The Effects of HIV Status Disclosure on Antiretroviral Treatment Adherence

by

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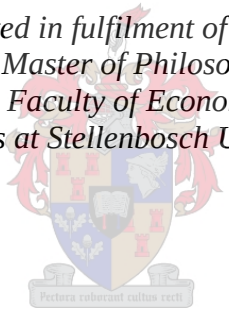

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Abstract

Successful antiretroviral therapy (ART) depends on appropriate use of antiretroviral agents; which ultimately prevents replication of Human Immunodeficiency Virus (HIV) thus delaying clinical progression of the disease. This study explored how HIV status disclosure affects adherence to antiretroviral therapy at Mamelodi Hospital, using a convenience sampling method with a sample size of 50 adults above 18 years who were on treatment for a minimum of two years prior to the study.

An interview protocol was used to uncover patients' demographics, sexual orientation, and HIV status disclosure, adherence to antiretroviral drugs, drug side effects, how often they missed their doses and how HIV status disclosure / non-disclosure affected their adherence to treatment. Patients' medical records were assessed to validate and correlate the information obtained from the interviews. The scientific test results used were the CD4count and Viral loads which are used to monitor the HIV/AIDS disease progression.

All partakers involved in the study made their HIV status known and reported taking their medicines regularly. The patients' CD4 count and VL were verified, the CD4 count has shown an upward trend while the VL load showed a downward trend in keeping with patients who are adhering to ART.

The majority of participants (54% or 27 patients) reported they had never skipped taking their medication. The participants also reported they had taken their medicine in front of other people and they constituted 74% (37) of the group. Of this 74%, 78.38% (29 patients) said it was because they had disclosed their status. This observation supports the fact that if you have disclosed your HIV status, you have better chances of adhering to prescribed medication.

Findings from the study at Mamelodi Hospital revealed that for as long as one has disclosed their HIV status, the outcome of treatment adherence will be better. The only shortfall noted was lack of partakers who did not divulge their HIV status thus a comparison could not be done. It was acknowledged that some participants in the study might have reported disclosure of their HIV status to be in good favour of the researcher to create an impression that they are adhering to their medication. The study has confirmed the existence of a relationship between HIV status disclosure and adherence to ART.

Opsomming

Suksessvolle antiretrovirale terapie (ART) hang af van die toepaslike gebruik van antiretrovirale middels, wat replikase van die MI-virus verhoed, en dus die kliniese vordering van die siekte vertraag. Hierdie studie het ondersoek hoe die bekendmaking van MIV-status die gehoorsaamheid tot ART beïnvloed het by die Mamelodi Hospitaal. ‘n Gerieflikheid-streekproef met ‘n groote van 50 volwassenes bo 18 jaar is gebruik en die deelnememers moes ten minste vir twee jaar voor die studie reeds op behandeling gewees het.

Data is deur middel van onderhoude ingesamel, met die doel om pasiënte se demografiese inligting, seksuele orientasie, MIV-status, gehoorsaamheid tot ART en newe-effekte van ART in te samel. Pasiënte se mediese rekords is nagegaan om die inligting wat uit die onderhoude verkry is te bevestig. Die wetenskaplike toetse wat gebruik is, was die CD4-telling en virale lading wat gebruik word om MIV/Vigs te monitor.

Al die deelnemers het hul MIV-status bekend gemaak en aangedui dat hul hul medikasie gereeld gebruik. Die pasiënte se CD4-tellings en virale lading is bevestig, die CD4-tellings het ‘n opwaartse neiging getoon terwyl die virale lading ‘n afwaartse neighing getoon het.

Die meerderheid van die deelnemers (54%) het aangedui dat hul nog nooit hul medikasie oorgeslaan het nie. 74% van die deelnemers het aagedui dat hul hul medikasie voor ander mense neem - hul noem dat dit as gevolg van die feit is dat hul hul status bekend gemaak het. Dit ondersteun die feit dat mense wie hul status bekend maak beter kanse het om gehoorsaam hul medikasie te gebruik.

Die studie by die Mamelodi Hospitaal toon dat solank mense hul MIV-status bekend maak, hul meer gehoorsaam is teenoor die gebruik van hul medikasie. Die studie bevestig dus die verband tussen bekendmaking van MIV-status en gehoorsaamheid tot ART.

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Table of Contents **Error! Bookmark not defined.**

Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CD4	Cluster of Differentiation 4
CEO	Chief Executive Officer
DNA	Deoxyribonucleic Acid
ENF	T20 Enfurvitide (Fuzeon)
ENT	Ear, Nose and Throat
ELISA	Enzyme linked Immunosorbent assay
FACS	Florescent Activated Cell Sorter
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
MHC	Major Histocompatibility Complex
Mrna	Messenger Ribonucleic acid
NASBA	Nucleic Acid Sequence Base Amplification
NNRTI's	Non-Nucleoside Reverse transcriptase Inhibitor
NRTI's	Nucleoside Reverse Transcriptase Inhibitor
OPD	Out Patient Department
PCR	Polymerase Chain Reaction
PI's	Protease Inhibitors
PLHA	People Living with HIV and AIDS
RNA	Ribonucleic Acid
UNAIDS	United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
VCT	Voluntary Counselling and Testing
VL	Viral Load

List of Tables

List of Figures

CHAPTER ONE

1.1.Introduction

Human Immunodeficiency Virus (HIV) is a chronic disease that eventually results in Acquired Immune Deficiency Syndrome (AIDS) and death unless managed appropriately with antiretroviral therapy (Wilson, Cotton, Better, Meyer, Venter & Martens, 2008, p. 514).

Successful antiretroviral therapy depends on appropriate use of antiretroviral agents; which ultimately prevents replication of HIV thus delaying clinical progression of the disease. There is a positive relationship between antiretroviral adherence and maintaining suppression of the virus. Non-adherence to antiretroviral therapy leads to poor suppression of the virus and the emergence of drug resistant viral strains that ultimately reduces the treatment options.

In the public health approach to antiretroviral therapy advocated by the World Health Organisation, adopted by most resource-limited countries including South Africa, only two sequential antiretroviral regimens are available. With limited antiretroviral options available, it is particularly important for antiretroviral programmes in Southern Africa to achieve high levels of adherence.

