BARRIERS TO ANTIRETROVIRAL TREATMENT ADHERENCE AMONG HIV INFECTED TUBERCULOSIS PATIENTS IN JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL KISUMU, KENYA

BY

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DECLARATION

This research project is my original work and has never been submitted for any award in any other university.

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DEDICATION

This research project is dedicated to my beloved wife Rose Mary, dear daughter Praise Junior and to my entire family members for their great love, support and encouragement which have seen me throughout my studies.

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LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	**–**	Acquired Immuno-Deficiency Syndrome.
ART	**–**	Antiretroviral Therapy (treatment)
ARV	–	Antiretroviral
CASE	-	Center for Adherence Support Evaluation
CPT	–	Cotrimoxazole Preventive Therapy
DAART	–	Directly Administered Antiretroviral Therapy
DHHS	–	Department of Health and Human Services
DLTLD	-	Division of Leprosy, Tuberculosis and Lung Disease
HAART	–	Highly Active Antiretroviral Therapy
HCP	–	Health Care Provider
HIV	**–**	Human Immuno-deficiency Virus
HIV+	-	HIV positive
JOOTRH	–	Jaramogi Oginga Odinga Teaching and Referral Hospital
KAIS	**–**	Kenya AIDS Indicator Survey

KEMRI/CDC - Kenya Medical Research Institute & Center for Disease Control and Prevention

MoH – Ministry of Health

NACC – National AIDS Control Council

NASCOP – National AIDS & STI Control Program

PMTCT – Prevention of Mother to Child Transmission

PSC – Patient Support Center

TB – Tuberculosis

TB+ – TB positive

UNAIDS – United Nations Agency for International Development

UNCRD – United Nations Center for Regional Development

UNDP – United Nations Development Program

USA – United States of America

WHO – World Health Organization

ABSTRACT

To achieve long-term viral suppression, near perfect ART adherence is required. Parallel administration of antiretroviral and antituberculous therapies among HIV and TB infected patients poses significant challenges, including cumulative drug toxicities, drug-drug interactions, high pill burden, and immune reconstitution inflammatory syndrome thus complicating treatment adherence among co-infected individuals. Socio-demographic, psycho-social, clinic setting and ART treatment factors have significant impacts on antiretroviral treatment adherence among HIV patients. However, there exists limited information on how the above factors contribute to ART non-adherence among patients from resource constrained settings. This study was conducted to examine barriers to antiretroviral treatment adherence among HIV infected TB patients in Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) in Kisumu, Kenya. The study addressed specific objectives which included: to determine how socio-demographic factors influence adherence to antiretroviral treatment, to establish influence of clinic setting factors on adherence to antiretroviral treatment, to examine influence of treatment factors on adherence to antiretroviral treatment and to assess how psycho-social factors influencing adherence to antiretroviral treatment among HIV infected TB patients in JOOTRH. The study adopted descriptive research design. Both quantitative and qualitative data were collected to gather comprehensive information on study variables. A standardized questionnaire was administered to 116 systematically sampled co-infected patients to generate quantitative data. An interview guide was used to facilitate in-depth interviews with 10 TB/HIV health care providers to generate qualitative data on structural barriers to ART adherence among co-infected patients. Descriptive statistics and content analyses approaches were used to analyze quantitative and qualitative data respectively, with the help of statistical software; SPSS v16.5 and Nvivo 8 in that order. The summary of study findings were presented in forms of tables, thematic extracts and discussions. The study measured adherence on the CASE scale and revealed that 49.1% of the respondents exhibited good adherence while 50.1% had poor adherence. Analysis showed that 29.3% and 21.6% of women and men exhibited poor adherence levels respectively. About 34.5% of the respondents aged 20-24 compared to 3.5% of those over 51 years exhibited poor adherence levels. The study also showed that clinical factors had negative impacts on ART adherence. Approximately 70.7% and 20.7% of the respondents reported that they have defaulted their as a result of poor drug supply and long waiting lines at clinic, out of which 42.2% and 3.4% exhibited poor adherence levels respectively. Majority of the respondents; 89.7% acknowledged the possibility of developing side effects as a result of treatment. However, 44.0% of them fell under poor adherence level regardless of being knowledgeable. Findings further showed that allergy and dietary restrictions had impacts on ART adherence since 44.7% and 43.1% of the interviewees who had experienced allergic reactions and dietary restrictions due to both medications fell under poor adherence levels in that order. Although an estimated 74.1% of the respondents had disclosed their HIV and TB statuses to their significant others, 44.8% of them fell under low adherence level. Estimated 81.9% of the patients felt stigmatized and felt embarrassed taking both TB and HIV medications in front of others. Out of 95.7% of the respondents remembered having received counseling services during their clinic visits, 49.1% and 46.6% exhibited good and poor adherence respectively hence indicating that counseling had an impact on adherence. Socio-demographic, clinic setting, ART treatment and psycho-social factors had significant impacts on ART adherence. There is need for comprehensive health education to promote treatment adherence among co-infected patients.

CHAPTER ONE

INTRODUCTION

1.1 Background to the Study

The convergent human immunodeficiency virus (HIV) and tuberculosis (TB) pandemics continue to collectively exact significant morbidity and mortality worldwide (WHO, 2011). Antiretroviral therapy (ART) has been a critical component in combating the scourge of these two conditions as both a pre-emptive and therapeutic modality (WHO, 2009). However, concomitant administration of antiretroviral and antituberculous therapies poses significant challenges, including cumulative drug toxicities, drug-drug interactions, high pill burden, and the immune reconstitution inflammatory syndrome (IRIS) (Burman *et al.,* 2007), thus complicating treatment adherence among TB and HIV co-infected individuals.

Approximately 34.2 million people are living with HIV and AIDS (PLWHA) worldwide (WHO, 2012). An estimated 2 million deaths have been attributed annually to HIV/AIDS (UNDP, 2011). One third of the world's population is infected with Mycobacterium tuberculosis. In 2007, there were approximately 9.3 million incident cases of TB (WHO, 2009).

Globally an estimated 1.37 million (14.8%) TB cases occur in HIV-positive persons, resulting in 456,000 TB-related deaths in this population (WHO, 2009). In the USA, one quarter of all TB cases occur in HIV-infected persons (Corbett, 2003). TB/HIV co-infection is particularly prevalent in populations with limited resources.

The prevalence of HIV infection among patients with TB ranges from 50% to 80% in sub-Saharan Africa, as compared to 2–15% in other parts of the world. The HIV pandemic has

fueled a rise in both TB incidence and mortality, with an approximately 40% increase in incident TB (Getahun *et al.,* 2010).

Concurrent treatment of TB and HIV is associated with a higher risk of adverse reactions compared to treatment of either infection alone (UNDP, 2011). In particular, the first-line antituberculous drugs isoniazid, rifampin, and pyrazinamide may each cause hepatotoxicity, compounded by concurrent use of protease inhibitors and nonnucleoside reverse transcriptase inhibitors (Burman *et al.,* 2001). Since HIV-infected persons are at increased risk for isoniazid-induced peripheral neuropathy, these patients should take vitamin B6 and avoid antiretroviral drugs with potential peripheral neurotoxicity (e.g. stavudine and didanosine). Additionally, gastrointestinal distress and high pill burden can contribute to reduced tolerability and adherence to a combined TB/HIV therapeutic regimen.

ART non-adherence among HIV-infected patients remains a public health concern. A meta-analysis of 569 ART studies conducted by DiMatteo (2004) revealed that patients display an average non-adherence rate of 25% globally, and 45% for North America. Another meta-analysis study divulged a combined continental non-adherence prevalence of 36% (Mills *et al.,* 2006).

In the developed nations, a study assessing ART adherence among HIV+ patients in the United Kingdom reported a composite measure of non-adherence rate of 58%, particularly among TB/HIV co-infected patients (Sherr *et al.,* 2008). A survey in the USA revealed that nearly 21% of AIDS patients, on ARV drugs, missed a dose in 24 hours while 34 % had skipped a dose in 3 days perhaps due to dietary restrictions, stigma and changes in lifestyles associated with the antiretroviral therapy (Stone, 2000).

In Cuba a study among 847 HIV patients showed 70.6% self-reported high adherence (Aragonés *et al.,* 2006) as a result of self-efficacy, changing treatment regimens, good communication with the clinician, commitment to and opinions about treatment improves adherence. This report is consistent with the findings of Mills *et al.* (2006) that reported ART adherence prevalence of 77% for Africa. From the available data, it is evident that ART non-adherence rates are higher among HIV+ patients in developed countries (D'Armino *et al.*, 2002). However, adherence rates are slightly higher in developing countries.

In Africa recent studies have reported non-adherence prevalence of 23% for (Wakibi *et al.,* 2011). However, optimal adherence is particularly difficult for HIV-positive (HIV+) individuals because ART regimens are complicated, have complex side effects, and associated stigma, psycho-social, clinical setting and cultural barriers (Peterson *et al.,* 2000).

In sub-Saharan African countries studies have shown low treatment adherence among HIV+ patients; with 63% adherence rate in South Africa (Orrell, 2003); 68% in Uganda (Byakika *et al.,* 2005), 54% in Nigeria (Iliyasu *et al.,* 2005). Non-adherence prevalences of 24% (Amberbir et al., 2008) and 13% (Marcellin *et al.,* 2008) were reported in Southwest Ethiopia and Cameroon respectively. Higher adherence rates in Cameroon were associated with consistent treatment of side effects in co-infected patients, counselling, social and economic support. At least 80% adherence is required for virological suppression of HIV and rates below this level are associated with poor adherence in patients (Paterson *et al.,* 2000).

Kenya is considered to have one of the highest co-infection prevalence rates of HIV/AIDS/TB in the world, accompanied by indescribable human suffering and socio-economic helplessness, with little hope of rapid change in sight. ART adherence rates in Kenya remain inconsistent. Different studies have reported varied rates with 64% adherence rate in Mombasa

(Munyao *et al.,* 2005); 48% in Kibera, Nairobi (Ellis *et al.,* 2006), and 56.8% in Eldoret (Talam *et al.,* 2008). A recent study by Wakibi *et al.* (2011) revealed a non-adherence prevalence of 18% among HIV+ patients in Nairobi. However, the study did not consider the influence of TB/HIV co-infection in ART adherence.

Non-disclosure of HIV status, alcohol use, being female, illiteracy, side-effects, stigma, and distance to hospital have been documented as the major barriers to optimal ART adherence (Mariana *et al.,* 2008; Sarna *et al.,* 2008). Similarly, lack of knowledge and negative perception towards HIV and TB medications have significantly affected treatment adherence (Chesney, 2003) among most co-infected patients.

KEMRI/CDC program in collaboration with the Ministry of Health is supporting an integrated TB/HIV clinic in JOOTRH. Based on the nature of TB and HIV medication, regular adherence monitoring is essential to follow the quality of treatment. However, no study has been conducted to determine adherence rates among TB/HIV patients in JOOTRH.

Lack of reliable tools to perfectly capture data among co-infected patients hinders ART adherence monitoring. The available tools include questionnaires, pill counts, self-reports and monitoring of pill collection regularity. All are limited in capturing behavioral factors associated with non-adherence. Given evidence indicating the inadequacy of accurate tools to monitor ART adherence in TB/HIV integrated clinics, contemporary data are specifically lacking.

1.2 Statement of the Problem

Globally, 8% of TB cases are co-infected with HIV. A third of the co-infections occur in Africa. In Kenya, 50% of TB cases treated in DOTs centres are co-infected and 10% of all HIV infected develop TB yearly. HIV prevalence is highest in Nyanza Province at 14.9%, double the national rate (KAIS, 2007). Approximately 70% of TB patients in the Province are HIV infected and about 31% of HIV-infected TB patients are on ART.

Kenya has recorded ART non-adherence prevalence of 23% among HIV infected patients (Wakibi *et al* 2011). However, this study did not consider non-adherence among co-infected patients hence creating need to establish the prevalence among co-infected patients.

ART non-adherence prevalence among co-infected patients in JOOTRH is unclear given the status of the facility as a referal center. ART adherence history of most patients referred remain unknown given the non-standardization of referral tools ART monitoring tools. The tools do not capture adequate information on socio-demographic, psycho-social, ART treatment and clinic setting factors that influence adherence.

TB clinic has recorded high ART non-adherence rates among young patients with low levels of education and social support. Similarly, it has been established that male co-infected patients with low of levels of income often do not meet the required ART adherence standards. It is therefore apparent that socio-demographic factors influence ART adherence. It is therefore critical to establish the extent to which demographic factors influence ART non-adherence among co-infected patients.

