MEDICATION RELATED PROBLEMS AND PREDISPOSING FACTORS AMONG ADULT PSYCHIATRIC PATIENTS ON ANTIPSYCHOTIC DRUGS AT MATHARI TEACHING AND REFERRAL HOSPITAL

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U56/38154/2020

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A Research Dissertation submitted in Partial Fulfilment of the requirements for the award of the Degree of Master of Pharmacy in Clinical Pharmacy of the University of Nairobi

NOVEMBER, 2023

DECLARATION OF ORIGINALITY

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DEDICATION

I wish to dedicate this dissertation to my parents Dr G.G Wagah and Dr Mical Wagah for their unwavering support and encouragement.

ACKNOWLEDGEMENT

I wish to express my heartfelt gratitude to the Almighty God for enabling me to complete this dissertation.

I am grateful to my parents, Dr. George Wagah and Dr. Mical Wagah, for their encouragement and support in pursuing my master's degree. I appreciate both the financial and emotional support you provided me throughout the program.

I appreciate my supervisors, Dr. David G. Nyamu and Dr. Peter N. Karimi for their tireless efforts to see me through the program and help me improve in knowledge, and to help me achieve my academic goals.

I am grateful to all of my classmates who gave of their time and resources to impart information and make the journey easier.

Finally, I would like to thank the Mathari National Teaching and Referral Hospital for allowing me to conduct my research and assisting with data collection process.

God bless you all.

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ABBREVIATIONS AND ACRONYMS

ADE- Adverse Drug Events

APA- American Psychological Association

CNS- Central Nervous System

DDI- Drug-drug Interaction.

DSM V- Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

KNH/UoN-ERC- Kenyatta National Hospital/University of Nairobi Ethics and Research Committee.

MNTRH- Mathari National Teaching and Referral Hospital

MRP- Medication Related Problem

PCNE- Pharmaceutical Care Network Europe

WHO- World Health Organization.

OPERATIONAL DEFINITIONS

Adherence- The extent to which a patient continues an agreed-upon mode of treatment without close supervision.

Co- morbidities- This is the presence of an extra medical condition(s) concurrently with a primary disease and which require long term treatment.

Medication related problem- Refers to an event or circumstance involving medication therapy that actually or potentially interferes with an optimum outcome for a specific patient.

Polypharmacy- The concurrent use of two or more drugs to manage one medical condition.

Psychiatric Disorder- Refers to a disabling mental illnesses associated with disruption in cognition, emotion, psychosocial and occupational functioning.

Prevalence refers to the proportions of persons who have a disease at or during a particular period.

ABSTRACT

Background: Psychiatric patients often take multiple medications making them more predisposed to medication related problems, but the extent to this problem has not been widely studied especially in Kenya.

Objective: The aim of study was to characterize the types of medication related problems and their predictor factors among adult psychiatric patients on antipsychotic medication in Mathari Hospital.

Methodology: A descriptive cross-sectional study was conducted in Mathari National Teaching and Referral Hospital. Simple random sampling was used to select 122 adult patients with psychiatric disorders. Using predesigned questionnaires, the patient's information, such as social demographics, laboratory findings, and treatment were collected. Patient interviews were used to assess any issues with the prescribed pharmaceutical therapy. Data was entered into Microsoft Excel 2016 and analyzed using STATA version 15.0. Descriptive, binary and multivariable logistic analyses was employed to describe the population at a 95% confidence interval and determine the strength of association between the socio-demographic factors, drug related factors, patient factors and the selected medication related problems.

Results: Among the 122 participants, females were the majority (52.5%), and the median age was 31 [26-41] years, with a range of 18 – 68 years. The prevalence of medication related problem was 54.9%. The most common medication related problem category was the need for additional drug therapy (47.3%), followed by adverse drug event (30.9%) and different drug needed (18.2%). Multivariate logistic analysis found the odds of experiencing medication-related problems for those with "College/University" education were 0.007 times (or 99.3% lower) than the odds for those with "Secondary & below" education (aOR=0.007, 95%CI: 0.00-0.0052, p=0.026).

Conclusion: There is a high prevalence of medication related problems occasioned by need for additional drugs and low level of academic achievement among adult psychiatric patients.

Recommendation: A comprehensive system review to be done for every patient because the need for additional therapy was a typical MRP, indicating that some of the patient's problems were not being addressed. Similar research with a larger sample size, prospective in nature and of a longer duration in several centers is recommended. This will give findings on the incidence rather than prevalence of the medication related problems.

CHAPTER ONE: INTRODUCTION

1.1 Background

More than 25% of people experience mental, neural, or substance use disorders at some point in their lifetime. Psychiatric diseases have been a concern for public health around the world contributing 14% to the burden of disease. The WHO estimates that 10% of adult and child populations experience at least one mental condition at any given moment (1). It is estimated that nearly four hundred and fifty million people have mental disorders. The three most prevalent psychiatric disorders are schizophrenia (21 million), bipolar disorders (60 million), and depressive disorders (350 million) (2). Psychiatric illness account for the majority (31.7%) of years spent with long term disability and dependency. Bipolar disorder (2.4%), schizophrenia (2.8%), and unipolar depression (11.8%) have all contributed to the disability (2). In Sub-Saharan Africa (SSA), psychiatric disease accounts for 19% of years lived with a disability (3). In South Africa, neuropsychiatric illnesses rank third in terms of years lived with a disability.

Up to 25% of outpatients and up to 40% of inpatients in health facilities in Kenya are thought to have mental illnesses. Additionally, 1% of Kenya's population is thought to have psychosis on average. Mental illnesses with the highest prevalence of diagnoses in general hospitals include depression, substance abuse, stress disorders, and anxiety disorders (1).

A medication related problem (MRP) is defined as an event or circumstance involving drug therapy that actually or potentially interferes with optimal health outcomes. MRPs are mostly common among patients with psychiatric disorders due to the pharmacokinetic and pharmacodynamic characteristics of antipsychotic drugs (3). MRPs have been associated with major health problems worldwide and have risen significantly in recent decades. Every year, over 140,000 drug-related hospital admissions occur worldwide (4).

Despite the significant morbidity, the public health agenda frequently ignores mental health (4). In addition, there are numerous drugs available that can have adverse effects on patients if they are not taken properly. These medications are meant for the treatment, prevention, or diagnosis of medical issues. Psychiatric conditions have a significant financial impact. By 2030, it is anticipated that the global expense of psychiatric illnesses will increase to $6.0 trillion from the estimated $2.5 trillion in 2010. Early mortality, lost resources and productivity, unemployment,

and absenteeism from work are some of the indirect economic consequences (5). Proper management of these disorders can therefore help on saving on additional costs. This can be achieved by early identification of medication related problems among these patients on antipsychotic medication.

According to research done in the United States, unspecified antidepressant poisoning (accidental (unintentional), intentional self-harm, assault, as a side effect, and under-dosing were the most frequent causes of poisoning by psychotropic drugs (6). Another study found that antidepressants are the drugs that people intentionally overdose on to commit self-harm the most (7).

Studies are therefore needed to explore medication related problems among psychiatric patients on antipsychotic medication; hence determining medication-related problems among adult psychiatric patients taking antipsychotic medication is the primary goal of this research.

1.2 Problem Statement

Psychiatric problems have been a burden for public health, accounting for 14% of all diseases worldwide (2). Despite the fact that medications play critical roles in the prevention, control, and treatment of several diseases, improper medication use can be detrimental and lead to medication-related problems which impact negatively on the clinical outcome of patients with psychiatric disorders (8). For instance, untreated psychiatric illness is linked to increased morbidity, longer hospital admissions, and eventually higher healthcare expenses. This frequently results in wasteful, expensive, and ineffective usage of medical resources, as well as issues with these patients' diagnosis and treatments (9). Furthermore, patients receive low doses three to four times more commonly than overdoses in today's healthcare system (10).

Patients with mental illnesses use both prescribed and over-the-counter medications making them more likely to have more sophisticated medication regimens. For example, drug interactions among mentally ill individuals could be an issue from an economic and societal standpoint (10). Prescribers also typically employ more than one medicine in clinical practice today to address the comorbid disorders of each of their patients. When patients visit additional healthcare professionals with different expertise, it becomes even more difficult and could lead to MRPs.

Medication related problems have been linked with serious public health issues worldwide and have risen significantly in recent decades. The predicted global hospital admissions attributable to

MRPs were 5- 10%, with half (50%) of these preventable or avoidable (12). In the United States, medication related problems are one of the top ten main causes of death, while adverse drug reactions are responsible for 3-5% of hospitalizations, or around one million hospitalizations per year, at an estimated cost of $130 billion (13).

On the other hand, adverse effects of antipsychotics are one of the main difficulties in treating patients with psychotic disorders (11). The most often reported adverse drug reactions (ADRs) of antipsychotics are extrapyramidal symptoms, drowsiness, sexual dysfunction, increased weight, memory and attention deficits and metabolic side effects (11). Following the consumption of responsible drugs, drug-induced parkinsonism (DIP) and akathisia (DIA) typically appear days, weeks, or months later (15). Psychotropic medications causing the above effects include antidepressants, mood stabilizers, and anti-convulsants (12).

Several studies have been conducted to document the types and scope of medication related problems in developed countries (16) . However, there is a scarcity of published data on the nature and scope of MRPs in developing nations such as Kenya. The limited information on MRPs in psychiatric patients among the healthcare providers may be the cause of treatment failure among these patients, long hospital stays and poor quality of life. The study therefore seeks to address this problem by examining the various medication related problems and their causes among patients with psychiatric disorders.

1.3 Research Questions

1.3.1 Main research question

What are the medication related problems and predisposing factors among adult psychiatric patients on anti-psychotic drugs at Mathari Teaching and Referral Hospital?

1.3.2 Specific Research Questions

1. What is the prevalence of medication related problems (MRPs) among adult psychiatric patients on antipsychotic drugs in Mathari Hospital?
2. What are the characteristics of MRPs in adult psychiatric patients on antipsychotic medication in Mathari Hospital?
3. What are the predisposing factors to medication related problems in adult psychiatric patients on antipsychotic medication in Mathari hospital?

1.4 Objectives

1.4.1 Broad Objectives

To assess medication related problems among adult psychiatric patients on antipsychotic drugs in Mathari Teaching and Referral Hospital.

1.4.2 Specific Objectives

1. To determine the prevalence of medication related problems among adult psychiatric patients on antipsychotic drugs in Mathari hospital.

2. To characterize the MRPs among adult psychiatric patients on antipsychotic drugs in Mathari hospital.

3. To identify the risk factors associated with medication related problems among the adult psychiatric patients on antipsychotic drugs in Mathari hospital**.**

1.5 Justification of the Study

The study's findings will help healthcare professionals address the risk variables that can be changed in order to lower patient mortality and morbidity from drug-related causes among patients with psychiatric disorders.

One step toward reaching better health outcomes is comprehending the root causes of medication-related problems. The results of this study will serve as a roadmap for the creation of more effective treatment plans that aim to reduce MRPs and enhance the therapeutic outcomes for individuals with psychiatric disorder. Additionally, the study's findings may be helpful in medication therapy management and inform on the development of various practices that will optimize treatments among patients with psychiatric disorders. This study therefore aims to identify MRPs and their possible causes in patients with psychiatric disorders.

1.6 Delimitations

The study was done in Mathari Teaching and Referral Hospital among adult psychiatric patients taking antipsychotic medications and also those with substance abuse taking antipsychotic medication**.** MNTRH is a specialized mental national referral hospital that serves patients across Kenya. It was presumed that the hospital's procedures are typical of other public hospitals in Kenya. The study was done as cross- sectional study with data collection restricted to three months.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter addresses the weight of psychiatric disorders worldwide and regionally. It also reviews the types of medication related problems and their risk factors.

2.2 Prevalence of Psychiatric disorders

According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM V), a psychiatric disorder is a syndrome that displays a clinically significant disturbance in a person's cognition, emotion regulation, or behavior and reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning (17). Major psychiatric diseases, which account for 14% of the worldwide burden of disease, include schizophrenia, substance addiction disorders, bipolar disorders, depression, anxiety, and others (2).

Up to 450 million people worldwide have mental or behavioral disorders, and every year, about 1 million people commit suicide (19). According to WHO's Global Burden of Disease, neuropsychiatric illnesses account for 33% of years lived with disability (YLD). For instance, unipolar depressive disorders alone account for 12.15 percent of years spent living with a disability and are the third largest cause of disease burden worldwide. Furthermore, neuropsychiatric illnesses such as depression, alcohol-use disorders, schizophrenia and bipolar disorder account for four of the top six reasons of years spent with a disability (18). Depressive disorders, bipolar disorders and schizophrenia are the most common psychiatric disorders (2). Additionally, the prevalence of substance misuse has increased, with at least 15.3 million people suffering from drug-related diseases and 76.3 million people with alcohol disorders (18).

