

**The Prevalence and Predictors of Antipsychotic Medication Non-adherence among
Clients with Psychotic Disorders in Mzimba, Malawi**

By

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DECLARATION

I, Japhet Myaba, declare that the work of this dissertation is my original work (except where acknowledgement indicate otherwise) and that neither part of it or whole has never been, or is being , or is to be submitted for another degree in this or any other higher learning institution.

Signature:

Signed by candidate

May, 2017

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DEDICATION

This dissertation is dedicated to my family members, my wife Tiwonge and two sons, Blessings and Brian. You cooperated when I was busy with my studies, and Tiwonge your continuous moral support was encouraging.

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ACRONYMS AND ABBREVIATIONS

MNS	Mental, Neurological and Substance use
LMIC	Low and Middle Income Countries
HIC	High Income Countries
W H O	World Health Organisation
AUDIT	Alcohol Use Disorder Identification Test
HIV	Human Immunodeficiency Virus
SPSS	Statistical Package for Social Sciences
UK	United Kingdom
USA	United States of America
APA	American Psychiatrist Association
EMEA	Europe, Middle East and Africa
YLD	Years Lived with Disability
YLL	Years of Life Lost
DALY	Disability-adjusted life years
MEMS	Medication Event Monitoring System
NICE	National Institute for Health and Clinical Excellence
FGA	First Generation Antipsychotics
SGA	Second Generation Antipsychotics
OR	Odds Ratio
CI	Confidence Interval

ABSTRACT

Background: Mental, neurological and substance use (MNS) disorders significantly contribute to the burden of diseases worldwide. Schizophrenia is one of the severe forms of MNS disorders. Antipsychotic medications play a significant role in the treatment and management of schizophrenia. However, non-adherence to antipsychotic medication is a recognized problem. At the present time, a majority of the research investigating non-adherence to medication in this population has been conducted in high income countries, with only a few studies available from low and middle income countries such as Malawi. This study aimed at determining the prevalence and predictors of antipsychotic non-adherence among clients with psychosis in Mzimba district, Malawi. The factors were categorized into patient-related, medication related and environmental related.

Methodology: This was a hospital based quantitative study conducted in Mzimba, Malawi. 150 patients attending outpatient treatment facilities from three mental health clinics were recruited in the study. All recruited participants had a diagnosis of psychosis. The recruitment process targeted every potential participant during a clinic day. Potential participants were approached by the research assistant after their appointment with the healthcare provider to participate in the study. The following measures were included in the interview administered survey: 1) the Morisky Medication Adherence Scale-8; the Birchwood Insight Scale; the Drug Attitude Inventory-10; the Glasgow Antipsychotic Side-effects Scale; a Social Support questionnaire, and the Alcohol Use Disorder Identification Test. A logistic regression model was developed to investigate the associations between socio demographic and illness related factors and non-adherence to medication. Ethical approval to conduct the study was obtained from the Faculty of Health Sciences Research Ethics Committee at the University of Cape Town before the beginning of the study. Ethical approval was also obtained from National Health Sciences Research Ethics Committee in Malawi.

Results: More than half of the participants were male (n=84). The average age of all participants was 34 years of age (sd=9.40). 43.9% of the respondents were identified as non-adherent (n=66). In the unadjusted logistic regression model, the amount of insight clients had about their mental illness, the side effects of antipsychotic medication, and the form or type of medication, were all found to be significantly associated with antipsychotic medication non-adherence. For example, participants with poor insight were less likely to adhere to antipsychotic medication (OR=0.48, 95% CI 0.24-0.95). When these three variables

were adjusted for age and gender, they all predicted non-adherence to antipsychotic medication; insight (OR=0.42, 95% CI 0.20-0.90); side effects (OR=1.10, 95% CI 1.03-1.17); and medication type or form (OR=0.30, 95% CI 0.15-0.91).

Conclusion: The study was the first to be conducted in Mzimba, Malawi in order to investigate non-adherence rates among patients with psychosis. Similar to other studies conducted globally, the non-adherence rates to antipsychotic medication reported in the present study was high. The risk factors predicting non-adherence have the potential to assist in the development and delivery of interventions to address medication non-adherence among this population.

Key words: Non-adherence, Psychosis, Schizophrenia, Antipsychotic Medication

CHAPTER ONE: INTRODUCTION

1.0 Background

Mental, neurological and substance use (MNS) disorders significantly contribute to the burden of diseases worldwide. MNS disorders account for 10.4 % of the disability-adjusted life years (DALY) globally (Whiteford et al., 2015), and almost 75% of this burden lies in low- and middle-income countries (LMIC) (Whiteford, 2013). In 2010, MNS disorders were directly responsible for 17.3 million years lived with disability (YLDs) and 8.6 million years of life lost (YLL), equivalent to 232 000 deaths (Whiteford et al., 2013).

One of the most debilitating MNS disorders is schizophrenia. It is also one of the most disabling psychotic disorders (APA, 2013). A person with schizophrenia or psychosis presents with a number of different symptoms. Some may hear voices while no one is around, have fixed false beliefs and interference with thinking, and some can present with disorganized behaviours (Gelder, Harrison & Cowen, 2006). These symptoms are also known as positive symptoms of schizophrenia (Lally & MacCabe, 2015) . Some people with schizophrenia also present with other symptoms known as negative symptoms (Sarkar, 2015). These include: slowness, lack of drive, social withdrawal, unchanging facial expression, poverty of content of speech, and in persistence of work or school (APA, 2013). Positive or negative symptoms of psychosis are as a result of brain neurotransmitter (dopamine) dysregulation or reduction of the neurotransmitters in the brain. For instance, Lally & MacCabe, 2015 report that the dysregulation of dopaminergic circuits with excess dopaminergic activity in the mesolimbic pathway leads to positive symptoms of psychosis. Furthermore, negative symptoms are conceptualized to be caused by the reduction of dopaminergic signalling in the mesocortical pathway. Therefore, the antipsychotic medications which are given to someone with a diagnosis of psychosis, acts as antidopaminergic agent. They block the dopamine D2 receptors, hence controlling the symptoms. Although the prevalence of schizophrenia varies from one country to another, it affects around 0.3% to 0.7% of people worldwide at some point in their life time (Van & Kapur, 2009).

Schizophrenia is considered to have a high cost of illness due to the range of health needs that are required. For instance, in the United Kingdom it was found that the estimated total societal cost of schizophrenia was 6.7 billion pounds (US \$9.9 billion) in 2004/05 (Mangalore & Knapp, 2007). In Ireland, an estimated total cost of €460.6 million (US \$494.4

million) in 2006 was reported (Behan, Kennedy & O'Callaghan, 2008). Furthermore, the total cost of lost productivity due to unemployment, absence from work and premature mortality was €277 million (US \$297.3 million) in Ireland. Developing countries are not exempt from these high costs. In Thailand, the annual overall cost of schizophrenia was estimated at 2600 US dollar per person, and at 925 million U.S dollar for the entire population with schizophrenia (Phanthunane et al., 2012). Schizophrenia significantly impacts on the lives of those who live with this disease and places a large burden on those who care for them, often resulting in life-time lost productivity (Awad & Voruganti, 2008).

There is evidence that the management of schizophrenia requires a package of evidence-based interventions which ease the burden for people living with schizophrenia and their caregivers (Awad & Voruganti, 2008). This package of care includes medication, psychotherapy, coping guidelines for the family and self-help methods of treatment (Grohol, 2013; Awad & Voruganti, 2008). Among the numerous interventions provided to people living with schizophrenia, antipsychotic medication is essential for long-term clinical management and is a key determinant for good prognosis (Canadian Psychiatric Association, 2005). Non-adherence to antipsychotic medication can lead to relapse, interpersonal relationship problems, discontinuation of education or work and stigmatization, all leading to low self-esteem and reduced quality of life (Kane, 2007).

Adherence is defined as the extent to which a patient's medication taking matches that agreed with prescriber (Haddad, Brain, & Scott, 2014). Compliance to medication is sometimes used interchangeably with adherence. Despite the interchangeable use of the words, compliance refers to unequal power balance between the prescriber and patient (Haddad et al., 2014). In this case, there is no mutual agreement to what has been prescribed. In contrast to compliance, WHO also defines adherence as the extent to which a person's behaviour corresponds with agreed recommendations from a health care provider (Sabate, 2001). In adherence there is patient's agreement to the recommendations i.e. patient takes part in the decision of the recommendations from the doctor or physician.

Despite the importance of medication in the management of schizophrenia, non-adherence to prescribed medication has been recognized as a problem worldwide and may be one of the most challenging aspects of treating people living with schizophrenia (WHO, 2003). A number of studies, predominantly from high income countries (HIC), have investigated adherence to antipsychotic medication and report that the prevalence of non-adherence range

from 20% to 89% (Lieberman et al., 2005) among people living with schizophrenia. Although a few studies have been conducted in LMIC, such as Ethiopia and Tanzania (Teferra et al., 2013; Sariah et al., 2014), there have been no studies that have investigated adherence to antipsychotic medication in Malawi. Therefore, the present study addresses this gap by investigating the prevalence and predictors of non-adherence among clients suffering from psychosis in Malawi.

1.2 Aim

The aim of the study was to determine the prevalence and predictors of antipsychotic non-adherence among clients with psychosis in Mzimba district.

1.3 Study objectives

This study specifically was done:

1. To determine the prevalence of antipsychotic medication non-adherence among clients with psychosis in Mzimba.
2. To determine patient-related, medication-related and environmental-related factors associated with non-adherence in clients with psychosis in Mzimba.

CHAPTER TWO: LITERATURE REVIEW

2.0 Introduction

The section begins by defining schizophrenia and its associated burden. This is followed by discussing the evidence based treatments available for people living with schizophrenia. In focusing on this, the prevalence of non-adherence and the implications of non-adherence both globally and in Africa are reviewed. Then, the section focuses on a review of available literature thereby investigating the factors associated with non-adherence to antipsychotic medication. These factors are in three categories, namely patient related, medication related and finally environmental related.

2.1 Burden of Schizophrenia

Schizophrenia is a severe mental disorder affecting approximately 24 million people worldwide (WHO, 2001). Its prevalence ranges from 4 to 7 per 1 000 persons, depending on the type of estimate used (Saha, et al., 2005; Bhugra, 2005). The symptoms of schizophrenia include: perception disturbances such as hearing voices while no one is talking to you, visual hallucinations, having fixed false beliefs, grossly disorganised behaviours and sometimes disorganised speech. People who live with schizophrenia present with symptoms which are acute or chronic in nature, depending on the duration of untreated illness. In developed countries, the duration of untreated psychosis has been found to be at least 18 months (Clarke et al., 2007). On the other hand, in LMIC, such as Malawi, the mean duration of untreated psychosis among people suffering from schizophrenia spectrum disorders is 52 months, much longer than in developed countries (Chilale et al., 2014).

Schizophrenia poses many difficulties and challenges for the individual living with the disorder, their guardians and society as a whole. Schizophrenia is one of the most devastating psychiatric disorders, with the potential to lead to long term and progressive disability in an individual (Yusuf et al., 2009). To begin with, the disorder if not treated or controlled, significantly affects the social and occupational functioning level of a person who has relapsed or is living with the disorder (APA, 2013). In a multi-centre study done across seven countries (Australia, Czech Republic, France, Italy, Russian Federation, Spain and Turkey), found that patients showed impaired personal/social functioning and unsuitability for work correlated with various patient factors. In this cross-sectional study, quality of-life assessments showed that 25% to more than 30% of patients had problems with mobility, washing or dressing (Nordstroem et al., 2017). In one of the LMIC, India, a randomised

control trial of participants with schizophrenia was conducted in order to assess the effectiveness of community based treatments (Chatterjee et al., 2014). Although participants randomized to the community based treatment intervention showed improvement in the severity of disability, participants in the control groups reported very low levels of individual, social and occupation functioning.

Secondly, the burden of schizophrenia impacts on the quality of life of those individuals who are responsible for caring for people living with the disorder (Uriza, Maldonado & Castillo, 2009). Carer burden was also reported to be correlated with the symptoms of psychosis in patients who had relapsed (Nordstroem et al., 2017). In the study (Nordstroem et al., 2017), carers were reported to have devoted an average of 20.5 hours per week to the patient, and with notable negative impact on quality-of-life measures. Similarly, in a systematic review of the burden experienced by caregivers of people living with schizophrenia, it was found that unmet needs, which include economic burden, lack of spare time, restoration of patient functioning in family and social roles (Uriza et al., 2009), led to physical, emotional and economic distress in caregivers, which in turn negatively affected caregivers' quality of life.

A high level of burden on caregivers is also reported in LMIC. For instance, in a study conducted in Nigeria, a high level of burden was found in 47.3% of the respondents (Yusuf et al., 2009). Similarly, there was a high level of burden among caregivers reported in the northern part of Malawi (Sefasi et al., 2008). In this study, the burden of being involved in the management of the patient was measured using the Involvement Evaluation Questionnaire. Interestingly, caregivers that had knowledge of schizophrenia such as knowledge on symptoms, medication, hospital treatment; had experienced greater burden than those that had no knowledge.

Thirdly, society as a whole is impacted by schizophrenia. For example, schizophrenia results in high economic costs. A Canadian study found that the direct healthcare and non-healthcare costs combined with the high unemployment rate due to schizophrenia resulted in an additional productivity morbidity and mortality. This resulted in a loss estimate of CAN\$4.83 billion, for a total cost estimate in 2004 of CAN\$6.85 billion (Goeree et al., 2005). In the United States, schizophrenia was found to impact on the economy, with the burden estimated at \$63 billion per year (Birnbaum et al., 2002). Similarly, studies conducted in LMIC such as Nigeria, reported high financial costs to the management and productivity loss related to schizophrenia (Igberase et al., 2010).

Although the burden of schizophrenia is high, there is effective treatment available that provides the opportunity for many people with schizophrenia to lead healthy and productive lives.

2.2 Treatment for people living with Schizophrenia

Treatment for people living with schizophrenia is vital to control symptoms of the illness and to maintain remission or a state in which the patient continues to function optimally. A treatment package for schizophrenia would ideally include the use of antipsychotic medications and psychological interventions. The use of antipsychotic medication is paramount and first line treatment in the treatment package of schizophrenia (Lehman et al., 2010). Ideally, however, psychological or psychosocial treatment or interventions should be included in a care package for people living with schizophrenia.

Although the present study focuses on adherence to antipsychotic medication among people living with schizophrenia, it is important to mention that a number of psychological interventions have been found to be effective. For example, individual cognitive behavioural therapy has been tested in HIC and has been found to be effective in decreasing positive and persistent symptoms (Zimmermann et al., 2005) and suicidal ideation (Bateman et al., 2007) among people living with schizophrenia. In a clinical trial with, Chafetz et al., (2008) found that the use of wellness training as a health promotion intervention improved the wellness and symptoms of patients living with a severe mental illness. Similarly, a number of psychological approaches have been tested in LMICs. Maneesakorn et al., (2007) conducted a randomized controlled trial in Thailand and found an improvement of psychotic symptoms among patients after 8 sessions of behavioural therapy. In rural India, a community based rehabilitation model delivered by mental health workers also helped clients to improve on treatment adherence, social inclusion, and social functioning (Chatterjee et al., 2009). These psychological treatment approaches or models are implemented while patients are continuing using the pharmacological treatment such as antipsychotic medication.

Psychotic conditions such as schizophrenia can be treated with first generation antipsychotics (FGAs) such as haloperidol and chlorpromazine or with second generation antipsychotics (SGAs) such as clozapine and olanzapine. Gaebel et al., (2007) reported that evidence from trials conducted in HICs indicate that first generation antipsychotics (FGAs) were as effective as SGAs for the treatment of the first episode of schizophrenia. This was similar to results reported in a meta-analysis which showed that oral haloperidol and chlorpromazine are more

effective than a placebo (Leucht et al., 2009). One of the reliable treatment guidelines, NICE (2009) also indicates that evaluations of the efficacy of antipsychotic medication have not demonstrated superiority for any individual agent for those experiencing a first episode of schizophrenia. For example, in a systematic review on treatment guidelines, Keating et al. (2016) reported that Clozapine, which is one of the SGAs, was found to be no more effective than chlorpromazine FGA as initial treatment. In the same study, chlorpromazine was as effective as the newer antipsychotic medications in the treatment of the main psychotic symptoms of schizophrenia. Second generation antipsychotic (SGA) medications are recommended in most treatment guidelines as the preferred initial choice, because of the view that the side effect profile of this group of medicines are more favourable (Hasan et al., 2012; Galletly et al., 2016). However, in most LMIC, the most commonly used antipsychotic medications are the first generations antipsychotics because they are relatively cheaper to buy than second generation antipsychotics.

Antipsychotic medications used in the treatment of schizophrenia take the form of tablets or injectables, both of which can be affected by non-adherence behaviours by patients. There are long acting injectables and short acting injectables. Short acting injectables work in a similar way as tablets; which are taken almost on daily basis while long acting injectables can take two or four weeks to the next injection. The injectable medications referred to in the current study are long-acting injectables. Heres et al., (2014) reported that there is increasing interest in the use of long-acting antipsychotic injectables early in schizophrenia treatment because of the potential to detect non-adherence early, reduce relapse and improve psychosocial functioning.