To avoid the possibility of the HIV virus evolving to a resistant strain, an adherence of 100% to all treatment regimens should be achieved. Wilson et al. has defined 95% adherence as skipping more than 3 doses of a twice daily treatment plan in a calendar month. This decreases the intended objective of viral suppression. The achievement of a 95% adherence level in HIV is onerous, since in other chronic diseases the levels are considerably lower than 95% (Wilson et al. 2008, p. 514).

In Sub-Saharan Africa the reported challenges hindering optimal drug adherence includes HIV status nondisclosure, stigma, excessive use of alcohol and complicated drug regimen (Bartlett, Gallant & Conradie, 2008).

Mills, Nachega, Buchen, Orbinski, Attaran, Sing, Rachlis, Wu, Cooper, Thabane, Wilson, Guyatt & Bangsberg, 2006) reported that a greater number of patients on ART who have made their status known to family and friends adhere to their regimen far better than those that have not disclosed their status. Educating and promoting HIV status disclosure in a community with ART availability may culminate in increased uptake of Voluntary Testing

and Counselling (VCT), resulting in reduction of stigma which subsequently enhances drug adherence (Mills et al., 2006).

Inconsistent intake of antiretroviral therapy has dire consequences like opportunistic infections, , antiretroviral drug resistance, increase in HIV infection rate, rapid progression to AIDS and ultimately premature death (Mills et al., 2006).

1.2.Mamelodi Hospital Profile

Mamelodi Hospital opened its doors in May 1981 as a community health centre. In October 1985 it got a hospital status operating 24 hours with 30 post natal beds, 30 short stay ward beds and 30 cradle beds. Mamelodi Hospital is situated on the eastern side of the Tshwane Metsweding District, serving the following outlying areas to the east of Mamelodi: Eersterus, Cullinan, Donkerhoek, Rayton, Boschkop, Bronkhorspruit, Pretoria East, Silverton and East-Lynn. The hospital serves a population of about 1,1million people.

Apart from rendering services to people residing in the above mentioned areas, the hospital will from time to time treat cross-border patients from Mpumalanga, Limpopo, Mozambique and Zimbabwe.

Currently Mamelodi Hospital has 281 beds and is earmarked for 400 beds. Health services provided by the hospital are organised along the service principles of the Gauteng Department of Health with the focus on access and delivering improved quality of service for all the communities.

The referral clinics include Stanza Bopape Community Healthcare Center, Phahameng Clinic, Holani Clinic, Mamelodi West Clinic, Cullinan Rehabilitaion Centre, Refilwe Clinic, Ekangala Community Healthcare Centre, Rayton Clinic and Bronkhorspruit Hospital (Public Private Partnership).

Mamelodi Hospital provides a 24 hour emergency service that includes Casualty, Maternity (delivery and post-natal), In-patient care, Medico-Legal services, Operating Theatre and X-Rays.

Out Patient Services that are provided are General Outpatient Department (OPD) and speciality clinics that include Family Medicine, Ophthalmology, Ear Nose and Throat (ENT),

General Surgery, Orthopaedics, Obstetrics and Gynaecology, Paediatrics, Psychiatry, Medical Male Circumcision (MMC) and Antiretroviral Therapy Clinic (ART).

The hospital also provides Allied Medical Services such as Pharmacy, Psychology, Physiotherapy, Occupational Therapy, Social Work, Optometry, Human Nutrition and Radiography.

1.3. Research Problem

Mamelodi Hospital ART clinic in the last three years has been seeing an average of 20 487 patients per annum. In 2011 they had 110 recorded treatment defaulters, in 2012 they had 34 and in 2013 they had 13 treatment defaulters. There have been a declining number of treatment defaulters over the years that could probably be associated with an increased number of patients that have disclosed their HIV status.

HIV status disclosure is an important aspect of HIV prevention and treatment. Many studies were done by Mills et al. (2006); Nachega, Stein, Lehman, Hlatshwayo, Mothopeng, Chaisson, and Karstaedt, (2004) and Nakiyemba, Aurugai, Kwasa, and Oyabba (2006), have demonstrated that there is an interdependence between disclosure of HIV status and adherence to therapy. It is for this reason that more scholars should investigate and have an opinion on the effect HIV status disclosure has on adherence to antiretroviral treatment. In this study we are going to make an attempt to come out with an opinion regarding the effect HIV status disclosure has on adherence to antiretroviral therapy.

I do not know what the effect of HIV status disclosure is to the adherence of antiretroviral therapy at Mamelodi Hospital.

1.4. Research Question

How does HIV status disclosure affect adherence to antiretroviral therapy at Mamelodi Hospital?

1.5. Significance of the Study

The data gathered will contribute to a pool of knowledge that is available to prevent and treat HIV disease effectively. The study will benefit patients and healthcare providers in the fight against the HIV pandemic, patients will be empowered with the necessary information and assist in creating the necessary support structures for patients to adhere to antiretroviral

therapy. The overall benefit to patients is improved quality of life while on antiretroviral therapy.

1.6. Aims and Objectives of the Study

The study aims to establish the relationship and effects of HIV status disclosure on adherence to antiretroviral therapy at Mamelodi Hospital.

1.6.1. Objectives

a. To identify whether patients who are on ART have disclosed their status.
b. To ascertain adherence to ART
c. To provide guidelines to support patients who are on ART in dealing with HIV status disclosure.

1.7. Methodology

The research will be conducted in a large group of patients at the Mamelodi Hospital Antiretroviral Therapy clinic. The sample size for the study will be 50 patients. They will be drawn from a population using the convenience sampling method. Patients who are 18 years and older and on antiretroviral therapy for more than 2 years (since May 2011) meet the criteria of inclusion.

A consent form will be signed by all participants selected prior to commencement of the study. An interview protocol will include the following topics:

a. Patient demographics
b. Sexual orientation
c. HIV status disclosure
d. Adherence to antiretroviral drugs
e. Drug side effects
f. How often they miss their doses
g. How does HIV status disclosure / non – disclosure affect their adherence to treatment.

