IMPACT OF SIDE EFFECTS OF ANTIPSYCHOTICS ON ATTITUDE AND ADHERENCE TO TREATMENT AMONG ADULT PSYCHIATRIC OUTPATIENTS AT MATHARI HOSPITAL IN KENYA

By
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U56/64069/2013

A Research Dissertation Submitted in Partial Fulfillment for the Degree of Master of Pharmacy in Clinical Pharmacy in the School of Pharmacy of the University of Nairobi

September 2014
DECLARATION

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Topic: Impact of Side Effects of Antipsychotics on Attitude and Adherence to Treatment among Adult Psychiatric Outpatients at Mathari Hospital in Kenya

Declaration

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DEDICATION

Commitment, effort, and dedication were fundamental elements for the completion of my masters’ dissertation, but even more was the support of my family. To them I dedicate this important professional achievement because without their presence, support, and encouragement I would have not achieved my goal.
ACKNOWLEDGEMENT

I have had the opportunity to wish and dream throughout my life. I have attained my professional goals, not only because of my innate abilities, but because I have had the opportunity of meeting wonderful people that have contributed to my life with knowledge, words of support, and motivation.

First of all I thank you the Almighty God, for life, health, and the energy that you have given me to reach my professional goals. Thanks to all the adult psychiatric patients who participated in this research, without you I could not have finished this work.

To all healthcare providers who are committed to ensure the well being of this population and allowed me to use their facilities to recruit participants. Thanks to the entire management of Mathari Psychiatric Hospital, to all psychiatrists, nurses and record officers for facilitating my research.

To my supervisors, my sincere thanks for sharing your knowledge and being excellent at what you do. To Dr. David Nyamu, Dr T. B. Menge and Dr. Peter Karimi thank you for sharing your expertise, you were always available to answer my questions. I appreciate your interest and patience. To my classmates thank you for sharing so many educational experiences and encouragement.

To my research assistants, Emmanuel and Duncan, thank you for always being available and your words of motivation. I treasured your time, knowledge and friendship. I genuinely thank you.

Mom, Dad, sisters and brothers, thank you for your words of encouragement. Your prayers, good wishes, and interest are specially treasured in my heart.
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<th>Description</th>
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<tbody>
<tr>
<td>DAI</td>
<td>Drug Attitude Inventory</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
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<td>EPS</td>
<td>Extrapyramidal symptoms</td>
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<tr>
<td>FGAs</td>
<td>First Generation Antipsychotics</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>GASS</td>
<td>Glasgow Antipsychotic Side effect Scale</td>
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<tr>
<td>KNH</td>
<td>Kenyatta National Hospital</td>
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<td>MARS</td>
<td>Medication Adherence Rating Scale</td>
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<tr>
<td>MBD</td>
<td>Mental Behavioral Disorders</td>
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<td>PI</td>
<td>Principal Investigator</td>
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<td>PTSD</td>
<td>Posttraumatic Stress Disorder</td>
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<td>SE</td>
<td>Side Effects</td>
</tr>
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<td>SGAs</td>
<td>Second Generation Antipsychotics</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for social Science</td>
</tr>
<tr>
<td>UoN</td>
<td>University of Nairobi</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>Definition</td>
<td>Description</td>
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<tr>
<td><strong>Adherence</strong></td>
<td>The extent to which a patient continues an agreed-upon mode of treatment without close supervision.</td>
</tr>
<tr>
<td><strong>Attitude</strong></td>
<td>In social or clinical psychology, a relatively stable and enduring predisposition or set to behave or react in a certain way towards persons, objects, institution or issues.</td>
</tr>
<tr>
<td><strong>Compliance</strong></td>
<td>The consistency and accuracy with which a patient follows the regimen prescribed by a physician or other health professional.</td>
</tr>
<tr>
<td><strong>Psychosis</strong></td>
<td>A mental and behavioral disorder causing gross distortion or disorganization of a person’s mental capacity, affective response, and capacity to recognize reality, communicate and relate to others to the degree of interfering with the person’s capacity to cope with the ordinary demands of every day.</td>
</tr>
<tr>
<td><strong>Side effect</strong></td>
<td>A result of drug or other therapy in addition to or in extension of the desired therapeutic effect; usually but not necessarily, connoting an undesirable effect.</td>
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ABSTRACT

Background
In psychotic disorders, early intervention with antipsychotic medication increases the likelihood of favorable long term outcome. However, the use of antipsychotic medication is associated with a significant number of side effects, ranging from primarily extrapyramidal motor side effects, sedation, weight gain, to sexual dysfunction, among others. These side effects affect the patients’ quality of life and the attitude towards their use, which may culminate to non-adherence and hence poor clinical outcome. This was the impetus for the current study.

Objective of the Study
To determine the impact of antipsychotic side effects on attitude and adherence to treatment among adult psychiatric outpatients.

Design
A cross-sectional, research design was used.

Method
A convenience sample of 164 adults’ patients aged 18 years and above on antipsychotic and attending psychiatric outpatient clinic at Mathari Mental Hospital was recruited. Participants were interviewed using pre-designed questionnaires on, social demographic characteristics, drug attitude, antipsychotic side effects and medication adherence. The collected variables were analyzed with descriptive statistics and regression analysis.

Results
Out of 164 participants, majority were males at 55.49%. Most of patients reported experiencing at least one side effect due to their medication (94.14%). More than half of the patients had a positive attitude towards their medication (53.65%). Severity of Side effects were positively associated with negative attitude towards medication (P= < 0.001). Only 39.63% reported complete adherence to their medication. Extrapyramidal symptoms (OR= 0.43,CI= 0.286-0.633,p=< 0.001), sedation (OR=0.23, CI= 0.103-0.545,p= 0.001), cardiovascular side effects (OR=0.81, CI=0.702-0.925,p= 0.002) and
gastrointestinal side effects (OR=20, CI=0.099-0.430, p=0.037) were significantly associated with reduced likelihood of adherence. Patient who had moderate to severe side effects also had a reduced likelihood of adherence (OR=0.89, CI=0.812-0.993, p= < 0.001). Patient counseling on medication side effects significantly improved adherence to medication (OR= 0.137, p= 0.028).

**Conclusion**
The findings showed that there was a high prevalence of antipsychotic side effects. Attitude towards antipsychotics was principally determined by the severity of side effects. Most patients did not completely adhere to their medications because of side effects. However patients who had a positive attitude towards medication had a high likelihood of adherence.

**Recommendation**
There is high prevalence of side effects due to use of Antipsychotics which would consequently lower adherence and have some negative attitude towards the treatment. Therefore, effort should be done to improve patient’s attitude towards treatment by managing the side effects adequately and counseling the patient about his or her medication. Most importantly, clinicians should develop treatment strategies where the regimen with minimal side effects is chosen.
CHAPTER I: INTRODUCTION

1.1 Background
Psychotic disorders are disabling illnesses associated with disruption in cognition, emotion, psychosocial and occupational functioning [1]. Psychotic disorders include schizophrenia, schizoaffective disorder, brief psychotic disorder, delusional disorder; substance-induced psychotic disorder, psychosis due to medical condition and postpartum psychosis. In addition, mood disorders like major depressive disorder and bipolar disorder can become severe enough to result in psychotic features [2]. About one third of people (33 countries with a combined population of two billion) live in nations which invest less than 1% of their total health budget in mental health [2].

Numerous antipsychotic medications are available with demonstrated efficacy in reducing the acute symptoms of schizophrenia and other psychotic disorders, improving the well-being of patients, and enabling some to live a more meaningful life [3]. Inadequate adherence to antipsychotic medications increases the risk of relapse and associated healthcare utilization and costs. A review by Sun et al. (2007) estimated that antipsychotic nonadherence in the US was responsible for between $1.4 and $1.8 billion in rehospitalization costs alone [4]. Adherence has been shown to be connected to side effects and medication efficacy, as well as effectiveness, taking into consideration medication related tolerability, independent living, alliance, quality of life and physical health [5].

1.2 Global Burden of Mental Disorders
The scale of the global challenge posed by mental illness has become increasingly clear in recent years. The World Health Organization (WHO) reported in 2001 that about 450 million people worldwide suffer from some form of mental disorder or brain condition, and that one in four people meet criteria at some point in their life [1]. About 14% of the global burden of disease is attributable to mental disorders. Further more
mental disorders accounted for 25.3% and 33.5% of all years lived with a disability in low and middle-income countries, respectively [1]

In the United States of America (USA), general lifetime prevalence of psychotic disorders was found to be 3.48%. They were as follows: 0.87% for schizophrenia, 0.32% for schizoaffective disorder, 0.18% for delusional disorder, 0.24% for bipolar I disorder, 0.35% for major depressive disorder with psychotic features, 0.42% for substance-induced psychotic disorders, and 0.21% for psychotic disorders due to a general medical condition [6]. Lifetime prevalence of mental disorders is the number of individuals in a statistical population that at some point in their life (up to the time of assessment) have experienced mental disorders, compared to the total number of individuals [6].

1.3 The Burden of Psychoses in Kenya and Sub-Saharan Africa

There is inadequate data on the prevalence of psychoses in Kenya and other Sub-Saharan African countries. The prevalence of psychoses was found to be 4.4% in Mozambique [7] and in another study done in Tanzania the prevalence of psychotic-like symptoms was 3.9%. [8]. In a cross sectional study by Ndetei et al. [2012], on the prevalence of psychotic-like experiences in Kenyan youths; it was found to be 3.5% [9].

The health and economic impact of mental and behavioral disorders (MBD) is wide-ranging and long-lasting. Psychotic disorders impact negatively on the patient’s ability to engage in productive work and social relationship [2]. In addition they are associated with a reduced life expectancy as a result of accidents, high comorbidity with medical conditions and suicide [2, 10]. Patients with schizophrenia and other psychotic disorders are most likely to die early from potentially treatable conditions [10, 11]. In the financial year 1998/99, the Kenyan economy lost approximately US dollars 13,350,840 due to institutionalized MBD patients [12]. In most cases hospitalization of mental patients is due to nonadherence to medication among other factors.
1.4 Statement of the Research Problem

About 14% of the global burden of disease is attributable to mental disorders. Even in sub-Saharan Africa, where communicable diseases are common, mental disorders account for nearly 10% of the total burden of disease. Mental disorders are linked to many other health conditions and are among the most costly medical disorders to treat [1]. The management of psychiatric illnesses requires pharmacological therapy with antipsychotics which have serious side effects. Studies have shown that side effects influence the uptake and compromise the adherence to the antipsychotics leading to relapse and hospitalization [5, 13].

