolactone >25 mg/day	Avoid in patients with heart failure or with a CrCl <30 mL/min.				
Central Nervous system					
Tertiary TCAs, alone or in combination: Amitriptyline Chlordiazepoxide-amitriptyline Clomipramine Doxepin >6 mg/day Imipramine Perphenazine-amitriptyline	Avoid				

Trimipramine					
Antipsychotics, first-(conventional) and second-(atypical) generation\n\nChlorpromazine\n\nFluphenazine\n\nHaloperidol\n\nLoxapine\n\nClozapine\n\nOlanzapine	Avoid use for behavioral problems of dementia unless non-pharmacologic options have failed and patient is threat to self or others.				
Thioridazine\n\nMesoridazine					
Barbiturates\n\nAmobarbital\n\nButabarbital\n\nButalbital\n\nMephobarbital\n\nPentobarbital\n\nPhenobarbital\n\nSecobarbital	Avoid				
Benzodiazepines\n\n*Short- and intermediate-acting:*\n\nAlprazolam\n\nEstazolam\n\nLorazepam\n\nOxazepam\n\nTemazepam\n\nTriazolam	Avoid benzodiazepines (any type) for treatment of insomnia, agitation, or delirium.				

Long-acting: Chlorazepate Chlordiazepoxide Chlordiazepoxide-amitriptyline Clidinium-chlordiazepoxide Clonazepam Diazepam Flurazepam Quazepam					
Chloral hydrate					
Meprobamate					
Nonbenzodiazepine hypnotics Eszopiclone Zolpidem Zaleplon	Avoid chronic use (>90 days)				
Ergot mesylates Isoxsuprine					
Endocrine					
Androgens Methyltestosterone Testosterone	Avoid unless indicated for moderate to severe hypogonadism.				
Desiccated thyroid					
Estrogens with or without progestins	Avoid oral and topical patch. Topical vaginal cream: Acceptable to use low-dose intravaginal				

	estrogen for the management of dyspareunia, lower urinary tract infections, and other vaginal symptoms.				
Growth hormone	Avoid, except as hormone replacement following pituitary gland removal.				
Insulin, sliding scale	Avoid				
Megestrol					
Sulfonylureas, long-duration Chlorpropamide Glyburide	Avoid				
Gastrointestinal system					
Metoclopramide	Avoid, unless for gastroparesis.				
Mineral oil, given orally					
Trimethobenzamide					
Pain medications					
Meperidine (pethidine)					
Non–COX-selective NSAIDs, oral Aspirin >325 mg/day Diclofenac Diflunisal Etodolac Fenoprofen Ibuprofen	Avoid chronic use unless other alternatives are not effective and patient can take gastroprotective agent (proton-pump inhibitor or misoprostol)				

Ketoprofen Meclofenamate Mefenamic acid Meloxicam Nabumetone Naproxen Oxaprozin Piroxicam Sulindac Tolmetin					
Indomethacin Ketorolac, includes parenteral	Avoid				
Pentazocine	Avoid				
Skeletal muscle relaxants Carisoprodol Chlorzoxazone Cyclobenzaprine Metaxalone Methocarbamol Orphenadrine	Avoid				
Abbreviations: ACEI, angiotensin converting-enzyme inhibitors; ARB, angiotensin receptor blockers; CNS, central nervous system; COX, cyclooxygenase; CrCl, creatinine clearance; GI, gastrointestinal; NSAIDs, nonsteroidal anti-inflammatory drugs; SIADH, syndrome of inappropriate antidiuretic hormone secretion; TCAs, tricyclic antidepressants					

APPENDIX E

DATA COLLECTION FORM FOR PATIENT INTERVIEW TO IDENTIFY RISK FACTORS FOR POLYPHARMACY

1. **Participant eligibility checklist**

Inclusion criteria (If any of the criteria is marked NO, then the prescription is not eligible for this study)

	YES	NO
• Is the patient 65 years old and above?	☐	☐
• Does the prescription have five or more medicines?	☐	☐

Exclusion criteria (if any of the criteria is marked YES then the prescription is not eligible for the study

	YES	NO
• Are any of the medicines in the prescription herbal?	☐	☐

2. Demographics

Age				
sex	Male ☐	Female ☐		
Highest level of Education	Less than high school ☐	High school ☐	College ☐	None ☐

3. Medication use data

a) What are the total numbers of prescription, over the counter medication you are currently taking?