Patients' medical records will be assessed to validate and correlate the information obtained from the interviews. This will be done with scientific test results e.g. CD4 and viral loads used to monitor the HIV/AIDS disease progression. The data for the study will only be

collected after all permission letters have been received from the Research Ethics committee at Stellenbosch University, Mamelodi Hospital's CEO and the Gauteng Department of Health. At the end of the study, all information will be analysed and interpreted using descriptive statistical methods and a conclusion will be drawn from the results.

CHAPTER TWO

LITERATURE REVIEW

2.1. Introduction

The literature covered focuses on the three aspects that affect Antiretroviral Therapy (ART) adherence namely HIV Disclosure, Stigma and Drug Adherence. There is no consensus about the relationship between HIV status disclosure and drug adherence, as it will be demonstrated in the discussions that will follow. Drug cost, HIV status non-disclosure, stigma, alcohol abuse and the multiple drug regimens have been reported to affect drug adherence (Bartlett et al., 2008).

2.2. Definition of Concepts

2.1.1. HIV status disclosure

Rabkin, EL-Sadr and Abrams (2005) define disclosure of HIV status as letting people know about the individual's HIV status. The HIV status is always known to self (following an HIV test) and that is why disclosure can be regarded as the *process* that leads to the act of telling rather than just the *act* of telling. A person that is HIV positive, once informed of their HIV positive – status, generally keeps the information to him- or herself and debates the issues around telling or not telling before finally deciding to disclose their status (Levy, Laska, Abelhauser, Delfraissy, Goujard, Boue and Darmont, 1999, p 1041; Petrak, Doyle, Smith, Skinner and Hedge, 2001, p. 70).

2.1.2. HIV stigma

HIV, like many other chronic conditions such as Diabetes Mellitus, carries a stigma with it. HIV stigma is affected by many factors including culture, gender, socio economic status and literacy. Social rejection and condemnation of HIV/AIDS infected people has always been a major factor contributing to the pandemic (UNAIDS, 2006). People Living with HIV and AIDS (PLHA) dread being stigmatized and discriminated thus reducing their ability to exercise prevention, undergo VCT, divulge their HIV status to others, seek medical attention and moral support as well starting and adhering to ART (UNAIDS 2006). Goffman (1963), defined stigma as a deeply discrediting attribute that results in dishonouring a person. He

further noted that stigma decreases life opportunities due to discriminatory actions. The concept of discrimination is not treated as a separate entity from stigma.

2.1.3. Drug adherence

Drug adherence refers to the act of patients taking their medication according to their prescription (e.g. taking medication 3 times a day) for the required duration. (Circulation. 2009; 119: 3028-3035). According to the above definition, the patient has a choice to agree or disagree to take the prescribed medication and both the patient and the healthcare provider must work together to establish treatment goals and the medical regimen.

In Antiretroviral therapy, Drug Adherence is very crucial as the degree of adherence determines the success of viral suppression and therefore the desired health outcomes and quality of life of people living with HIV/AIDS.

It is important to understand the scientific facts regarding HIV infection before attempting to unravel the effects of HIV status disclosure on Antiretroviral Therapy Adherence.

2.1.4. HIV diagnosis

HIV diagnosis is achieved through voluntary counselling and testing (VCT). This is a two-stage process starting with counselling of the individual to be tested and followed by testing of the person.

2.1.5. Counselling

HIV counselling intends to:

- provide a supportive environment
- help clients manage their problems and issues
- explore coping skills that clients have used before and help them to develop new ones
- empower clients to become self-sufficient in dealing with emerging issues and problems
- counsel HIV-negative clients so that they know how to remain negative
- counsel HIV-positive clients on how to avoid re-infection and how to prevent infecting others
- Explore options with clients that will help to bring about necessary changes in behaviour (e.g. abstinence, monogamy, i.e. mutual and faithfulness and the correct use of condoms) (Wilson et al., 2008).

2.1.6. HIV testing

Most clinical settings rely on antibody testing to make an accurate diagnosis of an HIV infection. The World Health Organisation (WHO) testing recommendations for regions where HIV prevalence exceeds 10% approves the use of two different enzyme-linked immunosorbent assay (ELISA) tests or two different rapid tests on site to confirm HIV infection. At lower HIV prevalence, a three-test strategy is recommended. Almost all ELISA and rapid tests are designed to detect both HIV-1 and HIV-2 antibodies.

There are several types on HIV diagnostic tests in the market namely:

- Enzyme-linked Immunosorbent Assay (ELISA)
- Rapid test devices
- The Western blot test
- The p24 antigen
- Polymerase Chain Reaction (PCR)
- Culture

2.1.7. The window period

Window period refers to a time lag after infection by HIV wherein sero-conversion takes place. During this period there is a delay in the detection of antibodies in the blood. This diagnostic "window period" is approximately four weeks. Tests for the virus itself reveal the infection somewhat earlier. The p24 antigen test is positive in the majority of patients a week before antibody ELISA tests becomes reactive. PCR testing can detect HIV in the blood from approximately two weeks after infection (Wilson, et al., 2008)

2.1.8. HIV disease monitoring

There are two important HIV disease monitoring tests, the viral load and the CD4 count. An analogy has been made comparing the information these two tests bring to the parameters of a train journey: the viral load measures the speed of travel of the train; the CD4 count indicates the distance from the crash, while the crash indicates the onset of AIDS. Therefore, viral load predicts the rate of disease progression (rate of loss of CD4 cells) and the CD4 count indicates the stage of disease that the patient has already reached (Wilson, et. al., 2008).

2.1.9. HIV viral load

The viral load refers to the concentration of free virus in the blood plasma. It is important to note that HIV is an RNA virus and therefore all commercially available viral load tests measure HIV RNA and the assays available are for only HIV-1.

- There are three main types of viral load tests: quantitative PCR;
- nucleic acid sequence based amplification (NASBA) and
- branch- chain DNA assay

These tests are equally reliable and can detect free HIV in the range of fifty to 1 million copies per millilitre of serum and the results are copies of virus/ml, or as a log value.