JOOTRH as a newly upgraded teaching and referral hospital experiences myriad of challenges associated with the change of status which may affect patients' treatment adherence.

This study was conducted in an attempt to examine various factors that influences ART adherence among patients enrolled in the facility.

1.3 Purpose of the Study

The purpose of the study was to determine barriers to antiretroviral treatment adherence among HIV infected TB patients in Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) in Kisumu, Kenya.

1.4 Objectives of the Study

i. To determine how socio-demographic factors influence antiretroviral treatment adherence among HIV infected TB patients in JOOTRH in Kisumu, Kenya.
ii. To establish the influence of clinical setting factors on antiretroviral treatment adherence among HIV infected TB patients in JOOTRH in Kisumu, Kenya.
iii. To examine the extent to which ART treatment factors influence antiretroviral treatment adherence among TB/HIV co-infected patients in JOOTRH in Kisumu, Kenya.
iv. To assess how psycho-social factors influence antiretroviral treatment adherence among TB/ HIV co-infected patients in JOOTRH in Kisumu, Kenya.

1.5 Research Questions

i. How do socio-demographic factors influence antiretroviral treatment adherence among HIV infected TB patients in JOOTRH in Kisumu, Kenya?
ii. What are the influences of clinical setting factors on antiretroviral treatment adherence among TB/HIV co-infected patients in JOOTRH in Kisumu, Kenya?
iii. To what extent do ART treatment factors influence antiretroviral treatment adherence among TB/HIV co-infected patients in JOOTRH in Kisumu, Kenya?

iv. How do psycho-social factors influence antiretroviral treatment adherence among TB/ HIV co-infected patients in JOOTRH in Kisumu, Kenya?

1.6 Significance of the Study

It was hoped that knowledge gained from this study on barriers to ART adherence among HIV+ TB patients would help in making recommendations regarding the development of appropriate health education strategies to inform patients on the importance of adherence to ART. The researcher was optimistic that information collected would be used in developing guidelines and education materials that could be used in adherence counseling before HIV infected TB patients are started on ART and in monitoring of treatments.

It was expected that the findings of the study would also contribute towards the review of the HIV/AIDS treatment protocols and procedures, review of health education programs for HIV positive patients to improve clinical management of HIV/AIDS. Finally, the researcher believed that recommendations from the study would provide scholars with avenues for further studies.

1.7 Basic Assumptions of the Study

The study was aware that there were barriers that were likely influence adherence to antiretroviral treatment among HIV infected TB patients in JOOTRH. Socio-demographic, clinical setting, psycho-social, and ART treatment factors can impact on the patient's adherence to HIV treatment. However, cultural and religious practices are largely uniform among most patients in JOOTRH and awareness creation continuously done to patients through regular counseling sessions. Hence these may not affect participation rates differentially. It was therefore be assumed that cultural practices, hospital authorities and religious values would not

significantly affect optimal adherence to HIV treatment. Further assumption was that both political and administrative structures would remain uninterrupted at the time of the study.

1.8 Limitations of the Study

TB/HIV co-infected patients were reached in JOOTRH's TB clinic where they come for regular drug refill and clinical observations. The study was therefore conducted within the TB clinic's timetable. The data collection did not interrupt the flow of clinic activities as interviews were conducted to patients after their routine checkups. Prior interview appointments were done with the HCPs and appropriate timing done.

1.9 De-limitation of the Study

The study was confined to JOOTRH, a newly upgraded teaching and referal hospial, fomerly known as Nyanza Provincial General Hospital. The facility enrolls majority of the co-infected patients from Western Kenya due to its large capacity and the existence of integrated TB/HIV clinic. Given the new status, the hospital experiences myriad of challenges associated with the change of status which may affect patients' treatment adherence. The study explored various factors that influence adherence among co-infected patients in JOOTRH and the findings generalized to other newly upgraded referral hospitals in Kenya.

1.10 Definitions of Significant Terms used in the Study

Antiretroviral Treatment Adherence - starting and continuing with antiretroviral drugs for HIV treatment as prescribed by the health care provider.

Antiretroviral Treatment factors – include drug regimen, side effects, dietary restrictions, and treatment characteristics that influence a patient's adherence to ART

Barriers to Antiretroviral Adherence - clinical setting, psycho-social, ART treatment and socio-demographic factors occurring either at the patient level or health system level that restricts patients' initiation of and continuation into antiretroviral treatment.

Clinical Setting factors – aspects of clinic service provision, HAART re-supply, daily schedules and health facility resources that influence ART adherence.

Psycho-social factors – poverty, health literacy, perceived social support, mental health, substance abuse, stigma and cultural factors that influence ART adherence.

1.11 Organization of the Study

Chapter one presents the general background to the study, statement of the problem, research objectives, and research questions, significance of the study, limitations, delimitation, basic study assumptions and operational definitions of key terms used in the study. Chapter two presents a comprehensive literature review of barriers to antiretroviral treatment; both at the health facility and patient levels. The chapter also presents a review of relevant conceptual and theoretical frameworks. Chapter three describes the research methodology adopted for the study and highlights procedures that will be carried out during the research process. It also discusses the justification of the choices made for research process. Chapter four consists of data analysis, presentation and interpretation of the study findings. Lastly, chapter five contains summary of findings, discussion, and contribution to body of knowledge, conclusions and recommendations.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter entails literature review of the following major themes; concept of adherence, psycho-social factors, socio-demographic factors, ART treatment factors and clinical setting factors that influence non adherence to ART among HIV infected TB patients.

2.2 The Concept of Antiretroviral Treatment Adherence

Adherence plays an important role in determining quality of life, in either positive or negative ways. As social and behavioral factors affect adherent behavior, these variables are likely to exert important influences on health care utilization and therefore on health outcomes of persons living with HIV (Paterson *et al.,* 2000). Adherence may be operationalized in various ways. Dose adherence refers to the number and proportion of doses taken; schedule adherence refers to adherence to doses taken on time; and dietary adherence refers to doses taken correctly with food (Schonnesson *et al.,* 2006). In achieving optimal results from ART, all of these dimensions of adherence are required.

Non-adherence to ART may thus take various forms, such as not taking the medication at all, taking the medication at the wrong time, taking the wrong dose due to misunderstanding treatment directions, or prematurely terminating the medication without consulting the health provider (Miller, 1997). Other patterns of behavior indicative of non-adherence include not filling prescriptions, self-adjusting the regimen to modulate side effects and toxicities, and incorrectly understanding the doctor's instructions (Chesney, 2003).

Measurement of ART adherence is often problematic as patients may overestimate their adherence due to recall bias, the demand characteristics of the patient–provider consultation, and

the desire to avoid criticism (Gao & Nau, 2000). The most common methods used to measure adherence are pill counts, pharmacy refill records, drug level monitoring, and various self-report instruments (Gill *et al.,* 2005). Several studies have shown a mismatch between self-reported adherence and biomedical markers. In a sample of South Africans only 57% of patients who reported 100% adherence achieved an undetectable viral load, that is <50 copies/ml (Brown, Macintyre, & Trujillo, 2003). Assuming a high negative correlation between reported adherence and viral load, this mismatch suggests that these patients were unable to accurately report adherence levels.

Three types of factors have been identified as barriers to optimal ART adherence, namely, regimen characteristics, patient characteristics, and the relationship between the provider and patient (WHO, 2003). Regimen characteristics include dosage, the requirement of ingestion with specific foods, toxicity, and side effects. This study is concerned primarily with the clinical setting, socio-demographic, treatment effects, and psychosocial factors that influence non adherence among TB/HIV co-infected patients a public health facility, NPGH, Kisumu.

2.3 Socio-demographic Factors Influencing ART Adherence

Demographic factors have considerable influence on HIV treatment adherence. Age as a demographic factor, may influence adherence. Studies have found that apart from the most elderly adherence increases with age (Wenger *et al.,* 1999). In two studies associated with HAART adherence, non-adherence showed a positive correlation with younger age (Kaplan *et al.,* 1999). These findings are consistent with the findings of a study conducted in Kibera, Nairobi which revealed that younger respondents below the mean age (39.7 years) were more likely not to adhere to HAART although age did not predict.

Better adherence among older adults may be explained by survivor effect in that, individuals who maintain greater compliance with treatment recommendations may actually outlive those who are non-adherent. In addition to the age factor, treatment outcomes to a greater extent are also dependent on a patient's level of education. A Lower level of general education and poorer health literacy impacts negatively on some patient's ability to adhere whilst a higher level of education has a positive impact (Catz *et al.,* 1999).

Majority of people living with HIV in sub-Saharan Africa (60%) are women and girls (WHO/UNAIDS, 2008). According to KAIS (2007), a significantly greater proportion of women (8.4%) than men (5.4%) were infected with HIV in Kenya. Despite being vulnerable to HIV infection, women are more likely to adhere to ART treatment compared to men (DiMatteo, 2004). In Kenya, the proportion of females who maintained high levels of adherence is two-fold that of males (NACC, 2008). This was also evident in a survey by Wakibi *et al.* (2011) which found that the number of females with optimal adherence level was two-fold that of males among study participants in Nairobi, Kenya.

Poverty is an increasing feature of the face of HIV especially in the third world where many people are living below the poverty line (Grierson *et al.,* 2000). In the Futures II study, which surveyed 924 Australian HIV positive people, more than half of the respondents reported experiencing some difficulty in meeting the cost of daily living (Grierson, *et al.,* 2000). Medications and clinic visits cost money and may stress an already stretched budget. In the developing countries, there is no medical insurance or disability pension for people living with HIV infection (Katabira, 2002).

Social and family supports are key factors that influence ART adherence (Mariana *et al.,* 2008). Living alone and lack of support have been associated with an increase in non-adherence

and social isolation is predictive of non-adherence (Williams & Friedland, 1997). Not living alone, having a partner, social or family support, peer interaction, and better physical interactions and relationships are characteristics of adherent patients.

Interpersonal relationships can affect adherence behaviors (Mariana, 2008). Lack of trust or dislike of a patient, health care-provider, social isolation, negative publicity regarding medical establishment (Andersen, 1995), discouraging social network are impediment to ART adherence. However, family or social support, having an understanding partner, peer interaction and better physical interactions and relationships are some of the facilitators that can enable patients to achieve optimal adherence (Castro, 2005; Mills *et al.,* 2006).

A patient's beliefs about their illness and the effectiveness of medication are predictive of adherence (Wenger *et al.,* 1999). A patient's level of knowledge about HIV disease, a belief that HAART is effective and prolongs life (Stone *et al.,* 2000), and a recognition that poor adherence may result in viral resistance and treatment failure (Wenger *et al.,* 1999) all impact favorably upon a patient's ability to adhere. Conversely, lack of interest in becoming knowledgeable about HIV (Kammann *et al.,* 1999) and a belief that HAART may in fact cause harm adversely affect adherence (Horne *et al.,* 1999).

2.4 Influence of Clinical Setting Factors on ART Adherence

Access to reliable primary health care is related to increased adherence to HAART, whereas missed clinic appointments are associated with virologic failure. There are a number of aspects of a clinical setting that may be associated with adherence including transportation, waiting time, convenience of scheduling appointments, integrated services and confidentiality. In a study done in Botswana by Weiss *et al.* (2003), 30% of patients cited frequency of clinic visits

as a barrier to treatment adherence and there were patients who missed out on clinical tests and medication refills because of confidentiality concerns (Peterson *et al.,* 2000).

Clinic characteristics such as; proximity to the patient's home or place of work, the expense of getting there, lengthy delays between appointments, clinic opening and closing times, long waiting times, lack of services such as child care, privacy, confidentiality, and unsympathetic or inconsiderate staff impact ART adherence (Kammann *et al.,* 1999).

Frequent referrals to various service delivery points such counseling rooms, laboratories, examinations rooms, pharmacies, TB and HIV clinics, X-ray rooms within the facility has been a major organization factors that lead to loss of HIV/TB co-infected patients in Kenya's public health facilities (Sitienei, 2007).

Obtaining a prescription before a clinic visit was reported as an obstacle to adherence (Burgos *et al.,* 1998). For just over half of PLWHA a prescription for HAART lasts for 3 months in developed countries, however 40% receive a prescription for one month and 12% for 2 months (Grierson *et al.,* 2000). In addition, some dispensing pharmacies will only dispense one month's medication at a time. Not all health care centers are dispensing anti-HIV and TB drugs; as a result, some co-infected patients attend their local clinic for most prescription medicine and a specific health facility for their anti-HIV therapy or TB medication. In developing countries the story is very worrying as lengthy waits in a few hospitals that do not have extended hours may also impede adherence.