Few studies have been done in other countries assessing the impact of antipsychotic side effects on attitudes and adherence to treatment. In Kenya like many other African countries, there are no documented studies assessing the relationship between patient reported side effects and self-reported adherence. This patient perspective is vital as it provides insight into how the perception of side effects is associated with specific non-adherent behaviors; something that cannot be obtained from objective assessments of adherence. It is against this that the study set out to determine the impact of side effects on attitude and adherence to treatment among psychiatric outpatients.

1.5 Purpose of the study

The primary aim of this study was to establish the relationship between antipsychotic side effects and their impact on patients’ attitude and adherence towards antipsychotic treatment. The secondary aim of this study was to determine the prevalence of antipsychotic side effects among psychiatric outpatient at Mathari Psychiatric Hospital.

1.6 Objectives

1.6.1 General Objectives

To determine the impact of antipsychotic side effects on attitude and adherence to treatment among adult psychiatric outpatients at Mathari Mental Hospital.
1.6.2 Specific Objectives

1) To determine the prevalence of side effects of antipsychotics in psychiatric adult outpatients at Mathari Psychiatric Hospital
2) To determine the impact of side effects on patients’ attitude towards antipsychotic medication at Mathari Psychiatric Hospital
3) To determine the association between the side effects of antipsychotics and the level of adherence to treatment at Mathari Psychiatric Hospital

1.7 Research Questions

This study was designed to answer the following questions.

1) What was the prevalence of side effects of antipsychotics among adult psychiatric adult outpatients in MH?
2) What was the relationship between the side effects of antipsychotics and patient attitude towards their use?
3) What was the relationship between the side effects of antipsychotics and the level of drug adherence among psychiatric adult outpatients at MH?

1.8 Study Justification

Much of the burden of psychotic disorders placed on patients, care givers, the health service and society, is the result of relapses, which normally disrupt psychosocial and occupational adjustment, and increase the risk of hospitalization and suicide [14]. The public attitudes tend to characterize people suffering from psychotic disorders as dangerous, unpredictable, and unreliable. This can be compounded by the numerous antipsychotic side effects which may lead to more stigmatization and nonadherence to medication among the users [15].

Understanding the association between the side effects, patient attitude and adherence towards medication is one step in achieving better health outcome. The findings of this study aimed to guide the development of suitable treatment strategies that intents to
alleviate side effects and reduce negative attitude towards antipsychotic medications and improve adherence. The study also aimed to determine the extent of antipsychotic side effects among psychiatric outpatients and their impact on patient’s treatment, a vital step towards holistic and individualized patient care.
CHAPTER II: LITERATURE REVIEW

2.1 Introduction
About 14% of the global burden of disease is attributable to mental disorders. Even in sub-Saharan Africa, where communicable diseases are common, mental disorders account for nearly 10% of the total burden of disease. Mental disorders are linked to many other health conditions and are among the most costly medical disorders to treat [1]. Antipsychotics are the mainstay treatment in schizophrenia and other psychotic disorders. However, antipsychotics are associated with a number of side effects with potentially harmful effects on patients function and quality of life.

Negative societal reaction related to having a serious mental illness and the socially undesirable side effects associated with antipsychotic medication treatment may combine to worsen stigma associated with treatment for mental illness [13-15]. These side effects may have a negative impact on the patient attitude towards antipsychotics and lead to poor drug adherence [15].

2.2 Antipsychotic Medications Overview
The efficacy of antipsychotic medication in the acute and maintenance treatment of schizophrenia and other related disorders is clear from large meta-analyses of placebo-controlled trials Antipsychotic medications are divided into two groups: First-generation (typical) and second-generation (atypical) antipsychotics [16].
Table 1: Antipsychotics common in the Kenyan market

<table>
<thead>
<tr>
<th>Typical Antipsychotics (Low Potency)</th>
<th>Typical Antipsychotics (High Potency)</th>
<th>Atypical antipsychotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpromazine HCL</td>
<td>Fluphenazine</td>
<td>Olanzapine</td>
</tr>
<tr>
<td>Chlorprothixene</td>
<td>Haloperidol</td>
<td>Quetiapine</td>
</tr>
<tr>
<td>Thioridazine</td>
<td>Pimozide</td>
<td>Risperidone</td>
</tr>
<tr>
<td>Perphenazine</td>
<td>Thiothixene</td>
<td>Clozapine</td>
</tr>
<tr>
<td></td>
<td>Flupentixol</td>
<td>Amisulpride</td>
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<tr>
<td></td>
<td>Prochlorperazine</td>
<td>Aripiprazole</td>
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</table>

Typical antipsychotic drugs correlate closely their clinical potency in reducing psychotic symptoms with their relative ability to block D₂ receptors in the mesolimbic system of the brain [16]. Their non-selectivity in blocking dopamine receptors contribute to their side effects. Atypical antipsychotic drugs block 5-HT (2A) receptors coupled with weaker antagonism of the dopamine D (2) receptors hence fewer side effects [16, 17, 18].

Antipsychotics are indicated in the following conditions [17, 18]: Schizophrenia, Schizoaffective disorder, Bipolar disorder, Psychotic depression (in combination with antidepressants), Obsessive- compulsive disorder (Risperidone), Post traumatic stress disorder, Personality disorder [19], Autism (Aripiprazole and Risperidone) and others

2.3 Side Effects of Antipsychotics Drugs
The use of antipsychotic medication entails a trade-off between the benefits of alleviating psychotic symptoms and the risk of troubling side effects. Typical antipsychotics exhibit a broad range of side effects including extrapyramidal symptoms, sedation, sexual – dysfunction, Anticholinergic, cardiovascular side effects, gastrointestinal side effects among others [20, 21]. Atypical antipsychotic are commonly associated with weight gain and metabolic side effects [22, 23].
2.3.1 Extrapyramidal Symptoms

Most patients who receive typical antipsychotics experience movement disorders, which not only can be wearisome to patients but also concern caregivers. These extrapyramidal symptoms include dystonia, Parkinson-like symptoms, akathisia and Tardive dyskinesia [20, 21, 22]. Atypical antipsychotics have been thought to cause fewer extrapyramidal side-effects (EPS) than first-generation antipsychotics, but recent pragmatic trials have indicated equivalence [22, 23]. All patients should be assessed for the presence of EPS when treatment with antipsychotics begins and regularly thereafter.

Akathisia is characterized by a sense of inner restlessness and compulsion to move accompanied by restless motion [23, 24]. This symptom is probably the most intolerable of the acute EPS and has been associated with violence and suicide. Akathisia due to FGAs has an estimated prevalence of at least 20% to 75% which is higher as compared of Second Generation Antipsychotics (0% to 12%) [25]. Several approaches have been used to manage akathisia: reduction of the dose, substitution with SGAs and treatment with lipophilic beta blockers (propranolol) [26]. Anticholinergic agents and benzodiazepines have also proved to be effective [26].

Catatonic symptoms associated with antipsychotics include akinesia, stupor, and mutism, and less often catalepsy and waxy flexibility [22, 23]. It develops within hours to days after drug exposure and is expected to resolve in a similar period of time after drug discontinuation. There is no whether prophylaxis with benzodiazepines or other agents would prevent catatonia in susceptible patients [26]. Dystonia is an acute, alarming involuntary movement disorder that can be painful and distressing, and erodes patient trust and adherence [22]. Dystonia commonly involves the head, neck, jaw, eyes and mouth resulting in spasmodic torticollis, trismus and dental trauma, forced jaw-opening or dislocation, grimacing, tongue biting, protrusion or twisting, and distortion of the lips [26].
Drug-induced Parkinsonism is a sub-acute syndrome that mimics Parkinson’s disease [27]. It is characterized by masked faces, reduced arm swing, slowed initiation of activities, soft speech and flexed posture. Patients may also experience resting or action tremors, sialorrhea and postural or gait disturbance [20, 21, 27]. In industry-sponsored trials, haloperidol has been associated with two to four times the risk of Parkinsonism compared with SGAs (22% to 38% versus 4% to 14% [27]. The stiffness, slowness of movement and tremor can make it difficult for patients to write, fasten buttons and tie shoelaces, leading to reduced quality of life [27]. These symptoms make the patient to stand out as different, hence contributing to stigma and non-adherence.

2.3.2 Tardive dyskinesia
Tardive dyskinesia (TD) is the principal adverse effect of long-term treatment with conventional antipsychotic agents. Tardive dyskinesia (TD) is characterized by involuntary muscle movements, most commonly associated with the mouth and tongue, although any muscle group may be affected [20, 28, 29]. The prevalence rate of Tardive dyskinesia among the psychiatric in-patient at Mathari Hospital was found to be 11.9% [28].

2.3.3 Cognitive Impairment
Disturbances in cognitive abilities are cardinal features of schizophrenia from its earliest phases and account for much of the functional disability associated with the illness. Long-term antipsychotic treatment for schizophrenia is often associated with the emergence of Tardive dyskinesia (TD), and TD presence is also accompanied by more severe cognitive impairment [20]. Oxidative stress-induced damage may be involved in the development of TD and contribute to cognitive deficits in schizophrenia [20, 29].

It is likely that long-term concomitant administration of Anticholinergic exacerbates the underlying cognitive impairment in patients with schizophrenia and subsequently affects patients' quality of life [29].
2.3.4 Sedation
Typical antipsychotics especially those with low potency are sedating, a likely effect of histamine blockade and it is usually dose related. Initially sedation may be beneficial in the treatment of highly agitated psychotic patients but at long term it is often mistaken for contrary behavior and interferes with rehabilitation [30, 31]. Sedation can be difficult to distinguish from mental slowing of cognitive impairment [30]. Antipsychotic induced sedation causes daytime drowsiness and this may interfere with activities that require the maintenance of vigilance [31].

2.3.5 Sexual Dysfunction and Reproductive Side Effects
Patients who experience sexual dysfunction may experience poor relationship with their partners. Sexual dysfunction is estimated to affect 30-80% of patients with schizophrenia and a major cause of poor quality of life and treatment adherence [32,33]. The associated sexual dysfunction symptoms may concern penile erection, lubrication, orgasm, libido, retrograde ejaculation, sexual arousal and overall sexual satisfaction. It is known to be caused by the hyperprolactinemia that results from the D2 receptor blockade among other mechanism [32, 34].

Several approaches have been employed in the management of sexual dysfunction secondary to antipsychotics including, dose reduction, drug holiday, symptomatic therapy, switching antipsychotic and even use of sildenafil [34].