2.1.10. CD4 count

CD4 count is an important test that gives us the information about the stage of the disease as already discussed above. Our immune system has T-lymphocytes which constitutes our cell mediated immunity. The T-lymphocytes have T-cell receptors that are also referred to as CD3 molecules. CD4 is a molecule found on the surface of helper T-lymphocytes. There's another molecule the CD8 found on the cytotoxic T-lymphocytes. Both the CD4 and CD8 molecules play a subsidiary role in the binding of CD3 to MHC-II and MHC-I respectively, during antigen presentation. The CD4 molecule is the major receptor for HIV, and CD+ T-lymphocytes are the main target of HIV infection and they are directly and indirectly destroyed by HIV. Initially early in the disease the CD4 has a high turnover replacing the cells as quickly as they are destroyed, but over time as the disease progresses, the regenerative capacity of the immune system gets exhausted, with the resultant drop in the total CD+ cells.

The CD4 cells are the pillars of the immune system and they act by centrally stimulating the immune system upon exposure to infections, and their drop in number will therefore correlate with an increasing degree of immune suppression.

The CD4 cells are detected using the monoclonal antibodies to the CD4 molecule. A fluorescent-activated cell sorter (FACS) machine is commonly used to count them (Wilson et al., 2008).

2.1.11. Antiretroviral therapy

Antiretroviral therapy reduces the occurrence of opportunistic diseases and decreases short-term mortality from HIV infection. Its cost–effectiveness, particularly in relation to the

prevention of mother-to-child transmission, has been demonstrated in both developed and developing nations. Furthermore, it has been shown to be able to be implemented in resource poor settings (Spencer, 2005, p4).

The overall survival with untreated HIV-1 infection is approximately 10 – 12 years. This appears to hold for communities in the industrialized regions of the world. Survival is slightly worse for those in resource-poor nations. In a study of rural Ugandans, the median time from sero-conversion to death with AIDS was 9.8 years. Estimated survival in 10 European countries has increased with the use of Highly Active Antiretroviral Therapy (HAART) (Spencer, 2005, p4).

Antiretroviral therapy suppresses but does not cure HIV, so therapy is lifelong (Wilson, et al., 2008). Highly Active Antiretroviral Therapy (HAART) is a combination of at least three antiretroviral drugs from different classes.

2.1.12. Goals of therapy

The clinical goals are to improve quality of life and increase life expectancy. The virologic goal is to get viral load reduction to < 50 c/ml (cells/millilitre). The immunologic goal focuses on achieving reconstruction of the immune system indicated by the increase in the number of CD4 cells towards the normal range. The therapeutic goals are aimed at rationalising drug sequencing in a manner that will accomplish the previously mentioned goals, sustaining treatment options, preventing drug toxicity and facilitating adherence. The ultimate objective is to achieve the epidemiological goal of reducing HIV transmission (Bartlett, Gallant, Conradie, 2008, p.38). Good compliance with medication is the basis of good viral control.

2.1.13. Classes of antiretroviral agents

Antiretroviral drugs are classified in the main by their site and mechanism of action. To get a clear picture of this classification we must first review the HIV life-cycle; the events are illustrated on the following page with the diagrammatic presentation of the events on page 12.

Specific events in the life cycle of HIV:

1. Free virus (HIV)
2. Fusion with CD4 receptor and cell membrane
3. Penetration and entry of HIV into cytoplasm of cell

4. “Uncoating” of the virus and liberation of “free” virus and its associated viral enzymes
5. Transformation of viral RNA into viral DNA: Reverse Transcription
6. Penetration of nucleus of the cell and integration of viral DNA into host(genomic) DNA Integration
7. Activation of the CD4 cell leads to the transcription of proviral DNA into its original (genomic) viral RNA and messenger, mRNA: Viral Transcription
8. Viral RNA leaves the nucleus together with viral mRNA. mRNA is translated into appropriate viral proteins (structural, enzymic) on the ribosomes of the endoplasmic reticulum: Translation
9. Translated viral proteins and genomic viral RNA are processed, assembled, packaged and released in the form of new infectious virus: New viral assembly.