Common barriers related to daily schedules included: disruptions in routine or having a chaotic schedule, finding HAART too inconvenient or difficult to incorporate and difficulties in coordinating adherence with work, family or care giving responsibilities at home (Castro, 2005).

Difficulty in balancing the numerous strict dietary requirements associated with HAART; sleeping through a dose; being away from home and not bringing medication, being too distracted or busy and having no time to refill prescriptions or other pharmacy related problems and difficulties with a particular dose the middle-of-day or early morning dose (Mills *et al.*, 2006).

Economic, political, and social realities play an important role in determining the kinds of services that patients receive, the economic strains they experience, and their vulnerability to dropping out of treatment (Coetzee *et al.*, 2011). According to Coetzee and team, only two health care services exist in South Africa; one private and well resourced, and the other public and comparatively poorly resourced, which is a reflection of the economic realities that characterize South African society and indeed many African countries.

An example of a systemic problem is the understaffing of public health clinics. The WHO/UNAIDS (2008) estimated that roughly 32,000 nursing positions are vacant in the public health sector in South Africa, due to non-competitive salaries, incentives to work abroad or private sector, and the stress and burnout that occur within the public health center (Kagee *et al.*, 2007). Kenya is facing a deficiency of about 50 000 nurses in the public sector (Kibet & Obala, 2012). This shortage has brought about additional workload, paralyzed interaction with stigmatized and sometimes very ill patients, leads nurses to become ambivalent about the treatment. It is for such reasons that patients may experience negative attitudes from health care workers hence choosing to opt out from treatment from a given health facility.

Nationwide provision of antiretroviral medication to improve the quality of life among HIV infected Kenyans is top priority (MoH, 2005). However, the achievement of this policy has been minimized as a result of inadequate resources such as health care workers, medical

equipment, irregular supply of drugs, nutrition supplements (Wakibi *et al.,* 2011) and TB co-infection which increases pill burden hence leading poor treatment adherence.

2.5 Antiretroviral Treatment Factors Influencing ART Adherence

Since 1996, an overwhelming amount of evidence from clinical trials has been published validating the use of HAART for the treatment of human immunodeficiency virus (HIV) infection. Suppression of HIV replication, immune reconstitution, a halt in disease progression, increased survival; reduced morbidity and a better quality of life have been defined as the biological and clinical goals of treatment. In countries where access to this standard of care is available, AIDS related mortality and morbidity have significantly declined (Pallela *et al.,* 1998).

To achieve success near-perfect ART adherence to combination regimens is required. Failure to suppress viral replication completely inevitably leads to the selection of drug resistant variants limiting the effectiveness of therapy (Condra, 1998). Non adherence in patients on anti-HIV therapy is the strongest predictor of failure to achieve viral suppression below the level of detection and faulty adherence to anti-HIV drugs most often underlies treatment failure. It would appear that > 95% adherence may be necessary to adequately suppress viral replication, produce a durable response and halt disease progression (Paterson *et al.,* 2000). This means that missing more than one dose of a regimen per week may be enough to cause treatment failure.

A multitude of variables have been shown to affect adherence to HAART, some more than others. Almost all PLWHA who are currently using anti-HIV drugs are on a regimen of 3 or more drugs (HAART) (Grierson *et al.,* 2000). Furthermore, TB patients receive additional TB regiments thus increasing the number of drugs that TB/HIV co-infected patients take. The likelihood of a patient's adherence to a given regimen declines with polypharmacy, the frequency of dosing, the frequency and severity of side effects, and the complexity of the regimen

(Williams & Friedland, 1997). Drug hypersensitivity is far more common in patients with HIV and regimen associated toxicity is a common predictor of, and reason for, non-adherence across many studies (Murri *et al.*, 1999).

Side effects associated with each individual antiretroviral drug are well described, and whilst not universal for every patient can be predicted. Usually they defect after the first few weeks of therapy but for some, they persist. Anticipation and fear of side effects also impacts upon adherence (Wakibi *et al.,* 2011). Poor adherence has been associated with patients' desire to avoid embarrassing side effects in certain situations, for example, whilst on a date or attending a job interview (Burgos *et al.,* 1998).

Concurrent treatment of TB and HIV is associated with a higher risk of adverse reactions compared to treatment of either infection alone. In particular, the first-line antituberculous drugs isoniazid, rifampin, and pyrazinamide may each cause hepatotoxicity, compounded by concurrent use of protease inhibitors and nonnucleoside reverse transcriptase inhibitors (Burman *et al.,* 2001). Since HIV-infected persons are at increased risk for isoniazid-induced peripheral neuropathy, these patients should take vitamin B6 and avoid antiretroviral drugs with potential peripheral neurotoxicity (e.g. stavudine and didanosine). Additionally, gastrointestinal distress and high pill burden can contribute to reduced tolerability and adherence to a combined TB/HIV therapeutic regimen.

Dietary conditions add to the complexity and often require adjustments in lifestyle. Patients can find their meal schedule compromised by anti-HIV drugs that require dosing on a fasted stomach. This can be particularly difficult if work mates, family or friends are unaware of the patient's HIV status (Grierson *et al.,* 2000). Complicated regimens with rigid dosing intervals may also interrupt sleep. The physical aspects of a particular medication (taste, size, formulation,

smell, etc.) may also impact on a patient's ability to be adherent (Crespo-Fierro, 1997). Several studies have reported high non-adherence rates among patients who are receiving medications for both TB and HIV. This is mainly attributed to adverse treatment effects and increased pill burden resulting from efforts to treat the side effects associated with TB/HIV medication.

2.6 Psycho-social Factors on ART Adherence

It has been suggested that social and economic factors may combine to yield poor adherence outcomes. Poverty in itself is likely to affect adherence as funds for travel to the ART clinic may not be available, and resources may not be adequate to provide the recommended diets. The competing demands of several responsibilities such as work and family life, along with the stresses associated with poverty and difficult life circumstances such as unemployment, may obviate an acknowledgement of the importance of complying with treatment regimens in general (Simoni *et al.,* 2002). In addition, food required to be taken alongside medication may not be easily affordable and money for external prompts such as alarms and diaries may not be available.

There exists a pervasive stereotype that persons living in poverty are unable to take their medications in the way they are required to (Africa Action, 2006). However, existing data refute such stereotypes and concerns as there is consistent evidence that patients in various resource limited countries have been successfully retained on ART programs and that their viral loads have been effectively suppressed (Coetzee *et al.,* 2004).

In a study conducted in Cape Town, no association was found between socioeconomic status and ART adherence (Orrel *et al.,* 2003). In a meta-analysis of ART adherence in which 31 studies from North America and 27 studies from sub-Saharan Africa were incorporated, it was demonstrated that high levels of adherence could be indeed achieved in African settings but that

it remained a concern among patients in North America (Mills *et al.,* 2006). It is evident therefore that the stereotype of African patients living under conditions of poverty as being unable to adhere to ART is false.

Poverty as a barrier to adherence may be regarded as structural in nature. Having a low income may inhibit clinic attendance because of patients' inability to pay for transport or food. However, poverty is also an environmental and political problem in the sense that appropriate transport infrastructure may not exist in many rural areas. As shown by Kagee *et al.* (2007), transport problems and the need to take time off work without pay to attend clinic appointments were serious barriers to adherence among patients with hypertension and diabetes, to the extent that many failed to arrive for appointments or fill prescriptions.

Poverty related barriers such food insecurity, substance abuse, transport and migration affects the patients' access and adherence to ART treatment (Coetzee *et al.,* 2011). In Nairobi Kenya, poor nutrition, long distances to ART dispensing facilities and forgetfulness due busy work schedules have been established as the major predictors of non-adherence (Wakibi *et al.,* 2011). Patients living in poverty experience difficulties associated with clinic attendance which is endemic and systemically embedded, to the extent that systemic changes are required to yield better patient health outcomes.

Health literacy is a barrier to adherence among many patients living with chronic illnesses (Sullivan *et al.,* 1995). Health literacy involves an awareness of the importance of adherence despite the absence of actual symptoms (Turk, Salovey & Litt, 1986). Many medical patients only consider medication as a tertiary measure following the onset of symptoms, rather than as a prophylactic intervention (Kagee *et al.,* 2007). Yet, the longer-term health consequences of non-adherence may be severe, as symptoms will inevitably develop and the

disease will progress unchecked (Pradier *et al.,* 2006). As health literacy is often related to educational level, among poor communities in Africans characterized by limited educational opportunities, health literacy is likely to be low, accounting in part for low levels of adherence.

In a cross-sectional study of HIV clinic patients in Soweto, South Africa, 65% indicated that missing ART doses might lead to deterioration in health, while 49% stated that they believed ART could 'cure' HIV (Nachega *et al.,* 2005). The belief that ART could cure HIV was associated with a low level of education. Closely tied to health literacy regarding ART is HIV-related knowledge, which has often been shown to be associated with ART adherence (Weiss *et al.,* 2003). Weiss *et al.* (2003) recommend that health providers include questions focused on knowledge of HIV in their assessments of medication readiness and the need for adherence support.

Poor health literacy has been associated with low levels of understanding of medical instructions and adherence to ART (Kalichman *et al.,* 2000). Yet, specific psychosocial interventions designed specifically for patients with low literacy skills have been shown to yield adequate levels of adherence (Kalichman, Cherry& Cain, 2005). In the absence of properly designed interventions aimed at enhancing treatment literacy among patients in Kenya, predicting ART adherence levels remain difficult co-infected patients. The relationship between health literacy and ART adherence may also require further elucidation in Kenya.

Considerable research has demonstrated consistently that perceived social support is a strong predictor of medical adherence (Bearman & La Greca, 2002). Social support for adherence is defined as encouragement from family and friends for the patient to co-operate with the recommendations and prescriptions of a health professional (DiMatteo, 2004). The expression of concern and encouragement from others to engage in health promoting behaviors,

including medication adherence, may combine with social desirability needs on the part of the patient to yield higher rates of medical co-operation. There is strong evidence that positive social support, including being married, is associated with adherence to ART (Holstad *et al.,* 2006).

Conversely, in a qualitative study of HIV positive women, participants reported that ruptures in positive social support such as the death of a spouse, the end of an intimate relationship, divorce and family conflict resulted in some questioning their need to adhere to medication (Wood *et al.,* 2004). In Africa, difficult family circumstances contributed to by high rates of migration, teenage pregnancy, overcrowded living conditions, family violence, and substance abuse are likely to create conditions under which social and family support are poor, resulting in compromised adherence rates. On the other hand, for many patients concern for the wellbeing of their children bring into focus the need for good adherence in order to remain healthy and thus continue caring for their families (Wood *et al.,* 2004).

The health worker is often seen as a person in authority, in possession of specific expertise, and in whom the patient invests hope for assistance in the recovery process (Bury, 2004). On the other hand it has been shown that well-intentioned efforts by medical providers to emphasize the importance of adherence may actually undermine adherence (Tugenberg *et al.,* 2006). In Tugenberg *et al.'s* (2006) study, participants reported that when providers insisted on perfect adherence, they chose to conceal adherence information, as apprehension about failing to adhere perfectly led some of them to stop taking ART at all.

In a review of various studies documenting the challenges to ART adherence, mental health problems such as depression, hopelessness, anxiety, avoidance, substance abuse, and other psychological problems were identified as the most common barriers (Fogarty *et al.,* 2002).

Substance abuse is a further threat to adherence. In a study of 1889 HIV positive patients receiving ART, difficulties in obtaining medication was associated with non-adherence among heavy drinkers while a poor fit of the regimen with the patient's lifestyle was associated with non-adherence among drug users who drank heavily (Tucker *et al.,* 2004). Similarly, among a sample of HIV positive persons whose ART use was electronically monitored, those with poor adherence had higher rates of substance abuse than those who adhered adequately (Levine *et al.,* 2006).

Persons living with HIV are often subject to stigmatization and discrimination. It has been noted that stigma against HIV may be a barrier to medication adherence mainly due to the interaction between adherence and disclosure (Klitzman *et al.,* 2004). If patients are seen by members of their social constellation such as neighbors, family members, or friends, to be taking ART, this is likely to convey a signal that they are HIV positive or living with AIDS. Other factors that may affect adherence include attempts to hide the medication, change dosing schedules, or suppress observable side effects of treatment. It has been suggested that even disclosure to others may result in negative attitudes that may inhibit adherence (Klitzman *et al.,* 2004).