Given the type of antipsychotic medication and mode of administration that is used to treat schizophrenia, the risk of a patient to non-adherence behaviours with these different types or mode of administration differs as well. It is important to understand the antipsychotic medication type and whether it is a tablet or injectable in order to manage better non-adherence behaviours which are suspected to come as a result of medication use.

2.3 Prevalence of non-adherence to antipsychotic medication

The WHO (2003) describes adherence as the extent to which a person's behaviour (e.g. taking medication, following a diet, and or executing lifestyle changes) corresponds with agreed recommendations from a health care professional. However, estimating the level of non-adherence among people living with schizophrenia can be challenging.

Firstly, as there are various definitions of adherence, these can have implications when trying to measure non-adherence. For instance, in a systematic review by Mohr and Volavka (2012), experts agreed that patients taking at least 80% of prescribed medication may be considered fully adherent, 50-79% are partially adherent and those taking less than 50% are non-adherent. In the same review, Velligan et al., (2009) defined non-adherence using medication gaps (off medication during a certain interval). In this case, the experts agreed that a medication gap of at least one week during a period of 3 months would be considered as an adequate definition of non-adherence. This definition was specifically agreed upon for the diagnosis of schizophrenia.

Secondly, there is a lack of consistency in how adherence is measured. Different measuring methods can either over estimate or underestimate the non-adherence rate. The methods used to measure medication adherence also vary and each method has its own strengths and weaknesses. For instance, adherence to oral medication can be assessed by either subjective or objective methods (Mohr & Volavka, 2012). Subjective methods include patient self-report, significant other report, provider report, or chart review. Objective methods such as pill count, monitoring of pharmacy refills, Medication Event Monitoring Systems (MEMS), and blood or urine medication level testing, are also used in assessing adherence. MEMS is a method in which the opening of the pill bottle is electronically recorded.

When pill count is used for measuring adherence behaviour, pill removal from the container or pill pack may not be equivalent to taking the medication resulting in an overestimate of adherence levels. Similarly, measuring medication adherence using plasma levels are limited by pharmacokinetic biases, and by a phenomenon known as “white-coat adherence”, in which patients improve their medication-taking behaviour in the 5 days before and after an appointment with the health care provider (Osterberg & Blaschke, 2005). Measuring adherence using plasma levels are also costly for large cohort studies. These are some of the challenges in the process of measuring adherence behaviours by using objective methods.

Patient self-report and provider report are the most frequently used method to assess adherence in research studies (Velligan et al., 2006) and in clinical practice, despite the fact that there is not gold standard instrument available. Similarly, Bayle et al., (2015) explains that medication adherence questionnaires (self or provider report) are the most used methods because of their cost effectiveness and their ease of use in large samples. The risk of over estimation or recall biases by questionnaires is minimized by asking the adherence

behaviours in a specified period, such as a week prior to assessment for outpatient participants and just before hospitalization for the hospitalized participants.

It is important to keep these issues in mind when interpreting the results of studies investigating the prevalence of non-adherence among people living with schizophrenia. A number of systematic reviews have been conducted investigating non-adherence to medication and the correlated factors (Higashi, 2013). For instance, in schizophrenia, non-adherence can exceed 60% (Gilmer et al., 2004). Velligan et al., (2008) found similar non-adherence rate which is greater than the adherence rates found in bipolar disorders, which ranged from 20 to 60%.

A number of studies in HIC have shown relatively high rates of non-adherence. For instance, a study conducted in France found that the prevalence of non-adherence to medication among clients suffering from schizophrenia was 30%. In a study conducted in South Korea, 54% of patients with schizophrenia receiving oral antipsychotics reported non-adherence (Kim et al., 2008). The high prevalence of non-adherence was also found in England by Gibson et al., (2013), where 77% of the participants suffering from either schizophrenia or bipolar disorder recruited in a study reported to have deviated from the prescription recommendations (i.e. doing something different to the recommendations given). In the United States, an analysis of medication adherence using the database linking hospital admissions also indicated poor treatment adherence in patients suffering from schizophrenia and bipolar disorder, with a mean medication non-adherence proportion rate of 55% and 37%, respectively (Berger et al., 2012). Furthermore, in a recent study of Asian Americans with schizophrenia, 41% of the patients were either non-adherent or partially adherent to their medication (Gilmer et al., 2009).

High rates of non-adherence were also reported by psychiatrists in a combined study in 13 Asia-Pacific Countries (APAC). This study investigating psychiatrist's awareness of non-adherence or partial adherence among patients suffering from schizophrenia, found that psychiatrists across APAC regions perceived that 56% of patients were non-adherent or partially adherent to their medication (Olivares et al., 2013). The psychiatrist's perception on adherence was similar to the nurses' perception in a cross sectional survey conducted in Europe, the Middle East and Africa (EMEA). In this survey, nurses perceived that 54% of the patients suffering from schizophrenia did not adhere (taken <30% of the prescribed dose) to medication and had a risk of relapse or hospitalisation (Emsley et al., 2015).

A few studies conducted in LMIC have investigated adherence to medication amongst people living with other health conditions (Ambaw et al., 2012), with a few focusing on mental health. For example, Alene et al (2012) found that 48% of the patients on antipsychotic medication were non-adherent in Ethiopia. In the same country, Gurmu et al., (2014) reported a 50% non-adherent rate among patients on antipsychotic medication. Demoz et al., (2014) found a 69% non-adherence rate among patients on antipsychotic medication in Ethiopia, while Ibrahim et al., (2015) reported a non-adherence rate of 56% among patients on antipsychotic medication. . These rates are similar to those reported in a recently published study conducted in Ethiopia, where 46% of the patients taking medication for schizophrenia were classified as non-adherent (Mamo et al., 2016). In this study, Mamo et al (2016) found that within those that did not adhere to treatment (46%), 14% sometimes missed their daily doses, 11% only missed taking their dose at the specific scheduled time and 19% missed both taking their dose at the specific schedule and sometimes missed their daily dose.

In Malawi, adherence to medication has mostly been studied for physical conditions. For instance, Bell et al. (2009) studied adherence to anti-malaria medication. They reported that 90% of patients were adherent to anti-malaria treatment in urban centres of Malawi. In rural areas of Malawi adherence to anti-malaria medication was much lower at 65% (Mace et al., 2011). However, there is no evidence on the prevalence or risk factors for non-adherence to antipsychotic medication in Malawi. And yet, non-adherence to antipsychotic medications has several implications to the client, carers as well as the community as discussed in the follow up section.

2.4 Implications of non-adherence to antipsychotic medication

Medication non-adherence in people living with schizophrenia and other serious mental disorders has been associated with relapse, hospitalisation and high health care costs (Gilmer et al., 2004; Pomykacz et al., 2007). For example, in a San Diego Medicaid population (2,801 person-years), patients who were non-adherent were approximately 2.5-fold more likely to be hospitalized for psychiatric reasons versus adherent patients (Gilmer et al., 2004). Similarly, in a study of 1,646 patients with schizophrenia hospitalized after a relapse, non-adherence to antipsychotic medication was the most frequently cited reason (58.6%) for hospitalization (San et al., 2013; Shuler., 2014). It has also been reported that non-adherence to medication for mental disorders substantially limits treatment effectiveness and resulting into relapse, hospitalisation, suicidal behaviours and disability (Sajatovic et al., 2010).

When a client relapses not only does it affect the well-being of the patient (DiBonaventura et al., 2012) and the family (Caqueo, Gutierrez & Miranda, 2009), but also the economy. For instance, in a UK survey of institutionalized patients receiving antipsychotic medication (n=658), non-adherence was associated with excess inpatient costs of approximately £2,500 per patient per year and excess total service costs of more than £5,000 per patient per year (Knapp et al., 2004). Similar results were found in a San Diego Medicaid population (2,801 person-years) where hospital-related costs were significantly higher in non-adherent patients than in adherent patients. However, total estimated costs were higher for adherent patients because of increased pharmacy-related expenses (Gilmer et al., 2004). Furthermore, high costs of non-adherence were reported in a study conducted in a Florida population of people living with schizophrenia who have medical aid (n=10,330). Results indicated that adherence was negatively associated with health care costs (Becker et al., 2007). In the same study, the total per-user-per-month costs were higher in patients with negligible adherence (25%) compared with patients with maximal adherence (75%–100%) for all three medication classes that were evaluated. This included atypical antipsychotic monotherapy (\$133 higher) typical antipsychotic monotherapy (\$294 higher), and a combination of atypical and typical antipsychotic combination therapy (\$221 higher) (Becker et al., 2007).

Given the high prevalence of patients living with schizophrenia who do not adhere adequately to their medication, and the implications of non-adherence on the patient, the family and society, an understanding of factors that influence adherence in this vulnerable population is essential.

2.5 Factors affecting adherence

Chakrabarti (2014) argues that adherence or non-adherence from the patient's perspective is often a considered decision by people making their own choices about benefits and disadvantages of treatment. This is based on their beliefs, their personal circumstances and the information available to them. Similarly, the WHO (2003) describes medication non-adherence in people living with schizophrenia and other serious mental disorders as multi-determined. Although there is no one theory that explains adherence, several theories have been proposed (Weiden, 2007). Examples of these theories include: 1) the Health Belief Model; 2) The Theory of Planned Behaviour; and 3) a traditional medical model or theory of doctor - patient relationship.

To begin with, the Health Belief Model focuses on the attitudes and beliefs of individual in respect to the behaviour in question (Barbara, Rimer and Glanz, 2005). The Health Belief Model (Barbara, Rimer and Glanz, 2005) addresses the following components: 1) individual's perceived susceptibility and severity-this is related to the belief that the individual is susceptible to the condition and the health condition is severe. 2) Individual's perceived benefits of avoiding the threat-this refers to the belief that taking action would reduce the susceptibility, 3) factors influencing the decision to act-these relates to the factors that will help to take action. It includes the belief that costs of taking action are outweighed by the benefit. For example, in a study investigating medication adherence among people living with schizophrenia, it was found that patients who had perceived the benefit of medication were more likely to adhere to medication than those who did not (Kikkert et al., 2006). The use of Health Belief Model had predicted non-adherence behaviours as reported in a systematic review by Holmes et al., (2014). In this review perceived benefit was able to predict adherence among 73% of the population. Similarly, a study conducted by Wiesjahn et al (2014) included a number of questions pertaining to attitude towards antipsychotic medication and then used these attitudes to predict the variance in adherence variance. The findings showed that the beliefs of participants to medication were significant to predict adherence behaviours.

The Theory of Planned Behaviour describes the relationship between behaviour and beliefs, attitudes and intentions (Barbara, Rimer & Glanz, 2005). LaMorte, (2016) explains that Theory of Planned Behaviour (TPB) describes behavioural achievement. This behavioural achievement is dependent on both motivation (intention) and ability (behavioural control). There are six constructs of TPB that represent a person's actual control over the behaviour (Barbara, Rimer & Glanz, 2005).The six constructs as described by LaMorte (2016) are: 1) Attitudes-this refers to the degree to which an individual or a person has a favour or unfavourable evaluation of the behaviour of interest. 2) Behavioural intention- this is the motivational factors that influence a given behaviour where the stronger the intention to do a particular behaviour, the more likely the behaviour will be done. For instance, Barbara, Rimer and Glanz (2005) describes that this is the construct in which behaviour is measured on how likely or unlikely it is to be performed. 3) Subjective norms- this is related to the belief that whether most people approve or disapprove the behaviour. 4) Social norms-this refers to the customary understanding of behaviour in a larger cultural context. The norms referred to in this case are either considered normal or standard in a group of people. 5)

Perceived power-this refers to the perceived presence of factors that can facilitate or impede performance of a particular behaviour.6) Perceived behaviour control- this refers to an individual's perception on how ease or difficult it is in performing the desired behaviour of interest. The principles of Theory of Planned Behaviour were used to modify a multifamily group therapy in a 3-arm randomised clinical trial among patients with a diagnosis of schizophrenia in America (Kopelowicz et al., 2012). In the trial, in which adherence was tested following the multifamily group therapy sessions, the results indicated that participants in a modified multifamily group were more adherent to treatment than those in a standard group or in the treatment as usual group. TPB has also shown relevance in the domains of medication adherence in chronic conditions such as schizophrenia, and facilitates well the norms of following physician instructions on the prescribed medication (Poremski et al., 2016). This theory also predicted non-adherence behaviours, however, the prediction of non-adherence was increased when the Health Belief Theory was used in combination with the Theory of Planned Behaviour (Holmes, Hughes, & Morrison, 2014).

Other theories have been used to explain non-adherence behaviours. For instance, one of the theories is a traditional medical model or theory of doctor - patient relationship. Kelly and Barker (2016) explained that this model was reported by Parson in 1951; and it is based on the premise that patients have an information deficit and come to see medical practitioners to consult them for their expertise to remedy their deficiency in knowledge and understanding. Indeed, Kelly and Barker (2016) indicated that this explanation may be better suited for patients with acute conditions, rather than with chronic conditions. For the chronic conditions, patients may have sought consultation from the doctor where information on the condition might have been given. The other reason for this is that patients need to understand that they do not require information only, but a good doctor-patient therapeutic relationship. For example, in a European multi-centre study on therapeutic relationship and antipsychotic medication adherence, a good therapeutic relationship was associated with adherence to treatment (McCabe et al., 2012). In this study, for each unit increase in clinician rated therapeutic relationship score, the odds ratio of good compliance was increased by 66% (95% CI: 35%-105%). This indirectly relates with the Theory of Planned Behaviour which assumes that behaviour intention is the most important determinant of behaviour (Barbara, Rimer & Glanz, 2005). In this theory, behaviour intention is influenced by a person's attitude towards performing behaviour, and thus relates well with the understanding of patient-doctor

relationship theory. The information will be understood and taken if the attitude developed over the relationship between doctor-patient is good.

These behavioural models can provide a theoretical basis for the development and assessment of interventions for non-adherence problem. These theories, however, are mainly based on the behaviour component in predicting non-adherence, whilst there may be other factors which contribute to non-adherence, which are not behaviour related but related to patients' attributes and environment. Given that the theories or model explained are based on behaviour, other attributes which are not behaviour can be missed such as medication related factors such as type or form of medication. Therefore, the present study will investigate other factors or attributes that may be associated with non-adherence.

Some modifiable attributes or factors that can affect antipsychotic non-adherence may not necessarily require behaviour interventions but resource availability or allocation. For example, some studies found out that the use of an injectable form of antipsychotics improves medication adherence compared to medication administered in the oral form (Lehman et al., 2004). Walden (2007) classifies such attributes or factors as patient-related, medication-related and environmental related. Interventions to improve adherence often target specific factors associated with non-adherence, and so in the current study, investigating these particular factors in the three domains: patient-related, medication-related and environment-related may have more tangible or relevant implications for policy, practice and research.

A few studies from LMIC have investigated the factors associated with antipsychotic medication adherence among patients with psychosis; however the majority of available studies have been conducted in developed countries. These are reviewed below.

2.6 Factors associated with non-adherence behaviors

2.6.1 Patient-related factors

There are a number of patient-related factors described in the literature that could potentially impact on adherence. Age as one of the social demographic factors has been found to affect adherence differently in different studies. For instance in the United States, Valenstein et al., (2004) found that patients younger than 45 years of age were likely to be less adherent to antipsychotic medication than patients aged 45 years to 64 years of age. This differs with what Demoz et al., (2014) reported in their study where adherence increased with increasing age. In the same study, individuals with ages ranging from 26 to 35 years were more

significantly adherent to antipsychotic medication than those in the age range of 15 to 25 years. In this study, it was also noted that being female, of tertiary education and living with family were associated with better adherence to antipsychotic medication (Demoz et al., 2014). Gender and occupation class also were found to be independent predictors of adherence in Ibrahim et al., (2015)'s study. For instance, males were over 3 times more likely to be adherent than females; and those that had lower levels of occupation were more likely not to adhere to medication. Similarly, Valenstein et al., (2006) also reported that patients who were younger and who had a psychiatric hospitalization, or predominant treatment with first-generation antipsychotics were more likely to have consistently poor adherence. However, in a systematic review by Higashi et al., (2013), age, marital status, education, ethnicity and occupation status did not predict adherence.

Co-morbid conditions can also have an impact on adherence to psychiatric treatment. Moore et al., (2012) in a Californian study assessed group treatment adherence among HIV positive and bipolar disorder participant who were taking both ART and psychiatric medication. In this study, non-adherence rate for psychiatric medication in the group of HIV+ and with bipolar disorder was 33% as compared to the group of HIV+ and without bipolar disorder which was 17%.

The other co-morbid factor which has been reported to predict antipsychotic non-adherence is alcohol and substance use. For instance, Valenstein et al., (2006) reported that patients with a substance use disorder and a psychiatric hospitalisation had significantly poorer adherence to antipsychotic medication compared to those that had no substance use disorder. Similarly, in an Australian study of perspectives of physicians on reasons of non-adherence to antipsychotic medication, it was found out that one of the reasons for non-adherence was drug and alcohol abuse (Kulkarni & Reeve, 2015). In the same country, almost half of the participants of those that were suffering from schizophrenia reported to have used alcohol and missed antipsychotic medication (MacCann et al., 2008). Novic et al., (2010) in the UK found similar results: alcohol dependence and substance abuse were predictive factors for non-adherence. Despite these different results, Danzer and Rieger, (2016)'s systematic review on improving medication adherence for severely mentally ill adults, concluded that non-adherence to antipsychotic medication is associated with an increase in substance use and abuse, and in violence and other high-risk behaviours. A similar finding was noted in a study on adherence to mood stabilizing medication, where co-morbid substance abuse and negative attitudes toward medication are some of the primary determinants of medication

treatment adherence (Sajatovic et al., 2009). Furthermore, some studies found that alcohol and substance use predicted non-adherence behaviours. For instance, Higashi et al., (2013), in a systematic review also found out that alcohol and substance use predicted non-adherence among patients suffering from schizophrenia. Teferra et al., (2013)'s study in Ethiopia also found similar results that alcohol and substance abuse was one of the factors associated with non-adherence in participants who had history of alcohol abuse. Novick et al., (2010) in an outpatient study of patients with a diagnosis of schizophrenia reported low adherence to medication for patients who had a co-morbid alcohol abuse history.