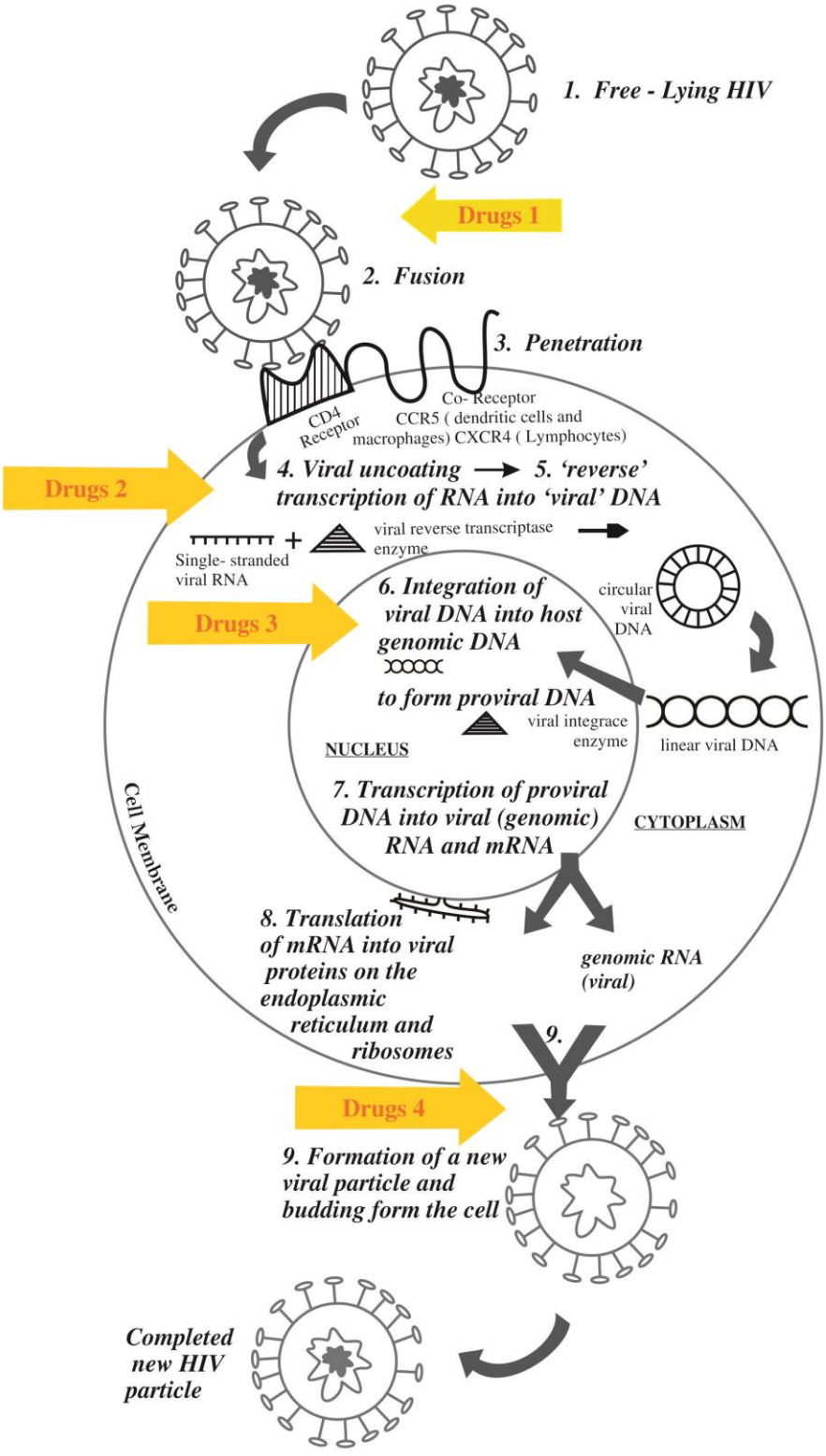

Figure 1: Diagrammatic representation of HIV Life Cycle: (Spencer, 2005)

Anti –retroviral therapies directed to the viral life cycle:

Drug 1: HIV- entry inhibitors

Drug 2: Reverse –transcriptase inhibitors

Drug 3: Integrase Inhibitors

Drug 4: Protease Inhibitors (PI's)

HAART involves the use of at least 3 different antiretroviral drugs: historically, two nucleoside reverse transcriptase inhibitors (NRTI's) together with a protease inhibitor (PI), but now also taken to 2 NRTIs with a non-nucleoside reverse transcriptase inhibitor (NNRTIs). These are used in combination. Three NRTI's used together generally do not constitute HAART (e.g. zidovudine, lamivudine and abacavir). This combination has been shown to possess inferior antiretroviral activity when compared to HAART (Spencer, 2005, p14).

2.1.14. HIV –entry inhibitors

HIV entry inhibitors are not widely used in the treatment of HIV. An example is a drug called T20 Enfurvirtide (ENF) (Fuzeon) manufactured by Roche. This drug is not available in the developing nations.

2.1.15. Reverse Transcriptase Inhibitors

Nucleoside reverse transcriptase inhibitors

This class of drugs are essentially the nucleoside analogues and they resemble the natural nucleotide building blocks of DNA and block the conversion of viral RNA into proviral DNA. NRTI's are pro-drugs that need to be activated intracellularly by tri-phosphorylation (Wilson, et al., 2008). Examples in this class are: didanosine, stavudine, zidovudine, lamivudine, abacavir, tenofovir and emtricitabine.

Non-Nucleoside reverse transcriptase inhibitors

NNRTIs do not bind at the active site of reverse transcriptase, but cause a conformational change in the enzyme that inhibits it. There are two NNRTIs that are currently available, Efavirenz and Nevirapine. These drugs have a long half-life (Wilson, et al, 2008.).

2.1.16. Protease Inhibitors

This class of drugs interfere with the HIV protease enzyme, which cleaves transcribed viral polyproteins into functional proteins. Inhibition of protease results in the release of immature non-infectious viral particles. Small doses of ritonavir markedly increase the plasma concentrations and prolong the half–lives of most PI's. This is known as ritonavir boosting and has become the standard of care for administering these agents (Wilson, et al., p466, 2008)

2.1.17. Integrase Inhibitors

Drugs in this class of antiretroviral agents have not yet been approved for commercial use. Several are undergoing clinical investigation (Spencer, 2005, p20).

2.3. Who HIV Staging

The revised WHO clinical staging of HIV in adults and adolescents is divided into clinical stages according to the severity of the illness. There are four clinical stages starting with the asymptomatic stage 1 until you get to clinical stage 4 with opportunistic infections where a preliminary diagnosis can be made on the basis of clinical signs or simple investigations; see details in appendix F.

2.4. National Guidelines for Antiretroviral Therapy

The standardized national eligibility criteria for initiation of ART for both adolescents and adults in South Africa are based on CD4 count and presence or absence of opportunistic infections. All HIV positive pregnant or breastfeeding women should be immediately initiated on ART irrespective of their CD4 count to prevent mother to child transmission. In general patients who have a CD4 count of <350 c/ml must be initiated on ART. For more details on the initiation and ART regimen see appendix G.

2.5. Literature Discussion

Global HIV/AIDS medicine (UNAIDS, 2008, p. 207) states that approximately 39.4 million people are living with the HIV, An estimated 90% of those living with the virus reside in developing countries. Sub-Saharan Africa is home to 25.4 million people infected with HIV/AIDS, rendering it the hardest hit region. Virtually 14.4 million people globally require antiretroviral therapy however about 8 million of these were receiving treatment as of 2011 (UNAIDS Global Report, 2012). Unavailability of resources to treat HIV has posed a great

concern worldwide; this has been handled by many organizations and funding bodies internationally as an emergency. The reduction in cost of medication, monitoring of CD4 counts and viral loads accompanied by a surge in international funders' support has significantly increased access to therapy.

Despite the efforts of trying to amplify the spectrum of HIV treatment to all affected, a great concern of resistance against antiretroviral therapy has developed. Information from first world countries suggests that up to 10% of new infections and 50% of existing infections have resistant strains of the virus, negatively affecting treatment response (UNAIDS, 2008). It is very important to prevent the emergence of resistant viral strains in under developed countries due to restricted availability of second line regimens (UNAIDS, 2008).

It can be anticipated that drug resistance will occur in improper utilization antiretroviral treatment seeing as the HIV virus will not be suppressed. Socio-economic factors play a major role in poor adherence to therapy and worldwide spread of the drug resistant virus (UNAIDS, 2008).