0	1	2	3	4	5	6	7	8	9	10+

b) Do you have difficulty in keeping track of your medications				
Strongly agree ☐	Agree ☐	Neutral ☐	Disagree ☐	Strongly disagree ☐
c) Do you have trouble taking your medications				
Strongly agree ☐	Agree ☐	Neutral ☐	Disagree ☐	Strongly disagree ☐
d) Would you be able to describe the purpose of all your medications				
Strongly agree ☐	Agree ☐	Neutral ☐	Disagree ☐	Strongly disagree ☐
e) Would you be able to describe the instructions for all your medications				
Strongly agree ☐	Agree ☐	Neutral ☐	Disagree ☐	Strongly disagree ☐

f) Have you ever had an adverse drug reaction (ADR) from your medication?

Yes ☐	Not sure ☐	No ☐

g) Is there someone who helps you keep track of your medication?

Yes ☐	Not sure ☐	No ☐

h) How many doctors/ specialists do you visit

0	1	2	3	4	5	6	7	8	9	10+

i) How many pharmacies do you obtain your medicines from?

0	1	2	3	4	5	6	7	8	9	10+

j) Any other sources of drugs

……

…………………………

APPENDIX F

VOLUNTEER INFORMATION AND CONSENT FORM.

INTRODUCTION

Polypharmacy is the use of multiple medicines (at least five types of medicines) to treat a single patient. Polypharmacy can have positive and negative consequences. Positive consequences can be as a result of several effective clinical interventions. Therefore, it is important to distinguish between irrational and rational polypharmacy. Prescription quality, good prescribing practices as well as good dispensing practices are important in avoiding irrational polypharmacy. The elderly are at a risk of negative consequences of polypharmacy because of the pharmacokinetic and pharmacodynamic changes that occur as people grow old, therefore such patients tend to present with different disease patterns, often including two or more concurrent diseases, and have altered, usually slower response to treatment.

In this study I am assessing prescribing quality and polypharmacy in patients who are 65 years and above.

Permission is requested from you to enroll in this medical research study. This consent gives information about the study. Once you understand and agree to take part, I will request you to sign your name on this form. You should understand the following general principles that apply to all participants in a medical research.

i. Your agreement to participate in this study is voluntary

ii. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal

iii. Refusal to participate in the research will not affect the treatment that is being given in the hospital

Purpose of the study

The objective of the study is to determine the frequency of polypharmacy, the number of medications used by elderly patients, medication underuse and inappropriate prescribing in the elderly.

Procedures to be followed

With your permission I will go through your medical records to obtain information on the medicines that have been prescribed for you in the year 2013. I will also check whether you have experienced any bad reactions to your medicines.

Selection criteria

You will be selected to take part in this study if you meet the following criteria:

i.   You are an adult of 65 years and over.
ii.   You have attended a clinic in the in patient department or medical out patient clinic (MOPC) between January and December 2013.
iii.   You are taking 5 or more medicines.
iv.   You must have agreed to take part in the study.

Risks or/and discomfort.

There will be no risks involved in this study to you.

Benefits

The study may be of benefit to you and other patients in the hospital as the study will identify specific issues that contribute to polypharmacy that requires attention of healthcare providers so that they can improve the quality of care to elderly patients It may also inform policy makers on the need to review guidelines on quality prescribing in terms of deciding that a drug is indicated, choosing the best drug, determining a dose and schedule appropriate for the patient's physiologic status, monitoring for effectiveness and toxicity, educating the patient about expected side effects, and indications for seeking consultation.

Assurance on confidentiality

All information obtained from your file will be kept confidential and used for the purpose of this study only. Your name will not be used during data handling or in any resulting publications.Codes will be used instead. Your medical records will be kept under lock and key and information will be accessible to authorized persons only.