There are contextual and cultural factors unique to Kenya and particularly Nyanza region that may affect ART uptake and adherence in the context of the national roll-out. It has been noted that current HIV prevention and treatment programs are founded on notions of independence, decision-making, self-concept, and assertiveness rather than the social circumstance of people (Mlungwana, 2001). Therefore a focus on the potential barriers to adherence, such as health literacy, perceived social support, mental health, and substance abuse,

may unwittingly emphasize these individualistic barriers and ignore culturally relevant factors associated with adherence.

2.7 Theoretical Framework

The themes in this study will be interpreted through the Ecological Systems Theory (EST) in an attempt to describe the barriers that hinder adherence to antiretroviral treatment among TB/HIV co-infected patients. The EST was formulated by Urie Bronfenbrenner in 1975. The theory helps us understand why we behave differently when we compare our behavior in the presence of our family vis-à-vis when we are in school, hospital or at work (Bronfenbrenner, 1975). The EST holds that people encounter different environments throughout their lifespan that may influence their behavior and response to treatment in varying degrees (Darling, 2007). The EST systems comprise microsystem, mesosystem, exosystem, macrosystem, and chronosystem.

The microsystem comprises predisposing factors that influences an individual's interaction with family, friends, neighbors, and the church. This interaction is greatly influenced by socio-demographic factors such as age, marital status, employment status, education level, religion and locality of an individual. At this level, an individual is able to build social networks based on demographic elements thereby gaining a valuable source of support. Several studies have shown that positive social and family support is associated with relatively good treatment adherence (Holstad *et al.,* 2006). Non-disclosure and stigma disrupt the ability to form social networks in the microsystem. Inadequate interactions within the microsystem may result in a cascade of disruption throughout all tiers of systems of the EST model (Bronfenbrenner, 1975).

The mesosystem may be most closely associated with psycho-social and enabling factors that define poverty-related barriers to treatment adherence. Poverty appears to be associated with economic, financial and structural barriers such as transport difficulties, food insecurity, tight

work schedules, social support, substance abuse, mental health and non-adherence due to lack of early diagnosis of HIV. Most patients do not reside within walking distance of the clinic and require transport, which is expensive and not always available (Wakibi *et al.,* 2011). According to Wakibi *et al.* (2011), poor nutrition and forgetfulness due to busy work time-tables obstructed access and adherence to ART among HIV+ patients in Nairobi city.

In the context of unemployment statistics of above 40% (KNBS, 2011), the question of stigma combined with the employment crisis in Kenya has yielded a particular mesosystemic barrier to adherence. In a survey conducted in South Africa, clinicians reported that patients were reluctant to forgo a day at work by attending clinic appointments, and apparently felt they could not disclose their HIV+ status to their employers due to concerns about being stigmatized and discriminated at work (Coetzee *et al.,* 2011).

The exosystem is the third component of the ecological model. Political, economic and social systems within which the micro and mesosystem are located are defined at this level. Economic, political, and social realities play an important role in determining the nature of services that patients receive, the economic strains they experience, and their vulnerability to dropping out of treatment. This level therefore influences health facility level barriers; that is, resource and organization factors that impede adherence to HIV treatment. The level also describes institutional conditions such as limited traveling during working hours which may interfere with treatment schedules (Stone, 2000).

The macrosystem setting is the actual culture of individual hence cultural factors that define the behavior of a patient. The cultural contexts involve the socio-economic status of the person and/or his family, his ethnicity or race (Bronfenbrenner, 1975). The sets of interactions and behavior of patients are greatly shaped by the beliefs, practices, attitudes, myths, stereotypes,

stigma, marginalization and discriminations which are held by the members of the society shaped by their cultural practices (Coetzee *et al.,* 2011). The perceived stigma and exclusion described in this level has significant influence on the need factors which determine a patient's judgment to seek and or continue with treatment (Andersen, 1995; Mariana *et al.,* 2008).

The chronosystem includes the transitions and shifts in one's lifespan. This may also involve the socio-historical contexts that may influence a person's behavior (Darling, 2007). A classic example of shift is how divorce, as a major life transition, may affect not only the couple's relationship but also their treatment adherence (Coetzee *et al.,* 2011). Death of a partner or a significant other may have a negative impact on a person's access and adherence to ART.

TB/HIV co-infected patients are at the center of the ecological system and their treatment adherence is largely influenced by factors within each stratum in the system. The study attempts to describe the various factors found in each level of the EST that influence adherence to ART among co-infected patients. The theory has applicable tenets which will facilitate the interpretation of major themes in the study and enable the researcher to suggest strategies for promoting ART adherence.

2.8 Conceptual Framework

In this framework, factors influencing antiretroviral treatment adherence are considered as the independent variables. The factors have been categorized as socio-demographic, psycho-social, treatment and clinical setting factors which collectively act as barriers to ART adherence among co-infected patients. Antiretroviral treatment adherence is considered as the dependent variable.

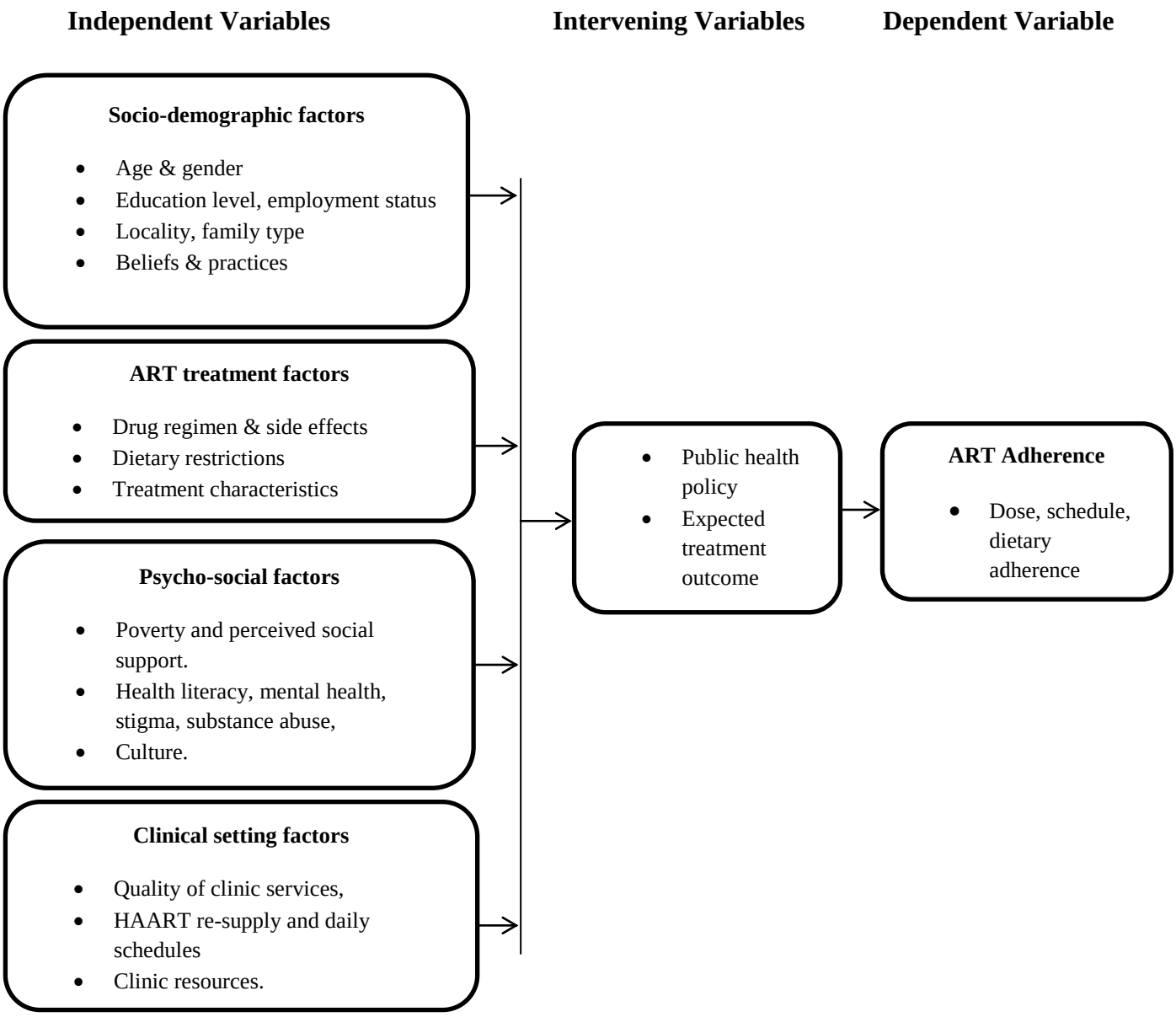

Figure 2.1: Conceptual Framework.

Adherence is the process of choosing, starting, managing to maintaining a given therapeutic medication regimen to control HIV viral replication and improve function of the immune system. It is determined by the characteristics of the health system and of the population at risk (patients) (Mariana *et al.*, 2008). Barriers to ART adherence are defined as any factor occurring at the population, patient level or health system level that restricts patients' initiation

and continuation into ART. ART is defined as any combination of drugs that have the primary intent to prevent the progression of AIDS (WHO, 2009).

Barriers at patient level comprise socio-demographic, psycho-social and treatment factors (Figure 1). These factors together determine the health-seeking behaviour of the individual. Socio-demographic factors include age, gender, marital status, family type, employment status, education level and locality of an individual.

Psycho-social factors include social and economic factors that define the beliefs, practices, perceptions, attitudes and poverty related factors; nutrition and transport problems that an individual faces. Psycho-social factors influences a person's judgment or evaluation of the illness level that may hold back or accelerate the use of treatment. The factors that inform an individual's judgement to seek medication include information about treatment, nutrition, perceived social/family support and substance abuse. The psyco-social barriers may be perceived either by the individual or by the medical care provider and influences attitudes or beliefs about treatment, medical practitioners and diseases.

Clinical setting factors are categorized as health system level barriers and consist of resource and organization factors. Resource factors include number of health care personnel, drug supply, infrastructure, equipment and material used in providing treatment. Organizational factors relate to the manner in which resources are coordinated and controlled in the process of providing treatment and may include treatment schedules, waiting hours, clinic appointments and referral systems.

For this framework, the moderating variables perceived to influence the relationship between the independent variable (IV) and dependent variable (DV) include public health

guidelines that outline HIV and TB treatment procedures among co-infected patients, and the patient's personal commitment to attain quality health status as a result of treatment despite their co-infection status. The IVs have a direct influence on the antiretroviral treatment adherence.

2.9 Gaps Identified in the Literature

Globally, ART non-adherence rate is high among co-infected patients. Studies in Kenya have reported big variations in adherence levels ranging from 64% in Mombasa (Munyao *et al.,* 2005); 48% in Kibera, Nairobi (Ellis *et al.,* 2006); and 56.8% in Eldoret (Talam *et al.,* 2008). These studies majorly focused on patients receiving ART treatments with little attention to adherence among TB/HIV co-infected patients.

Most studies reviewed have adopted quantitative research design. Drug adherence as a behavioral characteristic is best described through qualitative studies (Graneheim & Lundman, 2004; Elo & Kyngas, 2008). The study will adopt both quantitative and qualitative techniques for collection.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter discusses the study design, study population, instruments of data collection, validity and reliability of research instruments, data collection procedures, ethical considerations and methods of data analysis.

3.2 Research Design

The study adopted a descriptive survey design which is primarily concerned with finding out what, where and how of a phenomenon (Cooper & Schindler, 2003). The design was appropriate for behavioral studies and allowed for the collection of in-depth information on treatment adherence among patients thus allowed for generalization of the findings to a larger population (Sekaran, 2006).

The design helped in identifying the relationship between socio-demographic, psycho-social, clinical setting, ART treatment factors and ART adherence among co-infected patients in JOOTRH. The intention of adopting descriptive research design was to gather data at a particular point in time and use it to describe the nature of ART adherence to allow for the generalization of the findings to other populations.

Quantitative and qualitative data were collected using questionnaires and in-depth interviews respectively and analyzed to maximize the strengths of the findings (Kombo & Tromp, 2010). However, for qualitative data collection, only health care providers were interviewed to generate exhaustive information on factors hindering initiation and continuation of HIV treatment among co-infected patients.

3.3 Target Population

The study targeted 227 active HIV infected TB outpatients aged 18 years and above, enrolled for antiretroviral therapy by November 2012 and 25 health care providers (HCPs) delivering care and treatment services to TB/HIV co-infected patients in JOOTRH. HCPs comprised medical doctors, clinical officers, nurses, radiologists, pharmacists, laboratory technicians, counselors and peer educators.

3.4 Sample Size and Sampling Techniques

This section discusses the sample size determination method and the sampling procedure adopted by the study.