There was concern from different circles regarding the ability of patients from disadvantaged communities to achieve the requisite heights of adherence necessary to suppress the virus to prevent the development of HIV resistant virus. Others are proponents of a view that calls for the establishment of adherence programmes to prepare patients in such communities to be ready for large scale antiretroviral rollouts to prevent drug resistance. There is a growing amount of evidence with a differing view that suggests that disadvantaged communities have better adherence outcomes than their developed counterparts (Global HIV/AIDS Medicine, 2008).

The high HIV prevalence in Sub Saharan Africa has attracted a lot of interest from many scholars who focused their studies to this region. A number of researchers did studies in the poor countries with inadequate resources and the majority of the countries are in Sub Saharan Africa. The results of their studies revealed that drug adherence levels of more than 90% were achieved (Global HIV/AIDS Medicine, 2008).

Orrell (2008) showed in phase 3 studies conducted at a public hospital's ART clinic, with a sample size of 289 participants over a period of 48 weeks. The pill count at the clinic method was used and the results found that over 93.5% drug adherence was achieved. Similar studies

were done in Senegal where adherence levels of 91% were attained and in Uganda where adherence levels of between 91 to 94 % were achieved (Orrell, 2008).

In another study conducted in Kampala, Uganda in a mother to child transmission program, they used a different method of unexpected pill count. Their findings revealed adherence levels of between 97.3 – 99.8% (Byakika-Tusiime, Oyugi, Tumwikirize, Katabira, Mugyenyi and Bangsberg, 2005).

Clinical trials done at different facilities in Cameroon used a sample size of 60 patients using ART for the first time. A self-reported adherence method was employed and yielded an average adherence level of 99% (Byakika et al., 2005).

A common observation gathered from adherence studies in Sub-Saharan Africa suggests that the results are comparable to that of the well developed countries. This observation is further supported by two independent studies done in South Africa. In one study with a large sample size of 7812 participants in a private sector HIV/AIDS disease management programme, the adherence levels were reported to be more than 70% for 3908 participants. In the other study done in the public sector clinic in Soweto using a small sample size of 66 participants, the reported results revealed that 88% of the participants reported a 95% adherence (UNAIDS, 2008).

According to global HIV/AIDS medicine, challenges associated with non-adherence are experienced in both disadvantaged and advantaged settings. Challenges noted are alcohol abuse, medication intolerance due to regimen complexity, psychosocial elements, psychiatric conditions, young age, male gender forgetfulness working away from home with very busy schedules and marital status (UNAIDS, 2008).

However, disadvantaged settings have their own specific challenges such as language barrier, occasional unavailability of medicine and high costs, treatment centres situated far from patients' homes as well as stigma (UNAIDS, 2008).

In many disadvantaged communities stigma plays a significant role in non-adherence to treatment. In the Soweto study chances of obtaining more than 95% adherence diminished with an increased fear of being stigmatized (UNAIDS, 2008). Only 15 % of patients in the Botswana study have cited stigma as a major obstacle in adherence to medication.

There are high levels of illiteracy noted in disadvantaged communities amongst HIV infected populations which makes it difficult to attain high levels of adherence (UNAIDS, 2008). Speaking a different language from health care facility staff negatively influences adherence to therapy (Orrel, Byakika-Tusiime and Bangsberg, 2008).

Stigma is the biggest challenge in HIV prevention and treatment which lead to non-adherence to antiretroviral therapy. Many studies have shown that because of fear of stigmatisation, people infected with HIV taking ARV's fear to disclose their HIV status and as a result, they become less adherent to their ART. Rabkin, EL-Sadr and Abrams (2005) define disclosure of HIV status as letting people know about the individual's HIV status.

Once a person who is HIV positive is informed of their HIV-positive status, they generally keep the information to themselves and debate the issues around telling or not telling before she/he finally decides to disclose their status (Levy, Laska, Abelhauser, Delfraissy, Goujard, Boue and Darmont, 1999, p1041; Petrak, Doyle, Smith, Skinner and Hedge, 2001, p70).

HIV infected individuals prefer not to divulge their status to their partners, others and even healthcare providers for fear of stigmatisation and discrimination. Disclosure of HIV and adherence to ART can affect each other in several important ways as an individual taking ART could be identified as being HIV positive through others recognizing the tablets (forced disclosure) due to public awareness regarding the treatment.

Side effects caused by ART may also serve as a proxy for disclosure. In an effort to keep the secret about their HIV status, this may result in patients disguising their medication and or changing treatment. This could adversely affect adherence to their ART medication (Klitzmen, Kirshenbaum, Dodge, Remien, Ehrhart, Johnson, Kittel, Daya, Morin, Kelly, Lightfoot and Rotheram–Borus, 2004).

Studies done by Mills et al. (2006); Nachega et al., (2004) and Nakiyemba, Aurugai, Kwasa, and Oyabba (2006), support the existence of a clear relationship between HIV status disclosure and adherence to antiretroviral therapy, but Skhosana, Struther, Gray, and McIntyre (2006) argue that in a study conducted amongst antiretroviral users in Johannesburg South Africa, there was no direct relationship between disclosure of HIV status and adherence to ART.

The relationship between disclosure of HIV status and adherence clearly depends on the perception of both the patients and the person the information is disclosed to. Fear of being

stigmatised has often been reported as barrier to adherence to medication as this prevented patients from disclosing their HIV status and therefore losing out on social support (Skhosana et al., 2006). On the other hand in some instances, non-disclosure appeared as a facilitator of adherence (Ateka, 2006, p493-496; Nachega et. al, 2006, p.5131-5132, Nakiyemba et. al, 2006, p294; Skhosana et al., 2006, p20).

2.6. Summary of the Main Findings

There is genuine global concern about the emergence of drug resistant HIV strains and there is consensus that this is a result of poor adherence (UNAIDS, 2008). Data from the developed world indicates that up to 10% of new infections and 50% of prevalent infections carry resistant virus, which compromises treatment response (UNAIDS, 2008).

Stigma remains an important problem in many resource-limited settings. Stigma has been associated with non-adherence in Soweto and Botswana (UNAIDS, 2008). It is an interesting observation to note how stigma influences HIV status disclosure with secondary impact on drug adherence. A total of 15% of patients in the Botswana study claimed that stigma interfered with their ability to take medication (UNAIDS, 2008).