The WHO has stressed the importance of making sustainable development a top priority for mental health. The number of persons with a mental problem who do not obtain mental health care is estimated to be 85%, compared to 35–50% in high-income nations. Access to mental healthcare is still unequal, insufficient, and inefficient in developing countries (20). With a population of more than 50 million, Kenya is an East African nation with a low level of income. Previous research conducted in some areas of Kenya found that the prevalence of common mental disorders among adults was 10.8% (20).

2.3 Medication Related Problems

The American Society of Hospital Pharmacist use the term ‘medication-related problem’ and define it as “an event or circumstance involving medication therapy that actually or potentially interferes with an optimum outcome for a specific patient” (20). A foundational framework for DRPs from a pharmacovigilance perspective was published by Meyboom et al. in 2000. It is primarily intended for usage within the WHO and concentrates on unfavorable impacts. DRPs are distinguished inside the system from dose-unrelated issues and proper use from improper use.

An incident or situation involving drug therapy that hinders the attainment of targeted health goals is known as a medication-related problem (22). The primary processes involved in the delivery of pharmaceutical care include: identifying, preventing and resolving medication related issues (23). This makes it essential to define and categorize medication-related problems in a manner that will allow pharmacists and other healthcare providers to understand them uniformly. This has not been the case though, as there are a number of MRP classification systems available.

Inappropriate drug use can increase patient mortality and morbidity. The identification of medication-related problems enables patients attain their therapeutic goals and understand how to get the best results from pharmacological therapy. Medication-related problems are the clinical domain of the pharmacist (9). Pharmacists are commended for minimizing medication-related harm and improving the delivery of healthcare services. Activities including compiling medication admission histories, reviewing medication records after a patient has been discharged, providing pharmaceutical counselling, and actively participating in multidisciplinary ward rounds are all part of the pharmacist's responsibility in minimizing medication-related problems for inpatients (23).

2.3.1 Burden of MRPs in patients with psychiatric disorders

Psychiatric patients are more likely to experience medication related problems due to the high frequency of risk factors, including polypharmacy, which is frequently prescribed by several prescribers, numerous comorbidities, and insufficient adherence. MRP includes errors in pharmaceutical therapy that differ in their real or potential risks to harm patients, as well as non-preventable Adverse Drug Events (ADE) (25).

MRPs have been associated to 5.3% of all hospital admissions, according to an Australian study, and 15.1–16.9% of patients who are hospitalized may encounter an MRP. The study also showed that MRPs often extend a patient's hospital stay by 2.2 days. For instance, 1.4% of mental health

inpatients suffer from a severe MRP, such as agranulocytosis, delirium, seizures, or the neuroleptic malignant syndrome (27).

According to research conducted in Northwest Ethiopia, the total prevalence of MRPs was 60.9%, which was lower than the results from comparable studies in Jimma (74.1%) but higher than the 15.8% result from India (28). As opposed to other medical conditions, there is evidence of a higher occurrence of adverse drug effects and medication errors in the psychiatric context, which seriously jeopardizes the medication safety of mental patients (25).

Medication related problems are a common etiology of morbidity and may lead to death in serious health problems. Drug interactions are thought to be responsible for 6–10% of side effects, and the majority of these can be avoided with careful monitoring(27). Due to comorbidities, patients who take antipsychotics together with other concurrent medications run the risk of experiencing negative side effects as well as potential drug-drug interactions (pDDIs). Additionally, it causes drowsiness, toxicity to the central nervous system (CNS), cardiac arrhythmias, and alterations in blood pressure. For a number of reasons, including long-term pharmaceutical therapy and polypharmacy, it is difficult to prevent DDIs among these patients, which offers a challenge to the treating physicians (27).

2.3.2 Classification of MRPs

Medication-related problems (MRPs) are often categorized so that there are distinct process indicators for monitoring the efficacy of pharmaceutical care as well as for research on the type, prevalence, and incidence of such MRPs among the patients being managed (13). As a result, classifying MRPs is both desired and necessary for the development of pharmaceutical care practice. It is crucial to record MRPs as part of the care process(28).

Fourteen separate classification systems with distinct focuses were identified by Van Mil et al. However, the terminology employed ranged from "drug therapy problems," "drug related problems," "medication- related problems," "pharmaceutical care issue," and "clinical drug related problems." Of these, 9 systems were discovered that were founded on a clear description of drug treatment problems. The Helper Strand Classification provided the first definition of a medication-

related problem (MRP) among these 14 systems, defining it as "an event or circumstance involving a patient's drug therapy that actually or potentially interferes with an optimum outcome"(13).

Other classification systems of MRPs that have been employed in research work include; Cipolle/Morley/Strand classification, Hanlon Approach, Mackie classification, Helper-Strand classification, Kriska et al system, National Coordinating Council for Medication Error Reporting and Prevention (NCC- MERP) taxonomy of medication errors, Pharmaceutical Care Network Europe (PCNE) and the Westerlund system(23).

Hepler and Strand classified DRPs into eight categories: overdose, subtherapeutic dose, failure to receive medications, inappropriate medication selection, drug interaction, adverse drug reaction, medication use without indication, and untreated indication (30).

In an attempt to produce a consistent categorization structure that is appropriate and comparable for global studies, pharmacy practice researchers first developed the original classification in 1999 during a working session of the PCNE. This system is hierarchically organized and includes distinct codes for issues, causes, and solutions. It categorizes the medication related problems into three major groups; based on the effectiveness of the treatment given, how safe that treatment is and others(30). In terms of effectiveness, therapy may occasionally fall short of expectations, be less effective than desired, or fail to address a problem that called for a specific course of action. Regarding how safe the medication is for the patient; the manifestation of an adverse drug response is regarded as a stand-alone form of MRP.

2.4 Types of MRP

This current study proposes to use Cipolle/Morley/Strand classification system that has seven categories of medication related problems: Unnecessary therapy, need for additional therapy, Ineffective drug, Dosage too low, Adverse drug reaction, Dose is too high, Noncompliance problem. The conceptual framework in figure 1 strengthens this.

2.4.1 Unnecessary Drug Therapy

The patient develops this MRP when the medication therapy is started without a therapeutic indication (32). Studies have indicated that 17.4% of patients with dementia use “drug use without indication” and were amongst the most common MRP reported(33). Another study found that among patients with mental illness admitted to psychiatric wards in Ethiopia, there was a 4%

prevalence of unwarranted pharmacological therapy (28). Furthermore, a study done in Jimma indicated a 5% prevalence of psychiatric patients having duplication of therapy(8).

2.4.2 Need for additional therapy

This medication related problem arises when a medicine is required to treat or prevent a medical condition or illness from arising(31). A Danish study reported a 6.4% prevalence of psychiatric patients in need for additional therapy(35).The most typical MRP that was encountered in a study done in Ethiopia was the need for additional drug therapy. Another study reported a 27.3% prevalence for need of additional drug therapy among psychiatric patients admitted to psychiatric wards(8).

2.4.3 Adherence

This MRP occurs when the patient fails to take the medications appropriately or is not willing to take the medication as intended(31). Patients with serious mental illness presenting to Bahir Referral Hospital were found to be 55.2% more likely to not be taking their medications as prescribed(37). According to a study conducted in India, noncompliance accounted for 58.6% of patients' hospital admissions(38). Also, a study done among the Cambodian American population revealed a 30% prevalence of non-adherence among patients with clinically elevated symptoms of depression(39).

2.4.4 Ineffective Drug

Ineffective drug is considered when the least effective drug is used irrespective of the availability of the most effective drug. Additionally, it is taken into account when a medical condition that is resistant to the drug product is treated with it(32). A study done among schizophrenic patients attending a clinic of Tikur, Addis Ababa reported a prevalence of 20.5% of patients with an ineffective drug(37) . Ineffective drugs were being administered in the wrong dosage form to 8 out of 18 of these patients. Another study done at an ambulatory clinic of Mettu Karl Referral Hospital reported the overall frequency of ineffective drug therapy among patients in the psychiatric ward to be 8.9%(41).

2.4.5 Adverse reactions

A medication is said to have an adverse drug reaction when it has an unfavorable effect that is not dose-related (32). A cross-sectional study conducted in Ethiopia showed that 91.8% of the psychiatric patients had a negative reaction (39). Another study conducted in India also reported that 86% of patients with psychiatric illnesses experienced adverse medication reactions. The

majority of people experienced adverse effects on the central nervous system, followed by weight gain, gastrointestinal, skin, and cardiovascular issues (40). Furthermore, a study conducted in Mathari Hospital indicated 81.7% of the patient's experienced sedation as a major side effect. Other side effects that the patients experienced were extrapyramidal symptoms, anticholinergic side effects and weight gain (41).

2.4.6 Dose too high

Higher dosages result to undesirable events experienced by a patient (38). A study conducted in Southwest Ethiopia found that the incidence of the higher dose was 3.7%. Additionally, according to data from another study, 16.9% of patients took their prescription at a higher dose (42).

2.4.7 Dose too low

A dosage is considered low if the prescribed dose is less than the recommended one. A study done in Sweden reported a 4%prevalence of low dose among patients with dementia (33). Another study that was done among patients with schizophrenia reported a 20.5% prevalence of dose too low (40).

2.5 Literature Gap

Psychiatric patients are more likely to experience medication related problems (26). Despite the APA's guidelines, little study has been done on how to reduce medication mistakes and MRPs in mental patients (24). MRPs are a serious problem, and many of them are preventable, but there is little information available about their occurrence and scope in Kenya. Furthermore, several studies have been conducted to document the types and scope of medication related problems in developed countries (16) . However, there is a scarcity of published data on the nature and scope of MRPs in developing nations such as Kenya. Therefore, this study will determine the medication related problems and their predisposing factors among adult psychiatric patients on antipsychotic drugs at Mathari teaching and referral hospital.

2.6 Theoretical Framework

Medication related problems can be due to patient factors. This includes age which is positively associated with comorbidities. The older people are more prone to medication -related problems, which have been described as unfavorable patient experiences linked to drug therapy that actually or potentially interfere with desired patient outcomes(10). Due to age-related physiologic changes, polypharmacy associated with multiple morbidities, and changes in pharmacokinetic and

pharmacodynamic parameters, geriatric patients are more prone to developing medication-related problems (MRPs)(43).

The number of recommended medications rises when concomitant conditions like diabetes and cardiovascular disease are present. As a result, there are more negative side effects among these patients with psychiatric problems (16). The quantity and types of prescribed medications can raise the possibility of drug interactions and negative side effects (17). The relationship between patient specific predictive variables and the occurrence of selected medication related problem can be summarized in **Figure 1**.

2.7 Conceptual Framework

Medication related problems were the outcome of the study which was measured for the purposes of this study using the criteria established by Cipolle, Strand, and Morley (28). Sociodemographic factors, clinical characteristics, and drug-related factors was used to categorize the independent variables that may influence development of MRPs in antipsychotic medication patients. Socio-demographic factors include: patients age, gender, education level, monthly income and occupation. Clinical characteristics included presence or absence of comorbidities. Drug related factors included number of medications, class and type of drug and duration of treatment.