In some studies, substance use has not been associated with adherence levels to medication. For instance, in a study by Magura et al., (2012), all the study subjects had both life time and recent histories of substance use but the use did not predict medication adherence. In this study, suggested reasons for adherence among substance use subjects were that the degree of use did not impair the ability of patients to take their medication, because patients had adapted their functioning with the use of substances. . Similarly, Demoz et al (2014) found that adherence to psychiatric clients with drug addiction was found to be good, and a majority of the study subjects with a drug addiction (69%) had adhered to their medication.

Another patient related factor which has been investigated in relation to medication non-adherence is insight, that is, awareness for the need for medication and attitude to medication. A few studies have reported that lack of insight is strongly associated with non-adherence to antipsychotic medication (Bressington et al., 2013). A study exploring adherence to antipsychotic medication among patients with schizophrenia attending outpatient clinics in Hong Kong identified that non-adherence was predicted by awareness of illness, attitudes towards treatment, perceived benefits of medication, and younger age (Hui et al.,2006). The other study by Novick et al., (2015) reported that insight, therapeutic alliance and adherence are closely related and they all impact on clinical and functioning status in patients with schizophrenia in Europe. The study also clearly showed that insight predicted adherence in patients with schizophrenia (Novick et al., 2015). This was similar to a study done in Turkey by Mert et al., (2015), who reported that the leading factor to non-adherence was “not accepting the disease” (insight) and also “not willing to take medication” in a group of patients with schizophrenia. A systematic review by Higashi et al., (2013) also reported that better insight predicted adherence to antipsychotic medication. However, others studies such as a study done by Puschner et al., (2006) did not report the association between insight and non-adherence behaviours. Similarly, Linden et al., (2001) in a survey of patients suffering

from schizophrenia also reported that there was no relationship between adherence and lack of insight.

Studies in developing countries also reported that insight predicts or is associated with antipsychotic medication non-adherence. For instance, in South Africa, it was found that presence of a co-morbid depressed mood and lack of patient insight in patients suffering from schizophrenia increased risk of poor medication adherence (Kazadi, Moosa & Jeenah, 2008). A similar result was found in a hospital-based study in Ethiopia, where 53 % of the psychiatric patients who reported that “did not think were ill” were non-adherent to medication (Gurmu et al. 2014). In a systematic review done by Higashi et al., (2013), it was found that some symptoms of a psychotic disorder could inhibit the patient’s ability to cooperate during the process of getting treatment. This could be due to the severity of the disorder itself or it could be as a result of poor insight.

In addition to insight as a patient factor to predict antipsychotic medication non-adherence, beliefs and attitudes towards medication is another important factor which may contribute to non-adherence. In a Hong Kong study done by Bressington et al., (2013), beliefs and attitude towards antipsychotic medication of participants were found to be generally positive; and there were significant differences observed between adherent and non-adherent patients. In this study, adherence was associated with positive treatment attitudes (Bressington et al., 2013). This finding was consistent with reports from other studies in a variety of international settings (Adewuya et al., 2006). Similarly, Baby et al., (2009) in India and Rossi et al (2009) in Italy found the same results suggesting that positive attitudes towards treatment are associated with improved adherence rates. A systematic review on the factors that affect antipsychotic medication adherence among patient with schizophrenia, reported that patients’ belief that medications do not work also predicted non-adherence to antipsychotic medication (Higashi et al., 2013).

2.6.2 Medication-related factors

Apart from patient related factors, medication-related factors can also affect antipsychotic medication adherence. Published evidence relating to the relationship between side-effects and non-adherence is equivocal. Adverse effects are cited as having a negative influence on adherence with antipsychotics in some studies (Perkins, 2002). Side effects of antipsychotic medication have been found to be highly prevalent and significantly associated with lower adherence rates (DiBonaventura et al., 2012). Another cross-sectional study in Hong Kong

(Bressington et al., 2013) also reported that treatment non-adherence is associated with psychotropic side-effects (e.g. sedation, memory loss, cognitive impairment). Gibson et al., (2013) also found out that side effects were obstacles to antipsychotic medication adherence in England.

In LMIC, there were similar reports that side effects of antipsychotic medication impact on adherence to treatment. In South Africa, side-effects appeared to be one of the factors associated with poor adherence and likely to increase the risk of a relapse (Kazadi et al., 2008). Furthermore, a study done in Tanzania found out that non-adherence was due to the severity of drug side effects (Sariah, Outwater & Malima, 2014). Mamos et al., (2016) in Ethiopia, looked at medication adherence among patients with schizophrenia and reported a statistically significant association of medication side effects and adherence ($p < 0.05$).

Day et al., (2005) explained that when patients are making decisions about taking medication, the negative influence of side effects is moderated by the perceived efficacy of treatment. This view is supported by other studies which demonstrated that the perceived effectiveness of treatment is associated with adherence (Kikkert et al., 2006). Treatment form also impacts on adherence to antipsychotic medication. For instance, in a European multi-centre study conducted by McCabe et al., (2012), 22% of the patients receiving depot medication had poor adherence. In a study conducted in Hong Kong, patients that were prescribed oral antipsychotics were found to be more adherent than those on traditional depot antipsychotics (Bressington, Mui & Gray, 2013), although clinicians tend to prescribe depot medication to those who are suspected to be non-adherent to oral medication. Similarly in a Taiwan study, Chang et al (2012) also reported that different patterns of non-adherence were associated with different antipsychotic drugs. In terms of overall number of medication or number of doses on adherence, Moore et al., (2012) found no effect on adherence in a study done in California. Not only medication related factors impact on antipsychotic non-adherence, the next section discusses environmental related factors like that of social support and; alcohol and substance abuse.

2.6.3 Environment-related factors

Finally, an environmental-related factor, such as social support, was also found to be potential contributor to non-adherence to antipsychotic medication (Velligan et al., 2009).

Social support has been found to have an impact on adherence in some studies. A review by Velligan et al., (2009) reported that factors that were associated with non-adherence included a disorganized or a chaotic living situation, while family and social support predicted good adherence to antipsychotic medication. Similarly, lack of social support has been reported by Hudson et al., (2004) as one of the most common barriers to adherence. Again, in a study done by Robinovitch et al., (2009), non-adherent patients were less likely to have received a good level of social support. Coldham et al., (2002), similarly to other studies, found that non-adherent patients were less likely to have a family member involved in their treatment

It has also been found that caregivers' quality of life affects family interventions, which in turn affects adherence to antipsychotic medication. For example, most studies reviewed by Barkhof et al., (2012) showed that family interventions, such as psycho-education, improved adherence. Chan et al., (2009) investigated a psycho-education program for patients and family caregivers in the urban area of Hong Kong, which demonstrated a considerable improvement in adherence three months and six months following the intervention.

Another concept of social issues related to adherence behaviours has been explored by Hui et al., (2006) in a study done among urban Chinese first episode psychosis patients. It was found that patients feeling embarrassed about taking their medication in the presence of other family members was an important correlate of non-adherence, and went under-recognized by clinicians, especially in early onset of schizophrenia (Hui et al., 2006). Kampman et al., (2002) also reported similar findings: in addition to side effects, male gender and younger age, lack of social activities was one of the determinants of non-adherence. In a systematic review by Acosta et al., (2012), environments of poor familial and social support were found to be associated with non-adherence both by patients with schizophrenia and by patients experiencing their first episode of psychosis. In the same systematic review, living alone was also found to be a risk factor to non-adherence. However, living with other people such as friends or relatives was only found to be a protective factor of non-adherence if the involved interpersonal relationship was not distressing (Perkins, 2002).

In Malawi, there are presently no studies investigating the prevalence and predictors of antipsychotic medication non-adherence among patients with psychosis. For this reason, the study aims to understand the factors associated with non-adherence to antipsychotic medication. To that effect, it was decided that the different patient, medication and environment-related factors would be investigated (see Figure 1).

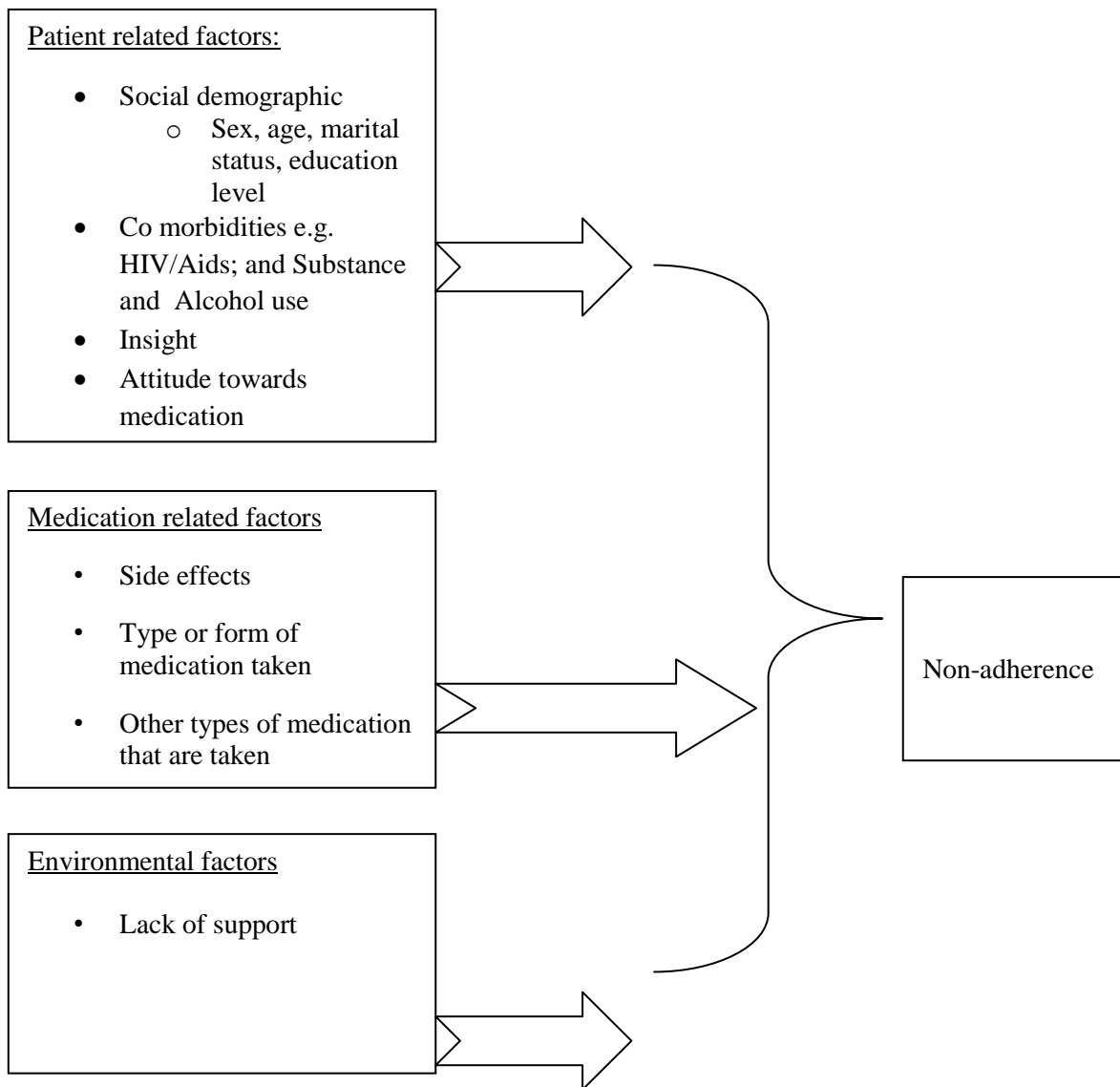


Figure 1: Categories of Predictive factors

In conclusion, this review describes psychosis generally and in particular one example of a psychotic disorder-schizophrenia. Schizophrenia and associated burden; and available treatment have also been reviewed before review of prevalence and implications of non-adherence to antipsychotic medications. The review also included theories regarding non-adherence and how they have influenced research elsewhere. This chapter concluded with a discussion of various factors that have predicted non-adherence in other settings categorized as patient related, medication related and environment related factors.

The next chapter explains in detail the methodology of the study; the study design, setting, participants and sample size are described, as well as the study's procedure, including measures that were used during the study, data analysis and the ethical considerations.

CHAPTER THREE: METHODOLOGY

3.1 Study design:

This study used a hospital based cross-sectional quantitative study.

3.2 Setting

The study was conducted in Mzimba district, Malawi (see appendix M). Malawi has a population of 13 066 320 people; and 853 305 people in Mzimba district (Malawi Demographic Health survey, 2008). In Mzimba the study was specifically done in three main mental health outpatient clinics, namely Mzuzu central hospital, Saint John of God Centre and Mzimba district hospital mental health clinic. Mzuzu Central hospital is one of the central hospitals in the northern region of Malawi; it runs a mental health clinic as well. Mzimba hospital and Saint John of God centre are secondary health service centres. Clients pay a consultation fee at Saint John of God centre and the other two clinics are free of charge.

3.3 Participants

Participants with a primary diagnosis of psychosis and attending the outpatient department were included in the study. The diagnoses which were included are schizophrenia and all other schizophrenia spectrum disorders such as schizophreniform; and also an HIV or substance induced psychotic disorder. Schizoaffective disorder and other disorders like depression with psychotic features, anxiety disorder, and bipolar disorders were excluded because of the additional mood symptoms. In these conditions antipsychotic medication is used together with other psychotropic drugs which have side effects similar to some antipsychotic medication (e.g. chlorpromazine, an antipsychotic medication, has sedative side effects similar to antidepressants such as Amitriptylline). Antidepressants such as Amitriptylline have side effect profile which can affect antipsychotic medication non-adherence as well. These were excluded to minimize the influence of other factors on adherence, e.g. primarily mood symptoms or effects of mood stabilizers such as antidepressants.

The diagnosis was known by checking in the case files of the clients. Participants were between 18 to 50 years old and taking either oral or injectable antipsychotic medication for not less than four months. The age was considered 18 years and above in order to allow individual consenting to the study. 50 years was a cut off point to minimize recall bias as a result of aging. Study participants can have a dual diagnosis (e.g. physical or substance use

disorder) as long as there is a primary psychotic diagnosis. This was cross checked with the mental health worker running the clinic. Acutely ill patients at the time of data collection were not included in the study. These were known by the report of a health worker running the clinic on the day of data collection. An acute episode was defined as experiencing at least two of the following symptoms for at least one week in intense and active way that interfered with their ability to carry out the ordinary requirements of life: delusions, hallucinations, disorganized behaviour, negative symptoms (American Psychiatric Association, 2000).

3.4 Sample size

The minimum required sample size for a multiple regression study, given the desired probability level of 0.80, 6 predictors in the model, an anticipated effect size of 0.15 (moderate), and the desired statistical power level of 0.05 is **139**. A total sample of **150** participants was targeted for this study, including a refusal rate of about 10%. It was estimated to take four to six weeks to recruit 150 participants for the study.

3.5 Study Procedure

Participants were interviewed at the clinic after their consultation with the mental health professional. Arrangements were done with the Clinician or Nurse working during the clinic day to refer all potential study participants to a research assistant on their exit. Every potential participant was approached by the research assistant on their exit from the clinic to participate in the study. The research assistants confirmed the primary diagnosis of a psychotic disorder in the participant's case file. Participants were informed that the participation in the study is voluntary and that their confidentiality and anonymity will be observed. It was also explained that withdrawal from the study would not affect their care from the hospital. Written consent was obtained from each participant and the interview was done in a private room within the clinic setting (see appendix A for consent form). Eight hundred Malawi kwacha voucher (2 US Dollars) was given to every participant who took part in the study compensating for the time taken. The structured interview was done by a research assistant who was either a Psychiatric Nurse or a Psychiatric Clinical Officer. The research assistants had been trained on the questionnaire to be used.

Participants found with a non-adherence problem were provided with a psycho educational sheet on importance of adhering to medication, and arrangements were made to refer such participants to Community Psychiatric Nurse within the hospital who are able to further assist them. Participants were referred to appropriate personnel at the hospital in cases of the

identified problems that required immediate attention. For instance, participants that had severe side effects were referred to Clinicians for possible alternative medication.

3.6 Measures

The interview consisted of measures assessing adherence to antipsychotic medication, as well as measures assessing patient-, medication- and environmental-related factors. The questionnaire was translated into a common local language, Tumbuku. This is a local language which is understood by the majority of the population in the northern part of Malawi. After translation to local language, it was back translated into English.