3.4.1 Sample Size

To determine the true proportion at 95% confidence level (Cl), appropriate sample size was computed for quantitative data collection. 25 HCPs working with co-infected patients were purposively sampled for qualitative interviews. A statistical formula recommended for cross sectional studies was used to compute the sample size;

$n = Z^2pq / d^2$; (Fischer *et al.,* 1998) as cited by Mugenda & Mugenda, (2003).

n = the desired sample size (if the target population is greater than 10 000)

Z = the standard normal deviate at the required Cl (given as 1.96 at 95% Cl)

p = proportion of HIV patients not adhering to ART taken at 23%; the continental non-adherence prevalence for Africa (Mills *et al.,* 2006).

q = 1 – **p**; the population who adhering to ART

d = acceptable error margin (precision of measurement, 5% at 95% Cl).

$$n = (1.96^2*0.23*0.77)/0.05^2 = 272$$

$$n = 272$$

272 was the desired sample size if the population, **N**≥10 000. However, the target population, **N**=227 was less than 10 000. The required sample size would therefore be smaller. We therefore found an estimated sample (**y**) using the formula; **y = n / [1+n/N]**, (Mugenda & Mugenda, 2003)

Where **N** = 227; the estimate of the target population.

y = the required sample size if N<10 000

$$\mathbf{y} = 272/ [1+ (272/227)] = 124$$

The assumptions were that a sample size of 124 co-infected patients was sufficiently representative of the target population; the sampling error would be small, the sample would be viable in the context of funds and time available for the research study. Systematic bias was controlled in a better way and study results would be generalizable (Kothari, 2004).

3.4.2 Sampling Procedure

The study adopted a systematic sampling design. TB/HIV clinic register was used as a sampling frame. It contains patients' clinic numbers in a sequential order as well as demographic information. Eligible patients' clinic numbers were first grouped under male and female categories for equal gender representation. Clinic numbers were picked systematically from each group at an interval of two until the required sample size is obtained for quantitative data collection. The sampling interval **k**, was determined as **k** = N/n = 227/124 = 2.

For qualitative data collection, 25 HCPs were purposively sampled for in-depth interviewing. The clinicians have a profound understanding of the patient's behavioral and clinical response towards antiretroviral therapy (Coetzee *et al.,* 2011). They shared critical information regarding structural barriers influencing ART adherence among co-infected patients.

3.5 Data Collection Instruments

A standardized questionnaire was designed according to the objectives of the study. The questionnaire comprised five sections, each section having questions on each of the four objectives. The fifth section contained CASE adherence questions. Likert types of questions were included whereby respondents indicated the degree to which the study variables influenced their HIV treatment adherence on a five point Likert scale. Structured questions were used in attempts to conserve time and money as well as to facilitate easy analysis as they were in immediate useable form (Sekaran, 2006).

Three questions were borrowed from CASE adherence tool to measure ART adherence. CASE is a widely used adherence tool developed by the New York Academy of Medicine's (Mannheimer *et al.,* 2006) for measuring ART adherence. It consisted of three adherence questions rated on a Likert scale. A composite score was computed from the responses to CASE questions. A composite score of 10 and above signify better adherence while a score of less than 10 signify poor ART adherence.

An interview guide was developed to facilitate qualitative data collection from HCPs through in-depth interviews. The guide comprised questions on three thematic areas namely; clinical setting, psycho-social and ART treatment factors that influence ART adherence.

3.5.1 Pilot Testing of the Study Instruments

The researcher carried out a pilot study to pretest the validity and reliability of data collected using the questionnaire. Six respondents; 5% of the sample size, selected from the PMTCT clinic within JOOTRH were interviewed face to face. Data collected was analyzed to test for validity and reliability of the research instruments. Participants interviewed at this stage did not take part in the final data collection phase. The clarity of the items in the instrument was determined to enhance validity and reliability.

3.5.2 Validity of the Instruments

Pilot-testing was used as an important step in making the instrument valid for the purposes of the study. Vague questions and unclear instructions revealed. Important comments and suggestions were captured from the respondents and enabled the researcher to improve the efficiency of the instruments, adjust strategies and approaches to maximize the response rate. The responses from different participants were analyzed to come up with a generalized position which stood the validity test. The study used a survey method which usually lessens bias hence the study collected valid data.

3.5.3 Reliability of the Instruments

To measure reliability the study used the test-retest method which involved selecting six respondents from the PMTCT clinic and administering the same instrument twice to the same group of participants after two weeks' time lapse. Internal reliability was assessed by using Cronbach's coefficient alpha;

$$\boldsymbol{\alpha = \frac{N.\check{r}}{1 + (N - 1).\check{r}}}$$

Where **N** is equal to the number of items and **ř** is the average inter-item correlation among the items. A measure of squared correlation will be done between observed and true scores (Mugenda & Mugenda, 2003). A Cronbach's co-efficient of 0.70 was considered adequate and a higher alpha signified higher reliability of the instrument.

3.6 Data Collection Procedures

Permission for data collection was sought from the Ministry of Higher Education through the department of National Council for Science and Technology. Ethical clearance was obtained from JOOTRH through the department of Research and Training to allow for data collection within the hospital. Primary was collected through administration of questionnaires and interview guides.

The researcher used clinic numbers systematically sampled to select patients' files from which clinic appointment dates were retrieved and marked against the selected patients' IDs in the study time table to plan for interviews. During data collection period, the study team liaised with the peer educators to identify patients whose clinic numbers were sampled to participate in the study. 97% of the targeted respondents consented and were interviewed during their clinic visits within the study period.

Attention was paid to the principle of voluntary participation and the requirements of informed consent were observed maximally. Study objectives were explained to the participants during consenting sessions in a language that they understand well; either in English, Kiswahili or Dholuo. Confidentiality measures were strictly observed and anonymous numbering used for identifying respondents.

All filled up questionnaires were reviewed on a daily basis to ensure accuracy and completeness. A maximum of two in-depth interviews for qualitative data collection were conducted in a day to allow for note taking and transcription in order to capture complete information.

Two research assistants, with minimum academic qualifications of diploma were recruited to facilitate the data collection process. They were trained on methodology and ethical considerations in data collection.

3.8 Data Analysis Techniques

The quantitative data generated from the questionnaires were coded and keyed into MS Access database. The Access database was imported into SPSS v16.5 for descriptive analysis to generate frequencies, percentages and tabulations. Frequencies and percentage distribution were used to examine the relation between independent and dependent variables individually.

Descriptive statistics, including frequency and percentages were generated for age, sex, level of education, and used to analyze the socio-demographic characteristics of the sample. The summaries of findings were presented using tables and discussions. Statistical significance of the associations between the independent and dependent variables were interpreted using the computation of an index that measures this relationship.

Verbatim transcription of in-depth interview notes was done in MS Word. The transcripts were imported into Nvivo 8 software for axial coding and categorization on pre-identified thematic areas. Coding was performed manually and inductively, in stages as per the requirements of Grounded Theory Method for qualitative data analysis (Corbin and Strauss, 1990). Thematic extracts were edited, without losing meaning, for reporting purpose.

Manifest and latent content analysis was applied for qualitative data analysis. Content analysis is a qualitative method which focuses on the presence of, meaning of, and relationships between concepts in text, emphasizing variation within and between what is described outright (manifest content) and underlying meanings (latent content) in text (Elo & Kyngas, 2008). All

transcripts were read through a number of times until there was a sense of familiarity with the data. The summaries of findings were presented using thematic extracts and discussions.

3.9 Ethical Considerations

Permission to conduct the study was obtained from the University of Nairobi, Ministry of Higher Education through the department for National Council of Science and Technology and JOOTRH. Respondents' informed consent obtained verbally either in English, Kiswahili or Dholuo. Only TB/HIV co-infected patients aged 18 years and above enrolled for ART at the facility were eligible to participate in the study. To ensure confidentiality, interviews were conducted in private areas and strict control maintained over data collected. Respondents' personal identifiers were not taken for the purpose of the study. An anonymous number was assigned to each respondent for the purposes of identification to enhance confidentiality.

The study did have any risk to the participant since the kind of questions asked were neither be personal nor sensitive. There was no direct benefit to the respondents, however, the study findings would be useful in promoting ART treatment adherence among HIV infected TB patients from resource constraint backgrounds.

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION, INTERPRETATION AND DISCUSSIONS

4.1 Introduction

This chapter presents data analysis in the following themes: response return rate, demographic characteristics of the respondents, the influence of clinical setting factors on antiretroviral treatment adherence, the influence of ART treatment factors treatment adherence, the influence of psycho-social factors on antiretroviral treatment adherence and ART adherence levels among TB/HIV co-infected patients interviewed.

4.2 Questionnaire Response Return Rate

A total of 116 out of the targeted 124 respondents were interviewed for quantitative data while 10 health care providers were interviewed to generate qualitative data. All the interviews were successful and the questionnaires were returned for analysis giving a return rate of 94%. The study realized the high return rate due to the fact that most of the respondents were reached at the TB and HIV clinics where they come for drug refill. The peer educators facilitated the data collection process by identifying those patients whose clinic numbers were sampled for interviewing. Eight sampled patients did not turn up at the facility during the data collection period. In-depth interviews with the HCPs were successful and the interview notes transcribed for analysis.

4.3 ART Adherence level among HIV Infected TB patients

To determine ART adherence levels of the respondents, three questions were borrowed from CASE adherence tool. CASE is a widely used adherence tool developed by the New York Academy of Medicine for measuring ART adherence. It consisted of three adherence questions

rated on a Likert scale. A composite score was computed from the responses to CASE questions. A composite score of 10 and above signifies better adherence while a score of less than 10 signifies poor ART adherence. Table 4.1 represents the frequencies of adherence among respondents;

Table 4.1: Distribution of the Respondents by ART Adherence Levels

	Frequency	**Percent**
Good adherence	57	49.1
Poor adherence	59	50.9
Total	**116**	**100.0**

From the table 4.1, 57 (49.1%) respondents reported good adherence while 59 (50.9%) reported poor adherence. The data concurs with the opinions of the HCP who agreed that most patients do not observe treatment adherence.

> *"...most of these patients do not complete their medications. Some of them would rather stop taking ARVs and continue with TB medicines only. Some even stop taking TB medicines when they start feeling better, that is, when one stops coughing...you know...they don't follow instructions"* (C**linical officer)**

In this extract, the clinical officer held the opinion that most co-infected patients do not complete their medications as required. The health care provider further indicated that some patients would continue with TB drugs only but stop once they start getting better. These opinions concur with the data which showed that 50.9% of the respondents had poor adherence.

The study findings gave a general impression that most patients do not observe treatment adherence requirements and hence a comprehensive health education, counseling, moral support

and treatment monitoring should be observed to improve adherence levels among co-infected patients.

4.4 Socio-demographic Factors Influencing ART Adherence

This section described the demographic characteristics of the respondents. The demographic information was collected on gender, age, level of education, marital status and occupation. The results were presented as follows in four sub-themes; the respondent's gender, age, level of education and marital status.

4.4.1 Distribution of the Respondents by Gender

The study considered the gender of the respondents as a socio-demographic factor that influences ART adherence. Respondents were asked to state their gender and results were given in the table 4.2.

Table 4.2: Adherence levels of Respondents by Gender

	Good Adherence		Poor Adherence		Total	
Male	29	25.0%	25	21.6%	54	46.6%
Female	28	24.1%	34	29.3%	62	53.4%
	57	49.1%	59	50.9%	116	100%

Large proportion of the respondents, 53.4% (62) was females while 46.6% (54) were males. This indicated that there were more females than males in this population. It therefore implied that future studies that target HIV infected TB patients should focus on strategies that target females and factors that influence their ART adherence. A cross tabulation between gender and adherence level showed that 34 (29.3%) women exhibited poor treatment adherence compared to 25 (21.6%) men.

An in-depth interview with a female nurse observed that;

> *"In this facility we have enrolled more women than men, though the difference is not that much. Some of the female patients are either widowed or divorced as a result of HIV and TB diseases. However, most of co-infected women do not follow their medications because they fear their partners especially those who have not disclosed their status."* **(Nurse)**

In this extract, the nurse asserted that there are more women than men enrolled for care in JOOTRH. She further noted that most of the co-infected women particularly those who have not disclosed their HIV+ status to their partners do not take their medications consistently due to fear of divorce, separation or discrimination. This statement is in agreement with the data which showed that many women do not observe treatment adherence.