The conceptual framework demonstrates the association between the predictor and outcome variables **(Figure 1).**

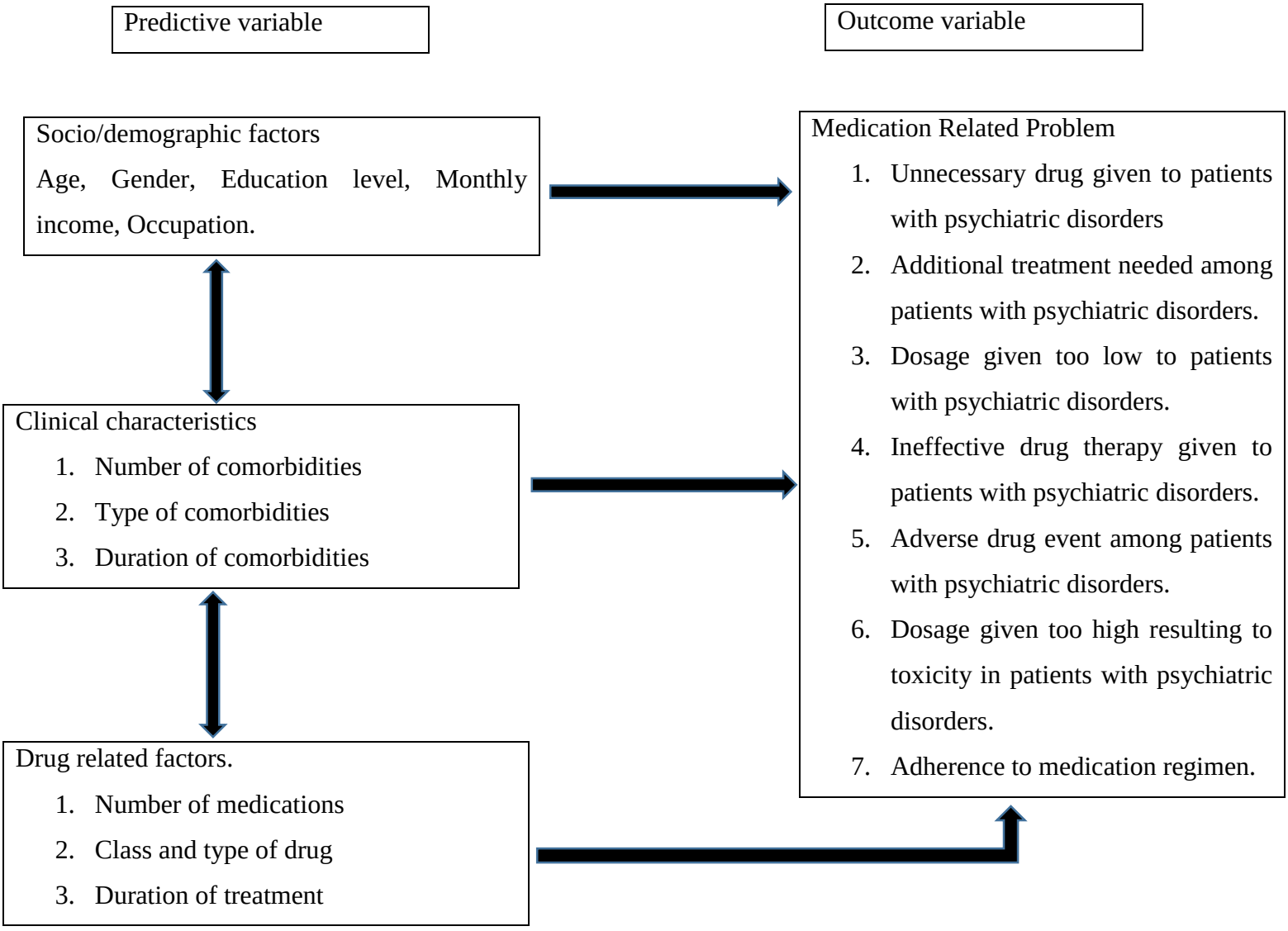

Figure 1:Conceptual frame work; (Source: Author)

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter outlines the procedure that was followed to accomplish the objectives of the study. These included the research design, location of the study, the target population, and the study population, including the inclusion and exclusion criteria. Additionally, the following items on methodology have been explained: sampling technique, sample size, research instruments, piloting method, data collection method, data management, data analysis, as well as ethical considerations.

3.2 Research Design

The study was a hospital based cross sectional survey of adult psychiatric patients on antipsychotic medication. The study was conducted in a period of three months from May – August 2023. The design study was selected as it can be used to determine the prevalence of medication related problems (MRPs) among adult psychiatric patients during the study period. This type of design was also used because the exposures and the outcome were both measured simultaneously.

3.3 Location of the Study

The study was conducted at Mathari National Teaching and Referral Hospital in Nairobi. It is the national mental referral hospital that serves as teaching hospital for the University of Nairobi. It has an in-patient population averaging 700, with 332 units serving the civil unit and 377 serving the maximum-security center (44).

There are twelve wards in the hospital, eight of which are civil unit wards and the other four are maximum-security units. Four male and four female wards make up each of the civic unit's eight wards. According to a 2019 report to the Kenyan Parliament, the hospital has 386 employees, including one hundred and sixty-four nurses, eleven psychiatrists, two clinical pharmacists, eight pharmacists, one pharmaceutical technologist, and five clinical officers (46). About 100 mentally ill patients who want outpatient services come to MNTRH(45).

3.4 Target population and Study population

The target population were all adult patients with psychiatric disorders being treated in public hospitals in Kenya. The study population was all the adult patients diagnosed and managed for psychiatric disorders at Mathari Hospital.

3.5 Eligibility criteria

3.5.1 Inclusion criteria

1. Adult inpatients at Mathari Hospital diagnosed with a mental illness.
2. Patients who were on at least an antipsychotic drug.
3. Patient must have been on medication for at least a month.
4. Adult patients or their guardian/caregiver who gave informed consent.

3.5.2 Exclusion criteria

1. Patients with clinical records that were incomplete and irretrievable hence, did not provide the required data.
2. A patient who had no working diagnosis.

3.6 Sampling

3.6.1 Sample size determination

The sample size was dependent on the overall prevalence of medication related problems in psychiatric patients which is 52.5%(34).

The formula for finite populations developed by Cochran was used to calculate the sample size.

$$n0 = \frac{z^2pq}{e^2} \quad \text{Equation 1}$$

n0 = sample size;

Z = desired confidence level; standard value of 1.96

p = estimated prevalence of MRPs

q = (1- p)

e = desired level of precision

In this case the z = 1.96; p = 0.53; q = 0.47; e = 0.05

$$n0 = \frac{(1.96)^2 \text{ X } 0.53\text{X } 0.47}{(0.05)^2}$$

Sample size = 382.7

The approximate sample size is 383

Using the Cochran correction formulae for finite population,

Equation 2: The Cochran correction formula for finite population

$$n = \frac{n0}{1 + n0 / N}$$

where;

n: minimum sample size required.

n0: calculated sample size (383 patients)

N: total number of psychiatric patients that visited the hospital between July 10 and December 8, 2017 based on the study that was chosen to estimate the prevalence of MRP.

$$n = \frac{383}{1 + 383 / 123}$$

93 patients.

The final sample size included an additional 30% to account for non-response and inaccuracy. In this case, 93 + (30% of 93) = 93 + 28= 121

The targeted number of participants was 121.

However, when one individual freely consented to engage in the research process making a sample size of 122.

3.6.2 Sampling technique

Simple random sampling was employed. All patients who met the set criteria were given an equal opportunity to be included in the study. Patient files were collected from the health records office in prior to a clinic day. The nurse in charge for a particular ward guided the principal investigator (PI) where the patients' files could be located. The PI perused through the patient file, screening it in accordance with the eligibility criteria (Appendix 1).

The PI provided each patient a random, unique number in order to prevent duplicate sampling and from being chosen again.

The procedure was repeated until the desired sample size was achieved.

3.7 Participants recruitments and Consenting process

The patient information and consent form were used to guide those who are interested in participating in the study through the consent process (Appendices A and 2B). Using the list obtained from the nursing officer in charge of a particular ward, the PI began by getting to know the patients and then screened the patients using the eligibility screening forms (Appendix 1). The participant's capacity for decision-making was evaluated by a physician. Once determined to be competent, the participant was informed on the research. Caregivers or psychiatrist in charge of the patient responded on behalf of the unstable patients. The principal investigator (PI) then gave a verbal explanation of the study's goals (procedure, confidentiality, benefit or harm) to the participants before giving them the English-language patient information form (Appendix 2A). The patient was then informed by the PI that they have the option to voluntarily withdraw from the trial at any time.

The PI then provided them a verbal and written consent form (Appendix 2A) as well as a Kiswahili translation of the form (Appendix 2C). After which proceeded to offer the participants the consent declaration form (appendices 2A/2C) to sign after getting the patient's informed consent to participate. Patients who chose not to participate were requested to give a reason why they felt that way. After then, the PI kept track of every patient who participated in the research. Finally, instructions on how to complete the questionnaires was given to the participants.

3.8 Research Instruments and Data Collection

The study used a survey from (appendix 1) to gather information verbally from the caregiver or from the patient's file. The form gathered information about the patient's socio-demographics, diagnosis, drug used to treat each diagnosis, presence of any comorbidities, drug used to treat comorbidities, any significant issues with medication therapy, and monitoring parameters.

3.9 Pilot Study or Pre testing

Twelve questionnaires representing 10% of the sample size was pre-tested at the Mathari Hospital civil unit wards and the outpatient unit to evaluate the tool’s relevance, completeness and usability of the data collection tool. They also tested on applicability of the data collection tool. In order to prevent response set, data distortion, and subjective response quality, the 10% were not be included in the final sample.

3.10 Validity, Reliability and Quality Assurance of the collected data

3.10.1 Validity

The validity of the study was attained by making sure the questionnaire is clearly laid out and pertinent to the aims of the research. Achieving the recommended sample size also ensured that the study is representative of the target population and also obtained the required statistical significance threshold. A random sample approach also ensured each participant got an equal chance of being selected to participate in the research hence eradicating selection bias. The use of a standard collection tool assisted in eliminating information bias that could arise during collection of data.

3.10.2 Internal and External Validity

The external validity of the study was assured based on the study site. Mathari National Teaching and Referral hospital is the largest psychiatric referral hospital in Kenya. Hence, participants were expected to be representative of the country's psychiatric population.

The use of a standard, easy-to-understand questionnaire as a data collection tool maintained the internal validity of the study.

3.10.3 Reliability

Prior to the actual study, a pilot study was done to test the reproducibility of the data collection instrument and make sure there were no ambiguities in the responses. A pilot study was also carried out to assess the reliability for the original instrument and translated version using the twelve participants. The questionnaire was based on the Cipolle/Morley/Strand tool whose reliability and validity have been proven in previous studies. Amendments were done where necessary to enhance applicability in the study setting.

3.10.4 Quality Assurance

The pre-designed questionnaires were pre-tested to make sure they were comprehensible and accepted. For a day, the research assistants received training with an emphasis on the tools, procedures, and instrument administration. Two research assistants were employed and they included a pharmacist intern and registered nurse who were trained by the principal investigator on how to collect data and research ethics such as confidentiality prior to carrying out the research. Data was rechecked at the field level by the principal investigator for any inconsistency.

3.11 Study Variables

The outcome variables were the medication related problems. The predictor variables included age, gender, number of comorbidities, number of medications per prescription, type of medication, dose and diagnosis.

3.12 Data Management

Data collected from each patient was kept confidential. The completeness of the questionnaires was verified right away following each interview. Data was collected and entered in Microsoft Excel 2019 where the principal investigator was able to access. Participants' data was entered daily and backed up as often. A hard drive and a flash disk were used to back up the data that was gathered. For security, a password was required to access any files or directories. All data was saved as coded data during the data entry phase, with each code being attached with a label. Data cleaning was done after data entry, and the cleaned data was then exported into STATA 15.0.

3.12.1 Data collection techniques

The principal investigator was assisted by research assistan**ts** who were registered nurses working at both the outpatient clinics and the wards. The research assistants were trained by the principal investigator on the data collection techniques. Techniques for data collection included the initial eligibility check of the chosen patients, which were aided by the eligibility screening form (Appendix 1). The consent explanation form (Appendix 2A) and consent declaration form (Appendix 2C) were thereafter given to the eligible patient. To maintain confidentiality, each participant who gave their consent received a unique code.

The research assistant then conducted an interview guided by the questionnaire (Appendix 3) while filling in the relevant answers to the questionnaire. The next step involved obtaining of data from the patient files which included laboratory tests, medication data and biodata. Data was filled into the relevant slots in the data collection tool (Appendix 3). The veracity of the information was obtained by cross checking the collected data with the information in the medical files. The consent form and the questionnaire were then allocated a unique code to ensure confidentiality.

3.13 Data Analysis

Microsoft Excel 2019 was used to enter the data and analyze it with STATA Version 15.0.

Frequency tables, pivot tables, graphs, and charts were be used to summarize descriptive information such the comorbidities, diagnoses, and sociodemographic data of the patients.

In order to summarize categorical data, frequencies and percentage proportions was used. A summary and presentation of numerical data was made using measures of central tendency, distribution and dispersion. The arithmetic means and standard deviation was applied to data that was normally distributed.

Confounding was controlled using binary and multi-variable logistic analysis. The association between the MRP and the patient-specific characteristics was analyzed using chi squared statistics. The odds ratios were utilized as the association measure after the prevalence and odds ratios were created. A binary logistic regression analysis was performed in the multivariate analysis, where odds ratios and associated p-values were calculated for each categorical variable in relation to the binary outcome (MRP). The significance level for both the bivariate and multivariate analyses was set at $\alpha=0.05$, corresponding to a 95% confidence interval.

3.14 Ethical Considerations

3.14.1 Ethical Approval

Application for ethical approval was sent to the KNH/UoN ERC and granted under the study number (P109/02/2023) (appendix 7). The study was carried out as per postulated guidelines and standards provided by the committee. Later on, authorization was obtained from the Mathari Hospital ethics committee through the Medical Superintendent. Understanding and completing the consent declaration forms was required before participation in the study was guaranteed.