3.6.1 Adherence scale:

Morisky Medication Adherence Scale-8 (Morisky, Green & Levine, 1986) was used to assess adherence to antipsychotic medication. Although the scale has not been validated in clients with psychosis in Malawi, it has previously been used to measure adherence in patients with Schizophrenia in the US (DiBonaventura et al., 2012). It is used in measuring medication adherence in chronic conditions like hypertension and was validated to be used in a number of outpatient settings (Morisky, Ang & Krousel-Wood, 2008). It consist of eight items with a scoring scheme of “Yes”=0 and “No”=1 for the first seven items and a 5-Likert response for the last item. The scale has questions, such as “Do you sometimes forget to take your pills?” or “have you ever missed your monthly injection in the last three months?” The items are summed to give a score, ranging from low adherence to high adherence. The total scores are interpreted as “0”=high adherence; “1-2”=medium adherence and “3-8”= low adherence. In the current study, it was dichotomised in order to use logistic regression. Adherence was assessed and categorized as yes or no during analysis. The scores were interpreted as 0-2=adherence and 3-8=non-adherence.

3.3.2 Patient related factors

Demographics: Information regarding participant’s age, gender, marital status, education level, occupation, religion and residential area will be collected. The type of medication that client has been on will also be collected, in addition to information on co-morbid conditions.

Birchwood Insight Scale (Birchwood, Smith, Drury, Healy, Macmillan &Slade, 1994) is a scale that measures the three dimension of insight, a patient-related factor. Birchwood et al., (1994) described the three dimensions as ‘Awareness’ of illness which refers to awareness of having a mental illness, ‘Relabel’ which refers to the attribution of one’s symptoms as part of

one's disorder; and 'Need for treatment'. Questions are scored on a 3-point Likert type scale from 0-2. Total score is summed for score range of 0-12 with higher scores indicating greater insight. The participants that had less score of 9 on the total sum were categorized as to have poor insight. Total score of 9 and above were regarded as having good insight.

Drug Attitude Inventory-10 (Hogan et al., 1983) is used to measure attitude of patients towards the medication that are taking, another patient-related factor. It is a 10 item scale which measures responses of patients to medication including both positive drug effect (e.g. prevention of relapse), and negative drug effects. It also measures patient's belief about and experiences with medication (Yoon et al., 2005). It consists of "yes" or "no" answer questions. The correct items score +1 and incorrect items score -1. It is interpreted as adherent or positive attitude when there is a positive score and negative score interpreted as non-adherent or negative attitude towards medication (Awad, 1993). Similarly in this current study, it is interpreted as negative attitude when the total score has a negative score and positive attitude when the total score has positive score.

3.3.4 Medication related factors:

Glasgow Antipsychotic Side-effects Scale (Waddel & Taylor, 2007) is a measuring tool used to assess antipsychotic side effects in clients who are on antipsychotic medication. This scale will measure medication related factors, in particular the side effects of antipsychotic medication. It consists of 22 items; the first 20 items are answered on a Likert scale ranging from "never"=0, "once"=1, "A few times"=2, to "Everyday"=3; the last two questions are binary, with responses "yes"=3 and "no"=0. A column "distress" is included with an intention of helping to assess patient views of the problem and will be used for management of the side effects. For instance, if patient is categorised as having mild side effects but has indicated that they are distressing, then the client will be referred to a Psychiatric Clinical Officer or Psychiatric Nurse on duty for proper management (Waddel & Taylor, 2007). Over all scores on the scale are 0-12=absent or mild side effects, 13-26=moderate side effects, and over 26=severe side effects.

3.3.5 Environmental related factors:

Social Support questionnaire (Sarason, et al., 1987) is a brief measure of social support. It asks people about who provides them with help in their life. Each question has two parts: the first asks about people that are known, and who is counted on for help or support; the second asks about satisfaction with overall support.

Alcohol Use Disorder Identification Test (AUDIT): It is an alcohol use screening tool, used to measure the consumption, dependence and alcohol-related problems (WHO, 2001). It includes questions such as: “How often do you have a drink containing alcohol? How often during the last year have you found that you were not able to stop drinking once you started?” The score of 8 or more was considered to be a harmful drinking in this study.

3.4 Data analysis

The researcher entered data into SPSS, and quantitative analysis was conducted using the same SPSS 22.0. Frequencies and descriptive statistics were used to present the socio-demographic variables, by gender (see Table 1). The non-parametrical Chi Square test was used to analyse categorical variables. Mann-Whitney U test was used to analyse age because it was not normally distributed in the sample. All variables were also analysed in relation to adherence using logistic regression test. Statistical significance was based on 2-sided tests and set at $\alpha = 0.05$. In addition, a multivariate logistic model was developed to control for independent variables on adherence to treatment. The results of the regression models have been reported as odds ratios (ORs) with 95% confidence intervals (CIs). Variables which were statistically significant in an unadjusted logistic regression were analysed again in an adjusted regression model, which was also adjusted for age and gender (see Table 2).

3.5 Ethical considerations

Ethical approval to conduct the study was obtained from the Faculty of Health Sciences Research Ethics Committee at the University of Cape Town before the beginning of the study (see Appendix K). Ethical approval was also obtained from National Health Sciences Research Ethics Committee in Malawi (see Appendix L). Then permission was obtained from Mzimba District Health Officer, Mzuzu Central Hospital Director and Saint John of God Hospital Director to conduct study in the following mental health clinic Mzimba District Hospital, Mzuzu Central Hospital, Saint John of God Hospital respectively. No potential harmful procedures were anticipated in this study. It was also noted that in the course of study some participants may be found with severe problems, like severe antipsychotic side effects or severe problems with alcohol or any other medical condition, which would need the attention of a Health worker. Arrangements were put in place to refer such clients to a Psychiatric Nurse on duty for proper management. There is an indirect benefit of the study anticipated to patients attending the clinic in general: it is hoped that the results of the study will help in the planning and provision of mental health services to patients.

Informed consent was obtained from each participant of the study. All study participants were given a consent form which described the study aims and highlighted that participation in the study was voluntary. Clients who decided not to take part were free to do so; and their medical care was not compromised in any way. In the course of study the Principle investigator was mandated to take up issues of concern to relevant authorities for solutions. Confidentiality was also observed as all questionnaires were anonymous. Participant codes were used instead of names to maintain anonymity. All completed questionnaires were kept in a lockable drawer in the office of the researcher at the hospital.

CHAPTER FOUR: STUDY RESULTS

4.0 Introduction

This chapter presents the findings of data collected in September, October and November, 2015 on the prevalence and predictors of antipsychotic medication non-adherence among clients with psychotic disorders in Mzimba, Malawi. The findings have been presented according to the study objectives under the following subheadings: a) socio-demographics and participants' physical and mental health status; b) the prevalence of antipsychotic medication non-adherence among clients with psychosis; c) patient-related, medication-related and environmental-related factors associated with non-adherence in clients with psychosis in Mzimba, Malawi.

4.1 Socio Demographics of the sample

The final sample consisted of 150 participants, meeting the sample requirements. Most of the participants were male (54%, n=81) and single (55.3%, n=47). The average age of male participants was 32 years (SD=9.03), which was younger than females who had an average age of 35 (SD=9.72). The majority of the male participants had gone up to secondary school level of their education (65.8%, n=48) as compared to females, who mostly went up to primary level of their education (57.1%, n=44; p=0.01) (see Table 1).

Table 1: Social demographics and Participant Physical and Mental health status

Variable	Total sample (n=150)	Male (n=81)	Female (n=69)	P value
Age (mean, SD)	33.6 (9.40)	32.0 (9.03)	35.1 (9.72)	0.09
Marital Status, n (%)				0.74
Single	85 (56.7)	47 (55.3)	38 (44.7)	
Married	65 (43.2)	34 (52.3)	31 (47.7)	
Employment				0.87
Employed	87 (58.0)	46 (52.9)	41 (47.1)	
Unemployed	63 (42.0)	35 (55.6)	28 (44.4)	
Education level				0.01
Primary	77 (51.3)	33 (42.9)	44 (57.1)	
Secondary	73 (48.7)	48 (65.8)	25 (34.2)	
Diagnosis				0.01
Schizophrenia spectrum Disorder	103 (68.7)	55 (67.9)	48 (69.6)	
Schizoaffective Disorder	15 (10.0)	4 (4.9)	11 (15.9)	
Substance Induced Psychotic Disorder	17 (11.3)	15 (18.5)	2 (2.9)	
General Medical Condition Induced Psychotic Disorder	15 (10.0)	7 (8.6)	8 (11.6)	
Antipsychotics				0.25
Pills	114 (76.0)	65 (80.2)	49 (71.0)	
Injectables	36 (24.0)	16 (19.8)	20 (29.0)	
Other medical conditions				
HIV/Aids	16 (10.7)	7 (8.6)	9 (13.0)	
Others:	14 (9.3)	6 (7.4)	8 (11.6)	
Duration on Antipsychotics				0.09
0-12 Months	24 (16.0)	17 (21.0)	7 (10.1)	
13-24 Months	38 (25.3)	16 (19.8)	22 (31.9)	
>=25 Months	88 (58.7)	48 (59.3)	40 (58.0)	

4.2 Participant Physical and Mental health status

The majority of the participants had a diagnosis of schizophrenia spectrum disorder (68.7%, n=103). The proportion of males and females to be diagnosed with schizophrenia spectrum disorder was similar (67.9%, n=55 and 69.7%, n=48 respectively), but a greater proportion of males were diagnosed with substance induced psychotic disorder (18.5%, n=15) compared to females (2.9%, n=2), and a greater proportion of females were diagnosed with schizoaffective disorder (15.9%, n=11) compared to males (4.9%, n=4). These differences were statistically significant ($p=0.01$). (See Table 1). A minority of the participants reported having a co morbid physical illness (20%, n=30). In this sample, there was a slightly lower proportion of males (8.6%, n=7) than females (13.0%, n=9) with a co morbid diagnosis of HIV/Aids.

All participants were on either injectable antipsychotic medication or taking antipsychotic medication which were in pill form (tablets). The majority of the participants were reported using medication in pill form (76%, n=114), and this did not differ significantly between males (80.2%, n=65) and females (71.0%, n=49). The duration that participants were on a particular medication was also explored, and most participants were on medication for a period of more than 25 months (58.7%, n=88). A greater proportion of males reported being on antipsychotic for less than a year (21.0%, n=17) compared to females (10.1%, n=7), but this difference was not statistically significant (See Table 1).

4.3 Prevalence of antipsychotic medication non-adherence among clients with psychosis

Nearly 44% of participants reported being non-adherent to antipsychotic medication (n=66), (See Table 2). The prevalence of non-adherence was higher for males than for females (OR=1.06, 95% C.I 0.51-2.17) but not statistically significant.

Table 2: Logistic regression

Variables	Adherence		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
	Yes n (%)	No n (%)		
Total sample, n=150	(n=84,56%,)	(n=66, 44%)		
Gender				
Male	44 (54.3)	37 (45.7)	1.00	
Female	40 (58.0)	29 (42.0)	0.86 (0.45-1.65)	1.06 (0.51-2.17)
Age (mean, SD)	33.2 (8.99)	34.2 (10.00)	1.01 (0.98-1.05)	
Marital Status				
Single	49 (57.6)	36 (42.4)	1 .00	
In Relationship	35 (53.8)	30 (46.2)	1.17 (0.61-2.24)	
Employment				
Yes	50 (57.5)	37 (42.5)	1 .00	
No	34 (54.0)	29 (46.0)	1.15 (0.61-2.21)	
Education				
no high school(Primary)	39 (50.6)	38 (49.4)	1 .00	
high school (secondary)	45 (61.6)	28 (38.4)	0.64 (0.33-1.23)	
HIV				
Yes	10 (62.5)	6 (37.5)	1. 00	
No	74 (55.2)	60 (44.8)	1.35 (0.47-3.93)	
Insight into Disorder				
Poor	23 (44.2)	29 (55.8)	1. 00	
Good	61 (62.2)	37 (37.8)	0.48 (0.24-0.95)	0.42 (0.20-0.90)
Attitude Towards Medication				
Negative	36 (62.1)	22 (37.9)	1. 00	
Positive	48 (52.2)	44 (47.8)	1.50 (0.77-2.93)	
Side Effects (mean, SD)	4.1 (4.00)	6.7 (6.20)	1.11 (1.00-1.22)	1.10(1.03-1.17)
Alcohol use (mean, SD)	2.1 (4.73)	2.8 (6.2)	1.02 (0.96-1.09)	
Social Support Q. (mean, SD)	6.7 (1.37)	6.4 (1.49)	0.88 (0.71-1.10)	

Antipsychotics				
Pills	58 (50.9)	56(49.1)	1.00	
Injectable	26(72.2)	10 (27.8)	0.40 (0.18-0.90)	0.37(0.15-0.91)
Duration on Antipsychotics				
0-12 Months	13 (54.2)	11(45.8)	1.00	
13-24 Months	15 (39.5)	23 (60.5)	1.81 (0.65-5.10)	
>=25 Months	56 (63.6)	32(36.4)	0.68 (0.27-1.68)	

4.4 Factors predicting antipsychotic non-adherence

In the unadjusted model, a number of variables significantly predicted non-adherence in the present study. To begin with, participants who reported having good insight into their mental health disorder were less likely to be non-adherent to medication than those with poor insight (OR=0.48, 95% CI 0.24-0.95). In other words the study participants with poor insight to antipsychotic medication were 52% in unadjusted and less likely to not adhere to antipsychotic medication. Second, the participants who reported a greater number of side effects from their medication were more likely to be non-adherent to their antipsychotic medication than those experiencing fewer side effects (OR=1.11, 95% CI 1.00-1.22). Finally study participants who receive antipsychotic medications in injectable form are less likely to not adhere to antipsychotic medication (OR=0.40, 95% CI 0.18-0.90) than those who receive their medication in pill form (See Table 2). The variables that were not associated with adherence in this sample included: social demographic variables including age and gender; HIV/Aids, alcohol use, attitude to medication, social support and duration of medication. However age was marginal in terms of predicting non-adherence to medication in both unadjusted and adjusted logistical models (OR=1.01, 95% C.I 0.98-1.05).

4.5 Factors predicting antipsychotic non-adherence in multivariable logistic model

When insight, side effects and antipsychotic medication form were included in a multivariable logistic model, adjusted for age and gender, all three variables remained significant. In this final adjusted regression model, participants who had poor insight were still more likely not to adhere to antipsychotic medication (OR=0.42, 95% CI 0.20-0.90). (See Table 2). It also showed that participants that reported greater side effects were more

likely not to adhere to antipsychotic medication (OR=1.10, 95% CI 1.03-1.17). Lastly, it also showed those who were taking medication in pill form were also more likely not to adhere to antipsychotic medication (OR=0.30, 95% CI 0.15-0.91).

CHAPTER FIVE: DISCUSSION AND CONCLUSION

5.0 Introduction

The purpose of this chapter is to discuss the findings presented in Chapter 4. It will start with a discussion of the study's main findings concerning the prevalence rates and predictors of antipsychotic medication non-adherence in Mzimba, Malawi. Thereafter, the study's limitations will be addressed. It is also important to note the cronbach's Alpha of the scales used in this study, particularly the non-adherence scale (morisky adherence scale) = 0.726, drug attitude inventory scale = 0.725, insight to illness scale (Birchwood scale) = 0.597, alcohol use assessment scale (AUDIT) = 0.922. The reliability of these scales is generally good. When it comes to the scale for assessment of side effects (GASS), individuals may experience some symptoms and not others so specific items on the GASS do not have to be related. The chapter will conclude with implications for intervention development and policy, as well as recommendations for future studies.

5.1 Overview of the main findings

This study resulted in a number of important findings. First, the prevalence of antipsychotic medication non-adherence at 44% was high. Second, the lack of insight the patient had into their illness was the only patient related predictor of antipsychotic medication non-adherence. Third, medication related factors that significantly predicted antipsychotic medication non-adherence was medication side effects and the form of medication that patient was using. None of the environmental factors were found to be associated with antipsychotic medication non-adherence in this sample.

5.2 Prevalence of non-adherence to antipsychotic medication

In the current study, the rate of non-adherence to antipsychotic medication among individuals with a general diagnosis of psychosis was 44%. This study is the first to provide evidence on the non-adherence rate to antipsychotic medication in Malawi, where past evidence has focused on other conditions, rather than psychosis (Mace et al., 2011; Nightingale et al., 2016).

Nonetheless, these high rates of non-adherence are consistent with a number of studies conducted in LMIC among people living with psychosis. For example, Tesfay et al., (2013) reported a similar prevalence of non-adherence of 41% in people with schizophrenia in a hospital based study in Ethiopia; and the highest rate (44.5%) was reported by individuals

diagnosed with other non-affective psychoses. Gurmu et al., (2014) also reported a non-adherence rate of 50% among patients suffering from psychosis in Ethiopia, using the medication adherence rating scale (MARS). In Nigeria, a slightly higher non-adherence rate was reported among patients with schizophrenia (55%), where the Morisky Medication Adherence Scale was also used (Ibrahim et al., 2015). Lacro et al., (2002) in a systematic review of prevalence of and risk factors for medication non-adherence in patients with schizophrenia, found a non-adherence rate of 50%. Finally, Julius et al., (2009) in a review of medication adherence indicated that non-adherence to various types of psychiatric medication ranged between 28% – 52% for major depressive disorder, 20%– 50% for bipolar disorder, and 20% – 72% for schizophrenia.