These findings were in agreement with a study carried out by WHO/UNAIDS (2008), which found out that majority of people living with HIV in Sub-Saharan Africa are women and girls. A survey conducted in Kenya showed that significant proportion of women in Kenya infected by HIV at 8.4% as opposed to 5.4% of men (KAIS, 2007).

The study findings had consistent results with the study done by Action Aid International in 2009 on the Extent and Impact of stigma and discrimination on women and children infected and affected by HIV/AIDS which found that 71% of the most affected respondents were women. However, the results contradicted a survey by Wakibi *et al.* (2011) which found that the number of females with optimal adherence level was two-fold that of males among study participants in Nairobi, Kenya.

4.4.2 Distribution of the Respondents by Age

The study sought to establish the age distribution of the respondents who were interviewed in order to determine adherence levels among various age groups and to inform future studies and interventions of the most vulnerable age group. The respondents were asked to indicate their ages and summarized in the table 4.;

Table 4.3: Adherence levels of the Respondents by Age

Years	**Good adherence**		**Poor adherence**		**Total**	
<20	4	04.4%	0	0%	04	3.4%
20-24	18	15.5%	22	19.0%	40	34.5%
25-29	16	13.8%	12	10.3%	28	24.1%
30-34	11	09.5%	13	11.2%	24	20.7%
35-40	3	02.6%	3	02.6%	06	5.2%
41-44	2	01.7%	8	06.9%	10	8.6%
≥ 51	3	02.6%	1	00.9%	04	3.5%
	57	**49.1%**	**59**	**50.9%**	**116**	**100%**

Majority of the respondents 34.5% (40) were aged between 20–24 years, followed by 24.1% (28) aged 25–29 years and 20.7% (24) were between 30–34 years old. From the results, it was evident that age the bracket 20-24 formed the bulk of patients in this population. Therefore, it is important that any study targeting TB/HIV co-infected patients should take note of this age bracket. The findings were similar to the KEMRI/CDC Tuberculosis cohort study concluded in 2010 where majority 55.7% were aged between 20-24 years, followed by 37.7 aged between 25-29 years.

From the table 4.3, it was revealed that 19.0%, 11.2% and 10.3% of the respondents aged 20-24, 30-34 and 25-29 were at the highest risk of non-adherence respectively. This indicated that age had an impact on ART adherence hence a lot health education should be targeted to these age groups to enhance higher health literacy and increased ART adherence. These findings are consistent with a study conducted by Kaplan *et al.,* (1999) which showed that non-adherence showed a positive correlation with younger age.

4.4.3 Distribution of the Respondents by Level of Education and ART Adherence

The study found it important to analyze the level of education of the respondents and their ART adherence levels. This was considered important because the level of education determines the capacity to observe treatment prescriptions. Respondents' education levels were compared with their adherence levels the results summarized in the table 4.4.

Table 4.4: Distribution of the Respondents by Level of Education and adherence level

	Good adherence		**Poor adherence**		**Total**	
Primary	03	2.6%	3	2.6%	6	5.2%
Post primary/vocational	01	0.9%	2	1.7%	3	2.6%
Secondary	29	25.0%	30	25.9%	59	50.9%
Post-secondary	12	10.3%	9	7.8%	21	18.1%
University degree	09	7.8%	12	10.3%	21	18.1%
No formal education	03	2.6%	3	2.6%	6	5.2%
Total	**57**	**49.1%**	**59**	**50.9%**	**116**	**100%**

About 50.9% of the respondents had attained secondary level, approximately 18.1% had post-secondary and 18.1% held university degree as the highest level of education.

From the table 4.4, the results showed that 25.9%, 7.8% and 10.3% of respondents with secondary, post secondary and university education exhibited poor adherence. This indicated that the level of education of the respondents had no significant influence on their adherence levels. The findings contradicted the results of a study conducted by Catz *et al.,* (1999) which found that lower level of general education and poorer health literacy had negative the patient's ability to adhere to medication.

4.5 Influence of Clinical Setting Factors on ART Adherence

The second objective was to establish the influence of clinical setting factors on antiretroviral treatment adherence among HIV infected TB patients in JOOTRH. To realize this objective, the respondents were asked to respond to various questions under the sub-themes: long waiting lines, poor supply of ARVs and attitudes of HCPs. The table 4.5 shows the distribution of clinical setting factors;

Table 4.5: Clinical Setting Factors and ART Adherence level

	Good adherence		**Poor adherence**		**Total**	
Long waiting line/queues	22	19.0%	2	1.7%	24	20.7%
Poor supply of drugs	33	28.4%	49	42.2%	82	70.7%
Harsh HCP	2	1.7%	3	2.6%	5	4.3%
Don’t know	0	0%	5	4.3%	5	4.3%
Total	**57**	**49.1%**	**59**	**50.9%**	**116**	**100%**

Findings from the table 4.5 showed that on average 70.7% of the patients reported that they had been discouraged from seeking treatment from the facility due to poor supply of drugs; an estimated 20.7% reported to have been discouraged from seeking ART and TB treatments

from JOOTRH due to long waiting queues while 4.3% felt discouraged by the attitude of harsh health care providers whom they perceived to have negative attitude towards co-infected patients. Poor drug supply had a significant influence on ART adherence since 42.2% of the respondents who cited inadequate drug supply as a barrier exhibited poor adherence to ART.

To establish a comprehensive understanding on the influence of clinical setting factors, care providers (HCPs) were asked to state their opinions on those factors and the following extracts highlighted;

> *"Sometimes we go out of stock of drugs. You know we depend on supplies from KEMSA, CDC and other partners so when they delay with the supply, we are forced to reschedule patients and give them new appointments. This causes some patients to default treatment especially when they come after completing their medicines from the last refill."* (**Pharmacist)**

> *"... in this facility we have few staffs but many patients. At times we find it difficult when a number of us are on leave, may be they have exams or other commitment. So when this happens and a few of us are left behind, patients have to wait for long hours to be served. And you know this discourages most of them especially those who come from far places."* (**Nurse)**

> *"....but you see some of these patients are stubborn, when you send someone to the lab or x-ray room and he doesn't want to go because there are many people there, you may feel annoyed (clicks) so when you insist they start complaining that you are mistreating them...and others just end up going home without drug refill for the month since we give them ARVs for one month and anti-TB for two weeks"* (**Clinical officer)**

From these statements, the HCPs observed that poor drug supply and staff shortages were the major challenges in the provision of HIV and TB treatments. However, the clinical officer in the last extract had the opinion that some patients have negative attitudes towards health care

providers together with treatment schedules which demand at least two clinic visits a month. The statements are consistent with the data in table 4.5 which indicated inadequate drug supply and long waiting lines as the main clinical setting barriers to ART adherence.

A study by Peterson *et al.*, (2000) revealed that access to reliable primary health care is related to increased adherence to HAART, whereas missed clinic appointments are associated with inadequate drug supply and negative attitude of HCPs. These findings indicated that any intervention aimed at addressing clinical setting barriers should focus on improving the reliability of drug supply at the facility in addition to increasing the number health care workers and clinical equipment to minimize waiting time at the TB/HIV clinic. There is need to promote counseling to change attitude that some patients hold towards the service delivery at the clinic.

4.6 Treatment Factors Influencing ART Adherence

This section described antiretroviral treatment factors influencing ART adherence among the respondents. The ART factors described here consisted of dietary restrictions, allergy to diets and side effects of ART and TB treatments.

4.6.1 Dietary Restrictions and Allergy

Patients' immune reactions to antiretroviral treatment had a greater bearing on their adherence behavior. From the table 4.6, it was realized that approximately 64.8% of the respondents had been restricted from taking certain types foods due ART and TB treatments. On further analysis, it was recognized that out the restricted group, 50 (43.9%) patients exhibited poor adherence to medication compared to 7% of those who had never been restricted. This showed that dietary restrictions had an impact on ART adherence.

Table 4.6: Adherence levels of patients restricted from certain food types

Restricted from food	Good Adherence		Poor Adherence		Total	
Yes	24	20.7%	50	43.9%	74	64.8%
No	33	28.4%	09	7.0%	42	36.2%
	57	49.1%	59	50.9%	116	100%

To determine the impact of allergic reactions due to medications, patients were asked to indicate whether they have experienced allergic reactions to certain foods or drugs. The results in table 4.7 showed that approximately 74.2% had experienced allergic reactions to some foods or drugs due to ARVs and anti-TB medications. Approximately 44.0% (51) of those allergic to some foods had poor adherence to ART compared to 6.9% of those without allergic reactions. It was apparent that allergic reactions due to treatment influenced patients' adherence levels.

Table 4.7: Adherence levels of patients with allergic reactions to foods due to treatment

Allergy to food	Good Adherence		Poor Adherence		Total	
Yes	35	30.2%	51	44.0%	86	74.2%
No	22	18.9%	08	6.9%	30	25.8%
	57	49.1%	59	50.9%	116	100%

These results second the contribution of Mills *et al.,* (2006); which indicated that patients experience difficulty in balancing the numerous strict dietary requirements associated with HAART; sleeping through a dose; being away from home and not bringing medication, being too distracted or busy and having no time to refill prescriptions or other pharmacy related problems and difficulties with a particular dose the middle-of-day or early morning dose can lead to poor drug adherence.

4.6.2 Treatment Side Effects and ART Adherence

To determine whether patients were aware of treatments side effects, they were asked to state whether they had been informed about treatment side effects by their health care providers. About 89.7% (104) of the respondents had been informed of the side effects as shown in the table 4.8.

Table 4.8: Adherence levels among patients informed of treatment side effects

Aware of side effects	Good Adherence		Poor Adherence		Total	
Yes	53	45.7%	51	44.0%	104	89.7%
No	04	3.4%	08	6.9%	12	10.3%
	57	49.1%	59	50.9%	116	100%

Although 89.7% of the patients were aware of the treatment effects, the findings revealed that 44% of them had poor adherence to ART. This implied that in addition to counseling services, more adherence strategies such as family support and use of reminders need to be strengthened. HCPs confirmed that patients got informed of the possible side effects of taking parallel medications. However, some patients end up defaulting medications once experience side effects as observed in the extract below;

"Some people may react to some TB and HIV medications. This can lead to side effects and you see when they start seeing those effects, some have stopped medication even without consulting with us." (**Counselor)**

In the extract, the counselor indicated that some patients developed side effects due to reactions with HIV and TB medicines. Some patients were at risk of defaulting medications on the onset of side effects without seeking advice from HCPs.

From the findings, side effects contributed to non-adherence hence closer follow up should be conducted particularly to patients undergoing parallel treatments for TB and HIV to enable patients seek immediate medical support in case of adverse treatment effects.

4.7 Psycho-social Factors Influencing ART Adherence

This section described the psycho-social factors influencing treatment adherence among the respondents. The results were presented in four main sub-themes; the respondent's level of income, disclosure of HIV status, disclosure, health literacy and counseling services. Respondents were asked to indicate their level of felt psycho-social support and results presented in table 4.9.

Table 4.9: Level of Psycho-Social Support Received towards HIV Treatment

Level_p/social support	Good Adherence		Poor Adherence		Total	
Never	06	5.2%	02	1.7%	08	6.9%
Rarely	13	11.2%	34	29.3%	47	40.5%
Sometimes	17	14.6%	11	9.6%	28	24.2%
Often	09	7.8%	05	4.3%	14	12.1%
Always	10	8.6%	05	4.3%	15	12.9%
Don't know	02	1.7%	02	1.7%	04	3.4%
	57	49.1%	59	50.9%	116	100%

Findings in the table 4.9 illustrated that 40.5% of the respondents rarely received reasonable level of psycho-social support, 24.2% received support occasionally, while only 12.9% always received reasonable level of psycho-social support from their significant others. About 29.3% of those who rarely received psycho-social support exhibited poor adherence compared to 4.3% who received support always. This implied that consistent psycho-social support had a positive impact on ART adherence. The results are consistent with the findings of

Holstad *et al.*, (2006) who found that positive social and family support was associated with relatively good treatment adherence.

4.7.1 Level of Income and ART Adherence

To determine the level of income, patients were asked to indicate their average monthly income. Analysis in the table 4.10, revealed that majority of the respondents, 23 (20%) earned less than Ksh. 5000 a month. About 17% (20) of the respondents earned between Ksh. 5001 – 10000 a month while 16 (14%) earned between Ksh. 10001 – 15000. It was established that only 6% (7) earn over than Ksh. 20000. However, 32.8% of the respondents considered themselves unemployed thereby could not estimate their monthly income. The results revealed that the amount of income of an individual is somehow proportional to their level of education.