3.14.2 Informed Consent

Potential participants who were competent and mentally stable were provided informed consent. Adults with impaired cognitive function had their caregiver consenting on their behalf. In the event that these participants were alone, the attending clinician who was not a part of the study was asked to consent on their behalf. The informed participants or their representatives (a doctor or caregiver) were guided through the consent process and given a thorough explanation of the study's scope as well as their legal rights throughout.

3.14.3 Confidentiality

Only the patient's file number was noted in the anonymous survey. To protect their privacy, each patient had a special code that identified them. To ensure that the procedure is conducted in private, the participants were subjected to a confidential interview. Only the lead researcher was given access to the patient's identification code. The completed forms were stored secretly, locked and all information kept confidential.

3.14.4 Benefits of the study

The study participants gained from the drug information and medical advice provided to them upon discovery of the medication related problems. The results of the study would encourage clinicians to manage psychiatric disorders more effectively and enhance the prescribing patterns for the benefit of the patients.

3.14.5 Risks of the study

The research was non- invasive therefore the patients were not in danger of physical risk. However, patients may have been at risk for loss of privacy if their information unintentionally ended up in the hands of unauthorized persons. To avoid this, the raw data was stored in a safe place that was locked and only the lead investigator was authorized to access it.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter provides results of the study. It comprises the patient's sociodemographic characteristics, types of psychiatric disorders among the study participants, the prevalence of medication related problems and their causes as well as bivariate and multivariate analysis for the factors associated with medication related problems.

4.2 Social Demographic characteristics of the study participants

Table 1 provides a summary of the sociodemographic characteristics of the study's participants**.**

The majority of the study participants were females (64, 52.5%), single (74, 60.7%) and had attained secondary level of education (48, 39.3%). The mean age of the patients was 33.8 years (SD 10.7). The youngest participant was 18 years and the oldest participant was 68 years. Most of the participants were aged between 32 and 45 years. More than a half of the participants were of normal weight (66, 54.1%).

Table 1:Sociodemographic characteristics of Study Participants (n=122)

Variable		Frequency (n) (N=122)	Percentage (%)
Age group (Years)	18-31	64	**52.5**
	32-45	41	33.6
	46-59	13	10.7
	≥60	4	3.2
Median (IQR)/ Mean (±SD)		31(26-41)	33.80±10.72
Sex			
	Male	58	**47.5**
	Female	64	52.5
BMI category			
	Underweight	32	26.2
	Normal	66	**54.1**
	Overweight	24	19.7
Marital status			
	Divorced	7	5.7
	Married	40	32.8
	Single	74	**60.7**
	Widowed	1	0.8
Religion			
	Christian	95	**77.9**
	Muslim	15	12.3
	Other beliefs	12	9.8
Education level			
	none	3	2.5
	primary	30	24.6
	secondary	48	**39.3**
	college/university	41	33.6
Employment status			
	Unemployed	35	28.7
	formal	21	17.2
	informal	64	**52.5**
	retired	2	1.6
Smoking status			
	current smoker	19	15.6
	never smoked	51	41.8
	previous smoker	52	**42.6**
Alcohol consumption			
	drinking	20	16.4
	never drunk	45	36.9
	previously drinking	57	**46.7**
Other recreational drug use			
	Recreational drug use	58	47.5
	Never used recreational drugs	64	**52.5**

KEY BMI – Body Mass Index, IQR – Interquartile Range, SD – Standard deviation

Some of the participants (n=52, 42.6%) had previously smoked, consumed alcohol (n=57, 46.7%), and used recreational drugs (n=58, 47.5%) **(Table 1).**

Among the recreational drugs, khat also commonly referred to as 'miraa' was the most common abused drug (n= 36, 29.5%). It was followed by cannabis also known as marijuana (n= 27, 22.1%) as shown in **Figure 2**.

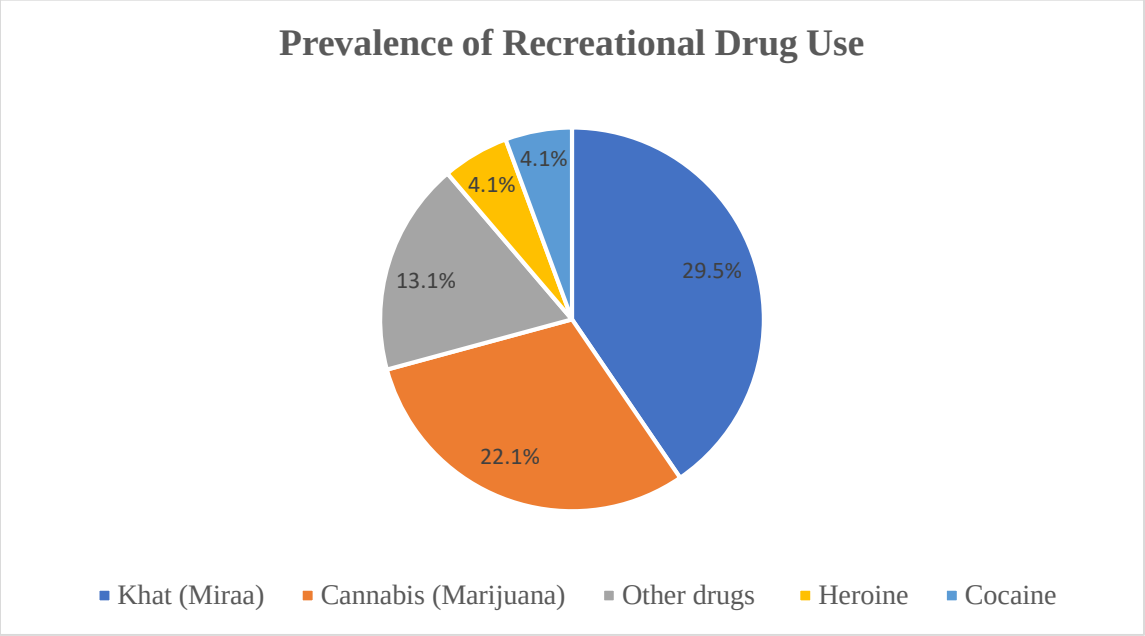

Figure 2: Prevalence of recreational drug use.

4.3 Types of Psychiatric Disorders, Duration of Illness and Comorbidities

More than half of the participants (n=84, 68.9%) had a history of psychiatric admission and also reported having comorbidities (n= 64, 52.5%) with substance use disorder (26.2%) being the most common **(Figure 4).**

Schizophrenia was the most prevalent psychiatric disorder (37.7%) followed by bipolar mood disorder (30.3%). Other psychiatric disorders that were prevalent include; drug induced psychosis (23%), depression (8.2%) and acute psychosis (4.1%). Epilepsy and mania were the least with 0.8% prevalence. The ailments listed above occurred either in isolation or in combination (**Figure 3)**. Many of the participants had more than five years of duration illness (n= 61, 48.0%) **(Table 1)**.

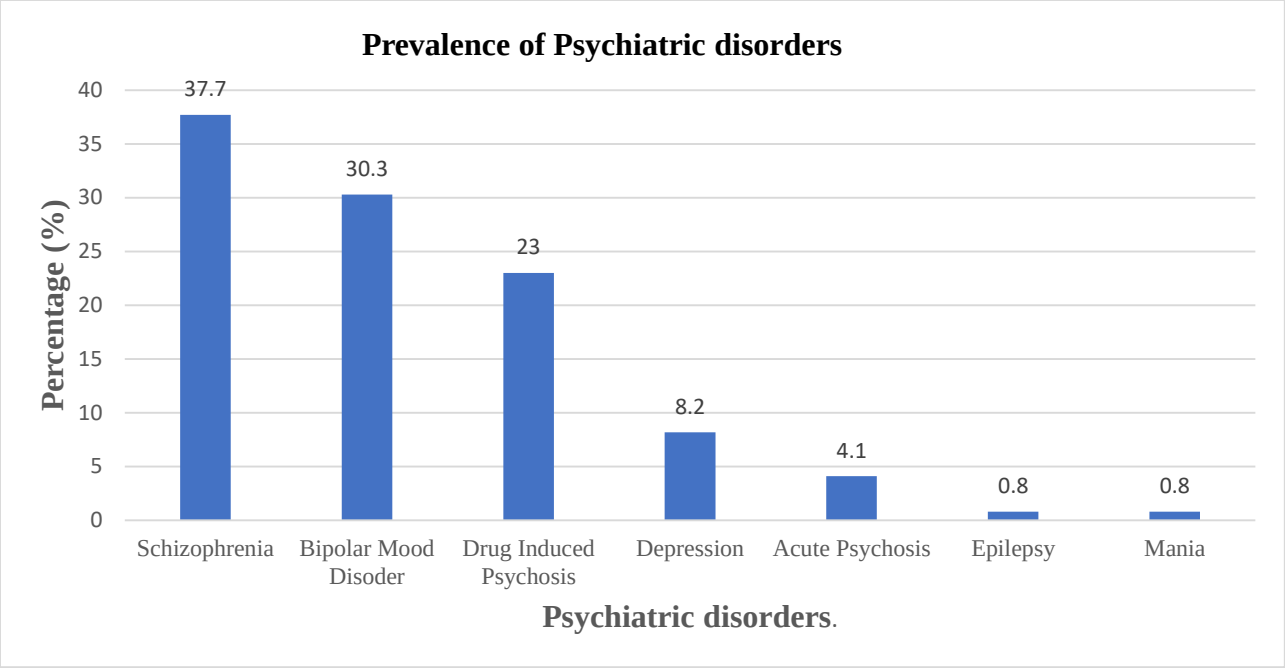

Figure 3:Distribution of Psychiatric Disorders among Participants

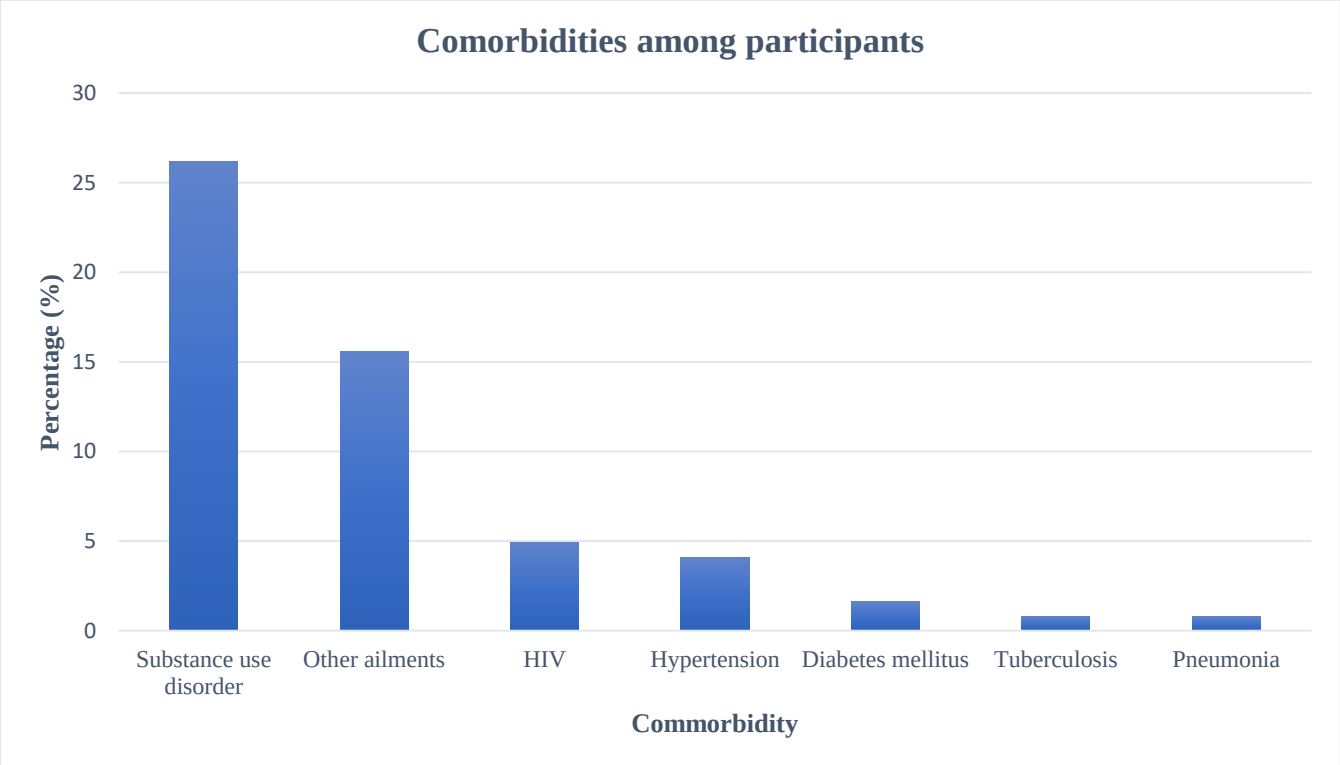

Figure 4:Types of comorbidities among patients with Psychiatric disorders

KEY: HIV- Human Immunodeficiency Virus.