Contacts

For any further information about this study you may contact me, my academic department or the Kenyatta National Hospital/University of Nairobi Ethics and research Committee using the contacts provided below:

Annie Wamaitha Mwaniki,

Department of pharmacology and pharmacognosy

School of Pharmacy,

University of Nairobi

P.O.Box 19676 Nairobi

Tel: 0722-733192

Dr. Eric M.Guantai,

Department of pharmacology and pharmacognosy

School of Pharmacy,

University of Nairobi

P.O.Box 19767 Nairobi

Tel: 0722955883

The chairperson,

The Kenyatta National Hospital/University of Nairobi Research and Ethics Committee,

P.O Box 19676- Nairobi.

Tel: 020-2726300 Ext 44102

STATEMENT OF CONSENT

I have understood the information on the consent form. I have had a chance of discussing the research study with the investigator and I have had my concerns addressed.

I_____ give consent to the investigator to use my medical records in his study. Dr. Annie Mwaniki has explained the nature of the study to me.

Signature _____ Date _____

DECLARATION

I confirm that I (Dr. Annie Mwaniki) have explained the nature and effect of the study to the participant named above and believe that the participant has understood and has willingly given their consent.

Signature: _____ Date: _____

APPENDIX G

DATA COLLECTION FORM FOR PATIENT INTERVIEW TO IDENTIFY RISK FACTORS FOR POLYPHARMACY

1. Participant eligibility checklist

Inclusion criteria (If any of the criteria is marked NO, then the prescription is not eligible for this study)

	YES	NO
• Is the patient 65 years old and above?	☐	☐
• Does the prescription have five or more medicines?	☐	☐

Exclusion criteria (if any of the criteria is marked YES then the prescription is not eligible for the study

	YES	NO
• Are any of the medicines in the prescription herbal?	☐	☐

4. Demographics

Age				
Sex	Male ☐	Female ☐		
Highest level of Education	Less than high school ☐	High school ☐	College ☐	None ☐

5. Medication use data

a)Ni mithemba iigana ya dawa cigwathiro ni dagitari ,na kwiyathira na kugura we mwene kuuma

ndukaini urahuthira ihinda riri?

0	1	2	3	4	5	6	7	8	9	10+

b) Ni ugiaga na mihinga ukigeria kuiga dawa ciaku wega

Gwitikira na Hinya muno	gwitikira	☐ Ndiri mwena Ngugua	☐ ndigwitikira	Ni ndarega gwitikira na hinya muno

c) No giaga na moritu ukihuthira dawa ciaku

Gwitikira na Hinya muno	gwitikira	Ndiri mwena Ngugua ☐	Ndigwitikira ☐	Ni ndarega gwitikira na hinya muno

d)No uhote gutaririra gitumi kia dawa ciaku ciothe

Gwitikira na Hinya muno	☐ gwitikira	Ndiri mwena Ngugua	☐ ndigwitikira	Ni ndarega gwitikira na hinya muno

e) No uhote gutariria maundu maria werirwo megii kuhuthira dawa ciaku ciothe				
Gwitikira na Hinya muno	☐ gwitikira	Ndiri mwena Ngugua	ndigwitikira	Ni ndarega gwitikira na hinya muno

f) Have you ever had an Adverse drug reaction (ADR) from your medication

f)Niuri wagia na mathina moru maimanite na kuhuthira dawa ciaku?

ii ☐	Ndiri na ma ☐	aca ☐	

g) I hari mundu ungi uguteithagia kumenyerera dawa ciaku wega

ii ☐	Ndiri na ma ☐	aca ☐	

f) Ni dagitari aigana /kana atalamu angi uthiaga kuona

0	1	2	3	4	5	6	7	8	9	10+

g)Ni nduka ciigana cia dawa woyaga dawa kuma kuri cio

0	1	2	3	4	5	6	7	8	9	10+

64

h) Kihumo kingi kia dawa………………………………………………………………………..

APPENDIX H

UHORO WA MWIRUTIRI NA KARATATHI KA WITIKIRI

KIAMBIRIRIA

Kuhuthira dawa mithemba miingi (ta dawa mithemba itano)guthodeka muruaru umwe nikuo gwitagwo na ruthiomi rwa githungu(polypharmacy) undu uyu no ukorwo na maundu mega kana ukorwo na maundu moru. Maundu mega mangioneka niundu wa maumirira ma kuhuthira njira mithema miingi ikuruta wira wega cia urigiti.