There's no consensus about the relationship between HIV status disclosure and drug adherence as it has been shown in several studies. However many authors has shown convincingly that such a relationship exist. Studies done by Mills et al. (2006), Nachega et al., (2004), support the existence of a clear relationship between HIV status disclosure and adherence to antiretroviral therapy.

I remain unconvinced by Skhosana et al. (2006), who argued that in a study conducted amongst antiretroviral therapy users in Johannesburg South Africa, there was no direct relationship between disclosure of HIV status and adherence to ART. Their argument that the relationship between disclosure of HIV status and adherence to ART depends on the perception of both the patients and the person the information is disclosed to, is not reason enough to support their argument.

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1. Introduction

This is a cross sectional study that was conducted at Mamelodi Hospital Antiretroviral Clinic (ART) on 50 patients during a period between 06 March 2014 and 03 April 2014. The patients were selected using a convenience sampling method as they attended the clinic for their routine checkup during the specified period. See the annexures of the following documents: informed consent, interview protocol, Ethics Review Committee (Stellenbosch University) permission letter, and permission letters from Gauteng Department of Health and Mamelodi Hospital CEO.

The Epistemiological approach in the study follows studying and analysis of data collected from previous studies done in the subject. The original data collected in this study will be analyzed and compared with the findings of the earlier studies. The approach in this study is evidence based. My positionality in the study as a researcher does not seem to threaten or intimidate the study participants. The participant's perception of the researcher is that of someone who has a potential to improve their treatment and their lives as the researcher is not their regular caregiver.

3.2. Aims and Objectives of the Study

The aim of the study is to establish the relationship and effects of HIV status disclosure on adherence to antiretroviral therapy at Mamelodi Hospital.

The objectives of the study include the following:

- To identify whether patients who are on ART have disclosed their status.
- To ascertain adherence to ART
- To provide guidelines to support patients who are on ART in dealing with HIV status disclosure.

3.3. Study Design

This is an empirical research study, where data will be collected, analysed, reported and the results interpreted accordingly (Christensen, Burke, Turner, 2011, p. 54).

The study design is more convenient because it allows for data to be collected from participants in a single brief period. The participants were recruited during their normal clinic visits for their routine medical check-up. This approach did not create an inconvenience for participants as it did not require extra, special visits.

A structured interview method was used to collect data from the research participants and the patient records were studied to correlate information gathered from the interview with actual patient's information on their file. The information used concerned patients' CD4 counts and viral loads. The CD4 and the viral loads were assessed to ascertain whether there was indeed an increase in the CD4 count and a corresponding viral suppression to support the patients claims that they were adhering to the treatment or to the contrary. In an interview, a trained interviewer asks research participants questions and records the responses.

The survey instrument used in interviewing looks much like a questionnaire, but it is given a more specialized label of interview protocol. The primary difference between a questionnaire and an interview protocol is that a questionnaire must be written so that participants can easily complete it without the aid of anyone. An interview protocol is a survey instrument that has been put into a script-like format so that the interviewer can systematically read the questions and easily record participants' responses. Interviews are generally preferred to questionnaires because the researcher has more control over data collection and can probe participants for follow- up responses (Christensen et al., 2011, p337).

The face-to-face method that was used, as the name suggests, is a person-to-person interview. This technique has the advantages of allowing the interviewer to clear ambiguities in the question asked and to probe further clarification of responses if the interviewee provides an inadequate answer. This method generally provides a higher completion rate and more complete respondent information. The primary weakness of this method is that it is the most expensive. It is also possible that the interviewer might bias the responses. For example, an interviewer might (either consciously or unconsciously) spend more time and probe more effectively with an attractive or especially interesting interviewee, resulting in biased results. Interviewer training can help interviewers learn how to conduct effective interviews to minimize any problems of this sort (Christensen et al., 2011, p337).

The sampling of participants in this study, was done using convenience sampling, where you simply ask people who are most available or the most easily selected to participate in a research study (Christensen et al., 2011, p158)

The study is a survey research. Survey research is a widely used type of non-experimental research. It is a research method where individuals fill out a questionnaire or are interviewed about their attitudes, activities, optional and beliefs (Christensen et al., 2011, p330). The questionnaire or interview protocol is usually standardised to present each research participant with the same stimulus (i.e. questions, directions). Survey research is oftentimes conducted with a sample selected from a target population of interest (Christensen et al., 2011, p330). Survey research can probe into a given state of affairs that exists at a given time as well as follow up changes over time (Christensen et al., 2011, pp330 – 331).

A sample is a set of elements drawn from a population. Sampling is a process of drawing a sample from a population. A population is a full set of elements from which a sample is selected (Christensen et al., 2011, p150). Since the study is empirical, the preferred method of sampling is the convenience sampling method, where you simply ask people who are most available or the most easily selected to participate in a research study. Convenience sampling falls under non-random sampling techniques, which tend to be weaker sampling methods, but sometimes they are necessary because of practical considerations (Christensen et al., 2011, p158).

A sample size of 50 participants was selected according to the inclusion and exclusion criteria: any patient who is 18 years and older and has been on ART for more than two years. The size of the sample was 50 because of the limited resources available for the study i.e. budget, time and human resources.

3.4. Methodology (Data Collection)

The research was conducted in a large group of patients at the Mamelodi Hospital Antiretroviral Therapy clinic. The sample size for the study was 50 patients who were drawn from a population using the convenience sampling method. The inclusion criteria were patients who are 18 years and older who have been on antiretroviral therapy for more than 2 years, i.e. at least since May 2011.

Consent was obtained from the selected participants and all participants signed the consent forms before commencing the study. The consent form was presented to them in English or translated to their vernacular languages by the researcher. The interview protocol used included the following:

1. Patient demographics
2. Sexual orientation
3. HIV status disclosure
4. Adherence to antiretroviral drugs
5. Drug side effects
6. How often they miss their doses
7. How does HIV status disclosure/non–disclosure affect their adherence to treatment?