Other ailments included- Malaria, Soft skin tissue infections, sexually transmitted infections (STIs), hepatitis, Gastritis and COVID.

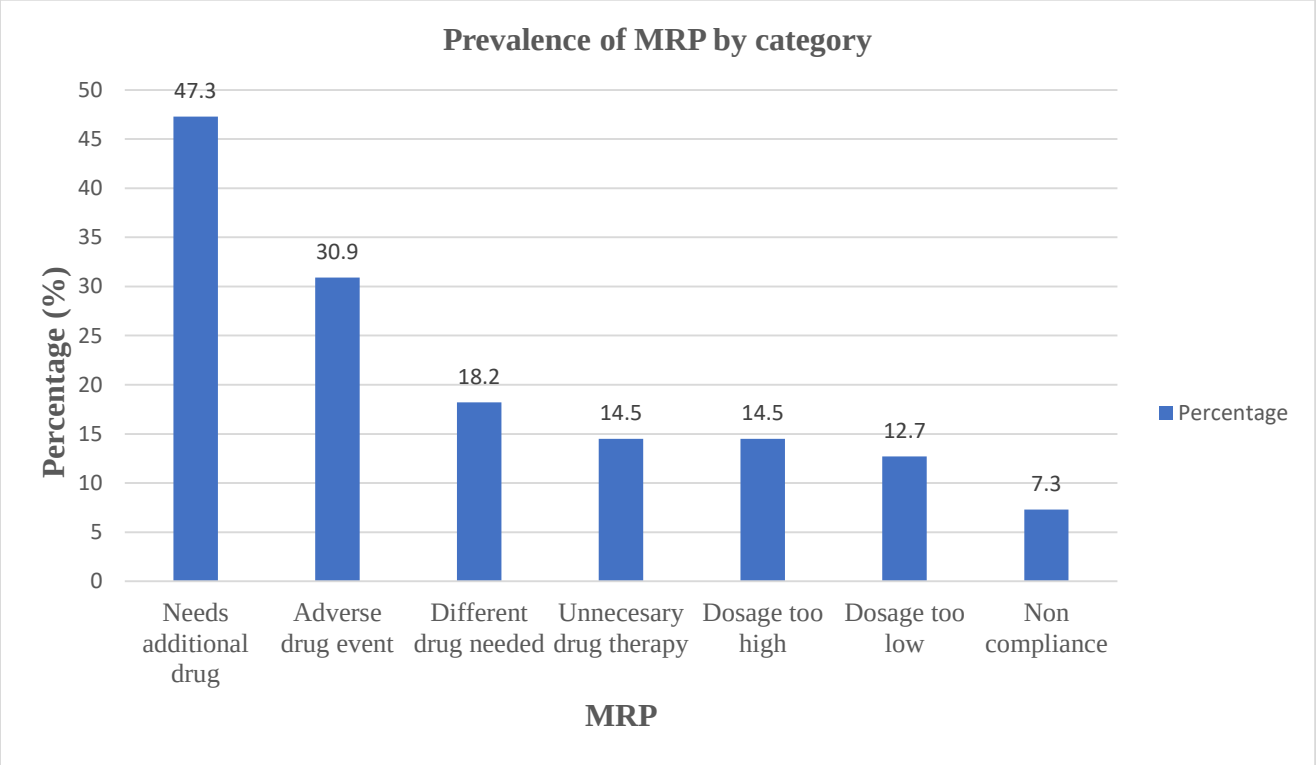

Figure 5:The prevalence of medication related problems by category

KEY; MRP- Medication Related Problem

In this study, sixty-seven participants (54.9%) had medication related problems (MRPs) (**Table 2).** As shown in the **figure 5**, the most common MRP was need for additional drug therapy followed by adverse drug event and different drug needed.

The most prevalent cause of MRP was untreated condition (n= 16, 29.1%) **(Table 2).** Other significant causes were more effective drug available (n= 12, 21.8%) and need for additional monitoring (n= 9, 16.4%).

Table 2: Prevalence of MRPs among adult psychiatric patients on antipsychotic medication

Parameter	Characteristic	Frequency (n)	Percentage (%)
MRP	Yes	67	**54.9**
	No	55	45.1
Needs additional drug	Untreated conditions	16	**29.1**
	Preventive	15	**27.3**
	Prophylaxis	6	10.9
	Synergistic	4	7.3
Adverse drug event	Undesirable effect	7	12.7
	Drug interaction causes undesirable reactions	7	12.7
	Allergic reaction	5	9.1
	Dosage administered or changed too soon	1	1.8
Different drug needed	More effective drug available	12	**21.8**
	Condition refractory to the drug	1	1.8
	Contraindication present	1	1.8
Unnecessary drug therapy	No valid medical indication	3	5.5
	Duplicate therapy	3	5.5
	Non drug therapy	3	3.5
Dosage too high	Dose too high	5	9.1
	Needs additional monitoring	5	9.1
	Drug interactions results in toxicity	2	3.6
	Duration too long	1	1.8
Dose too low	Needs additional monitoring	9	**16.4**
	Drug interaction reduces the amount of active drug	7	12.7
	Ineffective dose	2	3.6
	Frequently inappropriate	2	3.6
	Duration inappropriate	1	1.8
Non compliance	Patient prefers not to take	5	9.1
	Cannot afford drug product	1	1.8

Undesirable effect and drug interaction that caused undesirable reactions were the most common cause of an adverse drug event (n=7, 12.7%). Some patients preferred not to take the medication causing noncompliance (n= 5, 9.1%) while others received a high dose than the recommended dose (n= 5, 9.1%). A few participants had no valid medical indication causing unnecessary drug therapy (n=3, 5.5%).

4.4 Associations between sociodemographic and clinical characteristics and the presence of MRPs

Pearson's chi or Fischer's exact tests were used to examine associations between medication related problems and the individuals' sociodemographic and clinical characteristics.

The Chi- square test was employed to assess the independence of two categorical variables when dealing with situations where all cell counts were above 5. Fisher’s exact test was utilized in cases where at least one cell fell below 5 variables.

Table 3: Association between Sociodemographic characteristics and MRPs

		MRPs		
Socio-demographics		**Present (N=67)**	**Absent (N=55)**	**P value**
Age group	18-31	34 (50.7%)	30 (54.5%)	0.577
	>31	33 (49.3%)	25 (45.5%)	
Sex	Male	33(49.25%)	25 (45.5%)	0.718
	Female	34 (50.75%)		
BMI category	**≤ 25**	48 (71.6%)	42 (76.3 %)	0.781
	>25	19 (28.4%)	13 (23.7%)	
Marital Status	Living with spouses	22 (32.8%)	18 (32.7%)	0.744
	Living without spouses	45 (67.2%)	37 (67.3%)	
Pregnancy status	Pregnant	1 (1.5%)	53 (96.4%)	0.862
	Not pregnant	66 (98.5 %)	2 (3.6 %)	
Religious group	Christians	51 (76.1%)	44 (80.0%)	0.690
	Muslim and others	16 (23.8%)	11 (20.0%)	
Education level	Secondary & below	49 (73.1%)	32 (58.2%)	0.380
	College/University	18 (26.9%)	23 (41.8%)	0.380
Employment status	Employed	47 (70.1%)	38 (69.1%)	0.161
	Unemployed	20 (29.9%)	17 (30.9%)	
Income category	<5000	29(43.3%)	24 (43.6%)	0.809
	≥ 5000	38 (56.7%)	31 (56.4%)	
Smoking Status	Smokers	39 (58.2%)	32 (58.2%)	0.180
	Non smokers	28 (41.8%)	23 (41.8%)	
Alcohol consumption	Alcoholic	43 (64.2%)	34 (61.8%)	0.878
	Non alcoholic	24 (35.8%)	21 (38.2%)	
Cannabis (Marijuana)	No	54 (80.6%)	41 (74.5%)	0.561
	Yes	13(19.4%)	14(25.5%)	
Khat	No	42 (64.2%)	43 (78.2%)	0.137
	Yes	24 (35.8%)	12(21.8%)	
Heroine	No	66 (98.5%)	43 (78.2%)	0.137
	Yes	1(1.5%)	4(7.3%)	
Cocaine	No	64 (95.5%)	53 (96.4%)	1.000
	Yes	1(1.5%)	4(7.3%)	
Others	No	59 (88.1%)	47 (85.5%)	0.877
	Yes	8(11.9%)	8(14.5%)	

None of the variables showed a statistically significant association with Medication-Related Problems (MRPs) in the chi-square analysis, as all p-values were greater than the critical values and none had $\alpha \leq 0.05$ level of significance. This suggests that there was no significant relationship between these socio-demographic factors and the occurrence of MRPs in the studied population.

Table 4 Association between sociodemographic characteristics and adverse drug event

		MRP Adverse drug event		**Chi-square or Fishers exact test**
Socio-demographic factors	**Category level**	**Absent**	**Present**	**P-value**
Age group	18-31 Years	20	10	0.67
	>31 Years	18	7	
BMI category	<=25	31	12	0.362
	>25	7	5	
Marital status	Living with spouse	29	8	**0.033**
	Living without spouse	9	9	
Pregnancy status	No	36	17	1.000
	Yes	2	0	
Religious group	Christian	29	15	0.471
	Muslim/Other	9	2	
Educational level	College/tertiary	30	13	1.000
	Secondary and below	8	4	
Employment status	Employed	24	14	0.213
	Unemployed	14	3	
Income category	<=5000	19	5	0.155
	> 5000	19	12	
Insurance policy	No	16	9	0.456
	Yes	22	8	
Smoking status	Smoker	8	4	1.000
	Non-Smoker	30	13	
Alcohol consumption	Drinking	6	2	1.000
	Non-drinking	32	15	

The results showed that marital status has a statistically significant association with adverse drug events (P-value = 0.033) being a specific MRP. The other variables did not show a statistically significant association with adverse drug event as a specific MRP since all their p values were greater than 0.05.

Table 5 Association between sociodemographic characteristics and dosage too high

Socio-demographic factors	Category level	MRP Dosage too high		Chi-square or Fishers exact test
		Absent	Present	P-value
Age group	18-31 Years	21	4	1.000
	>31 Years	26	4	
BMI category	<=25	38	5	0.352
	>25	9	3	
Marital status	Living with spouse	29	8	**0.043**
	Living without spouse	18	0	
Pregnancy status	No	48	8	1.000
	Yes	2	0	
Religious group	Christian	39	5	0.335
	Muslim/Other	8	3	
Educational level	College/tertiary	37	6	1.000
	Secondary and below	10	2	
Employment status	Employed	32	6	1.000
	Unemployed	15	2	
Income category	<=5000	20	4	0.718
	> 5000	27	4	
Insurance policy	No	21	4	1.000
	Yes	26	4	
Smoking status	Smoker	12	0	0.178
	Non-Smoker	35	8	
Alcohol consumption	Drinking	6	2	0.329
	Non-drinking	41	6	

The results indicated that marital status has a statistically significant association with the occurrence of "Dosage too high" since the p-value of 0.043 is less than 0.05. Other variables did not have a statistically significant association with "Dosage too high" as a specific MRP since their p-values are all greater than 0.05.

Table 6 Association between sociodemographic characteristics and need for additional drug therapy

Socio-demographic factors	Category level	MRP Needs additional drug		Chi-square or Fishers exact test
		Absent	Present	P-value
Age group	18-31 Years	45	10	0.216
	>31 Years	47	17	
BMI category	<=25	75	23	0.590
	>25	20	4	
Marital status	Living with spouse	31	9	0.945
	Living without spouse	64	18	
Pregnancy status	No	93	26	0.531
	Yes	2	1	
Religious group	Christian	74	21	0.990
	Muslim/Other	21	6	
Educational level	College/tertiary	70	22	0.406
	Secondary and below	25	5	
Employment status	Employed	67	18	0.700
	Unemployed	28	9	
Income category	<=5000	42	11	0.748
	> 5000	53	16	
Insurance policy	No	38	15	0.150
	Yes	57	12	
Smoking status	Smoker	12	7	0.093
	Non-Smoker	83	20	
Alcohol consumption	Drinking	16	4	1.000
	Non-drinking	79	23	

None of the variables showed a statistically significant relationship with need for additional drug therapy as a specific MRP since all the p values were greater than 0.05.

4.5 Independent Factors associated with MRP

A binary logistic regression analysis was performed in the multivariate analysis, where odds ratios and associated p-values were calculated for each categorical variable in relation to the binary outcome (MRP).

The significance level for both the bivariate and multivariate analyses was set at $\alpha=0.05$, corresponding to a 95% confidence interval. **Table 7** below highlights the results of the binary logistic regression analysis.