2.3.6 Weight Gain
Typical antipsychotics though to a lesser extent than atypical antipsychotic are associated with drug induced weight gain ,that frequently result in obesity and secondary medical condition like diabetes . If the patient associate the weight gain with the drug use, it may lead to a negative attitude and poor adherence to medication [22,23]. Clinicians should consider the effect of weight gain on quality of life when prescribing antipsychotics and should help patients adopt weight maintenance behaviors.
2.4 Attitude towards Antipsychotic Medication

The efficacy of antipsychotic medication is evident in acute and maintenance treatment of these disorders, and most mental health professionals recognize antipsychotic drugs as a cornerstone in treating affected people. However, effectiveness and acceptability of these medications not only depend on the drug's pharmacological profile but through the interaction of different factors, including patients' attitudes toward their prescribed medications [35]. A negative drug attitude is a known risk factor for non-adherence in long-term schizophrenia as well as for medication discontinuation in first-episode schizophrenia [36].

In a Day et al [2005] study, the quality of relationships with clinicians during acute admission appears to be an important determinant of patients' attitudes toward treatment and adherence to medication [37]. When individuals with schizophrenia do not perceive themselves as ill, they are less inclined to enter or remain in treatment, underappreciate the benefits of medication, and put themselves at higher risk of discontinuing treatments, with concomitant increase in the risk of relapse [38].

The long-term course of the illness is often characterized by impaired social and occupational functioning and quality of life, in part because of the absence of a positive attitude toward available treatments, after realizing their benefits are limited [39, 40, 41]. In a Chiang et al [2011] study to determine the impact of side effects on attitude towards medication in schizophrenic patients, participants experienced psychic (80.2%), extrapyramidal (69.8%) and miscellaneous side effects (61.5%). Side effects positively correlated with dose and negatively correlated with prescription duration. Negative attitudes towards medication were positively correlated with side effects [42].

In another study by Rettenbacher et al [2004], found a positive correlation between compliance and the patients' feelings of a positive effect of the drug on the illness, between compliance and negative symptoms, and between compliance and antipsychotic-induced psychological side effects [43]. In a Lambert et al [2002] study, patients
presenting with present SE compared with patients without present SE had a significantly more negative general attitude toward antipsychotics, were more doubtful about their efficacy and were less likely to encourage a relative to take such a medication in case of need [44].

In a Freudenreich et al [2004] study, found that less awareness of current symptoms, presence of deficit symptoms, and employment predicted a negative attitude toward psychiatric medications. Drug attitudes were no different between patients taking first- or second-generation antipsychotics or Clozapine [45]. It has been established that continuous use of psychotropic medication shapes the opinion of the users toward a more beneficial perception of medications, but the opinion on the general population, where stigmatizing attitudes are born, is more negative toward them [46].

Psychiatrists and other health care providers must consider their patients' desire to participate in treatment decisions and explore how patients' views about psychiatric medications, influence their attitudes towards concordance [45, 46]. Attitudes towards antipsychotic medication may be positive in individuals who recognize therapeutic drug effects; however other individuals may view medications negatively due to a sense of stigma brought about by the side effects [43].

2.5 Adherence to Antipsychotics

Adherence to treatment prescriptions is a critical aspect of health care; however, it is often given far less attention in routine clinical practice than necessary. Many antipsychotic medications are available with demonstrated efficacy in reducing the acute symptoms of schizophrenia and other related psychotic disorders [16]. International treatment guidelines recommend long term antipsychotic treatment in schizophrenia.

Their use has lead to improvement of the patient well-being and enabling some to live more productive life [47]. However, adherence to these medications is important to receive optimal benefits. Rates of adherence among patients with schizophrenia are between 50%–60%, and among those with bipolar affective disorder the rates are as low
as 35% [48]. Inadequate adherence to antipsychotic medications increases the risk of relapse and associated healthcare utilization and costs [14, 47].

Nonadherence to medication remains a challenging problem in the management of patients suffering from psychotic conditions. In a comprehensive literature review by Lacro et al (2002), among the 10 reports that met a strict set of study inclusion criteria, a mean rate of nonadherence was found to be 41.2%; the 5 reports that met a stricter set of inclusion criteria had a mean nonadherence rate of 49.5% In the 39 articles [46]. A review of dropout rates in clinical trials found that 28%-55% of schizophrenia patients drop out of clinical trials before the study is complete; dropout rates were higher with classic antipsychotic medications compared with second generation antipsychotic medications due to side effects [49]. Up to 75% of all patients with schizophrenia discontinue treatment within 2 years of hospital discharge [50].

When clinicians and patients are aware of the side effects, treatment can be adjusted to minimize the problems e.g. by dose reduction, prophylaxis, treatment of the side effect or to switch to an alternative antipsychotic with less tendency to cause side effects [47]. Five clinically relevant factors that have been identified to affect adherence includes medication efficacy, external factors (such as patient support and therapeutic alliance), insight, side effects, and attitudes toward medication [46].

Studies have suggested that antipsychotic medication side effects are associated with lower levels of adherence. Although adverse effects of medication are often assumed by clinicians to be a major predictor of non-adherence, the results of patient surveys vary, and some specific adverse effects have more impact than others. In addition, some patients discontinue medication because of adverse effects that they might not even identify as such. Akinesia, for example, might not be identified by the patient as an adverse effect of medication, as might also be the case with akathisia. Even clinicians can fail to recognize or misdiagnose these phenomena [51].
There are few studies that have assessed the relationship between patient-reported side effects and self-reported adherence. This patient perspective is important as it provides insight into how the perception of side effects is associated with specific non-adherent behaviors and attitude towards medication; something that cannot be achieved from objective assessments of adherence [14]. Many patients who adhere poorly to medication do not inform their clinicians and may sometimes go to great length to hide their non-adherence (covert non-adherence) [41]. Identification of risk factors for nonadherence is an initial step toward designing effective treatment strategies
CHAPTER III: METHODOLOGY

3.1 Research Design
Hospital based Cross–sectional research design was used.

3.2 Study Area and Site Description
The study was carried out in outpatient psychiatric clinics at Mathari Psychiatric Hospital. Mathari Psychiatric Hospital is Kenya’s national referral and teaching psychiatric hospital located in Nairobi County with a capacity of 700 beds. The staff that provides services to the hospital includes a total of 243 nurses, 7 psychiatrists, two of whom are in full-time administration, 2 pharmacists and several support staff. The hospital attends to a large number of both outpatient and inpatient drawn from all over the country

3.3 Target Population
All adult psychiatric outpatients with a history of antipsychotic drug use at the hospital were eligible for the study.

3.4 Sampling Technique
3.4.1 Sampling Method
Convenient sampling method was used to draw sample from outpatients. Only participants who met the study inclusion criteria were selected.

3.4.2 Inclusion Criteria
1) Patients diagnosed with psychotic disorders according to the DSM-IV
2) All adult patients who consented and were on antipsychotic medication for at least two week
3) Patient aged ≥18 years.
4) Outpatients who are clinically stable
5) Patients who can read or write either in English or Kiswahili.

3.4.3 Exclusion Criteria
1) Patients who did not consent to the study
2) Patients who had severe physical illness
3) Those who were too mentally disturbed to understand or follow instructions
4) Need for an interpreter

3.4.4 Sample Size
The sample size was based on the prevalence of tardive dyskinesia as the principal adverse effect of long-term treatment with conventional antipsychotic agents [20]. A study carried out at Kenya’s Mathari Psychiatric Hospital found tardive dyskinesia prevalence rate of 11.9% among patients using conventional antipsychotics [28]. Sample size was determined using statistical Fischer’s formula for estimating of sample size.

\[ N = \frac{Z^2 \times P(1-P)}{d^2} \]

Where \( n \) = Sample size,
\( P \) = Estimated prevalence rate of side effect (Tardive dyskinesia)
\( Z = 1.96 \) which is \( Z \)-value corresponding to a significance level of 0.05
\( d = 0.05 \) which is the desired degree of accuracy for the study

\[ n = 1.96^2 \times 0.119(1-0.119) \]
\[ 0.05^2 \]
\[ = 164 \text{ (Hundred and sixty four participants were studied)} \]

3.5 Sample Recruitment and consent process
Psychiatrists and clinical staff were asked to identify participants fulfilling the study criteria with the help of a Study Eligibility Check List (Appendix 2). After potential participants were adequately informed of the study, they were asked by the principal
investigator if they were interested in participating. Of the 200 identified patients 180 accepted participating and gave written informed consent. All participants were assessed on their comprehension of the consent information before signing of the Consent Declaration Form (Appendix 5). Any questions and concerns the participants may have had about the study were adequately answered by the principal investigator.

3.6 Data Collection Procedure

After obtaining consent from the subjects to participate in the study, the research assistants (two trainee nurses) together with the principal investigator fully informed the participants about the study protocol. The subjects completed self-administered questionnaires: Demographic Data Questionnaire, Glasgow Antipsychotic Side effects Scale (GASS modified version), Drug Attitude Inventory (DAI-10) and Medication Adherence Rating Scale (MARS). Data regarding psychiatric diagnosis, other comorbidities and medication history was retrieved from medical files. The research assistant was available to answer questions during the completion of the questionnaires. The duration of the subject’s participation in the study was approximately 20 minutes.

3.7 Instrument

3.7.1 Demographic Data Questionnaire

The Demographic Data questionnaire consisted of two parts. Part one consisted of 5 questions about age, gender, education level, marital status and employment status. Part two was about patient clinical information. It consisted of three questions answered by writing the information in the provided space. This questionnaire addressed the subject’s psychiatric diagnosis and other chronic comorbidities, antipsychotic medications and other medications being used. It also had section of identifying those patients who were counseled about their medication. The English version of the demographic questionnaire is included in Appendix 6.
3.7.2 Glasgow Antipsychotic Side Effect Scale (GASS) Modified Version

This research instrument was used to determine the prevalence and severity of antipsychotic side effects. It was modified to achieve the research objectives. The GASS was designed by Waddell and Taylor in 2007. The benefits of this scale is that it allows a timely, sensitive and reliable method of gathering information on the number and severity of side effects an individual suffers from [52]. The GASS is 22 items, side effect rating scale on which respondents rate statements as never, once, a few times, everyday and distressing. Side effects were also clustered into seven pre-specified categories: 1-2 sedation/cognition (sedation, difficulty thinking or concentrating, sleepiness, and dizziness); 3-4 cardiovascular side effects; 5-10 extra pyramidal symptoms (EPS)/agitation (insomnia, restlessness/feeling jittery, agitation, and tremors); 11-13 anticholinergic side effects; 14 gastrointestinal (GI)" (nausea/vomiting and constipation); 17-21 prolactin/endocrine" (decreased interest in sex, sexual dysfunction, difficult or painful menstrual periods, male breast enlargement or secretions); and 22 weight gain [52].