On the other hand, a few studies conducted in LMICs reported quite different rates of non-adherence than those reported in the present study. For example, in a review of the literature on non-adherence conducted by Mert et al., (2015), the proportion of medication non-adherence was found to be 24% in patients suffering from schizophrenia much lower than what was reported in the present study. In contrast, a much higher non-adherence rate of 80% was reported in a study conducted in Ethiopia among patients suffering from psychotic disorder (Alene et al., 2012).

The contradicting findings on the level of non-adherence among patients with psychosis in LMICs may be a result of the way adherence is measured and whether subjective and direct methods were used (Velligan et al., 2006). As explained in chapter 2, direct or objective measures include pill count, blood or urine analysis, electronic monitoring, electronic refill records and pharmacy prescription refill records. On the other hand, subjective and indirect methods of measuring adherence include self-report, provider report, significant other report, and chart review. The use of one method over the other can have great implications on the rate of non-adherence reported. For example, a study conducted in Ethiopia measured non-adherence by both compliant refill method and self-report questionnaire. The results differed, 20% of the participants had compliant fills for all the prescriptions and based on the self-report 52% reported that had never missed the medication (Alene et al., 2012).

Despite the fact that both methods of assessing medication non-adherence have their own strengths and weaknesses, subjective methods are mostly used in cross sectional studies (Bayle et al., 2015) because they are relatively quick and inexpensive to administer. Such methods can also be easily replicated in other settings without requiring sophisticated

equipment or special tests. These were the only methods used to assess adherence in over 77% (124/161) of studies in a systematic review on assessing and defining adherence to oral antipsychotic medication (Velligan et al., 2006). They also provide a direct practical approach to clinicians when thinking of appropriate quick assessment tool for measuring adherence. It is for these reasons that the present study used subjective reports from patients on the adherence behaviours.

Some argue that differences in non-adherence rates can also be a result of different definitions of non-adherence. For instance, Higashi et al. (2013) reported that the definition of non-adherence can be based on a range of explanations like treatment refusal to a regular dose, or partial change of daily medication doses. Other study reviews have reported a different concept on a definition of non-adherence and also a relationship of illness and non-adherence behaviour. For instance, Rosa et al., (2005) suggested that illness severity is not necessarily a cause of non-adherence, but it may act in a bidirectional fashion, i.e., non-adherence causing worsening of symptoms and worsening of symptoms leading to lower adherence. However, the refusal to antipsychotic medication as a result of psychotic symptoms will still be called non-adherence.

Finally, the difference in findings could be as a result of the period over which adherence is assessed or how long the individual has been taking their medication (Haddad et al., 2014). For instance, non-adherence in some studies would be measured over a period of 3 months or 6 months to determine whether the patient is adherent to medication or not. Those asked about the previous 6 months may be more likely to have been non-adherent during this time, compared to those who were asked about 3 month adherence rates. There is also evidence that duration of illness may affect non-adherence, and may explain why rates of non-adherence differ in the literature. For example, patients whose illness duration was less than 5 years were more likely to stop the medication (Hui et al., 2006). In the current study, illness duration was not assessed, however participants who were on antipsychotic medication for 13-24 months had a non-adherence rate of 61%, compared to a rate of 46% among those who were on antipsychotics for less than one year.

5.3 Predicting factors to antipsychotic non-adherence

The present study investigated patient-related, medication-related and environment-related factors in relation to non-adherence of antipsychotic medication among people living with psychosis.

First, the amount of insight the patient had into his/her illness was the only patient related predictor of antipsychotic medication non-adherence in this study. Insight here refers to the ability of a patient to be aware of the illness that he or she is suffering from. Patients who had poor insight were more likely not to adhere to antipsychotic medication. This supports findings from other previous cross sectional studies, such as Nageotte et al., (1997), who reported on data from the Mississippi public mental health system for patients suffering from schizophrenia. The results indicated that patients with good insight had better medication adherence when compared to those with no insight to their illness (Nageotte et al., 1997). Lack of insight was also found to be a major factor of non-adherence to medication amongst people living with bipolar disorder and schizophrenia /schizoaffective disorder in France (Bayle et al., 2015). Unal et al., (2006) also reported that 50% of the patients lost to follow-up after discharge or those having an irregular attendance to follow up appointments did not have sufficient knowledge of their disorders. This was similar to one of the randomised control trials which reported evidence that increasing insight showed to improve medication adherence (Kemp et al., 1998).

However, it is important to note that the construct of insight may be more complicated than the construct measured in the present study. A study conducted by Kelly et al., (1990) found that treatment compliance was not related to participants' insight into their mental disorder, but rather related to an increased awareness of the specific clinical symptoms related to their illness. Furthermore, non-recognition of the need for treatment is often considered a dimension of 'poor insight' in psychosis (Amador & David 2005) and is also a symptom of the illness. This sheds light on the complexity of the construct of insight, and has implications on the interpretation of the present study's findings. Indeed, non-adherence, as reported in this study, could be as a result of the illness itself, and not necessarily a behaviour following the initiation of treatment for illness.

Interestingly, none of the other patient-related factors, that is, demographic variables and drug attitude, were found to be predictors of antipsychotic non-adherence in the present study. Drug attitude refers to negative or positive beliefs or perception about medication (Acosta et al., 2012). This is surprising, given that previous evidence suggests that drug attitude predicted non-adherence behaviours in other studies (Higashi et al., 2013; Hui et al., 2006). For instance, Higashi et al., (2013) report in a systematic review that belief that medication cannot work predicted non-adherence behaviour. In Hui et al.'s study, which assessed both drug attitude and social support, feeling embarrassed about medication was

significantly related to both forgetting to take medication and deciding to stop to take medication. In the same study, feeling worse without medication was also significantly related to forgetting to take medication, while a feeling that medication was beneficial did not show relationship to either forgetting or stopping medication. These results were generated by investigating each component of a drug attitude tool, whereas in the current study, attitude to drug/medication was evaluated using the overall score of the participants. This may explain the different results reported in the present study. However, other studies have evaluated drug attitude as a total score and found that it predicted non-adherence behaviours as well (Baby et al 2009; Rossi et al., 2009). It may be that the tool used to assess drug attitude was not suited for the study's context, and should have been validated for use in the setting of the study first.

Secondly, the side effects of antipsychotic medication were one of two medication-related factors found to predict non-adherence behaviours among patients with psychosis in this study. A number of side effects have been associated with the medication prescribed to treat psychosis, including neurological side effects, such as rigidity of the body or stiffness of the extremities; cardiovascular side effects, such as dizziness or drowsiness; and other side effects like weight gain and drooling saliva. In general, the side effects are the same whether patient has been given injectables or oral antipsychotic medication.

Given these side effects, it is not surprising that they have also been found to predict non-adherence in previous studies (Magura et al., 2014; Mert et al., 2015; Tel et al., 2010). In an expert survey, in Asian-Pacific countries, psychiatrists were asked about their perceptions of antipsychotic medication adherence levels among their patients living with schizophrenia, reasons for partial or non-adherence, their preferred methods of assessing adherence, and strategies to improve adherence (Olivares et al., 2013). According to these experts, one of the major factors predicting non-adherence to medication in patients suffering from schizophrenia was antipsychotic medication side effects (Olivares et al., 2013). In Olivares' study, experts reported that patients feared the distress associated with side effects or fear of potential side effects hence resulting into non-adherence to medication.

The other medication-related factor which predicted non-adherence in this study was medication form – that is, whether medication was given as an oral pill, or as an injection. Patients who received antipsychotic medication via injection form were less likely to not adhere to antipsychotic medications than those on oral medication. Given that in the majority

of cases, injections only need to be administered once a month to the patient, this finding is not too surprising. It has been argued that when injectables are used, the patient minimizes the chances of non-adherence because the injection is taken once in a particular period, such as two or four weeks apart. This is different with oral treatment which needs to be taken on daily basis. Kane, (2007) also report a number of advantages for depot and injectable treatments, which include a better adherence to medication. Injectables, especially long-acting injectables have actually been identified as a means of improving adherence (Buckley et al. 2009, Hosalli & Davis 2009) and preventing relapse (Morken et al., 2008). However, a meta-analysis highlights that despite the fact that injectables, such as fluphenazine deaconate, are effective and tolerable, and improves clinical outcome while improving adherence, compared to oral preparations (Zhao et al., 2016), there is evidence to suggest that there is still a lack of sustained adherence to long term maintenance treatment, regardless of form (Kane et al., 2009).

Though injectable and oral antipsychotic have similar side effects, they differ in terms of classes or types and side effect profile (NICE, 2009). Patients may also differ in their individual response or susceptibility to a particular medication side effect profile (NICE, 2009). For instance, Kishimoto et al. (2013) reported that the injectable treatment with fluphenazine deaconate, a first generation medication, is more effective than several oral antipsychotics, it is also in the group of antipsychotic medications that causes most of the side effects, especially extra pyramidal side effects. It is also important to note that first generation antipsychotics and second generation antipsychotics differ in terms of the side effects profile (NICE, 2009). For instance, Kishimoto et al.,(2013) reported that second generation antipsychotics tend to have fewer side effects than first generation antipsychotic medication hence improving adherence. Janssen et al., (2006) in a prospective study with 500 patients with schizophrenia in Germany found that patients who switched from a first generation antipsychotics to a second generation antipsychotic had a significantly higher rate of medication adherence at discharge than those who did not switch.

5.4 Implications for intervention development

In order to address non-adherence, it has been suggested that interventions should target specific factors that are associated with non-adherence behaviours (Haddad et al., 2014).

First, given the findings from the present study that insight predicts non-adherence behaviours, psycho-education for both patients and their caregivers could be a useful

intervention for this population. Psycho-education to both patient and guardians could help to highlight the importance of consistently adhering to treatment and make awareness of the illness. Hagashi et al., (2013) also support that educating the patient on medication's impact on symptoms and illness can help patients with poor insight, thereby improving adherence to antipsychotic medication. Mari et al., (2009), in their systematic review, recommended a simple and brief psycho-education that should be included in a package of care for the LMIC to decrease the treatment non-adherence among patients with psychosis.

Some studies have suggested that to address insight, it may be required to target other related factors which enhance support. Indeed, social support in the other studies was reported to improve insight and so enhance adherence behaviours among patients suffering from psychosis (Magura et al., 2014). But given that social support was not associated with adherence in the current study, the intervention targeting social support may not work in this population.

Given the results of the current study that participants who were taking injectables had showed adherence to antipsychotic medication, it is recommended to give injectables to patients that are non-adherent to antipsychotic. This is also similar to what was observed and recommended in a systematic review by Barkhof et al., (2011). In the review, it was noted that most guidelines recommended injectable medication for patients with known medication non-adherence. Similarly, Haddad et al., (2014) in the systematic review of challenges and management of non-adherence to antipsychotic medication, also recommended the use of injectables to patients with non-adherence problem. In the same review it was also argued that sometimes the negative preconception of clinicians that patients would not agree to the use of injectables, becomes a barrier to its use. One of the implications of injectables is cost. Injectables are costly than tablets especially in cases where second generation injectables are required (Haddad et al., 2014). However other studies have argued and showed evidence that antipsychotic injectables are cost effective. For instance, in a systematic review by Chue, (2007), it was found out that the number of hospitalisation and the need for outpatient consultations decreased significantly following the use of injectables such as Risperidone long acting injectable.

5.5 Implications for policy

In Malawi, there is a Mental Health Treatment Act of 1948, which is undergoing a review. The findings of the current study will inform the reviewers of the Act the prevalence and the

factors which are contributing to non-adherence behaviours. This information will help the policy direction. For instance, issues of medication prescription, the control over the prescriptions and supervision mechanism on health workers using or prescribing the medications will be enhanced to minimize the side effects and so improving adherence to medication.

There are a range of guidelines that are used in Malawi to prescribe antipsychotic medications. These include: Malawi standard treatment guide line (MSTG), British National Formulary (BNF) and other clinical medicine hand books such as Clinical hand book of Psychiatry and Paediatric hand book. The Malawi standard treatment guide line has been reviewed recently in 2015 and common mental health disorder management is included now. However, with the emerging evidence from different studies such as the non-adherence rate and factors predicting the non-adherence behaviours in the current study, it is recommended to consistently and periodically review the guide lines to incorporate the new evidenced strategies. A review and harmonisation of prescribing guidelines for clinicians is recommended and can also help to identify how the standard of proper prescription can be improved. Clinicians and nurses use different guidelines and approaches in management of people with psychotic disorders in Malawi. Keating et al., (2016) in the review of prescribing guidelines for antipsychotics, reported that clinical practice guidelines for the pharmacological treatment of first-episode schizophrenia exist but deficiencies in the evidence base make it difficult to address the key health questions relevant to medicines in clinical practice. Given the understanding of the available internationally recognized guidelines, it is important to make proper local assessment in the feasibility of using such guidelines in order to address mental health problems like non-adherence behaviours properly in a low resourced area like Malawi. A minimum, feasible management package for people suffering from psychosis should be clearly stipulated in a national mental health policy that will guide the holistic management of psychotic disorders and so addressing non-adherence behaviours as well. The Malawi standard treatment guide lines should be available at primary, secondary and tertiary health facilities; and monitored on the use.

Given evidence from this study that it is not one factor that can contribute or predict non-adherence behaviour in patients on antipsychotic medication, this study suggests that an intervention based on a multifactor model is more likely to be effective in increasing antipsychotic medication adherence.

5.5 Recommendation on clinical practice

On practice and training, the psycho education messages or information given to patients when patients are prescribed medication should also be directed towards addressing issues of non-adherence e.g. targeting the known factors that are associated with non-adherence behaviours. Patients are to be psycho educated to proactively report side effects for prompt management.

Clinicians and nurses should also make sure that the information about the medication which has been prescribed is as clear as possible. For example, Kane (2007) reported that unrealistic expectancies or unclear information on the medications can lead the patient to abandon the medication. This information given to patient is important because it will also help to determine the other areas to work with the patient in order to avoid the anticipated non-adherence behaviour.

The current study results indicate that side effects predicted non-adherence, therefore clinicians are also recommended to avoid using different types of antipsychotic medications at the same time unless indicated. Burton (2005) describes that whenever possible, pharmacological monotherapy is recommended over polytherapy. The advantage of using monotherapy is that it would help to reduce the risk of side effects. It would also help reduce the burden of taking a lot of medication which can easily forgotten

Clinicians and nurses are also supposed to talk about side effects of medication when patients are prescribed such medication to help reduce fear of the side effects, and to inform patients of what to do when they experience side effects. Reporting to the follow up clinics would also help clinicians and nurses to review and manage the side effects in the early stages before they impact on patients' adherence behaviour.

Medication adjustments or changing to different class of antipsychotics can be helpful in managing side effects. Given the side effects, prescribing second generation antipsychotic may also improve adherence. However, because of availability, only first generation medications tend to be prescribed and so low doses with ongoing monitoring of side effects may be the appropriate thing to do. Mari et al., (2009) also recommended the use of first generations antipsychotic medication by starting with low dose to monitor the occurrence of side effects and for prompt intervention.

5.6 Study limitations

Given that this study was cross sectional and was conducted in one district, the results cannot be generalized to the whole country. Participants were recruited from patients who attended the clinics at the time of the study, and did not follow up clients who missed appointment at the hospital at the time of study. This also contributes to information bias, as patients attending the clinic may be more likely to adhere to their medication.

Adherence behaviour is a complex issue and not easy to detect and quantify, and almost all methods have their own shortfalls. The use of a questionnaire, Morisky adherence scale, may therefore be criticized. It is a subjective method of assessing adherence as compared to objective methods like pill counts, plasma concentration, electronic monitors and pharmacy records. However, Velligan et al., (2006) reported that objective methods may have significant errors as well. Also, Morisky adherence scale has good psychometric properties and has shown to predict medication adherence (Morisky et al., 2008).

The other limitation is the absence of assessment of other factors like stigma, health worker-patient relationship, health systems level factors, and other drugs of abuse considering that these are also important determinants of medication adherence (Alene et al., 2012; Jenkins, 2007). These factors in the current study were not included because they were beyond the scope of the study.

5.7 Recommendations for further research

Given the limitations and constraint of the present study, additional research in the field of non-adherence is required. First, a similar study is recommended to investigate other factors related to non-adherence, which were not included in this study. Factors like other substances of abuse, such as cannabis or cocaine, rather than alcohol only, have not at all been studied in Malawi. Yet, Chapman and Horne, (2013) in their review reported that there is a link between substance abuse and non-adherence behaviour in patients suffering from psychotic disorder. A study done in Ethiopia (Alene et al., 2012) also reported that individuals noted to use social drugs e.g. cigarettes and alcohol, were significantly less likely to be adherent to their antipsychotic medications. Stigma is also another factor that should be investigated in relation to non-adherence behaviours in Malawi. For instance, Sajatovic and Jenkins, (2007) reported that stigma and negative perceptions about mental illness and psychiatric medication were widespread, and contributed to poor adherence among patients with a mental illness. It is also recommended to do qualitative studies in Malawi to have an in depth understanding of

non-adherence behaviours from patients as well as caregivers while using the theories for the behavioural change. Finally, another factor which needs to be studied is the health worker-patient relationship. Indeed, some studies such as European-multi centre study, have reported that health worker –patient relationship predicts non-adherence behaviours to antipsychotic medication (McCabe et al., 2012). This association still remains to be identified among patients with psychosis in Malawi, however.