The variables that were tested for the binary logistic regression included all the socio- demographic variables and other factors in the bivariate analysis whose p values were less than 0.05.

Table 7 Association between sociodemographic characteristics and MRPs

Sociodemographic variables		Bivariate analysis cOR (95%CI)	P-value	Multivariate analysis aOR (95%CI)	P-value
Age	18 – 31 years	Ref			
	>31 years	1.165(0.570,2.381)	0.676	0.963(0.796,1.166)	0.700
Sex	Female	0.859(0.420,1.755)	0.718	47.777(0.067,34076.55)	0.249
	Male	Ref			
BMI category	BM1<=25	Ref			
	BMI>25	0.782(0.320,1.912)	0.589	1.178(0.835,1.664)	0.351
Marital status	living with spouse	Ref			
	Living without spouse	0.995(0.465,2.127)	0.999	12.003(0.855,168.518)	0.065
Pregnancy	No	2.491(0.220,28.220)	0.588	2.311(0.072,74.529)	0.072
	Yes	Ref			
Religion	Christian	0.797(0.335,1.897)	0.607	1.512(0.003,760.821)	0.896
	Muslim and Other	Ref			
Education level	Sec & below	Ref			
	College/University	0.760(0.329,1.755)	0.519	**0.007(0.000,0.552)**	**0.026**
Employment status	Employed	1.051(0.484,2.282)	0.899	3.113 (0.538, 18.228)	0.208
	Unemployed	Ref			
Income levels	<5000	Ref			
	>5000	0.986(0.480,2.024)	0.969	0.412(0.034,4.982)	0.486
Insurance policies	Yes	0.862 (0.420,1.769)	0.685	0.743(0.074,7.454)	0.801
	No	Ref			
Smoking status	Smokers	Ref			
	Non-smokers	2.392(0.870,6.575)	0.085	7.683(0.277,213.282)	0.229
Alcohol consumption	Alcoholic	Ref			
	Non alcoholic	1.282(0.483,3.401)	0.617	0.424(0.011,16.406)	0.646
Recreational Drug Use:					
Cannabis	Yes	Ref			
	No	1.418 (0.602,3.342)	0.512	3.910(0.003,4936.129)	0.708
Khat	Yes	Ref			
	No	0.500(0.222,1.126)	0.112	291.817(0.649,131332.4)	0.069
Heroine	Yes	Ref			
	No	5.176(0.561,47.736)	0.174	0.0003(0.002,1.543)	0.063
Cocaine	Yes	Ref			
	No	0.805(0.130,4.998)	1.000	42.929(0.001,1323989)	0.476

Multivariable logistic regression showed that the independent correlate of MRP was the academic achievement of the participant. The odds of experiencing medication-related problems for patients with "College/University" education were 0.007 times the odds for those with "Secondary & below" education (aOR=0.007, 95%CI: 0.00-0.0052, p=0.026) **(Table 7)**.

An odds ratio of 0.007 suggests that individuals with "College/University" education have significantly lower odds of experiencing medication-related problems compared to individuals with "Secondary & below" education.

The p-value of 0.026 is less than 0.05 indicating that there is statistical evidence to suggest that the association between education level and medication-related problems is statistically significant. Other predictors had a p value greater than 0.05 making them statistically insignificant.

Multivariate analysis was also done on the individual MRPs and results are shown in the (**Table 8 and 9).**

Table 8 ***Sociodemographic factors versus adverse drug events***

Socio-demographic factors	Category level	Beta	Std Error	Adjusted Odds ratio 95% CI	P-value
Constant		-20.614	23114.863		
Age group	18-31 Years	Ref			
	>31 Years	-0.603	0.597	0.547(0.17, 1.764)	0.312
BMI category	<=25	Ref			
	>25	0.573	0.646	1.774(0.500,6.290)	0.375
Marital status	Living with spouse	Ref			
	Living without spouse	-1.113	0.65	0.329(0.092, 1.175)	0.087
Pregnancy status	No	19.298	23114.86	0.999(0, infinity)	0.999
	Yes	Ref			
Religious group	Christian	0.301	0.756	1.352(0.307, 5.952)	0.696
	Muslim/Other	Ref			
Educational level	College/tertiary	0.264	0.677	1.303(0.345, 4.911)	0.696
	Secondary and below	Ref			
Employment status	Employed	0.826	0.843	2.284(0.438, 11.911)	0.327
	Unemployed	Ref			
Income category	<=5000	Ref			
	> 5000	-0.09	0.699	0.914(0.232, 3.601)	0.898
Insurance policy	No	Ref			
	Yes	0.511	0.583	1.666(0.532, 5.224)	0.381
Smoking status	Smoker	Ref			
	Non-Smoker	-0.94	0.765	0.391(0.087, 1.749)	0.219
Alcohol consumption	Drinking	Ref			
	Non-drinking	-0.883	0.918	0.413(0.068, 2.48)	0.336

On multivariate analysis, none of the variables showed a statistically significant relationship with adverse drug event as a specific MRP.

Table 9 Sociodemographic factors versus dosage too high

Socio-demographic factors	Category level	Beta	Std Error	Adjusted Odds ratio 95% CI	P- value
Constant		-60.531	22036.342		
Age group	18-31 Years	Ref			
	>31 Years	0.260	0.761	1.296(0.292, 5.758)	0.733
BMI category	<=25	Ref			
	>25	1.763	0.908	5.828(0.983,34.557)	**0.052**
Marital status	Living with spouse	Ref			
	Living without spouse	19.713	5880.44	3.643*10^9(0, infinity)	0.997
Pregnancy status	No	18.267	19396.98	8.578*10^9(0, infinity)	0.999
	Yes	Ref			
Religious group	Christian	-1.088	0.996	0.337(0.048, 2.373)	0.275
	Muslim/Other	Ref			
Educational level	College/tertiary	0.932	0.934	2.539(0.407, 15.845)	0.319
	Secondary and below	Ref			
Employment status	Employed	0.109	0.967	1.115(0.168, 7.413)	0.911
	Unemployed	Ref			
Income category	<=5000	Ref			
	> 5000	0.554	0.856	1.740(0.325, 9.317)	0.517
Insurance policy	No	Ref			
	Yes	0.085	0.806	1.088(0.224, 5.283)	0.916
Smoking status	Smoker	Ref			
	Non-Smoker	20.0342	8647.423	5.010*10^9(0.000, infinity)	0.998
Alcohol consumption	Drinking	Ref			
	Non-drinking	0.418	1.079	1.519(0.183, 12.595)	0.698

Results obtained from multivariate logistic regression indicated that there was no statistically significant relationship with adverse drug event, need for additional drug therapy and dosage too high as categories of medication related problems.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATION

5.1 Introduction

This chapter discusses the results of the study comparing them to similar studies that have been done from different populations. It also gives a summary of the study findings, study strength and limitations and recommendations for practice and further research.

5.2 Discussion

The present study was carried out to characterize the medication related problems and associated factors among adult psychiatric patients on antipsychotic drugs in the largest teaching and Referral mental hospital in Kenya. The study found out that there was a high prevalence rate of MRPs at 54.9%; however, this was slightly lower compared to other findings from Ethiopia which had a 74.1% prevalence rate and Sweden which was (66%) (8,32). Such disparities could be explained by the differences in the hospital setup, study design, healthcare professionals and the difference in disease conditions of the participants. In addition, the difference in inclusion and exclusion criteria might be the reason for the difference in the prevalence of medication related problems.

Majority of the study participants were female (52.5%) and this was comparable to a study conducted in several general medical facilities in Kenya (9). This population was slightly different since most studies had more than half of the patients from the male gender (8,39). This could owe to the fact that more females were willing to provide consent to participate in the present study in comparison to the males. The median age of the patients was 31, indicating that psychiatric disorders affect the middle-aged Kenyan population, which is consistent with another study conducted in Kenya where the median age was 31 (41). Similar to an Ethiopian study, a higher proportion of the participants were single and had a secondary level of education and below (34).

The most common cause of medication related problem was need for additional drug therapy. This was similar to a study done in Jimma, Ethiopia (8). According to Cipolle/Morley/Strand, need for additional drug therapy may be due to untreated conditions, lack of prophylaxis or synergistic causes. The most common cause for need for additional drug therapy in this study was untreated conditions. Need for additional therapy means that the patients presented with more problems but did not receive medications for those problems. Another cause for need for additional drug therapy was the need for preventive therapy and this was similar to another study carried out in Addis Ababa among adult psychiatric patients (22). Some patients needed medications to prevent some adverse effects from occurring, however they did not receive the drugs.

Adverse drug event was the second most common cause of MRP. This was comparable to a study done in Mizan, Ethiopia that revealed a 91.8% prevalence of ADR among psychiatric patients (39). The most common cause of ADRs was unfavorable side effect, nature and severity of the underlying disease being treated and other concomitant drugs. ADRs are common with antipsychotic medications. The effects ranged from relative minor tolerability issues like sedation to severe like dystonia, weight gain and sexual dysfunction. Undesirable effects in patients on antipsychotic medication may be attributed to long term use of antipsychotic medication, administration of high doses of antipsychotic medication and polypharmacy. A study revealed that patients taking multiple psychotropic medication were ten times more likely to develop autonomic adverse reactions (39).

The third MRP was different drug needed (18.2%). This was comparable to a study conducted in Jimma (15.2%)(8). The most common cause of a different drug needed was patients were not administered the most effective drug for the indication they were being treated for. The choice of drug was inconsistent with evidence-based guideline recommendations. We found that other patients presented with a condition that was refractory to the drug while others had a contraindication present hence a different drug was needed.

The least identified MRP was noncompliance (7.3%) and this prevalence was similar to a study conducted by Richardson T *et al* (25). In this category, majority of the patients preferred not to take medications and this was due to the medication experiences like adverse effects and long duration of treatment. Few patients reported that they could not afford the medicines once they were discharged from hospital and this could be attributed to lack of an insurance policy or low socio-economic class.

A binary logistic regression analysis was performed in the multivariate analysis that revealed that individuals with a tertiary level (college/university) of education are significantly less likely to experience medication related problems compared to those with secondary and below level of education. A p value of 0.026 was obtained suggesting that there is a significant association between education level and a reduced likelihood of medication related problems.

A low level of education has been shown to be a risk factor for MRPs in this population. People with a lesser level of education may have a more limited understanding of the ailment and why they must take the medication. They may also be unable to comprehend instructions on how to take their prescriptions or what to do to avoid adverse drug reactions. This is in contrast to similar studies that has been done earlier where there was no correlation of education level and having MRP(26) The discrepancy could be due to the different populations and the difference in sample size.

5.3 Strength and limitation of the Study

The study was the first to be done on the subject of medication related problems among adult psychiatric patients in Kenya. The results obtained might be crucial in shaping the practice in the management of psychiatric disorders in Kenya. However, the study was conducted in a single center public referral hospital and the sample size was small, hence the results obtained would not be generalized to the general population. Simple random sampling was done to ensure all patients who met the set criteria had an equal opportunity to be included in the study.

5.4 Conclusion

The magnitude of medication related problems that were reported among adult psychiatric patients was quite high. The most commonly identified MRPs was the need for additional drug therapy, adverse drug event and different drug needed. Majority of the MRPs were caused by inappropriate drug selection, lack of preventive drug therapy and untreated conditions. There was also a significant association between low level of education and occurrence of an MRP.

5.5 Recommendations for policy change

Based on my findings, the following recommendations were made:

1. A comprehensive system review to be done for every patient. This is because the need for additional therapy was a typical MRP, indicating that some of the patient's problems were not being addressed.
2. A learning platform should be created where patients are given more knowledge and emphasis on understanding their disease condition and medications. This will help reduce medication related problems due to low levels of education.

5.6 Recommendations for Research.

1. Further similar research with a large sample size and several centers is recommended. A prospective study should be done with a longer duration which will give findings on the incidence rather than prevalence of the medication related problems.

2. Further studies to be done to assess the specific drugs that predispose patients to medication related problems. This will better the prescription patterns and hence improve patient health outcome.

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APPENDICES

APPENDIX 1: SCREENING AND ELIGIBILITY FORM

All participants must meet the eligibility criteria based on the inclusion/exclusion criteria in the application that will be approved by the KNH/UON Ethics and Research Committee.

I. Study Information.

Study title: **Medication related problems and predisposing factors among adult psychiatric patients on antipsychotic drugs at Mathari National Teaching and Referral Hospital.**

Principal Investigator: Audrey Akinyi Wagah.

Signature……

Date of screening…….

II. Patient unique code…….

Gender Male…….... Female……

III. INCLUSION/ EXCLUSION CRITERIA.

Inclusion criteria (Answered yes for inclusion)	Yes	No
1. Adult patient aged 18 years and above.		
2. Patient has a documented clinical diagnosis for a psychiatric disorder.		
3. Patient who will give consent to participate in the study.		
4. Patient current on antipsychotic medication at least one month.		