In this scale the extent of side effects is rated from none (zero points) to everyday (3 points) for question 1-20 and yes (3 points) and no (zero points) for question 21-22. A total score is interpreted as follows, (0-21) absent/mild side effects, (22-42) moderate side effects and (43-63) severe side effects. GASS as a clinical tool has been shown to have good discriminatory power and construct validity along with good re-test reliability [52]. The questionnaire was translated to Kiswahili for those who did not understand English. Reliability analysis for the original instrument and translated version was performed with 20 subjects, 60% (n=12) male and 40% (n=8). The English and Kiswahili translation are included in appendix 7a and 7b respectively.

3.7.3 Drug Attitude Inventory-10 Questionnaire (DAI-10)

This research instrument was used to assess patient attitude towards antipsychotic medications. The 10-Item self-report Drug Attitude Inventory (DAI-10) was used to assess attitude, experience and belief about antipsychotics. Scores ranged from -10 (very
poor attitude) to +10 (best possible attitude) [53]. It is preferred due to its simplicity and good psychometric properties. In a Nielsen et al. study DAI-30 and DAI-10 were found to be homogenous ($r= 0.82$ and $0.72$, respectively) with a good test-retest reliability of $0.79$ [53]. The correlation between the DAI-30 and DAI-10 version was high (0.94) [54]. Reliability analysis for the original instrument and translated version was performed with 20 subjects, 60% (n=12) male and 40% (n=8). The English and Kiswahili version are included in appendix 8a and 8b respectively.

### 3.7.4 Medication Adherence Rating Scale (MARS)

Adherence to medication was assessed using Medication Adherence Rating Scale (MARS), an instrument that has previously shown evidence for reliability and validity [55]. The MARS items include the presence and absence of adherence and non-adherence behavior indicators. Adherence is classified as a score of six and above out of 10 items. The MARS has been found to be reliable in determining medication adherence in psychoses [55]. The research instrument was translated to Kiswahili in order to achieve the research objectives. Pilot study was carried out to determine the reliability for the original instrument and translated version using 20 subjects, 60% (n=12) male and 40% (n=8). The English and Kiswahili version are included in appendix 9a and 9b respectively.

### 3.8 Pilot Study

The first 20 participants of this study comprised the subsample that evaluated possible language barriers, the level of comprehension and the internal consistency of the English and Kiswahili translated version of DAI-10, GASS Modified Version and MARS. The inclusion criteria, settings and recruitment process of this subsample were identical to those of the principal study. Difficulties in comprehension were also assessed at the end of the process through the use of an open-ended question (Are any words or sentences
difficult to understand?). Necessary corrections were made in order to achieve the study objectives.

3.9 Data Analysis

The data analysis was performed according to the research questions. Descriptive statistics were calculated to describe the patient characteristics, side effect, medication attitude and adherence for the entire sample. Unadjusted comparisons of patient characteristics between adherent and non-adherent groups were conducted using chi-square tests and ANOVA tests for categorical and continuous variables, respectively. The results of side effects were categorized based on GASS [52]. The degree of side effect was rated as mild, moderate and severe side effects.

The results on attitude towards medication obtained by the patients on the DAI-10 scale are reported for all patients and clinical subgroups. The result obtained from the scale was calculated as the total score with values in the range of −10 to +10. In addition, patients were divided into two groups according to positive (≥0) or negative (<0) scores on the 10-item DAI [53]. Drug attitude was rated as positive or negative subjective attitude. To assess the relationship between side effects and drug attitude, a logistic regression model was fitted for extent of side effect, adjusting for age, education, employment status and psychiatric diagnosis.

The results on medication adherence obtained by the patients on the MARS calculator were reported for all patients and clinical subgroups. The result obtained from the scale was calculated as the total score with values in the range of −10 to +10. In addition, patients were divided into two groups according to adherent (≥ 6) or non-adherent (< 6) scores on MARS calculator. Age, gender, education level, marital status, employment status, type of psychotic illness, side effects and type of antipsychotics were entered as independent variables. To examine the relationship between side effects and nonadherence, a logistic regression model was fitted for each side effect adjusting for
age, gender, education, employment status, and psychiatric diagnosis. All statistical tests were two-tailed. The significance level was set at $p<0.05$.

### 3.10 Ethical Consideration

Study approval was sought from KNH/UoN Ethical and Research Committee (study reference number P150/03/2014). Consent was sought from participants who met inclusion criteria and a Consent Declaration Form (Appendix 5a and 5b) presented for signing after participants were taken through a detailed consent explanation process by the PI (Appendix 3a and 3b). The signing was only done after determining participant’s comprehension of the consent information with the help of a checklist (Appendix 4)

Participants respect, privacy and information confidentiality was protected using a numbered code on all questionnaires. The principal investigator (PI) assigned a study identification number to each subject in the order in which the research subjects enrolled in the study. No names or identifying information was gathered on questionnaires. The PI maintained all consent forms and questionnaires in a locked and secure file cabinet in his home. The benefits and the risks involved in the study were adequately explained to the participants (Appendix 2a and 2b)

The data were entered into STATA software version 10, using only the numeric identification code to identify participants. The data entry was performed only by the PI. After finishing data analysis, all of the administered questionnaires and consent forms were kept safely waiting destruction using a paper shredder after a period of two years.

Our Research finding will be presented to Mathari Hospital inform of continuous medical education and copy of the dissertation left with the institution. The study was also included in the UoN electronic archives for future reference.
Chapter IV: RESULTS

Chapter IV presents the study results of statistical data analysis. The results of the study are presented according to the research questions. The results include sample socio-demographic characteristics, prevalence of antipsychotic side effects, attitude towards medication and adherence to treatment. The significance level was set at p< 0.05.

4.1 Study Participants Characteristics
The study consisted of 164 psychotic patients out of which 91 (55.49%) were males and 73 (44.51%) were females. The mean age of the sample was 33 year (± SD 10.22). The median age was 31 years, with a range of 18-68 years.

Most participants had some form of education, with those with the highest academic achievement of primary education being (39.63%), secondary education (35.98%), college (10.37%) and 14.02% had university education.

More than half of the participants (56.10%) were single, (31.71%) were married and 7.93% were separated. Majority of the participants were taking typical antipsychotics (87.20%) and a few were on atypical antipsychotics (21.34%). Most of the participants were unemployed (46.34%), 16.46% had full time employment, 32.93% were self employed and 4.27% were students (Table 2).
<table>
<thead>
<tr>
<th>Table 2: Study Participants Characteristics (N=164)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td><strong>Education Level</strong></td>
</tr>
<tr>
<td>Primary</td>
</tr>
<tr>
<td>Secondary</td>
</tr>
<tr>
<td>College</td>
</tr>
<tr>
<td>University</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
</tr>
<tr>
<td>Single</td>
</tr>
<tr>
<td>Married</td>
</tr>
<tr>
<td>Separated</td>
</tr>
<tr>
<td>Divorced</td>
</tr>
<tr>
<td>Widowed</td>
</tr>
<tr>
<td><strong>Employment Status</strong></td>
</tr>
<tr>
<td>Full employment</td>
</tr>
<tr>
<td>Self employment</td>
</tr>
<tr>
<td>Unemployed</td>
</tr>
<tr>
<td>Student</td>
</tr>
<tr>
<td><strong>Antipsychotic Medication</strong></td>
</tr>
<tr>
<td>Typical</td>
</tr>
<tr>
<td>Atypical</td>
</tr>
<tr>
<td>Mean</td>
</tr>
<tr>
<td><strong>Age</strong></td>
</tr>
</tbody>
</table>
The commonest diagnosis was schizophrenia, accounting for 77 cases (46.95%); followed by schizoaffective disorder 28 (17.07%); bipolar disorder 24 (14.63%); drug induced psychoses 8 (4.88%) and major depressive disorder 7 (4.27%). Other comorbidities included; 4 (2.44%) epileptic patients; 5 (3.05%) HIV/AIDS patients; 2 (1.22%) diabetic patients and 3 (1.83%) hypertensive patients (Figure 1).

Figure 1: Pie chart showing principal diagnosis among psychiatric outpatients (N=164)

All patients at the time of the study were on neuroleptic medication. Majority of the patients were taking typical antipsychotics (87.20%) and a few were on atypical antipsychotics (21.34%). Haloperidol (57.93%); chlorpromazine (46.95%); Fluphenazine
(29.88%) were the most widely prescribed neuroleptic. Olanzapine was the most widely prescribed atypical antipsychotic medication (see Table 3). Polypharmacy of antipsychotics and concurrent use of anticholinergics, anxiolytics, or hypnotics were more frequently found among participants. Frequently used adjunctive medications were, benzhexol (55.49%), carbamazepine (59.76%), diazepam (9.76%), sodium valproate (7.32%) and amitriptyline (7.93%) and thiamine (5.49%) (Table 3). Almost half more than of the patients were on more than one antipsychotic medication (64%).

Table 3: Commonly Prescribed drugs (N=164)

<table>
<thead>
<tr>
<th>Antipsychotic Medication</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpromazine</td>
<td>77</td>
<td>46.95</td>
</tr>
<tr>
<td>Haloperidol</td>
<td>95</td>
<td>57.93</td>
</tr>
<tr>
<td>Fluphenazine</td>
<td>49</td>
<td>29.88</td>
</tr>
<tr>
<td>Zuclopenthixol (acuphase)</td>
<td>13</td>
<td>7.93</td>
</tr>
<tr>
<td>Flupenthixol</td>
<td>4</td>
<td>2.44</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>4</td>
<td>2.44</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>21</td>
<td>12.80</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>5</td>
<td>3.05</td>
</tr>
<tr>
<td>Risperidone</td>
<td>5</td>
<td>3.05</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adjunct Medications</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzhexol</td>
<td>91</td>
<td>55.49</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>98</td>
<td>59.76</td>
</tr>
<tr>
<td>Sodium Valproate</td>
<td>12</td>
<td>7.32</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>13</td>
<td>7.93</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>9</td>
<td>5.49</td>
</tr>
<tr>
<td>Venlafaxine</td>
<td>1</td>
<td>0.61</td>
</tr>
<tr>
<td>Diazepam</td>
<td>16</td>
<td>9.76</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>2</td>
<td>1.22</td>
</tr>
<tr>
<td>Thiamine</td>
<td>9</td>
<td>5.49</td>
</tr>
</tbody>
</table>
4.2 Prevalence of Medication side effects

Majority of patients reported experiencing at least one side effect due to their medication (94.14%). Sedation and extrapyramidal symptoms were the most frequent adverse events with frequencies of 81.71% and 78.05% respectively. Furthermore, other side effects reported included: anticholinergic side effects (66.46%), weight gain (54.88%), sexual dysfunction (40.24%) and gastro-intestinal side effects (36.56%) (Figure 2). Sedation side effect was highly associated with use of chlorpromazine (odds ratio (OR) =2.92, CI= 1.214-7.018, p= 0.017).