Niundu wa uguo he bata guthutukania gatagatiini ka njira ina uteithio na njira itari na uteithio cia kuhuthira dawa mithemba miingi hamwe.kwandika dawa na ikiro cia iguru na kurumirira njira iria njitikiriku hari mwandikire wa dawa na miaheanire dawa iria miega ni maundu mari bata muno kugiriria miheanire miuru ya dawa mithemba miingi (polypharmacy).Andu aria akuru me mutinoini wa mathina moru niundu wa kuhuthira dawa mithemba miingi.nitondu wa guthiyo kwa dawa thiini wa mwiri na murutire wa wira wa dawa na ugaruruku uria wonekaga riria andu marakura,na niundu wa uguo aruaru ta aya nimonekaga mena ndwari ngurani,kaingi itukanite mirimu mithemba iri kana igo kanira ihinda rimwe na undu uyu ukagarura kana ukarehe kahora hari murutiire wa dawa urigitiini

Utwiriani uyu ndirarora ikiro cia miandikire ya dawa na uhuthiri wa dawa mithemba miingi hari aruaru aria makiritie ukuru wa miaka 65 guthii na iguru.

Niurahoywo rutha wiyandikithie hari utwiria uyu wa ugima wa mwiri. Karatathi gaka kawitikiri nigegukuhe uhoro wigii utwiria uyu.wamenya na wetikira kunyita itemi, ningukuria wikire kiara na ritwa riaku karatathiini gaka. Niwagiriirwo umenyo mawatho maria mahuthikaga hari anyiti itemi a motwiria ma ugima wa mwiri

i) Gwitikira gwaku kunyita itemi hari utwiria uyu nikwiyendera.
ii) No wiyeherie kuma kuri utwiria uyu inhinda oreothe ona utekuheana gitumi ona kiriku gia kwiyeheria gwaku

iii) Kurega gwaku kunyita itemi hari utwiria uyu gutikuhotomia urigiti uria uheanagwo thibitari ini ino.

GITUMI KIA UTWIRIA

Muoroto wa utwiria uyu ni kumenya nita mahinda maigana ta atia muheanire wa dawa mithemba miingi wikikaga ni muigana wa dawa mithemba iigana ihuthagirwo nia aruaru uhuthiri utari muiganu wa dawa,na mwandikire wa dawa hari adu akuru uria utagiriire.

Mutaratara Uria Ukurumirirwo

Na rutha rwaku ninguthurima mandiko maku megii urigiti nigue ndute uhoro wa dawa iria wandikiirwo mwakaini wa 2013.No ngucoka ndore kana niugumiirwo ni mathina kumana na dawa ciaku.

Njira ya guthurana

Uguthurwo kunyita itemi thiini wa utwiria uyu angikorwo niuhingitie maundu maya.

i. Wi mundu mugima uhitukitie miaka 65 na makiria
ii. Niukite kliniki hari ruhonge rwa arwaru kana ruhonge rwa kliniki ya aruaru ya guthondekwo ukiinukaga
iii. Niurahuthira dawa 5 kana makiria
iv. No nginya ukorwo witikirite kunyita itemi thiini wa utwiria

Mitino kana/na kwaga kuiganira

Hatiri mutino ukonainie na utwiria uyu kuri we.

Umithio

Utwiria uyu no ukorwo na umithio kuri we na aruaru angi thiini wa thibitari ni tondu niugukurana maundu kiene maria marehagirira uhuthiri wa dawa mithemba miingi uria ubataire, kubarwo ni aruti wira a ugima wa mwiri niguo magacirie utungata wa utangiri wa aruaru aria akuru.undu uyu no ucoke umenyithie athondeki mibango bata wa kubara mawatho ma kwandika dawa na ikiro cia iguru na njira ya

67

gutua kana dawa ni ibataranie , guthura dawa iria njega kumenya muigana na maita maria makunyua magiriire kuringana na kiuga na ugima wa muruaru,guthima murutire wira mwega wa dawa na guthuka kwayo.guthomithia muruaru cigii guthukirwo kwa dawa hari muruaru na ndariri iria ingebatarania kuonwo ni dagitari.