In Malawi, there is also need to study on how antipsychotics are prescribed in different mental hospitals and clinics, to identify whether the existing guidelines are followed in order to minimize side effects of the medication, which consequently reduce non-adherence behaviours. This includes issues to do with medication dosing and the commonly prescribed antipsychotic medication, and knowledge on the management of antipsychotic medication side-effects by primary health care workers. This will then allow identifying where training and supervision needs to be reinforced, and whether policy guidelines need to be adjusted, or rather just reinforced in practice.

There is also need for further research to engage more on literature debating on the relationship between mental illness and human rights. This would discuss further different examples on how human rights of patients with psychosis are violated and how it can be managed. The human rights debate would come together with issues of stigma and discrimination which can also impact on non-adherence behaviours.

5.8 Study conclusion

The study contributes to the evidence on the prevalence and predictors of antipsychotic medication non-adherence in patients with psychosis in Mzimba, Malawi. This is the first study of its kind in the northern part of Malawi, and will hopefully contribute to the evidence base used to develop targeted interventions to address the problem of non-adherence among this population. The study has also made several recommendations in possible intervention and policy, further research and practice in comprehensively addressing the non-adherence behaviour problems.

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APPENDIX A: INFORMED CONSENT FORM

Principal Investigator: Dr. Katherine Sorsdahl,

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Project Title: The Prevalence and Predictors of Antipsychotic Medication Non-adherence among Clients with Psychotic Disorders in Mzimba, Malawi. (MPhil Student: Japhet Myaba)

Introduction: I would like to invite you to take part in a research study. The aim of the study is to find out whether clients with a psychotic disorder in Mzimba, Malawi are taking their medication as prescribed by their doctor. We also want to know if there are any factors such as understanding ones illness, social support, or alcohol use effects, and whether people with such factors adhere to their medication more than others. You are eligible for the study because you are attending the clinic and being treated for a psychotic disorder, and you are 18 years or older.

What does the study involve or ask of you: You will be asked to answer a set of questions about adherence to your antipsychotic medication, your understanding of the illness, the antipsychotic medication side effects, your beliefs towards antipsychotic medication, your social support, and about alcohol consumption. A Psychiatric Nurse or Clinical Officer will ask you the questions in a private room at the clinic soon after your consultation with the doctor. If you agree to answer the questions, it will take about 40 minutes of your time. A voucher amounting to 800 Malawi kwacha will be given to you to compensate for the time taken from you to participate in a study. Arrangements for referral will also be made in case you are found with a problem in the course of the study. For example, if you are found with alcohol problem you will be referred to a Clinician, and in case of a non-adherence to

medication problem, you will be referred to a Community Psychiatric nurse for psycho education on importance of medication adherence.

Risks or Discomforts: There are no foreseen risks or discomforts to taking part in this study, besides the time taken to answer the questions.

Benefits of taking part in the study: The results of the study will provide necessary information for Health workers to plan and manage mental health services better, which will be beneficial to you and other mental health users.

Being in the study is voluntary: Taking part in the study is entirely up to you. The data collected will be used for research only. You can refuse now, or withdraw from the study at any point; this will not affect the health care service that you receive from the clinic.

Privacy and confidentiality: The questionnaire will be given a code instead of your name. The information that you provide will be kept private.

Who to contact with questions: If you have any questions about the research, your rights as participant, or any other problems, contact the Principal Investigator using the contacts above. You can also contact the National Health Research Ethics Committee of Malawi, Secretariate on (+265) 0888 344 443; (+265) 01 726 418; or Faculty of Health Sciences, Human Research Ethics Committee, University of Cape Town, Telephone: +27 21 406 6492, Fax: +27 21 406 6411, Email: shuretta.thomas@uct.ac.za.

Declaration by participant:

By signing below, Iagree to take part in the research study explained to me.

I declare that:

- I have read the consent form, or have had it read to me, and it is written in a language which I am fluent and comfortable with.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is voluntary and I have not been pressured to take part. I also understand that I do not give up my rights to privacy and confidentiality by signing below.
- I understand that I can withdrawal the study at any time.

Signed at (place)..... on (date).....

Signature of Participant..... signature of witness.....

APPENDIX B: INFORMED CONSENT FORM-TUMBUKA VERSION

Mudangilili wa kafukufuku: Dr. Katherine Sorsdahl,

Department of Psychiatry & Mental Health, University of Cape Town.

Email: Katherine.Sorsdahl@uct.ac.za *Mobile phone:* (0) 820 554 676

Mutu wa Kafukufuku: Ukulu wa suzgo kweniso ivyo vikupangiska kuti walubali wa suzgo la Vifusi waleke kugomezgeka kupokela mankhwala gha kuvwila matenda agho walinagho gha Vifusi ku Mzimba, Malawi. (**Mwana wa sukulu wakupanga kafukufuku: Japhet Myaba**)

Adada/Bamama: Nkhumupemphani kuti mutoleko nawo luwande mu kafukufuku.

Chakulata cha kafukufuku uyu ntchakuti tione kuti kasi waluwali wa suzgo la Vifusi ku Mzimba, Malawi wakulondezga kumwa panji kupoka mankhwala ghawo umo wayoyela a dokotala.

Tikukhumba kumanyaso vinthu ivyo vikupangiska kuti waluwali waleke kugomezgeka kupokela mankhwala ghawo, nge wowwili uwo wakupoka kufuma kuwanyawo panji wabali wawo, kupulikiska kwa uluwali uwo munthu wali nawo, kweniso kumwa moba.

Ndimwe wakwenela kupanga nawo kafukufuku uyu chifukwa mwiza nawo ku zakapokela wowwili wa suzgo panji matenda gha Vifusi, kweniso munavyaka 18 panji kujumpha.

Icho kafukufuku wakumupemphani: Mukufumbika kuzgola nawo mafumbo agho ghalebeka muvigawo 8 ghakukhwaskana na mutu wa kafukufuku uyu. A Dokotala panji a Nurse wamufumbeninge mafumbo pamwekhwa pala mwamala kulembeska za suzgo ilo mwiza nalo mwahuno.

Kuzgola mafumbo uku kumutoleleninge ka nyengo pachoko ka kumwana panji 40 minisi. Pali ka mphaso kachoko waka (katundu wakukwana ndalama MK200.00) ka kumuwongani chifukwa chakutola nawo luwande pa kafukufuku uyu.

Ndondomeko yawikika kuti pala mwasangika na suzgo lililose pa nyengo yakafukufuku , mutumizgike kwa a Dokotala panji muthu waliyose uyo wali wa kwenelela kuti walutizge ku muvwilani makola.

Vyakofya: Pali je chakofya chilichose pakutola lwande pa kafukufuku uyu, kuuskako kutolako ka nyengo kinu pachoko.

Uwemi wakuchita nawo kafukufuku: Vyakusangika pa umalilo wakafukufuku vizamuvwila kuti wa vya Umoyo wamanye kupanga panji kulutiska munthazi ndondomeko za kapwelelelo ka waluwali wa suzgo la matenda gha Vifusi nge ndimwe na wanyake uwo awo wakukhumbika wowwili nge niuwo mukupokela.

Kupanganawo kafukufuku: Khumbilo la kupanganawo kafukufuku ndimwe mwabenecho. Ivyo vifumbikenge pakafukufuku uyu vizamugwila ntchito ya kafukufuku mbwenu. Mungakana panji kuleka kupanga nawo panyengo iliyose , ndimwe wakuchichizgika yayi. Kweniso pala mwakana vizamukhwaskana panji kutimbanizga wowwili uwo mukupoka nyengo yose yayi.

Chisisi cha Kafukufuku: Zina linu lizamulembekapo yayi pa chikalata icho mwazgolapo mafumbo,tizamuwikapo nambala yachisisi; kweniso vizamusungika pa malo yakufikapo mwecho wakafukufuku mbwenu.

Ninjani uyo mungamufumba panji kumukhwaska vya kafukufuku uyu: Pala munamafumbo , kweniso vya kukhwaskana na ufulu winu, vya kukhwaskana na Kafukufuku uyu , kwaskanani na mudangilili pa manambala agho ghalembeka pachanya pa chikalata ichi.

Munga manyaso kukhwaskana na Ofesi ya walala wa vya Kafukufuku vya za Umoyo pa ma nambala agha (National Health Research Ethics Committee of Malawi, Secretariate): (+265) 0888 344 443; (+265) 01 726 418; or Faculty of Health Sciences, Human Research Ethics Committee, University of Cape Town, Telephone: +27 21 406 6492, Fax: +27 21 406 6411, Email: shuretta.thomas@uct.ac.za.

Kuzomelezga kwa wakutolako lwande pa kafukufuku:

Pa kusainila apa, Inenkhuzomelezga kutolako nawo lwande pa kafukufuku na umo banilongosolela.

Nkhuyowoya mwakupanikizga kuti:

- Nabelenga chikalata ichi, panji wanibelengela chikalata ichi muchiyowoyelo icho nkhopulika.
- Nangubaso na mwawi wakufumba mafumbo agho gha zgoleka makola
- Napulikiska kuti ndine wakuchichizgika yayi kutolako lwande mu kafukufuku uyu, kweniso paliye uyo wanichichizga. Nkhumanyaso kuti chisisi chane chamala yayi chifukwa cha ku saina kalata uyu.
- Nkhumanyaso kuti ningamanya kuleka kupanga nawo kafukufuku uyu nyengo ili yose iyo na khumba.

Na sainila ku (malo)..... pa zuwa la (deti).....

Saini ya wakutola lwande pa kafukufuku.....

Saini ya Kaboni.....

APPENDIX C: RESEARCH QUESTIONNAIRE

SECTION A: DEMOGRAPHIC DATA.

Respondent Code: _____

Location/Residential area of respondent: _____

Residential area: Urban Rural

Gender of respondent: Male Female

Age of respondent: _____

Marital status: Single Married Widowed

Divorced Separated

Occupation: Employed Student Farmer

Business man/Woman Unemployed

Education level: None Primary Secondary Tertiary

Religion: Christian Moslem Other -Specify-----

Primary diagnosis (Psychotic disorder) -----

Other Mental Health disorder:-----

Are you suffering from any of the following medical conditions:

HIV/Aids:-----Treatment:-----

Tuberculosis:_____Treatment:_____

Diabetes Mellitus:_____Treatment:_____

Hypertension:_____Treatment:_____

Other Medical conditions with their

treatment:

SECTION B

PARTICIPANT'S ANTIPSYCHOTIC MEDICATION

Instruction: Tick in the box which corresponds to the appropriate answer

Haloperidol tablets Haloperidol injection (depot)

Chlorpromazine tablets Chlorpromazine syrup

Chlorpromazine injection Stellazine tablets

Fluophenazine injection
(Modicate depot) Resperidone

Other antipsychotic medication :(specify)

Daily total dose of antipsychotic mentioned

above:_____

Other medication other than antipsychotic medication:

(specify)_____

For how long have you been on antipsychotic medication mentioned above?

<6 months 6-12 months 12-24 months 25 months and above

If <6 months

(specify): _____

Any other relevant information about antipsychotic medication mentioned above that client is taking: _____

SECTION C :

MORISKY MEDICATION ADHERENCE SCALE

Instruction: *Tick in the box which corresponds to the answer*

1. Do you sometimes forget to take your antipsychotic medication?

Yes No

2. Over the past two weeks, were there any days when you did not take your antipsychotic medication? s No

3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?

Yes No

4. When you travel or leave home, do you sometimes forget to bring along your medication?

Yes No

5. Did you take your antipsychotic medicine yesterday?

Yes No

6. When you feel like your psychotic disorder is under control, do you sometimes stop taking your medicine?

Yes No

7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your psychotic disorder treatment plan?

Yes No

8. How often do you have difficulty remembering to take all your antipsychotic medicine?

never/rare once in a while sometimes
Usually all the above

SECTION D

BIRCHWOOD SCALE

Now I will ask you questions patterning to your insight to your illness.

Instruction: *Tick in the box which corresponds to your answer*

1. Some of your symptoms are made by your mind.

Disagree Unsure Agree

2. You are mentally well.

Agree Unsure Disagree

3. You do not need medication.

Agree Unsure Disagree

4. Your stay in the hospital is necessary.

Disagree Unsure Agree

5. The doctor is right in prescribing medication for you.

Disagree Unsure Agree

6. You do not need to be seen by a doctor or psychiatrist.

Agree Unsure Disagree

7. If someone said you have a nervous or mental illness, they would be right.

Disagree Unsure Agree

8. None of the unusual things you are experiencing are due to an illness.

Agree Unsure Disagree

SECTION E.

GLASGOW ANTIPSYCHOTIC SIDE-EFFECT SCALE (GASS)

These questions are about how you have been recently. They are 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 or last box if you found that the side effect was distressing for you.

Over the past week:		Never	Once	A few times	Every day	Tick this box if distressing
1	I felt sleepy during the day					
2	I felt drugged or like a zombie					
3	I felt dizzy when I stood up and/or have fainted					
4	I have felt my heart beating irregularly or unusually fast					
5	My muscles have been tense or jerky					
6	My hands or arms have been shaky					
7	My legs have felt restless and/or I couldn't sit still					
8	I have been drooling					
9	My movements or walking have been slower than usual					

4. Medications make me feel more relaxed Yes No
5. Medication makes me feel tired and sluggish Yes No
6. I take medication only when I feel ill Yes No
7. I feel more normal on medication Yes No
8. It is unnatural for my mind and body to be controlled by medications. Yes No
9. My thoughts are clearer on medication Yes No
10. Taking medication will prevent me from having a breakdown Yes No

SECTION G.

AUDIT (ALCOHOL USE DISORDERS IDENTIFICATION TEST)

PATIENT: Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential, so please be honest. For each question in the chart below, place an X in one box that best describes your answer.

Question	0	1	2	3	4	
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 or more times a week	
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more	
	Never	Less than monthly	Monthly	Weekly	Daily or almost	

3. How often do you have 5 or more drinks on one occasion?					daily	
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
	No		Yes, but not in the last year		Yes, during the last year	

9. Have you or someone else been injured because of your drinking?						
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year	
Total						

Adapted from WHO

SECTION H.

SOCIAL SUPPORT QUESTIONNAIRE 6 (SSQ6)

Instructions:

The following questions ask about people in your life who provide you with help or support. Each question has two parts. For the first part, list all the people you know, excluding yourself, whom you can count on for help or support in the manner described. Give the person's initials and their relationship to you (see example). Do not list more than one person next to each of the numbers beneath the question.

For the second part, circle how satisfied you are with the overall support you have. If you have no support for a question, check the words "No one," but still rate your level of satisfaction. Do not list more than nine persons per question.

Please answer all questions as best you can. All your answers will be kept confidential.

E.g. Who do you know whom you can trust with information that could get you in trouble?

- | | | | |
|--------|------------------|-------------------|----|
| No one | 1) T.N (brother) | 4) T.N (father) | 7) |
| | 2) L.M (friend) | 5) L.M (employer) | 8) |
| | 3) R.S (friend) | 6) | 9) |

How satisfied?

- | | | | | | |
|---------------------|------------------------|-------------------------|----------------------------|--------------------------|------------------------|
| 6-very
satisfied | 5- fairly
satisfied | 4-a little
satisfied | 3-a little
dissatisfied | 2-fairly
dissatisfied | 1-very
dissatisfied |
|---------------------|------------------------|-------------------------|----------------------------|--------------------------|------------------------|

1. Whom can you really count on to be dependable when you need help?

- | | | | |
|--------|----|----|----|
| No one | 1) | 4) | 7) |
| | 2) | 5) | 8) |
| | 3) | 6) | 9) |

How satisfied?

- | | | | | | |
|---------------------|------------------------|-------------------------|----------------------------|--------------------------|------------------------|
| 6-very
satisfied | 5- fairly
satisfied | 4-a little
satisfied | 3-a little
dissatisfied | 2-fairly
dissatisfied | 1-very
dissatisfied |
|---------------------|------------------------|-------------------------|----------------------------|--------------------------|------------------------|

2. Whom can you really count on to help you feel more relaxed when you are under pressure or tense?

- | | | | |
|--------|----|----|----|
| No one | 1) | 4) | 7) |
| | 2) | 5) | 8) |
| | 3) | 6) | 9) |

How satisfied?

- | | | | | | |
|---------------------|------------------------|-------------------------|----------------------------|--------------------------|------------------------|
| 6-very
satisfied | 5- fairly
satisfied | 4-a little
satisfied | 3-a little
dissatisfied | 2-fairly
dissatisfied | 1-very
dissatisfied |
|---------------------|------------------------|-------------------------|----------------------------|--------------------------|------------------------|

3. Who accepts you totally, including both your worst and your best points?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

How satisfied?

6-very satisfied	5- fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied
---------------------	------------------------	-------------------------	----------------------------	--------------------------	------------------------

4. Whom can you really count on to care about you, regardless of what is happening to you?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

How satisfied?

6-very satisfied	5- fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied
---------------------	------------------------	-------------------------	----------------------------	--------------------------	------------------------

5. Whom can you really count on to help you feel better when you are feeling generally down-in-the dumps?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

How satisfied?

6-very satisfied	5- fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied
---------------------	------------------------	-------------------------	----------------------------	--------------------------	------------------------

6. Whom can you count on to console you when you are very upset?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

How satisfied?