![Figure 2: A bar graph showing the prevalence of side effects from the Glasgow](image)

Many participants (48.78%) were distressed by a number of side effects. These side effects included: sedation (19.51%), sexual dysfunction (7.93%), extrapyramidal side effects (6.71%), anticholinergic side effects (6.71%) and weight gain (5.49%) (Table 4).
Extrapyramidal (p=0.002), anticholinergic (p=0.004), Sexual dysfunction (p=0.043) were rated as statistically significantly more distressing than sedation.

**Table 4: Distressing side effects**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
<th>OR</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedation</td>
<td>32</td>
<td>19.51</td>
<td>1.230</td>
<td>0.104</td>
</tr>
<tr>
<td>Sexual dysfunction</td>
<td>13</td>
<td>7.93</td>
<td>1.141</td>
<td><strong>0.043</strong></td>
</tr>
<tr>
<td>Extrapyramidal side effects</td>
<td>11</td>
<td>6.71</td>
<td>1.325</td>
<td><strong>0.002</strong></td>
</tr>
<tr>
<td>Anticholinergic side effects</td>
<td>11</td>
<td>6.71</td>
<td>1.307</td>
<td><strong>0.004</strong></td>
</tr>
<tr>
<td>Weight gain</td>
<td>9</td>
<td>5.49</td>
<td>1.101</td>
<td><strong>0.231</strong></td>
</tr>
<tr>
<td>Gastro-intestinal side effects</td>
<td>4</td>
<td>2.44</td>
<td>1.250</td>
<td><strong>0.006</strong></td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>48.78</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Extent of side effects**

The extent of side effects was rated as mild, moderate and severe side effects according to Glasgow Antipsychotic Side-effect Scale. The extent of side effects felt by patients was, mild side effects (52.44%), moderate side effects (44.51%) and severe side effects (3.05%) (Figure 3). Majority of those who felt moderate to severe side effects were on more than one antipsychotic medication.
Figure 3: A bar graph showing extent of side effects in the sample population from the Glasgow Antipsychotic Side effect Scale.

4.3 Attitude towards Antipsychotic medication

More than half of the patients had a positive subjective attitude toward antipsychotics. A total of 88(53.65%) of the patients presented a positive attitude towards treatment. Many patients agreed that the good things about medication outweigh the bad (60.98%). Other demographic characteristics including; age, gender, education level and marital status did not statistically significantly influence attitude towards medication. However many (57.32%) also responded “I take medication only when I feel ill”. Severity of side-effects was a significant correlate of attitude, as a large number (65.79%) of patients with moderate side effects had overall negative subjective attitude (p= < 0.001, χ²= 20.02). (Table 5)
**Table 5: Social-demographic and clinical characteristics according to attitude towards treatment.**

<table>
<thead>
<tr>
<th></th>
<th>Positive DAI-10 Score (n= 88)</th>
<th>Negative DAI-10 Score (n=76)</th>
<th>P value</th>
<th>( \chi^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Male)</td>
<td>50 56.81</td>
<td>41 53.94</td>
<td>0.691</td>
<td>0.16</td>
</tr>
<tr>
<td>Single</td>
<td>49 55.68</td>
<td>43 56.58</td>
<td>0.141</td>
<td>3.28</td>
</tr>
<tr>
<td>Employed</td>
<td>9 10.22</td>
<td>18 23.68</td>
<td>0.884</td>
<td>0.02</td>
</tr>
<tr>
<td>Unemployed</td>
<td>41 46.59</td>
<td>35 46.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schizoaffective</td>
<td>14 15.91</td>
<td>8 10.53</td>
<td>0.280</td>
<td>7.23</td>
</tr>
<tr>
<td>Bipolar Disorder</td>
<td>17 19.32</td>
<td>7 9.21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate SE</td>
<td>23 26.14</td>
<td>50 65.79</td>
<td>&lt;0.001</td>
<td>20.02</td>
</tr>
<tr>
<td>Sedation</td>
<td>67 76.13</td>
<td>67 88.15</td>
<td>0.001</td>
<td>12.66</td>
</tr>
<tr>
<td>EPS</td>
<td>61 69.31</td>
<td>67 88.15</td>
<td>0.002</td>
<td>10.39</td>
</tr>
<tr>
<td>Sexual dysfunction</td>
<td>28 31.82</td>
<td>38 50.00</td>
<td>0.024</td>
<td>5.32</td>
</tr>
<tr>
<td>Weight gain</td>
<td>47 53.41</td>
<td>43 48.86</td>
<td>0.994</td>
<td>0.056</td>
</tr>
<tr>
<td>Anticholinergic SE</td>
<td>57 67.77</td>
<td>52 68.42</td>
<td>0.153</td>
<td>2.04</td>
</tr>
<tr>
<td>GIT side effects</td>
<td>25 59.09</td>
<td>35 46.05</td>
<td>0.219</td>
<td>1.53</td>
</tr>
<tr>
<td>Cardiovascular SE</td>
<td>31 35.22</td>
<td>41 53.94</td>
<td>0.003</td>
<td>9.16</td>
</tr>
</tbody>
</table>

**Note**: Patients were grouped according to positive (≥ 0) or negative (≤0) score on the Drug Attitude Inventory (DAI-10), \( \chi^2 \) -Chi-square, SE- side effects, EPS extrapyramidal symptoms
Negative subjective attitude towards medication were positively and statistically significantly associated with side effects including: sedation (p=0.001), extrapyramidal side effects (p=0.002), cardiovascular side effects (0.003) and sexual dysfunction (p=0.003). Weight gain, GIT side effects and anticholinergic side effects did not significantly impact negatively on the attitude towards medication (p>=0.05). Other factors such as male gender, unemployment, higher education level and psychiatric diagnosis (schizophrenia, schizoaffective and bipolar disorder) had no statistical significant effect on attitude (p > 0.05).

4.4 Adherence to Antipsychotic medication

Only 39.63% (n=65) reported complete adherence to medication. Table 7 below summarizes bivariate comparison between characteristics of adherent and nonadherent patients. There were no statistically significant differences in patient characteristics between groups. Variables like gender, high education level, marital status, employment status and psychiatric diagnosis did not significantly impact on patients adherence to medication (p= > 0.05) (Table 6).

Table 6: Characteristic of participants adherent and non-adherent to antipsychotic medication

<table>
<thead>
<tr>
<th></th>
<th>Adherent MARS score (n= 65)</th>
<th>Non-adherent MARS Score (n=99)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Female)</td>
<td>25 38.46</td>
<td>48 48.48</td>
<td>0.761</td>
</tr>
<tr>
<td>Education (university)</td>
<td>12 18.46</td>
<td>11 11.11</td>
<td>0.125</td>
</tr>
<tr>
<td>Marital status (Single)</td>
<td>35 53.84</td>
<td>57 57.58</td>
<td>0.349</td>
</tr>
<tr>
<td>Unemployed</td>
<td>28 43.07</td>
<td>48 48.48</td>
<td>0.118</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>36 55.38</td>
<td>41 41.41</td>
<td>0.907</td>
</tr>
<tr>
<td>Schizoaffective disorder</td>
<td>14 21.53</td>
<td>8 8.08</td>
<td>0.341</td>
</tr>
<tr>
<td>Bipolar Disorder</td>
<td>17 26.15</td>
<td>7 7.07</td>
<td>0.252</td>
</tr>
</tbody>
</table>

Note: Patients were grouped according to adherent (> 6) or non-adherent (<6) score on the Medication Adherence Rating Scale (MARS) calculator
Most side effects were associated with statistically significantly reduced likelihood of adherence. When grouped as side effect clusters in a single model, extrapyramidal symptoms (EPS)/agitation (OR = 0.43, CI=0.286-0.633, p = <0.001), sedation (OR = 0.23, CI= 0.103-0.545, p = 0.001), cardiovascular side effects (OR = 0.81, CI= 0.702-0.925, p = 0.002), and GIT side effects (OR = 0.20, CI= 0.099-0.430, p = 0.037) were all statistically significantly associated with lower rates of adherence. The severity of side effects was also positively associated with nonadherence.

Patients who had moderate to severe side effects were likely to be non-adherent to medication (OR= 0.89, CI=0.812-0.993, p = <0.001). (Table 7). More than half of the patients reported that they sometimes forget to take their medication (57.42%). Some reported that they stopped taking their medication when they felt better or worse. A number of patients did not agree that staying on medication will prevent them from getting sick.

**Table 7: Relationship between side effects and adherence levels**

<table>
<thead>
<tr>
<th>Side Effects</th>
<th>OR</th>
<th>95% Confidence Interval</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedation</td>
<td>0.23</td>
<td>0.103-0.545</td>
<td>0.001</td>
</tr>
<tr>
<td>Extrapyramidal side effect</td>
<td>0.43</td>
<td>0.286-0.633</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sexual dysfunction</td>
<td>0.82</td>
<td>0.651-1.022</td>
<td>0.014</td>
</tr>
<tr>
<td>Weight gain</td>
<td>0.98</td>
<td>0.832-1.148</td>
<td>0.786</td>
</tr>
<tr>
<td>Anticholinergic side effects</td>
<td>0.91</td>
<td>0.818-1.022</td>
<td>0.117</td>
</tr>
<tr>
<td>GIT side effects</td>
<td>0.20</td>
<td>0.099-0.430</td>
<td>0.037</td>
</tr>
<tr>
<td>Cardiovascular side effects</td>
<td>0.81</td>
<td>0.702-0.925</td>
<td>0.002</td>
</tr>
<tr>
<td>Moderate side effects</td>
<td>0.89</td>
<td>0.812-0.993</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Patients who had a positive attitude towards medication had an increased likelihood of adherence to medication (OR=7.41, p= < 0.001). Regression analysis indicated that nonadherence was influenced by negative attitude towards antipsychotic medications (OR= 3.58, CI 2.42-5.29, p= < 0.001) (Table 8).

Table 8: Table showing the relationship between attitude towards medication and adherence

<table>
<thead>
<tr>
<th>Attitude towards Medication</th>
<th>Adherent (n=65)</th>
<th>Non-adherent (n=99)</th>
<th>Odd Ratio</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Drug Attitude</td>
<td>54 83.08%</td>
<td>34 34.34%</td>
<td>7.41</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Negative Drug Attitude</td>
<td>11 16.92%</td>
<td>65 65.65%</td>
<td>3.58</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Majority of patients 112(68.29%), reported of not being counseled on their medication side effects. Those patients who reported to have been counseled on medication side effect had a high likelihood of being adherent (OR= 0.137, CI= 0.066-0.282, p= 0.028).
CHAPTER V: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction
This chapter presents the discussion of the research results within the perspective of previous research literature. The study findings and data analyses are also integrated throughout the discussion. The study limitations, conclusions, implications for the psychiatric practice, and recommendations for future research are also presented.