Table 4.10: Distribution of Income and adherence levels

Income (Kshs)	**Good adherence**		**Poor adherence**		**Total**	
<5000	8	6.8%	15	12.9%	23	19.8%
5001-10000	11	9.5%	9	7.8%	20	17.2%
10001-15000	9	7.8%	7	6.0%	16	13.8%
15001-20000	4	3.4%	3	2.6%	7	6.0%
20001 and above	9	7.8%	3	2.6%	12	10.3%
Unknown	16	13.8%	22	19.0%	38	32.8%
Total	**57**	**49.1%**	**59**	**50.9%**	**116**	**100.0**

Findings indicated that many people with low levels of income were more likely to miss their medication as opposed to those with high levels of income. Estimated 19.8% of the respondents earn less than Kshs. 5000; out of which approximately 42% of the respondents had missed ART doses due to lack of food and about 12.9% had poor adherence level. On the other

hand, an estimate of 10.3% of respondents earn an average income of above Ksh.20,000; out of which only 12% reported to have missed ART doses due to lack of food and 2.6% had poor adherence. The findings showed that the level income influenced ART adherence but did not show that optimal adherence was entirely determined by the level of income. This finding was consistent with the existing data by Coetzee *et al.,* (2004) which presented consistent evidence indicating that patients from various resource limited countries have been successfully retained on ART programs and that their viral loads have been effectively suppressed.

Social and economic factors may combine to yield poor adherence outcomes. Poverty in itself is likely to affect adherence as funds for travel to the ART clinic may not be available and resources may not be adequate to provide the recommended diets. The competing demands of several responsibilities such as work and family life, along with the stresses associated with poverty and difficult life circumstances such as unemployment may obviate an acknowledgement of the importance of complying with treatment regimens in general (Simoni *et al.,* 2002).

4.7.2 Disclosure of HIV Positive Status and ART Adherence

ART adherence was greatly influenced by psycho-social support that an individual received from people closer to them. To establish the influence of disclosure on adherence, patients were asked to state whether they had disclosed their HIV status. From table 4.11, the study findings showed that 74% (86) of the respondents had disclosed their HIV status to at least one significant person in life while 25% (41) had not disclosed their co-infection status despite having undergone treatment over a long period of time. It was evident that a lot of counseling should be provided to empower co-infected patients to disclose their status to increase the level of psycho-social and moral support. Most of patients cited stigma and fear of discrimination as

main barrier hindering them from discussing their treatment plans with family members and friends. Health education, counseling and awareness creation should be conducted to address stigma and discrimination associated with non-disclosure and treatment of HIV and TB.

Table 4.11: Distribution of respondents by the level of status disclosure

Disclosure	**Good adherence**		**Poor adherence**		**Total**	
Yes	34	29.2%	52	44.9%	86	74.1%
No	22	19.0%	07	6.0%	29	25.0%
DK	01	0.9%	00		01	0.9%
Total	**57**	**49.1%**	**59**	**50.9%**	**116**	**100.0**

Although it was found that approximately 74.1% of respondents had disclosed their HIV status, analysis revealed that an estimated 44.9% of HIV infected people who already disclosed their co-infection status exhibited poor adherence. It was therefore incorrect to assume that disclosure guaranteed psycho-social support and enhanced adherence. Based on these findings, it was confirmed that various variables in addition to psycho-social support influence an individual's adherence to ART and TB treatments.

To determine why many patients who disclosed their co-infection status had poor adherence, patients were asked to state whether they feel embarrassed taking their medications in front of other people. The results were presented in the table 4.12.

Table 4.12: Distribution of respondents who feel embarrassed taking medication in front of other people

Embarrassed	Good adherence		Poor adherence		Total	
Agree	45	38.8%	50	43.1%	95	81.9%
Disagree	08	6.9%	05	4.3%	13	11.2%
Not sure	04	3.4%	04	3.4%	08	6.9%
Total	**57**	**49.1%**	**59**	**50.9%**	**116**	**100.0**

From the table 4.12, it was revealed that irrespective of disclosure of HIV status to significant others, an estimated 81.9% of the respondents agreed that they felt embarrassed taking TB and HIV drugs in front of people. The results further indicated that 43.1% of the respondents who felt embarrassed taking medications in front of people had poor adherence compared to 4.3% who exhibited poor adherence but were never felt embarrassed.

4.7.3 Health Literacy and ART Adherence

The study presumed that counseling improved health literacy of the patients as it provided HCPs with opportunities to evaluate enabling factors and perceived barriers which were likely to influence adherence to long term treatment. In this study, respondents were asked to state whether they received ART counseling during clinic visits and results shown in table 4.13.

Table 4.13: Comparison of ART counseling and adherence levels

Received counseling	Good adherence		Poor adherence		Total	
Yes	57	49.1%	54	46.6%	111	95.7%
No	00		01	0.9%	01	0.9%
Not sure	00		04	3.4%	04	3.4%
Total	**57**	**49.1%**	**59**	**50.1%**	**116**	**100.0**

The results in the table 4.13 showed that 95.7% of the respondents had received counseling on their medications. However, 96.6% of those who received counseling exhibited poor adherence. This result indicated that co-infected patients under treatments required consistent treatment follow up and support. Furthermore, patients were asked to indicate whether they had any understanding on how both drugs work and the results presented in the table 4.14. This was aimed at establishing if they had adequate information regarding their treatments.

Table 4.14: Patients' who lack understanding of how TB and HIV drugs work

Lack understanding	**Good adherence**		**Poor adherence**		**Total**	
Agree	46	39.7%	51	44.0%	97	83.6%
Disagree	09	7.8%	04	3.4%	13	11.2%
Not sure	02	1.7%	04	3.4%	01	0.9%
Total	**57**	**49.1%**	**59**	**50.9%**	**116**	**100.0**

Table 4.14 showed that about 83.6% of the patients, out of whom 44% had poor adherence, admitted that they did not understand how TB and HIV medicines work. This illustrated that many co-infected patients found it difficult to handle challenges which arose as a result of parallel medication.

Considerable researches have demonstrated consistently that perceived social support, health literacy are strong predictors of medical adherence (Bearman & La Greca, 2002). Social support from family and friends enabled patients to co-operate with the recommendations a health professional. There is strong evidence that positive social support is associated with adherence to ART (Holstad *et al.,* 2006). The expression of concern from others to engage in health promoting behaviors; medication adherence, together with social desirability needs on the part of the patient to yield higher rates of medical co-operation can give optimal ART adherence.

CHAPTER FIVE

SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This section entails the summary of findings, conclusions of the study and recommendations for further research, policy and contribution to knowledge.

5.2 Summary of Findings

This study had four sub-themes; influence of socio-demographic factors, clinical setting factors, ART treatment factors and psycho-social factors on ART adherence. The study revealed that overall, 50.9% of the respondents exhibited poor adherence compared to 49.1% who had good adherence.

The first objective was to determine how socio-demographic factors influence antiretroviral treatment adherence among HIV infected TB patients. The study considered age, gender, education and marital status of the respondents as socio-demographic factors. The findings showed that 53.4% of the study respondents were women while 46.6% were men. The study measured adherence on CASE scale and found that 29.3% of women and 21.6% of men exhibited poor adherence compared to 24.1% and 25.0% of women and men demonstrated good adherence respectively. These findings showed that gender had an impact on ART adherence. In terms of age, the findings revealed that 19%, 11.2% and 10.3% of the respondents between the age brackets; 20-24, 30-34 and 25-29 were at the highest risk of non-adherence correspondingly. It can therefore be concluded that age had an impact on ART adherence.

Comparison between the level of education and ART adherence level showed 25.9%, 7.8% and 10.3% of the respondents with secondary, post secondary and university education

respectively exhibited poor adherence compared to 2.6% of patients with primary education who demonstrated poor adherence on CASE scale. This indicated that the level of education of the respondents had no significant influence on the adherence levels. This finding contradicted other previous studies which showed that education had an impact on adherence level.

The second objective was to establish the influence of clinical setting factors on antiretroviral treatment adherence among HIV infected TB patients. Under this objective, the respondents were asked to state their opinions regarding ART supply, clinic resources and attitudes of the health care providers. The responses were then compared with their adherence levels. The findings showed that 70.7% of the respondents out of which 42.2% had poor adherence, felt discouraged from seeking treatment services from the facility due to inadequate supply of TB and HIV drugs; an estimated 20.7% had been discouraged by long waiting queues as a result of few number of health care providers and medical equipment. About 4.3% of the respondents had been offended by negative attitude of 'harsh' health care providers at the facility. The study hence concluded that poor drug supply, inadequate medical facilities/providers and negative attitude of the HCPs had an impact on adherence.

The third objective was to examine the extent to which ART treatment factors influence antiretroviral treatment adherence among TB/HIV co-infected patients. The treatment factors considered here included dietary restrictions, allergy and side effects as a result of treatment. The findings showed that majority, 63% of the respondents had been restricted from taking certain foods as a result of adverse reactions with HIV and TB medications. From the restricted group, 43.1% had poor adherence levels. On the other hand, an average of 74.8% of respondents, out of which 44.7% had poor ART adherence, reported allergic reactions as a result of HIV and TB medications. It was found out that 89.7% had been informed of the likelihood of developing side

effects due treatment. However, 44.0% of those informed of side effects had poor adherence level on CASE scale. The study thus concluded that allergic reactions and side effects as a result of TB and HIV treatments had an impact on adherence levels hence needed to be addressed.

The fourth objective was to assess how psycho-social factors influence antiretroviral treatment adherence among TB/HIV co-infected patients. The study findings showed that approximately 74.1% of the respondents had disclosed their HIV+ status to their significant others. Despite the high rates of disclosure, only 44.8% of the patients who had disclosed their HIV+ status fell within poor adherence levels measured on CASE scale.

The study found out that culture and stigma influenced ART adherence levels significantly. Approximately 87% of the patients were worried over taking ARVs and 92% of the respondents felt worried of the long-term effects of ART. Furthermore, 81.9% of the interviewees, out of which 43.1% had poor adherence, felt embarrassed taking TB and HIV doses in front of people, including family members. About 56% of the respondents suffer avoidance due to co-infection with TB and HIV. These results concur with the findings of other scholars like Wenger *et al.,* (1999) and Stone *et al.,* (2000) that revealed most African patients are more likely to miss their medications due to stigma, discrimination, myths and beliefs in faith healing. The study found that disclosure had no impact ART adherence compared to stigma and discrimination which had impact on adherence.

5.3 Conclusions

From the present research findings, there is sufficient evidence that TB/HIV co-infected patients exhibited low levels of treatment adherence. Demographic, psycho-social support, clinic setting factors, stigma and discrimination contributed to poor adherence among the patients.

Most patients are however aware of the factors which make them vulnerable to non-adherence but are unable to overcome them due to inadequate information.

Socio-demographic factors such as age, education levels, income and family size influenced an individual's adherence to treatment. The study findings revealed that elderly patients with families are most likely to adhere to treatment compared to younger people. Women were most affected by HIV & TB and presented low levels of adherence and a lot of interventions on ART treatment should be targeted at empowering women and youth. The study also revealed that disclosure of HIV was relatively high however many patients still felt uncomfortable taking their medications in front other people perhaps due to fear of stigma, discrimination or avoidance. It was concluded that psycho-social factors impacted on ART adherence hence need for comprehensive counseling and health literacy to enhance adherence among patients.

JOOTRH enrolled many co-infected patients for care and treatment. The human resource and equipment capacity at the facility remained inadequate and could not provide services to all the patients at the required time thus making patients to wait for long hours to be served. It was found that many patients observed their treatment appointment schedules. However, some of them missed their medications due to drug shortage as result of inadequate drug supply and failure of medical equipment.

Concurrent TB and HIV medications posed adverse reactions to many patients. This led to restrictions from certain food types and drugs due to allergic reactions. Some patients found it challenging to continue treatments as a result of severe side effects while others had been discontinued from ART medication in order to complete TB treatment to avoid reoccurrence of severe side effects. This kind of treatment arrangement interrupted treatment adherence levels

and put some patients at the risk of drug resistance or adverse reactions. In conclusion, there is need to put emphasis on TB/HIV treatment guidelines for standardized care and treatment.

5.4 Recommendations

Having considered the theoretical framework, the conceptual framework alongside the literature review and the study findings, the following recommendations were made:

Socio-demographic factors in the microsystem had an impact on ART adherence among co-infected patients. There is need for general health education and awareness creation to enhance health literacy and family support among patients in order to promote adherence.

Clinical setting factors such as inconsistent drug supply and inadequate health care providers should be addressed by improving drug supply. The political and economic factors found in the macro and chronosystems have great impacts on ART adherence. There is need for political and managerial support to enhance ART and TB treatment service provision by ensuring adequacy of HCP and treatment equipment to minimize long waiting at the clinics.