6-very satisfied	5- fairly satisfied	4-a little satisfied	3-a little dissatisfied	2-fairly dissatisfied	1-very dissatisfied
---------------------	------------------------	-------------------------	----------------------------	--------------------------	------------------------

THANK YOU FOR PARTICIPATING IN THIS STUDY
END OF QUESTIONNAIRE

APPENDIX D: RESEARCH QUESTIONNAIRE-TUMBUKA VERSION

Date: _____

GAWO 1:

VYAKUKHWASKANA NA IMWE

Nambala ya uyo wazgola mafumbo: _____

Ndondomeko ya kazgolelo:

Chongani panji kulemba panji kuzingilizga zgolo linu ili lili la kwenelela.

Mukukhala nkhu: _____

Kutauni

kukaya

Ndine: Mwanalume / Mwanakazi

Vyaka : _____

Vyanthengwa:

Wambula kutola/kutengwa

Wakutola/wakutengwa

Walikufwa mwanalume/mwanakazi

Nthengwa ilikumala

Tilikupatukana

Ntchito:

Nilipantchito

Mwanawa sukulu

Mlimi

Wabizinesi

Wambula kugwila ntchito iliyose

Vinyake(Yowoyani) _____

Sukulu:

Nindasambilepo

Pulaimale

Secondary

Kolegi

Kwa ku sopa:

Mu khilisitu

Musilamu

Nkhusopa yayi

Vinyake: _____

Suzgo ilo mukuluwala (Primary diagnosis-Psychotic disorder): _____

Masuzgo gha nyake gha wongo(other mental health disorder): _____

Kasi mukuluwalakoso masuzgo agha:

HIV/Aids _____ Makhwala agho mukumwa: _____

Tuberculosis _____ Makhwala agho mukumwa: _____

Diabetes Mellitus: _____ Makhwala agho mukumwa: _____

Hypertension: _____ Makhwala agho mukumwa: _____

Masuzgo ghanyake kusazgapo pa agha ; na wowwili wake uwo mukupokela (other medical conditions and their treatments): _____

GAWO 2:

MANKWALA GHA MATENDA GHA VIFUSI AWO MUKUPOKELA

Chongani apo pakwenelela:

Haloperidol tablets .. Haloperidol injection (depot) ..

Chlorpromazine tablets v Chlorpromazine syrup v

Chlorpromazine injection .. Stellazine tablets ..

Fluophenazine injection
(Modicate depot) .. Resperidone ..

Mukupokela mankwala gh'anandi uli agho mukumwa pa zuwa agha mwayowoya (total daily dose) : _____

Pala nga kugwaza: Mukugwaziska kalinga pa mwezi? _____

Unandi wake ukuwa mbu (e.g mg): _____

Mankhwala gh'anyake agho mukupokela pa lwande pa agho mwazunula:

7. Kumwa mankhwala zuwa lililose nisuzgo kwa wanthu wanyake, mukuona kuti pali suzgo kuti mukwaniske pa kamwelo kinu ka mankhwala? Enya / Yayi
8. Nkhalinga ako mukusuzgika kukumbukila kumwa mankhwala ghinu gha matenda gha vifusi? Paliye_____ Kamoza panyengo_____ Nyengo zinyake_____ Nyengo yose_____ Mazgolo wose agha vikuchitika kwa ine_____

GAWO 4

BIRCHWOOD SCALE

Mafumbo agha sono mufumbikenge vya ku khwaskana na umo mu kumanyila za matenda gha vifusi agho mukuluwala.

Ndondomeko: *Belengani , pala mwabelenga chongani ilo nizgolo linu.*

	Fumbo	Zgolo		
1	Vimanyikwilo vyamatenda yinu vikaba vya m'mutu waka	<i>Nkhuzomeleza a chala</i>	<i>Nkhumanya yayi</i>	<i>Nkhuzomela</i>
2	Nakhala nilimakola kwambula kuluwala vifusi	<i>Nkhuzomela</i>	<i>Nkhumanya yayi</i>	<i>Nkhuzomeleza a chala</i>
3	Mukukhumbika mankhwala yayi	<i>Nkhuzomela</i>	<i>Nkhumanya yayi</i>	<i>Nkhuzomeleza a chala</i>
4	Kukhala kwinu mchipatala nkhwawenelela	<i>Nkhuzomeleza a chala</i>	<i>Nkhumanya yayi</i>	<i>Nkhuzomela</i>
5	A Dokotala bachita makola kunilembela mankhwala	<i>Nkhuzomeleza a chala</i>	<i>Nkhumanya yayi</i>	<i>Nkhuzomela</i>
6	Nkhwenela kuoneka na ba Dokotala bakukhwaskana na matenda gha vifusi Yayi	<i>Nkhuzomela</i>	<i>Nkhumanya yayi</i>	<i>Nkhuzomeleza a chala</i>
7	Pala munyake waboyenge kuti nili na Vifusi,nthe wakuneneska	<i>Nkhuzomeleza a chala</i>	<i>Nkhumanya yayi</i>	<i>Nkhuzomela</i>
8	Pavinthu vya chilendo ivyo			

mukuonanga palije icho chikuchitikanga chifukwa cha uluwali	<i>Nkhuzomela</i>	<i>Nkhumanya yayi</i>	<i>Nkhuzomelezg a chala</i>
---	-------------------	-----------------------	-----------------------------

GAWO 5

GLASGOW ANTIPSYCHOTIC SIDE-EFFECTS SCALE (GASS)

Mafumbo agha gha kukhwaskana na umo mwakhalila mwasonosono. Yakovwila kuona kuti ka pali masuzgo agho mwasanganapo nawo kufuma ku mankwala agho mukupokela ghakukhwaskana na matenda gha vifusi.

Chongani apo pa kukhwaskana na umo mwajipulikila na makwala gha matenda gha vifusi agho mukupokela.

Pa sabata yajumpha :		Yayi	Kamoza	Kwa mazuwa ghanyake	Zuwa lilose	Chongani umu pala vyamusuzgani chomene
1	Nkhupulika tulo muhanya					
2	Nkhupulika thupi kuba lizito (kuchepelwa nkhongono)					
3	Nkhupulika chizgumbu panji chidima pala naimilila					
4	Nkhupulika mtima wane ku khung'untha mwachilendo/ panji mtima kuchimbila					
5	Nyama zane panji thupi lane likumbwambwantha panji kuwa zizito					
6	Mwawoko ghane gha kumbwambwantha/ panji kunjenjemela					
7	Malundi ghane nkhutondeka kukhazikika malo ghamoza					

8	Nkhusulula dozo					
9	Mayendelo ghane panji kachitilo ka vinthu kawelela nyuma					
10	Naba kweniso wanthu waona kuti thupi lane likwenda lekha					
11	Kaonelo kane mmaso kawa ka kuzgeleleka/kasintha					
12	Mlomo wane waba wakomila					
13	Ninasuzgo pa kutunda					
14	Nkhupulika nge niluwalenge panji kuwa na mselu					
15	Nkhujitundila pa kugona					
16	Nkhupulika nyota na kutunda pafupi pafupi					
17	Nkhuona kuti kunthazi kwa mabele ghane kukutupa kweniso kuli vilonda					
18	Naona kuti mabele ghane ghakufuma maji					
19	Nawa na suzgo kuwa na khumbilo la kukhalila malo ghamoza/kugonana na mwanalume/mwanakazi					
20	Banalume: Nawapo na suzgo lakuti nkhule kutondeka kuwuka					
21	Banakazi: Nawona kusintha na kagezelo kane ka kumwezi					
22	Banakazi na Banalume: Naona kuti nkhututuwa					

GAWO 6

MAGHANOGHANO YANE PA MANKHWALA

- Kwa ine uwemi wa mankhkwala ukujumpha uheni wake** Enya / Yayi
- Nkhujipulika nge ndine waminthondwe pala nili pa mankhwala** Enya / Yayi
- Nkhumwa mankwala abo nakhumba namwenecho** Enya / Yayi
- Mankhwala yakunipangiska kuti nibe wakumasuka chomene** Enya / Yayi
- Mankhwala yakunipangiska kuti niboneke wakuvukavuka** Enya / Yayi
- Nkhumwa mankhwala pala naluwala pela** Enya / Yayi
- Nkhupulika makola pala nili pamankhwala** Enya / Yayi
- Ntchachilendo kuti thupi lane lendelenge mankhwala** Enya / Yayi
- Maghanaghano ghane nga kungweluka pa mankhwala** Enya / Yayi
- Kumwa mankhwala kunipangiskenge kuti nileke kulwalaso** Enya / Yayi

Pala munafundo yinyake yakukhwaskana na mankhwala panyake mafumbo agha mwafumbika apa lembani kuseli kwa pepala panji yowoyani.

GAWO 7

AUDIT (ALCOHOL USE DISORDERS IDENTIFICATION TEST)

MULUWALI: Chifukwa mowa ungawa na suzgo ku umoyo winu kweniso unganangiska kagwililo ka ntchito ka mankhwala ghanyake, ntchakwenelela kuti timufumbanipo mafumbo ya kukhwaskana naumo mukumwela mowa. Mazgolo binu yaghenge gha chisisi , sono tiphalileni unenesko winu wose.

Fumbo	0	1	2	3	4	
1. Moba mukumwa kalinga?	Yayi	Pamwezi kamoza	2 mpaka ka 4 pa mwezi	2 mpaka ka 3 pa sabata	4 panji kujumpha apo pa sabata	
2. Mukumwa kalinga chakumwa chakuloweleska pa zuwa?	1 or 2	3 or 4	5 or 6	7 to 9	10 panji kujumpha	
3. Nkhalinga ako mwasangikapo kuti mwamwa ma botolo 5 panji kujumpha gha mowa?	Yayi vindachitikepo	Kujumpha mwezi yayi	Mwezi uliwose	Sabata iliyose	Zuba lililose panji pafupi fupi zuba lililose	
4. Nkhalinga muchaka chamala ichi apo mwasangikapo kuti pala mwayamba kumwa mowa mbwenu no kulekezga panji kutondeka kulekezga	Yayi vindachitikepo	Kujumpha mwezi yayi	Mwezi uliwose	Sabata iliyose	Zuba lililose panji pafupi fupi zuba lililose	
5. Nkhalinga mchaka chamala ichi apo mwasangikapo kuti mukutondeka panji mwatondeka	Yayi vindachitikepo	Kujumpha mwezi yayi	Mwezi uliwose	Sabata iliyose	Zuba lililose panji pafupi fupi zuba lililose	

kukwaniska ntchito iyo mwenelanga kuti muchite chifukwa cha kumwa mowa						
6. Nkhalinga mchaka chamala ichi apo mwasangikapo kuti pala mwamwa chomene mowa mbwenu machelo ghake mukukhumba kuti chakwamba mbwenu mumweso dankha kabotolo kamoza?	Yayi vindachitikepo	Kujumpha mwezi yayi	Mwezi uliwose	Sabata iliyose	Zuba lililose panji pafupi fupi zuba lililose	
7. Nkhalinga mchaka chamala apo mwabapo wakujinkhwintha mwati mwamala kumwa mowa?	Yayi vindachitikepo	Kujumpha mwezi yayi	Mwezi uliwose	Sabata iliyose	Zuba lililose panji pafupi fupi zuba lililose	
8. Nkhalinga mchaka chamala apo mwatondeka kukumbuka ivyo vyanguchitika chifukwa cha kulowela mayilo ghake?	Yayi vindachitikepo	Kujumpha mwezi yayi	Mwezi uliwose	Sabata iliyose	Zuba lililose panji pafupi fupi zuba lililose	
9. Mulikupangapo ngozi panji kupanga ngozi munyinu chifukwa cha kulowela mowa?	Yayi		Enya, kweni muchaka chamala yayi		Enya, muchaka chamala ichi	

10. Kasi munyinu, panji a dokotala,panji waliyose wa chipatala wali kusachizgapo kuti muchepeske panji muleke kumwa mowa?	Yayi		Enya, kweni muchaka chamala yayi		Enya, muchaka chamala ichi	
Total						

GAWO 8

SOCIAL SUPPORT QUESTIONNAIRE 6 (SSQ6)

Ndondomeko yakazgolelo:

Mafumbo agha mwafumbika kuti timanye uyu wakumupani wowwili panji uyo wakumuvikililani pa umoyo winu. Fumbo lililose linavigawo viwili.

Chigawo chakwamba; zunulani pakuikako vyakwambila mazina ya wanthu awo wakumuvilani panji kumuvikililani. Kuzunula kujumpha wanthu 9 yayi.

Chigawo chachiwili; mukufumbika kuti muyowoye umo mukukholwela na wowwili uwo mukupokela kufuma kuwanthuawo wakumuvwilani.

Zgolani mwaunenesko winu, mazgolo ghose ghazamusungika mwachisisi

E.g. Ninjani uyo mungamugomezga kumuphalilako vinthu vinyake ivyo mungasangika navyo mumasuzgo?

- | | | | |
|--------|--------------------|-----------------|----|
| Palije | 1) T.N (mkuluwane) | 4) T.N (adada) | 7) |
| | 2) L.M (munyane) | 5) L.M (mnyane) | 8) |

3) R.S (munyane)

6)

9)

Ndimwe wakukhutiskika uli?

6-Wakukhutiskika

5- Wakukhutiskika

4- Wakukhutiskika

3-Wambula

Chomene nkhanila

chomene

pachoko

kukhutiskika

2-Wambula kukhutiskika

1-Wambula kukhutiskika

Chomene

Chomene nkhanila

1. Ninjani uyo mungamugomezga pala mukukhumba wowwili?

Paliye

1)

4)

7)

2)

5)

8)

3)

6)

9)

Ndimwe wakukhutiskika uli ?

6-Wakukhutiskika

5- Wakukhutiskika

4- Wakukhutiskika

3-Wambula

Chomene nkhanila

chomene

pachoko

kukhutiskika

2-Wambula kukhutiskika

1-Wambula kukhutiskika

Chomene

Chomene nkhanila

2. Ninjani uyo mungamugomezga kumuvwilani kuti muleke kuba wakupanikizgika?

Paliye

1)

4)

7)

2)

5)

8)

3)

6)

9)

Ndimwe wakukhutiskika uli?

6-Wakukhutiskika

5- Wakukhutiskika

4- Wakukhutiskika

3-Wambula

Chomene nkhanila

chomene

pachoko

kukhutiskika

2-Wambula kukhutiskika

1-Wambula kukhutiskika

Chomene

Chomene nkhanila

3. Ninjani uyo wakumupulikiskani chomene pa vinthu ivyo mwapanga makola na pa viheni uwo panji pa ivyo mwapanga uheni?

- | | | | |
|--------|----|----|----|
| Paliye | 1) | 4) | 7) |
| | 2) | 5) | 8) |
| | 3) | 6) | 9) |

Ndimwe wakukhutiskika uli?

- | | | | |
|------------------------|------------------------|-------------------|--------------|
| 6-Wakukhutiskika | 5- Wakukhutiskika | 4- Wakukhutiskika | 3-Wambula |
| Chomene nkhanila | chomene | pachoko | kukhutiskika |
| 2-Wambula kukhutiskika | 1-Wambula kukhutiskika | | |
| Chomene | Chomene nkhanila | | |

4. Ninjani uyo imwe mungamugomezga kuti wangamovwilani kwambula kutolela pa ivyo vikumuchitikalani?

- | | | | |
|--------|----|----|----|
| Paliye | 1) | 4) | 7) |
| | 2) | 5) | 8) |
| | 3) | 6) | 9) |

Ndimwe wakukhutiskika uli?

- | | | | |
|------------------------|------------------------|-------------------|--------------|
| 6-Wakukhutiskika | 5- Wakukhutiskika | 4- Wakukhutiskika | 3-Wambula |
| Chomene nkhanila | chomene | pachoko | kukhutiskika |
| 2-Wambula kukhutiskika | 1-Wambula kukhutiskika | | |
| Chomene | Chomene nkhanila | | |

5. Ninjani uyo imwe mukugomezga kuti wanga movwilani kupulika makola mu mtima winu?

- | | | | |
|--------|----|----|----|
| Plaije | 1) | 4) | 7) |
| | 2) | 5) | 8) |
| | 3) | 6) | 9) |

Ndimwe wakukhutiskika uli?

- | | | | |
|------------------------|------------------------|-------------------|--------------|
| 6-Wakukhutiskika | 5- Wakukhutiskika | 4- Wakukhutiskika | 3-Wambula |
| Chomene nkhanila | chomene | pachoko | kukhutiskika |
| 2-Wambula kukhutiskika | 1-Wambula kukhutiskika | | |

Chomene

Chomene nkhanila

6. Ninjani uyo wakumukhwimiskani pala mwakhuwazgika?

- | | | | |
|--------|----|----|----|
| Paliye | 1) | 4) | 7) |
| | 2) | 5) | 8) |
| | 3) | 6) | 9) |

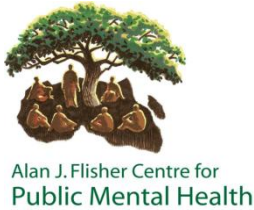
Ndimwe wakukhutiskika uli?