5.2 Discussions
Our study showed male predominance at 55.49% as has also been revealed by a similar study done by Ndetei et al (11). The likely explanation is that psychiatric illness is commoner in men than women [6, 11]. Median age of the study participants was 31 years. Most psychiatric illnesses become severe and require hospitalization in the early third decade of life [1, 11]. More than half of the participants (56.10%) were single; this may be because of decreased prospects of marriage due to psychoses.

This study attempted to find out the impact of side effect of antipsychotics on attitude towards medication and adherence in psychotic patients. Antipsychotic medication side effects were highly prevalent the participants. In this cross-sectional study of psychotic outpatients at Mathari Hospital, 94.14% of patients reported at least one side effect due to their medication with sedation (81.71%) and extrapyramidal symptoms (78.05%) being the most frequent adverse events reported by the patients. Other reported side effects included; anticholinergic side effects (66.46%), cardiovascular side effects (43.90%), GIT side effects (36.53%), sexual dysfunction (40.24%) and weight gain (54.88%).

Extrapyramidal side effects included: akinesia, akathisia “my legs have felt restless and or I couldn’t sit still”, dystonia “I have been drooling” and tardive dyskinesia “I have had uncontrollable movement of my face and body. Anticholinergic side effects reported included blurred vision, dry mouth and difficulty in passing urine. Cardiovascular side
effects reported included, dizziness when standing up (orthostatic hypotension) and palpitations. GIT side effects included, nausea and vomiting and constipation.

The possible explanation of the high prevalence of side effects is that majority of them [87.20%], were on typical antipsychotic medication, which have been reported to cause more sedation and extrapyramidal symptoms [20, 21, 25]. The high prevalence of side effects in this study is consistent with the findings of prior research [14, 25, 42]. In a cross-sectional survey of patients in the USA with schizophrenia, nearly 80% of patients reported at least one side effect due to their antipsychotic medication [14]. In a study done by Chiang et al [2011], many participants on antipsychotics experienced psychic (80·2%), extrapyramidal (69·8%) and miscellaneous side effects (61·5%) [42].

More than half of the patients of this study had a positive attitudes toward their antipsychotic medications [53.65%]. The type of antipsychotic medication did not significantly interfere with their attitude towards medication. Results of prior studies have been variable, with many reporting a similar pattern of predominantly positive attitudes among their patients [41, 43, 45]. However other studies have indicated that negative attitudes to antipsychotics are also common [56, 57]. However the high proportion of positive attitudes could be a function of the population that was studied, which was mainly made up of chronic, moderately ill and relatively stable patients. These classes of patients are more likely to have positive views about their medications than acutely ill patients [57], because they have been accustomed to the treatment. Several factors that influence patient attitude towards antipsychotic medication have been identified [37, 38, 44-46]. Among all these factors, severity of symptoms and side effects, level of belief, the doctors- patient relationship and attitude of family members have a great influence on patients’ attitude towards antipsychotics [44-46].

Our findings that patients with a higher burden of side effects, were more likely to have a negative attitude toward their medication was in agreement with several previous studies [42-44]. Nevertheless, others studies have shown no association between burden of side-
effects and attitude towards antipsychotics [37, 38, 45, 58]. In a Day et al [2005] study, the quality of relationships with clinicians during acute admission appears to be an important determinant of patients' attitudes toward treatment and adherence to medication [37]. Freudenreich et al [45] showed that, less awareness of current symptoms, presence of deficit symptoms, and employment predicted a negative attitude towards psychiatric medications. Extrapyramidal symptoms did not predict drug attitude. Drug attitudes were no different between patients taking first- or second-generation antipsychotics.

Our study revealed strong associations between side-effects and drug attitudes. The commonest side effects strongly associated with negative towards medication were: sedation (p= 0.001, $\chi^2=12.66$), extrapyramidal symptoms (p=0.002, $\chi^2=10.39$), cardiovascular side effects (p= 0.003, $\chi^2=9.16$) and sexual dysfunctions (p=0.024), probably because majority of patients in this study were on typical antipsychotics which are known to cause many side effects [20, 21, 25]. Remarkably cardiovascular side effects were found statistically and significantly impact negatively on patient attitude toward medication, an observation that has not been mentioned in many other studies [42, 44].

Many studies have shown that nonadherence to medication in psychiatric patients is a major problem [46-50]. The rate of nonadherence with antipsychotics in psychotic disorders varies between studies, because of differences in the populations studied and the methodology used in terms of the definition and measurement of adherence and the period of time over which it is assessed [59]. In our study 39.63% of patients reported complete adherence to their medication. Lacro et al [46] reviewed the studies published between 1980 and 2000 which identified risk factors for medication nonadherence. Across these studies, the mean non-adherence frequency was 40.5% (median=40%, range=4-72%).

Non-adherence in more recent studies was reported to be 48.4% (USA, nationwide, N=876, self-report) [16], 40.3% (Nigeria, N=313, self-report) [59]. A review of dropout
rates in clinical trials found that 28%-55% of schizophrenia patients drop out of clinical trials before the study is complete; dropout rates were higher with classic antipsychotic medications compared with second generation antipsychotic medications due to side effects [49]. Our study found a higher rate of non-adherence to antipsychotic medication among psychiatric outpatients at Mathari Hospital (60.36%). A large proportion 57.32% of patients indicated that they only take medication only when they feel sick. This implies that the patients are more likely to become non-adherent when psychiatric symptoms disappear.

It is also important to acknowledge that non-adherence is not necessarily irrational or misguided behavior. Non-adherence is highly influenced by patient knowledge, attitudes towards their illness and medication, side effects, as well as past experiences with their illness and its treatment [59]. Our study has revealed that the more the side effects, the less the likelihood of adherence. Extra pyramidal symptoms (OR = 0.43, p = <0.001), sedation (OR = 0.23, p = 0.001), cardiovascular side effects (OR = 0.81, p = 0.002), and GIT side effects (OR = 0.20, p = 0.037) were all statistically significantly associated with lower rates of adherence. These results are in agreement with other previous studies [42]. In this study weight gain as a side effect was not significantly associated with decrease in adherence rate [p= > 0.05]. This is in contrast with previous studies which indicated a negative association between weight gain and adherence [22, 23]. Perhaps these are chronic stable patients who have been accustomed to some side effects like weight gain, whose benefits does not outweigh the risk of stopping the medication.

A patient who perceives a drug as beneficial and important to their recovery may continue to take it despite it causing significant side effects. In contrast, a patient who sees little benefit from medication and is unconvinced by the explanation of their diagnosis or need for pharmacotherapy may stop treatment at the first sign of a side effect that causes relatively minor inconvenience to others [61]. It is important to explain to the patient the likelihood of side effects and come up with strategies of managing the side effects as soon as they are noted by the patient.
5.3 Conclusions
The findings showed that there was a high prevalence of antipsychotic side effects. Attitude towards antipsychotics was principally determined by the severity of side effects. Most patients did not completely adhere to their medications because of side effects. However patients who had a positive attitude towards medication had a high likelihood of adherence.

5.4 Recommendations
There is high prevalence of side effects due to use of typical antipsychotic which would consequently lower adherence and have some negative attitude towards the treatment. Therefore, effort should be done to improve patient’s attitude towards treatment by treating side effects adequately and counseling the patient about his or her medication. Most importantly, clinicians should develop treatment strategies where the regimen with minimal side effects is chosen.

Further research should be done to identify other risk factors for non-adherence among psychotic patients in Kenya.

5.5 Limitations
Firstly, as common with cross-sectional studies which involve self-reports and also recall bias, our participants may have either underreported or over reported their experience with side effects and their adherence level. Regardless of the actual reason for the experienced "side effect", a patient's perception of the reason for the side effect may be more important in predicting adherence. This limitation was minimized by confirming information about the patient medication history and diagnosis from the patient files.

It is possible that unobserved confounding may have influenced the observed results. For example, severity of the disease, polypharmacy, medication costs, among other variables, are likely associated with non-adherence but were not included in the current study. This limitation was minimized by recruiting stable patients who were on medication.
REFERENCE

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15. Nosé M, Barbui C, Tansella M. How often do patients with psychosis fail to adhere to treatment programmes? a systematic review. Psychol Med. 2003; 14(7):1149–1160. doi:


47. Marder S.R. Monitoring treatment and managing adherence in schizophrenia. [J Clin Psychiatry. 2013 Oct;74(10):e21


APPENDICES

Appendix 1: Proposal Approval Letter

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 35675 Code 00202
Telegram: varsity
(254-020) 2782300 Ext 44355

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 752106-8
Fax: 752172
Telegram: MEDSUP, Nairobi

Ref: KNH-ERC/CA/221

Dr. Edward Okinda Katavi
Dept. of Pharmaceutics and Pharmacy
School of Pharmacy
University of Nairobi

Dear Dr. Katavi

Research proposal: Impact of side effects of Antipsychotics on attitude and adherence to treatment among adult psychiatric outpatients at Mathari Hospital in Kenya (P159/03/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 4th July 2014 to 3rd July 2015.

This approval is subject to compliance with the following requirements:

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

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

Protect to Discover
Yours sincerely,

[Signature]

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

c.c. The Principal, College of Health Sciences, UoN
     The Deputy Director CS, KNH
     The Chairperson, KNH/JON-ERC
     The Assistant Director, Health Information, KNH
     The Dean, School of Pharmacy, UoN
     The Chairman, Dept. of Pharmaceutics and Pharmacy Practice, UoN
     Supervisors: Dr. David Nyamu, Dr. T.B. Menge,
Appendix 2: Study Eligibility Check List

Impact of Side Effects of Antipsychotics on Attitude and Adherence to Treatment among Adult Psychiatric Outpatients at Mathari Hospital in Kenya

Date:
Clinician signature:

Part A: Inclusion criteria (if any of the criteria is marked NO the participant is not eligible for enrolment)

Yes  No
[   ]  [   ]  1. Psychiatric outpatient
[   ]  [   ]  2. Participant who is mentally stable
[   ]  [   ]  3. Participants who can read in English or Swahili

Is the participant eligible for the study?

Yes [   ]  No [   ]

This form will be completed by the clinician attending to the patient then handed to the researcher through the participant.
Appendix 3a: Consent Explanation Form

Title: Impact of Side Effects of Antipsychotics on Attitude and Adherence to Treatment among Adult Psychiatric Outpatients at Mathari Hospital in Kenya

To be read and questions answered in language in which the subject is fluent in (Kiswahili or English).