Kuheana uira wa kuiga hitho

Uhoro wothe umanite na failo yaku niukuigwo na njira ya hitho na ukuhuthirwo tu na gitumi kia utwiria uyu. Ritwa riaku ritikuhuthirwo hindi ya kuoya uhoro kana kwandikwo kwa maumirira. Namba cia mwanya nicio ikuhuthirwo. Mandiko maku ma urigiti mekuigwo me mahingire na uhoro waku ungionwo tu ni andu aria etikirie.

Njira ya kwaraniria

Ha uhoro makiria wigii utwiria uyu no waranirie na nie,ruhonge rwakwa rwa githomo kana kamiti iria irugamagirira uigiririku na kihoto kia utwiria ya thibitari (Kenyatta National Hospital/University of Nairobi Ethics and research Committee) kuhitukira thimu na mathanduku ma maruwa maya magwete haha.

Annie Wamaitha Mwaniki,

Department of pharmacology and pharmacognosy

School of Pharmacy,

University of Nairobi

P.O.Box 19676 Nairobi

Tel: 0722-733192

Dr. Eric M.Guantai,

Department of pharmacology and pharmacognosy

School of Pharmacy,

University of Nairobi

P.O.Box 19767 Nairobi

Tel: 0722955883

The chairperson,

The Kenyatta National Hospital/University of Nairobi Research and Ethics Committee,

P.O Box 19676- Nairobi.

Tel: 020-2726300 Ext 44102

NDUMIRIRI YA WITIKIRI

Ni ndamenya uhoro uria uri karatathiini ka witikiri, ni ndagia na mweke wa kwariria utwiria uyu muthuthuria na ciuria ciakwa niciacokio

Nii _____nindaheana rutha kuri muthuthuria kuhuthira mandiko makwa ma urigiti thiini wa utwiria wake Dagitari Anne Mwaninki niatariria muthemba uyu wa utwiria kuri nii..

Kiara/ kirore _____ Tariki _____

KUHITUKIA

Ni nguruta uira ati nii (Dr. Annie Mwaniki) nindatariria muthemba wa utwiria na maundu mangirehwo ni guo kuri munyiti itemi uyu mugwete haha na ni njitikitie ati munyiti itemi ni a menya na aheana na kwirutira rutha rwake

Signature: _____ Date: _____

APPENDIX I

FOMU YA KUCHUKUA MAELEZO YA MAHOJIANO NA MGONJWA ILICHUNGUZA HATARI ZA MATUMIZI YA MADAWA ZAIDI YA MOJA

---

1 Orodha ya mshiriki kuhitimu

Vigezo vya kukubalika (ikiwa yoyote ya vigezo itawekwa alama ya LA, basi ya karatasi ya dawa haitahitimu kwa huu utafiti

- Je mgonjwa ako zaidi ya miaka 65 na zaidi? ☐ Ndio ☐ La

- Je karatasi ya dawa iko na madawa tano au zaidi? ☐ Ndio ☐ La

Kutokubalika kwa vigezo (ikiwa yoyote ya vigezo iko na alama ya ndio basi karatasi hiyo ya madawa haitahitimu kwa utafiti).

Kunazo aina zozote za madawa kwa karatasi ya madawa ambayo ni miti ni dawa?

☐ ☐

Ndio La

Demografiki						
miaka						
jinsia	mwanamm e	☐		mwanamke	☐	
Kiwango cha juu cha kimasomo	Chini ya shule ya upili	☐	shule ya upili ☐	chuo ☐	hakuna ☐	
2. Maelezo ya matumizi ya dawa						

a) Ni jumla ya namba ngapi za karatasi za madawa, madawa unayopata ambayo unatumia kwa sasa?

0	1	2	3	4	5	6	7	8	9	10+

b) Huwa unapata shida ya kufuatilia mpangilio wa madawa zako

Nakubaliana kabisa ☐ Nakubali ☐ katikati ☐ sikubaliani ☐ Sikubaliani kabisa ☐

c)

Huwa una shida ya kutumia madawa zako?