Exclusion criteria (Answered no for inclusion)		
1. Patient refused to give consent.		

APPENDIX 2A: PARTICIPANT INFORMATION AND CONSENT FORM
ENGLISH/KSWAHILI VERSION

ADULT PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY.

Study title: **MEDICATION RELATED PROBLEMS AND PREDISPOSING FACTORS AMONG ADULT PSYCHIATRIC PATIENTS ON ANTIPSYCHOTIC DRUGS AT MATHARI NATIONAL TEACHING AND REFERAL HOSPITAL.**

Principal Investigator\and Institutional Affiliation: Audrey Akinyi Wagah, Master of Pharmacy in Clinical Pharmacy student, University of Nairobi.

Supervisors/Co-Investigators and Institutional Affiliation:

1. Dr G.D. Nyamu, Senior Lecturer, Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi.

2. Dr P.N Karimi, Senior Lecturer, Department of Pharmaceutics and Pharmacy Practice,

School of Pharmacy, University of Nairobi.

Introduction.

I am Dr. Audrey A. Wagah pursuing a Master of Pharmacy in Clinical Pharmacy from the University of Nairobi. As part of my post graduate study, am doing a study on Medication related problems and associated factors among adult psychiatric patients on antipsychotic drugs at Mathari National Teaching and Referral Hospital.

This consent form will inform you about this research and enable you to decide whether to participate in the study. Feel free to ask questions related to the study such as, what will happen to you as a participant, the potential risks or benefits, the rights you have as a participant or any other information. After satisfaction with the study, you are free to enroll to the study by giving your consent. The name of this process is 'informed consent.' When you understand and decide to join in the study, you will be requested to sign your name on this form as proof of consent. You should understand the general principles which apply to all participants in medical research.

I. Your decision to participate in the study is entirely voluntary.

II. You may withdraw from the study at any time without necessarily giving an explanation for your withdrawal.

III. Refusal to participate in the study will not affect the services you get from the health facility or other facilities.

May I continue? YES / NO

The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee has approved this study via protocol No._P109/02/2023_____

What is the purpose of the study?

The study you are being requested to participate aims at assessing the medication related problems among adult psychiatric patients on antipsychotic drugs in Mathari National Teaching and Referral Hospital. In this study you will be requested to state your experiences with medications and issues you face while taking the medications. The purpose is to find out whether the medications you are prescribed for are working out for you or whether you are facing any challenges, to find out whether they are safe and effective, to find out other medications the patient is using or other actions the patient is doing that increase the occurrence of medication related problems.

What will happen if you decide to be in this research study?

If you accept to participate in this study, you will be interviewed privately, answering questions relevant to this study. You will provide answers to questions on your social, medical, and medication history. This interview takes approximately 15 minutes. In addition, the interviewer will access information from your medical file related to your social, medical, and medication history. In case more clarification is needed for this study, your telephone number will be needed. Your number will only be used by people working for this study and will not be shared with any other person.

Are there any risks or harms discomforts associated with this study?

Psychological, emotional, social and physical factors are some of the risks that may be introduced by medical research. However, efforts have been made to mitigate such risks. You could suffer a loss of privacy from this study. However, your information will be kept confidential whereby, a code number will be used to refer to you in a computer database that is password-protected. The use of a public space to collect personal information about you in a public setting create discomfort. To avoid this, the investigators will ensure that it is done privately and professionally. In case you are not willing to answer some questions asked from this interview, you are free to skip.

Are their benefits to the study?

Immediate benefit of the study to the participant is that a medication related problem can be identified within the course of the study, such will be reported to the physician for review. The study will also assist us improve health outcomes through development of guidelines and protocols that will prevent a medication related problem from occurring.

Will the study cost you anything?

The study will not have a financial implication on you.

Are there any reimbursements?

There is no any form of payments such as money or gifts as a result of participation in this study.

What if you have questions in the future?

If you have further questions or concerns about being part of this study, you are free to call or send a text message to the principal investigator before, during and after the study on the following number: Audrey Wagah (+254700303274). You may also contact my supervisor, Dr G.D. Nyamu (+254722403671). If more information about your rights as a research participant is needed, please

contact the Secretary/Chairperson, Kenyatta National Hospital University of Nairobi Ethics and Research Committee through the telephone number 2726300 Ext. 44102 or the email address: uonknh_erc@uonbi.ac.ke.

APPENDIX 2B: MAELEZO KUHUSU KUSHIRIKI KATIKA UTAFITI

MADA YA UTAFITI: KUTATHMINI SHIDA ZA MATIBABU ZINAZOWEZA KUTOKEA KWA WAGONJWA AMBAO WAKO NA MATATIZO YA AKILI KATIKA HOSPITALI YA MATHARI.

MCHUNGUZI MKUU NA USHIRIKA WA TAASISI

Mchunguzi mkuu katika utafiti huu ni Dkt. Audrey Akinyi Wagah ambaye ni mwanafunzi katika chuo kikuu cha Nairobi katika shule ya Famasia. Dkt Audrey Akinyi Wagah amesajiliwa katika taifa la Kenya kama daktari mwanafamasia na kwa sasa hivi ako katika mwaka wake wa mwisho wa masomo ya upeoni akiwa anafanya masomo ambayo hatimaye yatampa fursa ya kuhitimu katika somo la Clinical Pharmacy.

WASIMAMIZI / WACHUNGUZI WA USHIRIKIANO NA USHIRIKA WA KITAASISI

1. Dkt. David G. Nyamu

Idara ya Pharmacology, Clinical Pharmacy ana Pharmacy Practice

Shule ya Famasia

Chuo Kikuu cha Nairobi

2. Dkt. Peter Karimi

Idara ya Pharmacology, Clinical Pharmacy and Pharmacy Practice

Shule ya Famasia

Chuo Kikuu cha Nairobi

UTANGULIZI

Jina langu ni Dkt. Audrey A. Wagah, mwanafunzi wa shahada ya uzamifu katika kitengo cha “Clinical Pharmacy” katika chuo kikuu cha Nairobi.

Nina nia ya kufanya utafiti katika eneo la “KUTATHMINI SHIDA ZA MATIBABU ZINAZOWEZA KUTOKEA KWA WAGONJWA AMBAO WAKO NA MATATIZO YA AKILI KATIKA HOSPITALI YA RUFAA YA MATHARI na ninaomba fursa ya kukuongelesha kuhusu utafiti huu na ikiwezekana unipe fursa ya kukujumulisha kwa utafiti huu. Kuwa huru kuniuliza swali lolote ambalo unaeza kuwa nalo kuhusu utafiti huu wakati wowote ukisoma hii nakala ama nikiwa katika hali ya kukuelezezea kuhusu huu utafiti ama hata baada ya ukisoma. Baada ya ukisoma nakala hii ama hata baada ya kukuelezea ana kwa ana kuhusu utafiti huu, ukiridhika nakusihi ujisajili kuwa mmoja wa watakaoshiriki katika huu utafiti. Kuna nakala baada ya hii ambayo utajaza kuonyesha kwamba umeelezewa kuhusu utafiti huu na umekubali kuwa mhusika katika hii utafiti

Kabla tundelee, yafaa ujue kwamba kuhusika katika utafiti wowote ni kwa hiari na hakuna mtu atakulazimisha nyume na hiari yako. Pili, hata baada ya kujisajili kuwa mhusika katika utafiti wowote, uko na haki ya kujiuzulu kutoka kwa utafiti wakati wowote bila kujieleza. Tatu, hata ukitataa kuwa mhusika katita utafiti huu, hakuna haki zako ambazo utanyimwa na utapata matibabu yako kama tu wengine bile ubaguzi.

Je, tuendelee? NDIO / APANA

Utafiti huu umeidhinishwa na Kamati ya Kitaifa ya Hospitali ya Maadili na Utafiti ya Kenya ya Kenyatta na Chuo Kikuu cha Nairobi kupitia itifaki nambari. _____

JE UTAFITI HUU NI KUHUSU NINI?

Wagonjwa wengi hutibiwa na madawa. Baadhi ya wagonjwa hutumia Zaidi ya dawa moja kwa minajili ya kutibu hali zao. Hii huwa sanasana kwa wagonjwa wenye magonjwa ambayo hayatibiki kikamilifu kwa muda mchache. Utumizi wa madawa Zaidi ya moja au utumizi wa madawa kwa wagonjwa ambao wako na magonjwa ya kudumu. Matatizo ambayo hutokea wakati wagonjwa hawa wanatumia hizi madawa yanaweza changia hali kuwa mbaya Zaidi, kudhoofika kwa afya na mara kwa mara inachangia wagonjwa kutopata afueni.

Utafiti huu una nia ya kuchunguza baadhi ya shida za matumizi ya dawa ambazo wagonjwa wa matatizo ya akili hupata mara kwa mara wanapotumia dawa kutibu shida hii. Kwa kupitia rekodi zako za hospitali na kuongea na wewe ana kwa ana nina nia ya kutambua haya matatizo. Matokeo ya utafiti huu yatasaidia pakubwa kupambana na haya matatizo na kusaidia washiriki kutambua mbinu za kuzuia hayo matatizo kutokea tena kwako na kwa wengine.

NI NINI KITATOKEA IKIWA UTAAMUA KUWA KATIKA UTAFITI HUU?

Ikiwa utakubali kuwa sehemu ya utafiti huu, mhojiwa atapata habari kutoka kwa faili yako ya matibabu inayohusiana na historia yako ya kijamii, matibabu, na dawa. Kando na hayo, ntakuuliza maswali kuhusu matumizi yako ya dawa na taarifa yoyote ambayo itasaidia katika utafiti huu.

USHIRIKI WA KUJITOLEA

Kushiriki katika utafiti huu ni kwa hiari yako na kujitolea kwako. Sio lazima ushiriki katika utafiti huu. Ikiwa utaamua kwamba hutaki kushiriki, hakutakuwa na ubaguzi wowote katika

matibabu yako. Utahudumiwa tu kama kawaida na utatibiwa sawa na wengine bila ubaguzi. Ikiwa utakubali kuwa mhusika katika utafiti huu na ifike mahali uamue kujitoa kwa utafiti, una huru wa kufanya hivyo.

JE! KUNA HATARI YOYOTE AU HUDHURU USUMBUFU UNAOHUSISHWA NA UTAFITI HUU?

Kutoka kwa utafiti huu, unaeza kupoteza faragha. Walakini, habari yote itayokusanywa kutoka kwa faili yako itahifadhiwa kwa siri. Katika utafiti huu, nambari ya kisiri itatumiwa kukurejelea kwenye hifadhidata ya kompyuta ambayo inalindwa na nenosiri, na rekodi zote za karatasi zitahifadhiwa kwenye baraza la mawaziri lenye usalama. Tafadhali kumbuka kuwa bado inaweza kuwa mtu anaweza kupata rekodi za utafiti na kugundua kuwa wewe ni mmoja wa washiriki kwani hakuna mfumo wa kuhifadhi data ambao unaweza kuwa salama kabisa. Utafiti huu hahutahitaji mshirika kutumia madawa za ziada na operesheni za kudhuru mwili wa mshirika hazitatumika.

JE! KUNA FAIDA YOYOTE KUWA KATIKA UTAFITI HUU?

Unaweza kufaidika kwa kuwa sehemu ya utafiti huu. Ikiwa shida yoyote itagunduliwa, daktari atajulishwa na hii itakuwa ya faida kwako. Pia, matokeo ya utafiti huu yatakuwa muhimu kwa kuboresha ubora wa huduma unayoipokea wewe na wagonjwa wa baadaye.

JE! KUWA KATIKA UTAFITI HUU KUTAGHARIMU CHOCHOTE?

kushiriki katika utafiti huu hakutakugharimu pesa yoyote.

JE! UTAPATA MAREJESHO YA PESA YOYOTE ILIYOTUMIWA KAMA SEHEMU YA UTAFITI HUU?

Kwa kuwa hakuna matumizi ya kuonekana kwa kushiriki katika utafiti huu, hakutakuwa na Fidia inayotokana na kuwa mshiriki katika utafiti huu.

JE! IKIWA UNA MASWALI KATIKA SIKU ZIJAZO?

Ikiwa una wasiwasi zaidi kuhusu kuwa sehemu ya utafiti huu, tafadhali tuma ujumbe mfupi, au piga simu kwa mchunguzi kwa nambari ifuatayo:

Dkt. Audrey Akinyi Wagah

Nambari ya simu: 0700303274.

Barua pepe: addywagz@gmail.com

Ikiwa unahitaji habari zaidi kuhusu haki yako kama mshiriki wa utafiti, tafadhali wasiliana na Katibu / Mwenyekiti, Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi kupitia:

nambari ya simu 2726300 Ext. 44102 au

anwani ya barua pepe: uonknh_erc@uonbi.ac.ke

Utafiti huu una idhini ya kimaadili kutoka kwa chombo hiki.