Introduction
My name is Dr. Edward Okinda Katayi, a postgraduate student in Clinical Pharmacy at the University of Nairobi. As part of my training I am required to carry out a research project. This study by my team and I seeks to determine the impact of side effects of antipsychotics on attitude and adherence to treatment among adult outpatients at Mathari hospital. I would like to seek your permission to participate in the study.

Your agreement to enroll is voluntary and you will be at liberty to opt out from the study any time. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled to.

Study Title
Impact of Side Effects of Antipsychotics on Attitude and Adherence to Treatment among Adult Psychiatric Outpatients at Mathari Hospital in Kenya

Objectives
To determine the impact of antipsychotics side effects on the patient attitude towards antipsychotic treatment and adherence among psychiatric adult outpatients at Mathari Psychiatric Hospital

Confidentiality
Study participants will be assured of confidentiality and anonymity. Their names will only appear on the consent form, which will be signed and kept separately by the principal investigator for identification.

Other study documents and research instruments will be identified only by a serial number. Access to the data will be limited to the principal investigator.
**Study Implementation**

The researcher will interview and administer the questionnaires to you. The administration of questionnaire will take 15 to 20 minutes. All information will be handled with confidentiality and will only be used for the purpose of this study.

**Participation**

Your agreement to participate in this study is voluntary. You are free to opt out from the study at any point without necessarily giving any reason and this will not in any way jeopardize the care that you are receiving at this hospital.

**Benefits**

The findings of the study will assist the clinicians in formulating better treatment strategies.

For those patients suffering from side effect, appropriate information will be given to help in alleviating the symptoms.

**Risks**

Participant will be asked some questions concerning their private life e.g. their sexuality and how they perceive their body.

Participants will be asked some questions concerning their social life e.g. how the drugs affect their social life and well being.

There are no anticipated physical risks which will occur during your participation in the study. The research will involve use of interviews and questionnaires to collect data and no physical examination or invasive procedures will be used.

**Question**

In case of any questions or clarifications about the study, you are free to contact any of the persons in the contacts provided below. If you have any ethical concerns or questions about your rights as a patient you may contact the Secretary of Kenyatta National Hospital /University of Nairobi /Ethical and Research Committee (KNH/UoN-ERC). Full contacts are provided below.
Contacts

1. Principal investigator (PI)
   Dr. Edward O. Katayi, Post-graduate student (Clinical Pharmacy),
   Department of Pharmaceutics and Pharmacy Practice, P.O. Box 30197–00400, School of
   Pharmacy, University of Nairobi, Mobile Number: +254 723006706

2. The first Supervisor;
   Dr. David Nyamu
   Lecturer, Department of Pharmaceutics and Pharmacy Practice, P.O. Box 30197–00400,
   School of Pharmacy, University of Nairobi, Department’s telecom No: 2726300 Ext. 43673

3. The second supervisor;
   Dr. T.B Menge
   Lecturer, Department of Pharmaceutics and Pharmacy Practice, P.O. Box 30197–00400,
   School of Pharmacy, University of Nairobi, Department’s telecom No: 2726300 Ext. 43673

4. The Secretary, KNH/UoN-ERC
   Kenyatta National Hospital,
   P.O Box 20723-00202, Nairobi
   Tel No. 2726300-9 / 2716450 ext. 44102, Fax: 725272

Ethical Approval

Ethical approval will be granted by Kenyatta National Hospital /University of Nairobi
/Ethical and Research Committee (KNH/UoN-ERC) to conduct this study at the KNH,
medical outpatient clinic.
I, therefore, kindly request you to sign the attached consent form. Thank you for your
consideration.
Appendix 3b: Fomu ya Mapelezo ya Kukubali

Athari za Madhara ya Madawa ya Magonjwa ya Akili Juu ya Tabia na Kuzingatia Matibabu Miongoni mwa Wagonjwa wa Akili Katika Hospitali ya Mathari Inchini Kenya

Isomwe kwa lugha anayoilewa mshiriki.

Utangulizi
Jina langu ni Dr. Edward Okinda Katayi; Mwanafunzi wa shahada ya uzamili ya utabibu wa dawa katika shule ya famasia, chuo kikuu cha Nairobi. Nafanya utafiti juu ya athari za madhara ya madawa ya magonjwa ya akili juu ya tabia na kuzingatia matibabu miongoni mwa wagonjwa wa akili katika hospitali ya Mathari inchini Kenya.
Hivyo basi, nakuomba kwa ruhusa yako ukubali kushiriki katika utafiti huu. Tafadhali jisikie huru kuuliza maswali yoyote wakati ninapokupatia maelezo ya nini kitafanyika.

Utafiti
Athari za Madhara ya Madawa ya Magonjwa ya Akili Juu ya Tabia na Kuzingatia Matibabu Miongoni Mwa Wagonjwa wa Akili katika Hospitali ya Mathari inchini Kenya

Malengo
Lengo kuu la utafiti huu ni kubainisha athari za madhara ya madawa ya magonjwa ya akili juu ya tabia na kuzingatia matibabu miongoni mwa wagonjwa wa akili.

Utekelezaji wa Utafiti
Utafiti itakuwa kwa njia ya mahojiano na kujibu maswali. Hi yote itachukua muda wa dakika 15 hadi 20. Taarifa yote itachukuliwa kwa siri na kutumika tu kwa ajili ya utafiti huu pekee.

Ushiriki
Kukubali kwako kushiriki katika utafiti huu ni hiari. Uko huru kujitoa katika utafiti huu katika hatua yoyote bila lazima ya kutoa taharifa na hii haitaathiri kwa aina yoyote huduma anazopata katika hospitali ya Mathari.

Faida
Matokeo ya utafiti itasaidia daktari kuunda njia bora ya kutibu magonjwa yake.
Ikiwa utapatika kuwa na shida na ikiwa utakuwa na swali lolote kuhusu utumizi wa madawa yako utasaidiwa njia ya kupunguza shida hizo.

**Hatari**

Baadhhi ya maswali yatahusu maisha yako kwa kibinafsi kwa mfano habari kuhusu maisha yako ya mapenzi.

Baadhhi ya maswali yatahusu mahusiano yako kwa wakuwengene wa karibu. Maswali haya yanaweza uhisi vibaya.

Hakuna matarajia ya hatari ya kimwili ambayo yatatokea wakati wa kushiriki kwako.

Utafiti utafanyika kwa njia ya matumizi ya mahojiano na maswali na hakuna uchunguzi wa kimwili utakaofanyika.

**Usiri**

Taharifa zote utazotoa zitatumika kwa usiri mkubwa, namba zitatumika badala ya jina lako kwa ajili ya kuhifadhi utambulisho wako, taharifa zitakazokusanywa zitahifadhiwa na mtafiti mkuu pekee chote cha utafiti.

**Maswali**

Kwa maswali zaidi au ufafanuzi juu ya utafiti huu unaweza kuwasiliana na yeyote kati ya anwani zilizoandikwa hapo chini. Kama una wasi wasi wa kimadili au maswali kuhusu haki zako kama mgonjwa unaweza kuwasiliana na katibu wa hospitali ya taifa ya Kenyatta/chuo kikuu cha Nairobi/Kamaty ya maadili ya utafiti (KNH/UON-ERC).

Mawasliano kamili hapo chini.

**Mawasiliano.**

1. Mtafiti mkuu;
   Dkt. Edward Okinda Katayi , mwanafunzi uzamili (utabibu dawa),
   Idara ya Pharmaceutics na Pharmacy Practice, S.L.P 30197–00400, Shule ya Pharmacy,
   Chuo kikuu cha Nairobi, Simu Namba: +254 705 144 687.

2. Msimamizi wa kwanza;
   Dkt. David Nyamu
   Mhadhiri, Idara ya Pharmaceutics na Pharmacy Practice, P.O. Box 30197–00400, Shule
   ya Pharmacy, chuo kikuu cha Nairobi, simu ya idara No: 2726300 Ext. 43673
3. Msimamizi wa pili;
Dkt. T.B Menge.
Mhadhiri, Idara ya Pharmaceutics na Pharmacy Practice, P.O. Box 30197–00400, Shule ya Pharmacy, chuo kikuu cha Nairobi, simu ya idara No: 2726300 Ext. 43673
3. Katibu mkuu, KNH/UoN-ERC
Hospitali ya taifa ya Kenyatta,
S.L.P 20723-00202, Nairobi
Tel No. 2726300-9 / 2716450 ext. 44102, Fax: 725272

Uthibitisho wa kimaadili
Utafiti huu utathibitishwa kimaadili na Hospitali ya taifa ya Kenyatta/chuo kikuu cha Nairobi/ Kamati ya maadili ya utafiti (KNH/UoN-ERC) ili ufanyike Hospitali ya Mathari kliniki ya wagonjwa wan nje.
# Appendix 4: Assessment of Comprehension of Consent Information Check List

To be read in a language the participant understands better.

<table>
<thead>
<tr>
<th>Patient Serial No.</th>
<th>Date:</th>
<th>Open ended question/ Statement</th>
<th>Required points of comprehension.</th>
<th>√</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>Please describe your understanding of the purpose of the study?</td>
<td>1. How side effects influence adherence.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>What do you understand about the possible risks of participating in this study?</td>
<td>1. A feeling of stigmatized</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. No physical harm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>What are the benefits of participating in the study?</td>
<td>Counseling, management of side effects.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>What should the participant do if he or she has a question about the study or a problem related to being in the study?</td>
<td>Conduct the study staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>Are the participants who join the study allowed to leave the study?</td>
<td>Although participants will be asked for the option of staying in the study, yes he or she may opt out of the study without penalty.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Instruction:** Ask the question and then tick each sub-item the participant demonstrate comprehension.

For items that are ticked, commentary category a or b should appear.

For items that are not ticked, comment category c or d should appear

Comment category

a-Answered correctly on first try
b-Answered correctly after probing
c-Could not answer.

Staff signature …. 