Nakubaliana kabisa ☐ Nakubali ☐ katikati ☐ sikubaliani ☐ Sikubaliani kabisa ☐

d)

Unaweza kuelezea nia zote za madawa yako?

Nakubaliana kabisa ☐ Nakubali ☐ katikati ☐ sikubaliani ☐ Sikubaliani ☐ kabisa

e				
Unaweza kuelezea masharti yote ya madawa yako?				
Nakubaliana kabisa ☐	nakubali ☐	katikati ☐	sikubaliani ☐	Sikubaliani kabisa ☐

f) Umewahi kuwa na madhara mabaya yanayohusiana na madawa kutokana na madawa yako?		
ndio ☐	sina uhakika ☐	la ☐

g) Labda kuna mtu mwingine ambaye hukusaidia kufuatilia mpangilio wa madawa yako		
ndio ☐	sina uhakika ☐	la ☐

f) Ni madaktari/madaktari wakuu wangapi huwa unatembelea

0	1	2	3	4	5	6	7	8	9	10+

g)

Ni maduka ngapi ya madawa ambayo huchukua madawa yako kutoka?

0	1	2	3	4	5	6	7	8	9	10+

h)mahalikwingineunapatamadawa…………………………………………………………………………………………

………………………………………………………………….

APPENDIX J

MAELEZO YA KUJITOLEA KWA MSHIRIKI NA NAKALA YA MAKUBALIANO

Utangulizi

Utumizi wa madawa mengi (ikizidi aina tano za madawa)ili kutibu mgonjwa mmoja huitwa(Polypharmacy) kwa kingereza. Utumizi wa madawa mengi inaweza kuwa na matukio mazuri na mabaya. Matukio mazuri yanaweza kuwa ni mbinu nyingi zinatumika kwa utabibu.Kwa hivyo ni muhimu kutambua katikati ya utumizi mbaya na uzuri wa utumizi wa madawa mengi. Ubora wa karaatasi ya madawa, mazoezi ya kuandika madawa vizuri na hata mazoezi ya kupeana madawa vizuri ni muhimu ili kuzuia utumizi wa madawa mengi vibaya.Watu wa umri wa uzee wako katika hatari ya matukio mabaya ya utumizi wa madawa mengi kwa sababu ya famakokinetiki na famakodinamiki mabadiliko ambayo hutokea wakati watu wanapokuwa wazee, basi hivyo wagonjwa kama hao huwa wanajitokeza na aina tofauti za magonjwa,mara nyingi ikihusisha magonjwa aina mbili au zaidi,na huwa inakuwa polepole kutibika kimatibu.

Kwa huu utafiti ninachunguza ubora wa kuandikwa kwa madawa na utumizi wa madawa mengi kwa wagonjwa walio na miaka 65 na zaidi.

Ruhusa inaitishwa kutoka kwako ili uandikishwa kwa huu utafiti wa madawa. Nakala hii ya itikio inakupa maelezo kuhusu utafiti. Mara utakapoelewa na ukikubali kushiriki, nitakuomba uweke sahihi ya jina lako kwa fomu hii. Yafaa uelewe nguzo misingi ambazo hutumika kwa washiriki wote wa tafiti za madawa. Yafuatayo:

i. Uamuzi wako kushiriki kwa utafiti huu ni kwa hiari.

ii.Unaweza kutoka kwa utafiti wakati wowote bila lazima ya kupeana sababu zako za kutoka.

iii. Kukataa kushiriki kwa utafiti haitaathiri matibabu yako ambayo yanapeanwa kwa hospitali.

Nia ya Utafiti

Nia ya utafiti huu ni kuchunguza uzoefu wa utumizi wa madawa mengi, nambari ya madawa yanayotumika na wagonjwa wazee, utumizi wa madawa kidogo bila kujali. kuandikiwa kwa makaratasi ya madawa kwa wazee.

Taratibu zitakazofuatwa

Nikiwa na ruhusa yako nitapitia rekodi zako za kimatibabu ili kupata maelezo ya madawa ambayo umeandikiwa kwa mwaka wa 2013.Na pia nitaangalia ikiwa uliwahi kupata madhara mabaya kutokana na madawa yako.