The study found that ART treatment factors such as allergic reactions to food stuffs and side effects have an impact on adherence. Counseling and prompt treatment of side effects should be enhanced to minimize cases of patients defaulting medication as a result of allergy and side effects.

Co-infected patients need continuous encouragement and support to disclose their status to significant others for moral, spiritual and emotional support by family members. Predisposing and enabling factors in the micro and mesosystems of the EST should be strengthened to promote familial and communal support for co-infected patients. Comprehensive counseling for the families of co-infected persons and public health education should be promoted to address

stigma, discrimination and avoidance of co-infected patients. This will increase acceptance and support for co-infected individuals.

The dearth in literature on the factors that influence ART adherence among co- infected patients in Kenya calls for more empirical work of qualitative nature to explore why the adherence levels are poor. To enhance adherence, continuous health education on various issues surrounding ART should be prioritized while ensuring continuous engagement with the society and families the co-infected persons to improve psycho-social support and knowledge on how the medicine works.

Co-infected patients are an important target group for ART treatment adherence interventions and it is important to provide adequate counseling and continuous support to enable them overcome barriers associated with parallel treatments.

5.4.1 Recommendation for Policy Issues and Practice

Health education and communication strategies for HIV and TB treatments need to be improved to increase the understanding of HIV and TB patients and communities on factors that influence ART adherence. This means that the responsibilities of patients, community members and HCPs should be clearly defined for the success of ART adherence.

There is need for the development of standardized data capture tools to collect comprehensive information on the socio-demographic, clinical setting, ART treament and psyco-social factors that influence ART adherence among co-infected patients.

5.4.2 Suggestions for Further Studies

There exists limited literature on factors that influence ART adherence among co-infected patients in resource constrained settings. In Kenya, very few studies have been conducted to

establish factors that influence adherence among co-infected patients, yet it is an essential area for future research which can provide accurate information on factors that influence TB and HIV treatments.

Empirical work of qualitative nature needs to be done to explore the factors that contribute to non-adherence among co-infected patients from resource constrained backgrounds.

Table 5.1 Contribution to body of Knowledge

Objectives		Contribution to body of knowledge
i.	To determine how socio-demographic factors influence antiretroviral treatment adherence among HIV infected TB patients	There is need to strengthen health education to increase health literacy among women and youth as they are the most at risk of ART non adherence.
ii.	To establish the influence of clinical setting factors on antiretroviral treatment adherence among HIV infected TB patients	A lot of misinformation exists among most patients who are unable to distinguish between facts and myths. There is need to promote health awareness to supplement counseling services provided at the facility.
iii.	To examine the extent to which ART treatment factors influence antiretroviral treatment adherence among TB/HIV co-infected patients	Health care providers should provide continuous counseling and education to patients to improve their awareness on changes brought about due to TB/HIV medications.
iv.	To assess how psycho-social factors influence antiretroviral treatment adherence among TB/ HIV co-infected patients.	Comprehensive health education should be conducted to create treatment awareness at the household and community levels to increase psycho-social support to co-infected patients.

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APPENDIX I: INFORMED CONSENT

RE: PARTICIPANT INFORMATION AND CONSENT

My name is Onyango Daniel Oloo. I am a student in the University of Nairobi, Kisumu Campus. I am presently conducting a research project as a requirement for the award of Master of Arts degree in Project Planning and Management. The research project is titled; ***"Barriers to Antiretroviral Treatment Adherence among HIV infected TB patients in Jaramogi Odinga Teaching Referral Hospital Kisumu, Kenya."***

The study is targeting 124 randomly sampled HIV infected TB patients enrolled for care and treatment in JOOTRH Kisumu, Kenya. You have been chosen through a random sampling process to participate in this research study. The study is conducted for academic purposes only and the information collected will not be used for any other purpose other than academic.

The purpose of this statement is to seek for your informed consent to participate in the research study. If you agree to participate in the study, you will be asked some questions related to your care and treatment. The questions will tackle four thematic areas namely; socio-demographic, clinical setting, ART treatment and psycho-social factors that influence adherence to antiretroviral therapy.

The study does not have any risk to the participant since the kind of questions to be asked are neither be personal nor sensitive. There will be no direct benefit to you as a respondent, but it is hoped that the study findings will be useful in promoting ART treatment adherence among HIV infected TB patients from resource constraint settings. The information collected will be kept confidential and will be used for academic purposes only. Your personal identifiers will not be used at any point in the study process or in any report generated from the data collected.

The decision to participate in the study is absolutely personal. You have the right to participate or not. Even if you accept to participate you have the right to withdraw at will. You can choose to skip any questions you feel uncomfortable answering.

In case you need any clarifications, kindly address to them to me or the research assistant who has issued you with this form.

Statement of Consent

I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

Signature: _____ Date _____

APPENDIX II: PATIENTS' QUESTIONNAIRE

SECTION 1: DEMOGRAPHIC FACTORS

1. Sex □ Male □ Female

2. How old were you at your last birthday? ____ ____

3. What is your current marital status?
□ Never married □ Married □ Divorced/separated □ Widowed

4. If married, what is the type of your marriage?
□ Monogamous □ Polygamous

5. Have you ever been widowed? □Yes □No

6. What is your religion?
□ Catholic □ Anglican □ Other Christian □ Islam □ No religion □ Others (specify) _____

7. Have you attended school? □ Yes □ No

8. If yes, what is the highest level of school you attended?
□ Primary

□ Post-primary/Vocational

□ Secondary

□ Post-secondary

□ University degree

9. Are you currently employed?
□ Yes □ No **[skip to 11]**

10. *If employed:* Are you?
□ Regularly employed

□ Employed seasonally, on short-term contract, or on a day-to-day basis

□ Self-employed (business, farming)

11. *If unemployed:* Are you?
□ Unemployed and looking for work

□ A homemaker with no other work outside

□ A student

□ Retired or disabled

□ Other (specify): _____

12. On average, what is your monthly income from all the sources that you have? (in Kenya shillings)

□ <5 000 □ 5001-10 000 □ 10 001-15 000 □ 15 001-20 000 □ 20 001 & over

13. How often do you visit your TB/HIV clinic for drug refill and checkups?
□ Once a month □ Twice a month □ More than twice a month.
14. What mode of transport do you use to NPGH when going for ART refill and checkups?
□ Walking □ Bicycle (bodaboda) □ Motorbike (bodaboda) □ Matatu □ Private car
15. How much Kenya shillings do you pay for transport to NPGH from where you live currently?

_____

SECTION 2: PSYCHO-SOCIAL SUPPORT

16. What is the size of your house?
□ 1 room □ 2-3 rooms □ 1 bedroom □ 2 bedrooms □ ≥3bedrooms
17. Who are you living with presently? □ Family □ Friends □ Alone
18. Are you currently living with your children? □ Yes □ No □ No child
19. Have you ever disclosed your HIV status to your significant others (spouse, parents, children or friends)? □ Yes □ No
20. Who reminds to take your ARV medicines? □ Family member □ Friends □ None
21. Have you ever felt any form of social support towards HIV treatment from your significant others? □ Yes □ No
22. In your view, what is the level of psycho-social support, towards your HIV treatment, that you receive from your significant others? [circle one response]
□ Never □ Rarely □ Sometimes □ Often □ Always

Instruction: ***Now I'll find out what you think about the group of HIV medicines called antiretroviral therapy. From now on, we'll refer to these medicines as ART. Kindly tell me if you agree or disagree:***

Health literacy

23. Missing doses of ART leads to HIV getting worse.
□ Agree □ Disagree □ Don't know

24. Taking ART on schedule can help someone with HIV to prolong his/her life.
□ Agree □ Disagree □ Don't know

25. HIV/AIDS can be cured with ART.
□ Agree □ Disagree □ Don't know

26. Once a person starts ART, he/she should take ART every day for life.
□ Agree □ Disagree □ Don't know

27. I lack understanding of how ART and TB medicines work
□ Agree □ Disagree □ Don't know

Culture and stigma

28. Taking ARVs routinely worries me.
□ Agree □ Disagree □ Not sure

29. I worry about long-term effects of ART
□ Agree □ Disagree □ Not sure

30. People avoid me because I am infected with both HIV and TB
□ Agree □ Disagree □ Not sure

31. I am embarrassed taking TB and HIV drugs in front of people
□ Agree □ Disagree □ Not sure

SECTION 3: ART TREATMENT

ART Non-adherence

32. Are you currently taking both your HIV and TB medications? □ Yes □ No

33. If No in **Question 33** above, why? .....

34. Have you ever missed your ART doses? □Yes □No **[skip to 36]**

35. If yes, what things can make it hard for you to remember taking your tablets?
□ Developed toxicity/ side effect □ Forgot to take ART □ Felt better/improved

□ Too ill □ Fear of stigma/disclosure □ Finished ARVs □ Drunk alcohol

□ Too many pills/ pill burden □ No food

□ Other (specify) _____

36. If no, what helps you remember to take ART medicines regularly?
□ Health improved □ Someone reminded me □ Used alarms
□ Health care-provider encouraged me
□ Other (specify) _____

37. Are you able to follow ARV therapy regimen? □ No □ Yes

Food and Nutrition

38. What is the main source of food for your household?
□Purchase (market/grocery/kiosk) □Welfare/NGO support □Household farm/garden □Relatives/friends □Other (specify)……..

39. About how much money in Kenya Shillings do you usually spend on buying food for one day in your household?..... □don't know

40. How many meals do you afford to take in day? □One □Two □ Three □ ≥4

41. Are you restricted from taking certain foods as a result of TB/HIV treatment?
□ Yes □ No

42. Are allergic or reacting to some food stuffs as a result of ART medications?
□ Yes □ No

SECTION 4: CLINICAL SETTING

Practice of Health Care Providers and Patients On ART

43. Were you told the importance of completing the full course of treatment? □ Yes □ No

44. Were you told about the side effects and interactions of these drug(s) given? □Yes □No

45. Have you received any counseling during your treatment? □ Yes □ No

46. Do you think counseling is useful for HIV patients on treatment? □ Yes □ No
47. Was privacy maintained during consultation? □ Yes □ No
48. What discourages from seeking HIV treatment from this facility; NPGH?
□ Long waiting queues/time □ Poor supply of drugs □ Harsh health care providers

49. Have often do you miss ARVs medicines at the clinic, due to drug stock out?
□ Never □ Rarely □ Sometimes □ Most of the time □ All of the time

SECTION 5: NON-ADHERENCE: CASE ADHERENCE INDEX QUESTIONNAIRE

Please ask each question and circle the corresponding number next to the answer.

50. How often do you feel that you have difficulty taking your HIV medications on time? By *'on time'* we mean no more than two hours before or two hours after the time your doctor told you to take it.
4 Never **3** Rarely **2** Most of the time **1** All of the time

51. On average, how many days per week would you say that you missed at least one dose of your HIV medications?
1 Everyday **2** 4–6 days/week **3** 2–3 days/week **4** Once a week **5** Less than once a week **6** Never

52. When was the last time you missed at least one dose of you HIV medications?
1 Within the past week **2** 1–2 weeks ago **3** 3–4 weeks ago **4** between 1 and 3 months ago 5 More than 3 months ago **6** Never

Thank you for your time.

APPENDIX III: PROVIDER INTERVIEW GUIDE

ICE BREAKER

Let us start by talking about your clinical work experience in general and TB/HIV in particular.

How long have you worked in health c bnh zare? How long have you worked in the field of TB? Which TB or HIV-related trainings have you found to be the most useful for your work?

BARRIERS AND OBSTACLES OF HEALTH SEEKING ACTIONS

I would now like your opinions on any obstacles or barriers that may influence one's health seeking behavior and what can be done to improve services.

i. What do you know about the relationship between HIV and TB in Kenya?
   [Probe for the TB/HIV co-infection rate in the country, district, health facility,
ii. What do you know about the effect of TB on the HIV epidemic and health service provision and
iii. What do you know about the effect of HIV on TB epidemic and health service provision?
iv. How do people in this community associate TB and HIV/AIDS?
v. In your opinion, what barriers do co-infected (HIV infected TB patients) patients experience in accessing HIV care in this facility?
   [Probe about different days for HIV and TB clinics, transport]

vi. What encourages co-infected (HIV infected TB patients) patients to access HIV care and treatment services?
vii. What are your thoughts about providing ARVs in your TB clinic? What are the challenges and opportunities related to this?
   [Probe about how these challenges can be addressed]

Thank you for your time.