Baada ya kupitia fomu hii ya idhini, kama umeridhika na unataka kushiriki katika utafiti huu, tafadhali idhinisha Fomu ya Ridhaa (Fomu 3B) inayofuata.

APPENDIX 2C: FOMU YA RIDHAA (KUKUBALI KUSHIRIKI)

Taarifa ya Mshiriki

Hii ni kudhibitisha kuwa nimesoma habari hii ya idhini au nimesomewa. Nimejadiliana na mshauri wa utafiti kwa undani kuhusu utafiti huu, na maswali yangu yameshughulikiwa kwa lugha ambayo ninaelewa.

Ninajua faida au/na hatari za kuwa mmoja wa washiriki. Ni wazi kwangu kwamba ushiriki wangu ni wa hiari, na wakati wowote katika somo hili, niko huru kujiondoa. Kwa hivyo, nimekubali kushiriki katika utafiti huu kwa uhuru.

Ninaelewa kuwa mtafiti atafanya juhudi zote iwezekanavyo kudumisha usiri wa rekodi zangu za kibinafsi na kitambulisho. Ninaelewa kuwa kwa kukubali utafiti huu, sijatangulia haki zangu za kisheria, ambazo ninastahiki kama mshiriki wa utafiti.

Mshiriki: ……. Tarehe: ……...

Shahidi: …… Tarehe: …….

Taarifa ya Mtafiti

Baada ya kuelezea mshiriki kila kitu kuhusu utafiti huu, hii ni kudhibitisha kuwa mshiriki anajua haki zake, anaelewa utafiti ni kuhusu nini na nimejibu maswali yote aliyouliza na amesema ameelewa kila kitu na ametoa ruhusa ya hiari kuwa mhusika katika huu

Jina la Mtafiti: ……. ……

Tarehe: ……...

Sahihi: ……

APPENDIX 3: QUESTIONNAIRE

RESEARCH TOPIC: MEDICATION RELATED PROBLEMS AND PREDISPOSING FACTORS AMONG ADULT PSYCHIATRIC PATIENTS ON ANTIPSYCHOTIC DRUGS AT MATHARI TEACHING AND REFERAL HOSPITAL

INSTRUCTIONS.

a) Please answer the following questions and feel in these details in the spaces provided.

b) Feel free to ask for any clarification if needed.

SECTION A: PATIENT SURVEY

Code number of the patient. _____

I. **PATIENT- DEMOGRAPHIC STATUS.**

1) Age _____ years

2) Sex……. Male (0) Female (1)

3) Weight……Kg Height……Meters BMI……...

4) Marital Status: Single (0) Married (1) Divorced (2) Widowed (3)

5) Pregnancy Status: Yes (0) No (1)

6) Religion: Christian (0) Muslim (1) Others (2)

7) Level of Education: Primary (1) Secondary (1) College/ university (2) none (3)

B) OCCUPATION.

8) What is your employment status? Formal (0) Informal (1) Unemployed (2) Retired (3)

9) Category of monthly income Ksh < 5000 (0) 5000-10000 (1) 10000-30000 (2) >30000 (3)

10) Do you have a health insurance policy? Yes (0) No (1)

C) SOCIAL DRUG USE

11) Smoking status: current smoker (0) previous smoker (1) never smoked (2)

12) Alcohol intake status: currently drinking (0) previously drinking (1) never drunk (2)

13) Another recreational drug use? Yes (0) No (1)

If yes, which drug? ……

II. CLINICAL CHARACTERISTICS

14) Which psychiatric disorder are you being treated for?.....

15) How long have you been having the condition?

16) Do you have other ailments? Yes (0) No (1)

17) If yes which illness in the list have you suffered?

CONDITION	Present (1)	Absent (0)
Hypertension		
Diabetes mellitus		
HIV		
Cancer		
TB		
Pneumonia		
Hepatitis		
Substance use disorder		
Others, specify		

B) **PAST MEDICAL HISTORY**

18) Have you ever been admitted in a hospital due to a psychiatric disorder? Yes (0) No (1)

19) Have you ever had a blood transfusion? Yes (0) No (1)

20) Have you ever used complimentary medicine to manage you condition? Yes (0) No (1)

III. **DRUG RELATED FACTORS**

21) Do you like taking medications? Yes (0) No (1)

22) If no to question 21 above what was the reason?

a) Drugs don't work. Yes (0) No (1)

b) Drugs cause more problems. Yes (0) No (1)

c) I don't take any medications. Yes (0) No (1)

d) The cost of drugs. Yes (0) No (1)

e) Availability of the drug. Yes (0) No (1)

23) What do you expect from the medications you use? Cure (0) Relief (1)

24) Do you have concerns regarding the medications? Yes (0) No (1)

25) If yes to the above question what are your concerns?

26) The number of pills. Yes (0) No (1)

27) The number of times you taking the drugs. Yes (0) No (1)

28) Side effect of the medication. Yes (0) No (1)

29) Do you currently suffer from any side effect from the medication? Yes (0) No (1)

30) Do you choose to take the medications without being compelled? Yes (0) No (1)

31) Do you choose to refill your prescription? Yes (0) No (1)

32) When you feel that your condition is under control do you sometimes stop taking the medications for a while? Yes (0) No (1)

IV MEDICATION EXPERIENCES

33) Do you know the dose(s) of the medication(s) you are taking? ……

Correct (0) Incorrect (1)

34) How many times do you take in a day? ……

Correct (0) Incorrect (1)

35) Do you know the duration within which you should take your drugs?.....

Correct (0) Incorrect (1)

36) How should I take the medications with regards to food? With food (0) before food (1) after food (2) with no regard to food (3) I don't know (4).

37) Do you know why you are using this medication?

Correct (1) Incorrect (2)

38) Do you hold any cultural or religious beliefs for or against the use of any medication?

Yes (1) No (2)

39) What are the prescription patterns and characteristics of drug therapy problems in patients?

Condition	Drugs	Dosage	Lab result /signs/symptoms	Pharmacotherapy outcome status	Medication related problem	Cause

SECTION C

EVALUATION OF MEDICATION RELATED PROBLEMS

40) Did the patient have any MRP? Yes (0) No (1)

41) If yes to question 1, classify the MRP according to the table shown below.

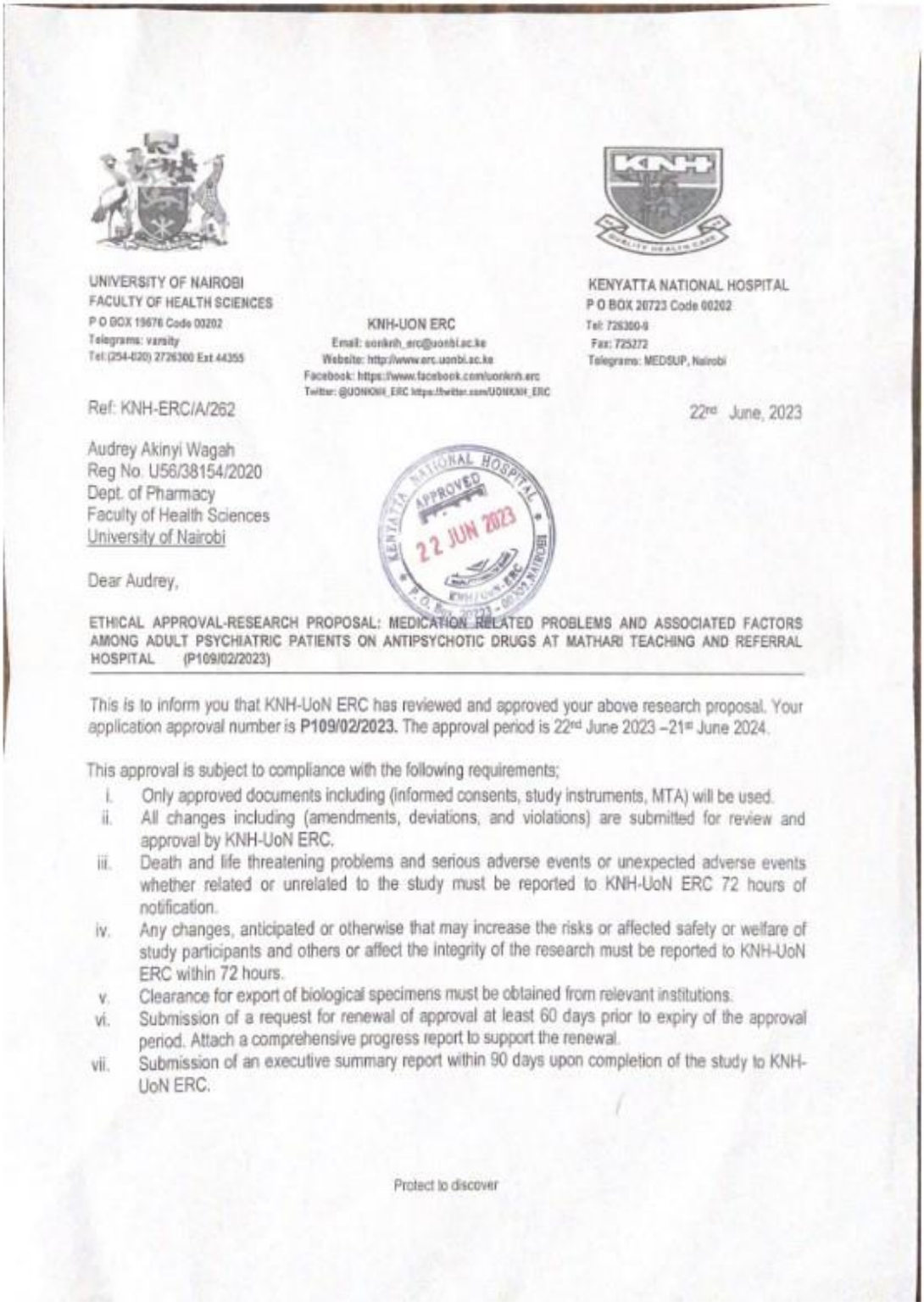
MRP	CODE	CAUSE	CODE	COMMENT
Unnecessary drug therapy.		No valid medical indication	0	
		Duplicate therapy	1	
		Non drug therapy	2	
		Treating avoidable ADR	3	
		Addictive or recreational drug	4	
Needs additional drug therapy.	2	Prophylaxis	5	
		Untreated condition	7	
		Preventive	8	
		Synergistic/ potentiating	9	
Different drug needed.	3	More effective drug available	10	
		Dosage forms inappropriate	11	
		Condition refractory to the drug	12	
		Contraindication present	13	
		Drug not effective for the condition.	14	
Dosage too low	4	Ineffective dose	15	
		Needs additional monitoring	16	

		Frequency inappropriate	17	
		Drug interaction reduces the amount of active drug.	18	
		Duration inappropriate.	19	
ADR	5	Undesirable effect	20	
		Dosage administered or changed too soon	21	
		Allergic reactions	22	
		Drug interaction causes undesirable reactions	23	
		Unsafe drug for the patient.	24	
		Contraindications present	25	
Dosage too high	6	Dose too high	26	
		Needs additional monitoring	27	
		Frequency too short	28	
		Duration too long	29	
		Drug interaction results in toxicity	30	
Non compliance	7	Patient does not understand instructions	31	
		Patient prefers not to take	32	
		Cannot afford drug product	33	
		Patient forgets to take	34	
		Drug product not available	35	
		Cannot administer	36	

42. Develop a final analysis of MRPs present in the patient and summarize them in the table below.

NO	DTP	Yes (0)	No (1)
1	Unnecessary drug therapy		
2	Needs additional drug		
3	Different drug needed		
4	Dosage too low		
5	Adverse drug event		
6	Dosage too high		
7	Non compliance		

APPENDIX 4: APPROVALS



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Ref: KNH-ERC/A/262

22nd June, 2023

Audrey Akinyi Wagah
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Dept. of Pharmacy
Faculty of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 22 JUN 2023 P.O. Box 20723 - 00202 NAIROBI KNH/UoN-ERC

Dear Audrey,

ETHICAL APPROVAL-RESEARCH PROPOSAL: MEDICATION RELATED PROBLEMS AND ASSOCIATED FACTORS AMONG ADULT PSYCHIATRIC PATIENTS ON ANTIPSYCHOTIC DRUGS AT MATHARI TEACHING AND REFERRAL HOSPITAL (P109/02/2023)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P109/02/2023.** The approval period is 22nd June 2023 –21st June 2024.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected 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.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. 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.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover

A study to characterize the types of medication related problems and their predictor factors among adult psychiatric patients on antipsychotic medication in Mathari Hospital.

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