Viegezo vya uchaguzi

Utachaguliwa kushiriki kwa huu utafiti ikiwa utatimiza viegezo vifuatazo:

  i.   Wewe ni mtu mzima wa miaka 65 na zaidi.
 ii.   Umetembelea kliniki kwa sehemu ya kulazwa au ulipata kutibiwa na kurudi nyumbani (MOPC) kati ya Januari na Disemba 2013.
iii.   Unatumia madawa 5 au zaidi.
 iv.   Lazima uwe ulikubali kushiriki kwa utafiti.

Hatari au/na Kutoridhika

Hakutakuwa na hatari zozote zitakazohusisha utafiti huu kwako.

Faida

Utafiti huu huenda ukawa wa faida kwako na wagonjwa wengine kwa hospitali kwani utafiti utachunguza mambo haswa ambayo huchangia utumizi wa madawa mengi ambayo yanahitaji uangalifu wa wanaopeana huduma za kiafya ili waweze kuboresha ubora wa huduma kwa wagonjwa wazee.Huenda pia ikawajulisha waundaji sera kuna haja ya kuchunguza mikakati ya ubora wa karatasi ya madawa kama vile uamuzi wa dawa imefahamika,kuchagua dawa nzuri,uamuzi wa kiwango ,kuendelea kupanga vilivyo ukiangalia hali ya mgonjwa,kuangalia kufanya kazi na sumu ya madawa, kumfunza mgonjwa kuhusu madhara yanayotarajiwa,na dalili za kutaka kumwona muuguzi tena.

Uhakikisho wa usiri

Maelezo yote yatakayopatikana kutoka kwa kitabu chako yatawekwa kuwa ya kisiri na yatatumika kwa nia ya utafiti pekee. Jina lako halitatumika wakati wauchukuzi wa maelezo au kwa machapishi yatakayotolewa.Nambari za siri zitatumika badala yake. Rekodi za kimatibabu zitawekwa na zitatumika kwa nia ya utafiti huu pekee. Jina lako halitatumika wakati wa uchukuzi wa maelezo au kutokea kwa machapishi yoyote. Rekodi zako za kimatibabu zitawekwa ndani ya kufuli na ufunguo na maelezo yataangaliwa na watu waliokubaliwa pekee yao.

Mawasiliano

Kwa maelezo zaidi kuhusu utafiti huu unaweza kuwasiliana na mimi,idara ya masomo yangu au kamati ya maadili ya hospitali ya kitaifa ya Kenyatta/chuo kikuu cha Nairobi ukitumia anwani zilizopeanwa hapo chini:

Dr. Annie Wamaitha Mwaniki,

Department of pharmacology and pharmacognosy

School of Pharmacy,

University of Nairobi

Sanduku la posta 19676 Nairobi

Tel: 0722-733192

Dr. Eric M.Guantai,

Department of pharmacology and pharmacognosy

School of Pharmacy,

University of Nairobi

Sanduku la posta 19767 Nairobi

Tel: 0722955883

Mwenyekiti,

Kamati ya maadili ya Hospitali ya Kitaifa ya Kenyatta/Chuo kikuu cha Nairobi,

Sanduku la posta 19676- Nairobi.

Tel: 020-2726300 Ext 44102

TAARIFA YA ITIKIO

Nimeelewa maelezo kwa nakala ya itikio. Nimekuwa na fursa ya kujadili utafiti na mpelelezi na hofu yangu imetatuliwa.

Mimi _____ nimepeana itikio kwa mpelelezi ili atumie rekodi zangu za kimatibabu kwa huu utafiti.Dkt.Annie Mwaniki amenielezea namna ya huu utafiti kwangu.

Sahihi_____ Date _____

THIBITISHO

Nimehakikisha kuwa mimi(Dkt.Annie Mwaniki) nimeelezea namna na athari za utafiti kwa mshiriki aliyetajwa hapo juu na ninaamini kuwa mshiriki ameelewa na kwa hiari yake amepeana itikio.

Sahihi: _____ Tarehe: _____