- | | | | |
|------------------------|------------------------|-------------------|--------------|
| 6-Wakukhutiskika | 5- Wakukhutiskika | 4- Wakukhutiskika | 3-Wambula |
| Chomene nkhanila | chomene | pachoko | kukhutiskika |
| 2-Wambula kukhutiskika | 1-Wambula kukhutiskika | | |
| Chomene | Chomene nkhanila | | |

YEWO CHOMENE PAKUTOLAKO NAWO LWANDE PA KAFUKUKFUKU UYU

MAFUMBO GHAMALILA PENIPAPA

APPENDIX E: REQUESTING PERMISSION TO CONDUCT A STUDY AT SAINT JOHN OF GOD HOSPITAL



**Alan J Flisher Centre for Public Mental
Health**

Department of Psychiatry and Mental Health

University of Cape Town

46 Sawkins Road, Rondebosch, 7700

Cape Town, South Africa

The Director of Services

Saint John of God Hospitaller Services

P.O.Box 744, Mzuzu

Malawi.

16 July, 2015

Dear Sir/Madam,

APPLICATION FOR PERMISSION TO CONDUCT A STUDY IN YOUR SERVICE

I write this letter to request your permission to enable me to conduct a study at your mental health clinic (Saint John of God Mzuzu-Centre).

I am a Mental Health Clinical Officer currently studying a Master of Philosophy degree in Public Mental Health (MPhil PMH) at University of Cape Town, South Africa. The study is entitled “**The Prevalence and Predictors of Antipsychotic Medication Non-adherence among Clients with Psychotic Disorders in Mzimba, Malawi**”.

This study will be done in fulfilment of my award and it has been approved by the University ethics committee: **HREC: 274/2015**.

Overview of the study: In Malawi, not much has been studied on the prevalence and predictors of antipsychotic medication non-adherence; therefore the study aims at understanding the factors associated with non-adherence to antipsychotic medication, namely patient, medication and environment-related factors. When this is done, the understanding of the factors that predict non-adherence to antipsychotic medication will help Health workers to plan interventions to improve adherence, consequently better functioning level of those on antipsychotic medication.

For more information you can contact **Japhet Myaba** on the contacts below or either of the following Supervisors:

Dr. Claire van der Westhuizen
Alan J Flisher Centre for Public Mental Health
Mental Health

Department of Psychiatry and Mental Health
Mental Health
University of Cape Town

Mobile: 0834456016

clairevdwest@gmail.com

Emily Baron
Alan J Flisher Centre for Public

Department of Psychiatry and
University of Cape Town

emily.baron@uct.ac.za

Your consideration will be greatly appreciated.

Your faithfully,

JAPHET MYABA.

MPhil. Public Mental Health Fellow.

Student ID number: MYBJAP001

Email: myabajaphet@yahoo.com;

Mobile: (+265) 888 563 977/ (+265) 999 119 617.

APPENDIX F: CLEARANCE LETTER FROM SAINT JOHN OF GOD HOSPITAL



Saint John of God Hospitaller Services

Registered company under Companies Act 1984

21st July, 2015

Japhet Myaba
Saint John of God Hospitaller Services
P.O. Box 160
Lilongwe

Dear Sir/Madam,

RE: PERMISSION TO CONDUCT A STUDY WITHIN ST. JOHN OF GOD HOSPITALLER SERVICES.

Your earlier communication requesting permission to conduct a study within St. John of God Hospitaller Services.

I am pleased to grant you permission to carry out the said exercise subject to the following conditions:-

- Participants will be facilitated to understand the purpose of your study, their personal involvement in the study and involvement of other people/groups.
- Consent of participants will be sought before participation in the study – the participants will also be given freedom to withdraw during any stage of the study.
- Participants will be assured of confidentiality e.g. their identity and views.

Would you need any clarification on any of the above, feel free to contact the undersigned.

Wishing you the very best in your research project.

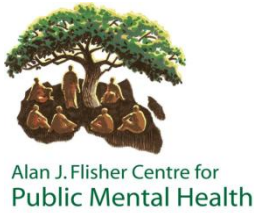
Faithfully yours,

Mwawi Ngoma/
Programme Manager.
For: **DIRECTOR OF SERVICE.**

P.O. Box 744 Tel: 265 (0) 1 311 495 Fax: 265 (0) 1 311 213 Email: sjog@sjog.mw Web: www.sjog.mw
Katoto, Mzuzu,
Malawi

Hospitality . Compassion . Respect . Justice . Excellence

APPENDIX G: CLEARANCE LETTER FROM MZIMBA DISTRICT HOSPITAL



**Alan J Flisher Centre for Public Mental
Health**
Department of Psychiatry and Mental Health
University of Cape Town
46 Sawkins Road, Rondebosch, 7700
Cape Town, South Africa

The District Health Officer
Mzimba District Hospital
P.O.Box 131, Mzimba
Malawi.

16 July, 2015

Dear Sir/Madam,

APPLICATION FOR PERMISSION TO CONDUCT A STUDY AT YOUR HOSPITAL

I write this letter to request your permission to enable me to conduct a study at your mental health clinic (Mzimba District Hospital).

I am a Mental Health Clinical Officer currently studying a Master of Philosophy degree in Public Mental Health (MPhil PMH) at University of Cape Town, South Africa. The study is entitled **“The Prevalence and Predictors of Antipsychotic Medication Non-adherence among Clients with Psychotic Disorders in Mzimba, Malawi”**.

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Overview of the study: In Malawi, not much has been studied on the prevalence and predictors of antipsychotic medication non-adherence; therefore the study aims at understanding the factors associated with non-adherence to antipsychotic medication, namely patient, medication and environment-related factors. When this is done, the understanding of the factors that predict non-adherence to antipsychotic medication will help Health workers to plan interventions to improve adherence, consequently better functioning level of those on antipsychotic medication.

For more information you can contact **Japhet Myaba** on the contacts below or either of the following Supervisors:

Dr. Claire van der Westhuizen
Alan J Flisher Centre for Public Mental Health
Mental Health

Department of Psychiatry and Mental Health
Mental Health
University of Cape Town

Mobile: 0834456016

clairevdwest@gmail.com

Emily Baron
Alan J Flisher Centre for Public

Department of Psychiatry and
University of Cape Town

emily.baron@uct.ac.za

Your consideration will be greatly appreciated.

Your faithfully,

JAPHET MYABA.

MPhil. Public Mental Health Fellow.

Student ID number: MYBJAP001

Email: myabajaphet@yahoo.com;

Mobile: (+265) 888 563 977/ (+265) 999 119 617.

APPENDIX H: MZIMBA DISTRICT HOSPITAL PERMISSION LETTER



Alan J Flisher Centre for Public Mental Health
Department of Psychiatry and Mental Health
University of Cape Town
46 Sawkins Road, Rondebosch, 7700
Cape Town, South Africa

The District Health Officer

Mzimba District Hospital

P.O.Box 131, Mzimba

Malawi.

16 July, 2015

Dear Sir/Madam,

APPLICATION FOR PERMISSION TO CONDUCT A STUDY AT YOUR HOSPITAL

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This study will be done in fulfilment of my award and it has been approved by the University ethics committee:
HREC: 274/2015.

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For more information you can contact **Japhet Myaba** on the contacts below or either of the following

Supervisors:

Dr. Claire van der Westhuizen
Alan J Flisher Centre for Public Mental Health
Department of Psychiatry and Mental Health
University of Cape Town
Mobile: 0834456016
clairevdwest@gmail.com

Emily Baron
Alan J Flisher Centre for Public Mental Health
Department of Psychiatry and Mental Health
University of Cape Town
emily.baron@uct.ac.za

Your consideration will be greatly appreciated.

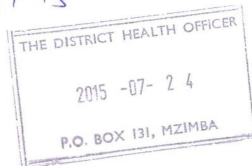
Your faithfully,

JAPHET MYABA.
MPhil. Public Mental Health Fellow.
Student ID number: MYBJAP001
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Mobile: (+265) 888 563 977/ (+265) 999 119 617.

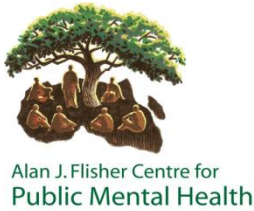
*Mzimba DHO
perm permission to conduct the study has been
granted*

24/7/15

for DHO



APPENDIX I: CLEARANCE LETTER FROM MZUZU CENTRAL HOSPITAL



**Alan J Flisher Centre for Public Mental
Health**

Department of Psychiatry and Mental Health

University of Cape Town

46 Sawkins Road, Rondebosch, 7700

Cape Town, South Africa

The Hospital Director

Mzuzu Central Hospital

Private Bag 209, Luwingu, Mzuzu 2

Malawi.

16 July, 2015

Dear Sir/Madam,

APPLICATION FOR PERMISSION TO CONDUCT A STUDY AT YOUR HOSPITAL

I write this letter to request your permission to enable me to conduct a study at your mental health clinic (Mzuzu Central Hospital).

I am a Mental Health Clinical Officer currently studying a Master of Philosophy degree in Public Mental Health (MPhil PMH) at University of Cape Town, South Africa. The study is entitled **“The Prevalence and Predictors of Antipsychotic Medication Non-adherence among Clients with Psychotic Disorders in Mzimba, Malawi”**.

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Alan J Flisher Centre for Public Mental Health
Mental Health

Department of Psychiatry and Mental Health
Mental Health
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clairevdwest@gmail.com

Emily Baron
Alan J Flisher Centre for Public

Department of Psychiatry and
University of Cape Town

emily.baron@uct.ac.za

Your consideration will be greatly appreciated.

Your faithfully,

JAPHET MYABA.

MPhil. Public Mental Health Fellow.

Student ID number: MYBJAP001

Email: myabajaphet@yahoo.com;

Mobile: (+265) 888 563 977/ (+265) 999 119 617.

APPENDIX J: MZUZU CENTRAL HOSPITAL PERMISSION LETTER

Telephone: 01 320 916 / 875

Fax: 320223/320873/270

directormch@malawi.net



In reply please quote No.

The Hospital Director,
Mzuzu Central Hospital,
Private Bag 209
Luwinga,
Mzuzu 2.

4th August, 2015.

Mr. Japhet Myaba
University of Cape Town
46 Sawkins Road,
Rondebosch, 7700
Cape Town, South Africa.

Dear Sir,

REQUEST TO CONDUCT A RESEARCH STUDY AT MZUZU CENTRAL HOSPITAL

Reference is hereby made to your letter in which you requested for permission to conduct a research study here at Mzuzu Central Hospital on a topic "*Prevalence and Predictors of Antipsychotic Medication Non-adherence Among Clients with psychotic Disorders in Mzimba, Malawi.*"

I am pleased to inform you that your request has been approved. However you need to submit approval letter from the National Health Sciences Research Committee (NHSRC) or College of Medicine Research and Ethics committee (COMREC) before you can start the data collection at this Hospital.



Yours sincerely,

B.K. Nyirenda

Deputy Research Coordinator

For: THE HOSPITAL DIRECTOR

APPENDIX K: UNIVERSITY ETHICS APPROVAL

 **UNIVERSITY OF CAPE TOWN**
Faculty of Health Sciences
Human Research Ethics Committee 

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

01 July 2015

HREC REF: 274/2015

Dr K Sorsdahl
Alan J Flisher Centre for Public Mental Health
Department of Psychiatry
46 Sawkins Road
Rondebosch
7700

Dear Dr Sorsdahl

PROJECT TITLE: THE PREVALENCE AND PREDICTORS OF ANTIPSYCHOTIC MEDICATION NON-ADHERENCE AMONG CLIENTS WITH PSYCHOTIC DISORDERS IN MZIMBA, MLAWI (Masters Candidate – Mr J Myaba)

Thank you for your letter to the Faculty of Health Sciences Human Research Ethics Committee received on 29 June 2015.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th July 2016.


Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the student Japhet Myaba will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely


PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical

HREC 274/2015

APPENDIX L: NATIONAL ETHICS APPROVAL

Telephone: + 265 789 400
Facsimile: + 265 789 431
e-mail: mohdoccentre@gmail.com
All Communications should be addressed to:
The Secretary for Health



In reply please quote No. MED/4/36c
MINISTRY OF HEALTH
P.O. BOX 30377
LILONGWE 3
MALAWI

17th September 2015

Japhet Myaba
Saint John of God Hospital Services

Dear Sir/Madam,

RE: Protocol # 15/9/1470: The prevalence and predictors of antipsychotic medication non-adherence among clients with psychotic disorders in Mzimba, Malawi

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has reviewed and **approved** your application to conduct the above titled study.

- **APPROVAL NUMBER** : NHSRC # 15/9/1470
The above details should be used on all correspondence, consent forms and documents as appropriate.
- **APPROVAL DATE** : 17/9/2015
- **EXPIRATION DATE** : This approval expires on 17/09/2016
After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING** : All serious problems having to do with subject safety must be reported to the National Health Sciences Research Committee within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using standard forms obtainable from the NHSRC Secretariat is required before implementing any changes in the Protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on Telephone No. (01) 789314, 0888344443 or by e-mail on mohdoccentre@gmail.com
- **Other**:
Please be reminded to send in copies of your final research results for our records as well as for the Health Research Database.

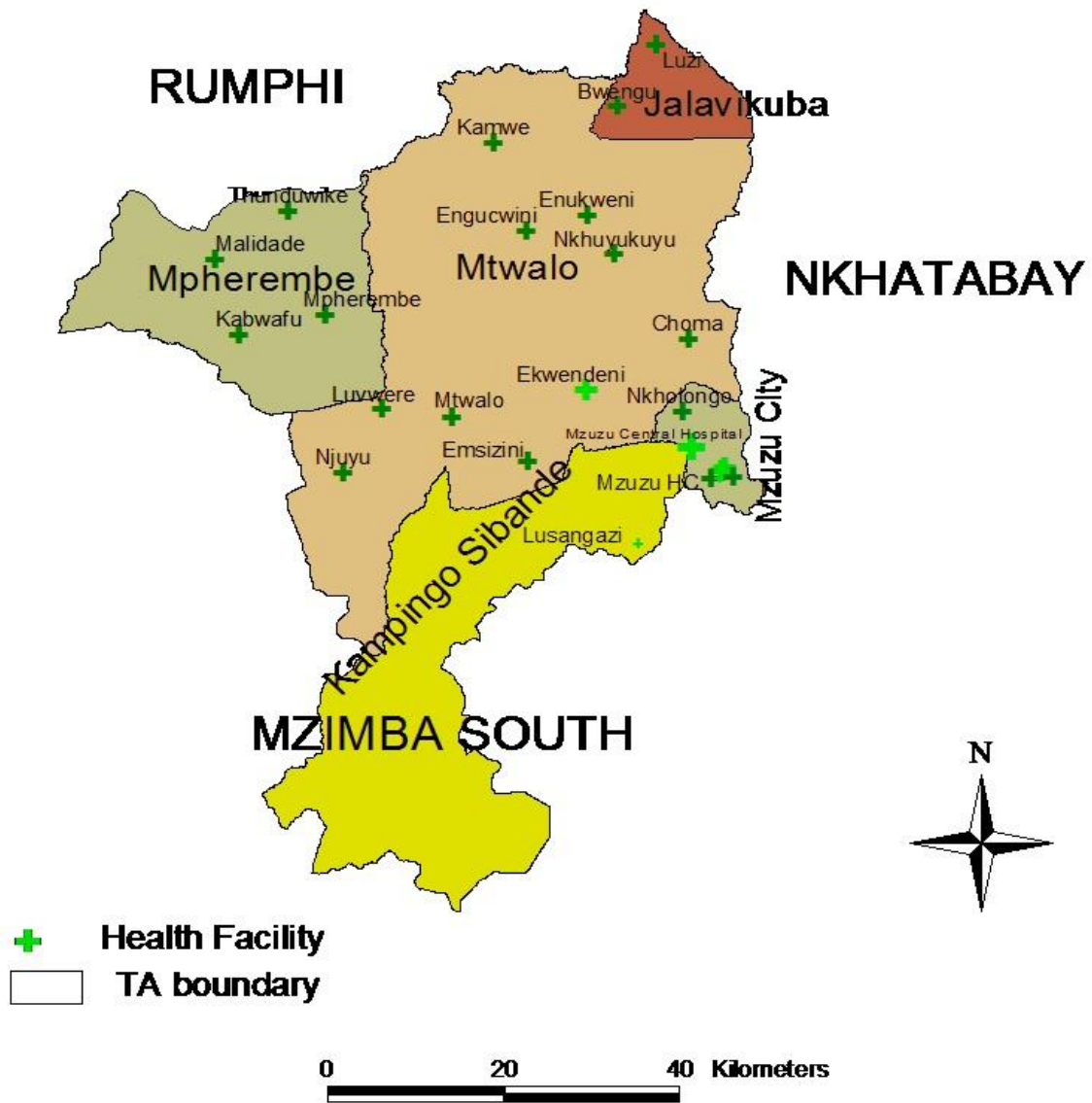
Kind regards from the NHSRC Secretariat.

.....
FOR CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

PROMOTING THE ETHICAL CONDUCT OF RESEARCH
Executive Committee: Dr. B. Chilima (Chairman), Prof. E. Molyneux (Vice Chairperson)
Registered with the USA Office for Human Research Protections (OHRP) as an International IRB
(IRB Number IRB00003905 FWA00005976)

APPENDIX M: MAP OF MZIZMBA

Map of Mzimba North showing distribution of Health Facilities



APPENDIX N: MAP OF MALAWI