To be completed by the researcher before administering the questionnaire
Appendix 5a: Consent Declaration Form

Title: Impact of Side Effects of Antipsychotics on Attitude and Adherence to Treatment among Adult Psychiatric Outpatients at Mathari Hospital in Kenya

I ________________________________ (name of participant), being 18 years and more and having full capacity to consent, hereby do consent to voluntarily participate in this study. The nature of the study has been explained to me by the principal investigator and I have been given opportunity to ask questions concerning the study which have been answered to my satisfaction. The benefits and risks of this study have been clearly explained to me and I am aware that I am free to withdraw from this study at any point and this will not jeopardize the care I receive at the hospital.
I therefore give consent to be interviewed and answer the questionnaires and that information from my file can also be used having understood the purpose of the study.
Signature:
Date:

Researcher’s Declaration Statement

I ________________________________.Being the study researcher have adequately explained to the above named participant on the nature and purpose of the study and has agreed to voluntarily participate in the study.
Signature:
Date:
Contacts: 0723006706.
Appendix 5b: Tibithisho la Kushiriki

Mimi……………………………… (jina la mshiriki), nikiwa na umri wa miaka 18 au zaidi na nikiwa na akili timamu ya kushiriki kwenye utafiti huu. Ninakubali kushiriki kwenye utafiti huu. Aina ya utafiti na yatakayofanyika nimeelezwa kwa ufasaha na mtafari mkuu, nimepewa fursa ya kuuliza maswali na kupata ufadhaanu zaidi, nimeridhika. Faida ya matokeo ya utafiti huu nimeelezwa na nimelewa kwamba naweza kujitoa katika utafiti huu wakati wowote bila kuhathiri huduma ninazopata hospitalini hapa. Kwahayo ninaruhusu kuuliza maswali na kujibu maswali na kuchukuliwa kwa taharifa za matibabu yangu katika faili langu kwa madhumuni ya utafiti huu.

Sahihi:
Tarehe:

Azimio la Mtafiti

Mimi ………………………………… Nikiwa mtafari wa utafiti huu nimeelezea vya kutosha mshiriki juu ya asili na madhumuni ya utafiti na amekubali kwa hiari kushiriki katika utafiti.

Sahihi:
Tarehe:

Numbari ya simu : 0723006706
Appendix 6: Socio-Demographic and Patient Clinical Data Questionnaire

1. Serial No. Date.
2. Age in years:
3. Gender. Male [ ] or Female [ ]
4. Education Status. Informal [ ] Primary [ ] Secondary [ ] College [ ] or University [ ]
5. Employment Status. Employed Full Time [ ] Self-Employed [ ] Unemployed [ ] Student [ ]

Patient Clinical Data

6. Psychiatric Diagnosis ……..
7. Other comorbidities………..
8. Antipsychotic medication(s) and total daily dose

<table>
<thead>
<tr>
<th>Antipsychotic Medication(s)</th>
<th>Daily dose</th>
</tr>
</thead>
</table>

Other medication(s)

9. Have you been counseled about your medication Yes [ ] No [ ]
Appendix 7a: Glasgow antipsychotic Side-Effect Scale (GASS) Modified Version

Serial No: 
Date: 

This questionnaire is about how you have been recently. It is being used to determine if you are suffering from excessive side effects from your antipsychotic medication. Please place a tick in the column which best indicates the degree to which you have experienced the following side effects.

Also tick the end of last box if you found that the side effect was distressing for you.

<table>
<thead>
<tr>
<th>Over the past week</th>
<th>Never</th>
<th>Once</th>
<th>A few times</th>
<th>Everyday</th>
<th>Tick this box if distressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I felt sleepy during the day.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I felt like drugged or like a zombie</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I felt dizzy when I stood up and/or have fainted.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I have felt my heart beating irregularly or unusually fast.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. My muscles have been tense or jerky</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. My hands or arms have been shaky</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. my legs have felt restless and /or I couldn’t sit still</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Saliva has been coming out of my mouth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. my movements or walking have been slower than usual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. I have had uncontrollable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
movement of my face or body.

11. My vision has been blurry

12. My mouth has been dry.

13. I have had difficulty passing urine.

14 (a) I have felt like I am going to be sick or have vomited.

14 (b) I have had a problem opening my bowel (constipation)

15. I have wet the bed

16. I have been very thirsty and/or passing urine frequently.

17. The areas around my nipple have been sore and swollen.

18. I have noticed fluid coming from my nipples

19. I have had problem enjoying sex

20. **Men only.** I have had problem getting an erection,

<table>
<thead>
<tr>
<th>Tick yes or no for the last three months</th>
<th>Yes</th>
<th>No</th>
<th>Tick this box if distressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. <strong>Women only.</strong> I have noticed a change in my periods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. <strong>Men and women.</strong> I have been gaining weight.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

THANK YOU FOR YOUR PARTICIPATION
Appendix 7b: Glasgow Antipsychotic Side-Effect Scale (GASS) Modified Version (Swahili Translation)

Nambari ya kujitambulisha:
Tarehe:
Maswali haya ni kuhusu jinzi umekua ukijihisi hivi karibuni. Yatatumika kubainisha madhara ya madawa ya akili unayoyatumia. Weka alama kulingana na kiwango cha madhara unayohisi.
Weka alama mwisho wa sanduku kama madhara haya yanakusumbua zaidi

<table>
<thead>
<tr>
<th>Wiki iliopita</th>
<th>Hapana</th>
<th>Mara moja</th>
<th>Mara chache</th>
<th>Kila siku</th>
<th>Weka alama kama inakusumbua sana</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nahisi usingizi mchana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Sijifahamu</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Nahisi kizunguzungu nikisimama</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Naskia moyo ukipiga</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Misuli yangu hukakamaa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Mikono yangu inatingika</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Miguu yangu inahisi kutotulia/ Siwezi kaa mahali pamoja.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Mate imekua ikitoka kwa mdomo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Mwendo wangu umekua wa pole.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Uso wangu unasonga songa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Sioni vizuri</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Mdomo wangu umekua mkavu</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Nimekua na ugumu wa kukoja.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Nimekua na shida kwenda haja kubwa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 8a: Drug Attitude Inventory (DAI-10)

Serial no:
Date:
The aim of this questionnaire is to gain some understanding of what people think about medications and what experiences people have on them. Your answers will be used for research purposes only, are strictly confidential and will in no way affect your treatment.

How to fill in this questionnaire:-
1. Read each statement and decide whether it is true as applied to you or false.
2. If a statement is TRUE to you, circle the T at the end of the line.
3. If a statement is FALSE to you, circle the F at the end of the line.
4. If you want to change an answer, mark an X over the incorrect answer and circle the correct answer.
5. If a statement is not worded quite the way you would put it, please decide whether the answer is mostly true or mostly false to you.
There is no right or wrong answer. Please give YOUR OWN OPINION, not what you think we might want to hear.
Do not spend too much time on any one question.
Please answer every question.
The medications referred to are those for mental health needs only.

<table>
<thead>
<tr>
<th></th>
<th>For me the good things about medication outweigh the bad.</th>
<th>T F</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>I feel strange “doped up “on medication.</td>
<td>T F</td>
</tr>
<tr>
<td>3</td>
<td>I take medications of my own free choice.</td>
<td>T F</td>
</tr>
<tr>
<td>4</td>
<td>Medications make me feel more relaxed.</td>
<td>T F</td>
</tr>
<tr>
<td>5</td>
<td>Medication makes me feel tired and sluggish.</td>
<td>T F</td>
</tr>
<tr>
<td>6</td>
<td>I take medication only when I feel ill.</td>
<td>T F</td>
</tr>
<tr>
<td>7</td>
<td>I feel more normal on medication.</td>
<td>T F</td>
</tr>
<tr>
<td>8</td>
<td>It is unnatural of my mind and body to be controlled by medication.</td>
<td>T F</td>
</tr>
<tr>
<td>9</td>
<td>My thoughts are cleared on medication.</td>
<td>T F</td>
</tr>
<tr>
<td>10</td>
<td>Taking medication will prevent me from having a breakdown.</td>
<td>T F</td>
</tr>
</tbody>
</table>

**Appendix 8b: Drug Attitude Inventory (DAI-10) (Swahili Translation)**

Nambari ya kutambulisha:

Tarehe:

Lengo la dodoso hili ni kupata baadhi ya ulewawa wa nini watu wanadhani kuhusu dawa na uzoefu wao juu ya dawa hizo. Majibu yako zitatumika kwa madhumuni ya utafiti tu, ni madhubuti za siri na hakuna njia ya kuathiri sana matibabu yako.

Jinsi ya kujaza dodoso hili; -

1. Soma kila kauli na kuamua kama ni kweli kulingana na wewe au uongo.
2. Kama taarifa ni kweli kulingana na wewe, weka alama kwa Ndio.
Usitumie muda mwingi kujibu swali moja. Jibu maswali yote.
Maswali haya yana husu madawa ya magonjwa ya akili pekee.

<table>
<thead>
<tr>
<th>Swali/ taarifa</th>
<th>Ndio</th>
<th>La</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huwa unasahau kumeza dawa?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Huwa unazingatia wakati wa kumeza dawa?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unapopata nafuu ,huwa unawacha kumeza dawa?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wakati mwingine ukihisi vibaya ukimeza dawa huwa unawacha kuzitumia?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Huwa nameza dawa nikiwa mgonjwa?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Si kawaida akili na mwili wangu kutegeMEA dawa.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mawazo yangu yako sawa nikiwa natumia dawa.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kwa kuendelea kumeza dawa nazuia kuwa mgonjwa.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Madawa yananifanya kuwa mlegevu.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matumizi ya dawa yatanizuia mimi kujihisi vibaya</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 9a: Medication Adherence Rating Scale (M.A.R.S Calculator)

Serial No:
Date:

<table>
<thead>
<tr>
<th>No.</th>
<th>Question / Statement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Do you ever forget taking medication?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Are you careless at times about taking your medication?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>When you feel better, do you sometimes stop taking your medication?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Sometimes when you feel worse when you take medicine, do you stop taking it?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>I take my medication only when I am sick.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>It is unnatural for my mind and body to be controlled by medications.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>My thoughts are cleared on medication.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>By staying on medication, I can prevent getting sick.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>I feel weird, like a zombie on medication.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Medication makes me feel tired and sluggish.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 9b: Medication Adherence Rating Scale (M.A.R.S Calculator) (Kiswahili Translation)

Namabri ya kujitambulisha:
Tarehe……

<table>
<thead>
<tr>
<th>Nambari</th>
<th>Swali</th>
<th>Ndio</th>
<th>La</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Huwa unasahau kumeza dawa?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Huwa unazingatia wakati wa kumeza dawa?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Unapopata nafuu huwa unawacha kumeza dawa?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Wakati mwingine ukihisi vibaya unapozitumia dawa, huwa unawacha kuzitumia?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Huwa nameza dawa nikiwa mgonjwa.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Si kawaida akili na mwili wangu kutegemea dawa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Mawazo yangu yako sawa nikiwa kwa madawa.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Kwa kuendelea kumeza dawa nazuia kuwa mgonjwa.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Nahisi kutojifahamu nikiwa kwa madawa.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Madawa yananifanya kuwa mlegevu.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ASANTE KWA KUSHIRIKI