The data collection process started on 06 March and ended on 07 April 2014. The researcher was allocated one of the consulting rooms where the interviews were conducted. The study was conducted during the normal clinic visits, the participants were recruited by the nursing staffs that were trained about the study protocol. The researcher obtained consent from the participants who were willing to participate in the study. The consent was obtained in English and translated into either Sotho/Tswana or Zulu for those who did not fully understand English. An interview protocol was used to collect data from participants and their responses were recorded.

After the data collection process was concluded, the data was captured using the Excel computer software. The data was then transferred to a statistical software program (STATA) for data cleaning, editing, analysis and statistical computing in order to minimise error. Since the study is empirical in nature, like many other survey studies, the descriptive statistical method of analysing the data was used. Frequency distributions were used to analyse the data collected. A frequency distribution is a systematic arrangement of data values in which the unique data values are order ranked and the frequencies are provided for each of these values. Oftentimes, the percentages for each frequency are also included in a frequency distribution (Christensen, et al., 2011, p393).

Measures of Central Tendency techniques were also used to describe the data collected. A measure of central tendency is the single numerical value that is considered most typical of the values of a quantitative variable. Measures of central tendency can be described in three different ways: the mode, mean and the median. The commonly used ones are the mean and the median. The mode is the most frequently occurring number for a variable. The mean is the name researchers use to refer to the arithmetic average. The median is the center point in a set of numbers that has been arranged in ascending or descending order. If you have an odd

set of numbers, the median is the middle. If you have an even number of numbers, the median is the average of the two centremost numbers (Christensen, et al., 2011, p399-400).

Measures of Variability are also used in descriptive statistics. A measure of variability is defined as the numerical index that provides information about how spread out or how much variation is present in a variable. Range is the highest or largest number minus the lowest or smallest number in a set of numbers. The variance is the average deviation of the data values from their mean in "square units". The variance can be turned into more meaningful units, e.g., the Standard Deviation. The standard deviation (i.e. the square root of the variance) is an approximate indicator of the average distance that your data values are from their mean. Variance and standard deviation are the two most popular measures of variability. They are superior to the range because they take into account all of the data values for a variable and they both provide information about the dispersion or variation around the mean value of a variable (Christensen et al., 2011, p402).

In descriptive statistics it is often helpful to use graphical presentations of data to communicate the research findings. There are a number of graphs that can be used give a pictorial representation of the data. Graphical representations can be used for one or more variables. Examples of graphic representations of data include the following: Bar graphs, Histograms, Line graphs and Scatterplots.

3.5. Shortcomings and Limitations of Data

The data collected during the interviews is of good quality. The participants were all interested and eager to give more information as they perceived the study as a necessary intervention in the fight against the HIV pandemic. The sample size was small and therefore will pose challenges when we want to generalize the findings of the study to the whole population. The data collected from the patients' files were often incomplete e.g., missing CD4 count results and in other instances missing viral load results. The patients' records in most public hospitals are not held up to standard.

CHAPTER FOUR

RESEARCH RESULTS

4.1. Introduction

The study was conducted on 50 participants at Mamelodi Hospital Antiretroviral Clinic during the period March to April 2014. Of the 50 participants, 62% were female and 38% were males. The age varied between 26 and 62 years with the mean age of 42.12 and standard deviation of 9.2. The majority of the participants were heterosexual with only one homosexual.

The participants had their first year of diagnosis spread between 1992 and 2012. The mean year of diagnosis was 2007.46 and standard deviation of 3.49. One percent of participants were diagnosed in 1992 and 50 percent by 2010. The majority of participants, 78%, started treatment in their first year of diagnosis. The participants that were diagnosed in 1992 started treatment after seventeen years.

Ninety four percent of the study candidates were voluntarily diagnosed while only 6% were involuntarily diagnosed. Of the 50 participants, only 2 % reported that they did not receive pre and post-test counseling and 94% of the participants reported that they found counseling to be helpful while only 6% did not realize the value of counseling.

4.2. CD4 Count and Viral Load Measurements Analysis

During an average follow-up period of 7 years, 216 CD4 count and 193 viral load (VL) measurements were collected from the fifty participants. Table 1 and 2 below demonstrates the average CD4 count and log viral loads measured at 11 different time points. Baseline CD4 counts of 241.8 with SD = 226.02 is the lowest compared to other follow-up CD4 counts. The trend sharply increases from baseline CD4 count to the next CD4 count and steadily increases over time. This can be observed on the graphs presented on page 27 - 28.

Table 1 Time point in years for CD4 count and viral load analysis

	1	2	3	4	5	6	7	8	9	10	11
Time point (years)	0	1.1	1.82	2.64	3.33	4.31	5.25	5.86	5.94	6.33	7

Table 2 Mean CD4 counts and their corresponding standard deviations at different time points

Variable	Observation	Mean	Standard Deviation	Minimum	Maximum
Cd4count1	50	241.8	226.0201	2	930
Cd4 count 2	45	366.2667	250.3322	14	1307
cd4 count 3	37	383.6757	216.5191	26	933
Cd4 count 4	31	400.9677	189.4442	31	901
cd4 count 5	20	471	209.6144	36	831
cd4 count 6	12	545.8333	350.7778	28	1394
cd4 count 7	9	431.2222	317.8887	46	1089
cd4 count 8	6	413	324.2678	27	799
cd4 count 9	4	559.5	330.368	90	801
cd4 count 10	1	701	.	701	701
cd4 count 11	1	970	.	970	970

Table 3 Mean log viral load and their corresponding standard deviations at different time points

Variable	Observation	Mean	Standard Deviation	Minimum	Maximum
Logvl1	48	5.89495	4.059199	2.890372	14.91412
Logvl2	43	4.270039	2.578309	2.995732	13.03054
Logvl3	33	3.880572	2.068957	2.995732	10.81122
Logvl4	24	3.490057	1.703258	2.995732	11.20601
Logvl5	14	3.781037	1.700146	2.995732	9.191463
Logvl6	13	4.285002	2.573454	2.995732	10.84704
Logvl7	10	3.589235	1.87682	2.995732	8.930758
Logvl8	5	5.972615	4.251658	2.995732	12.14713
Logvl9	2	2.995732	0	2.995732	2.995732
Logvl10	1	2.995732	.	2.995732	2.995732

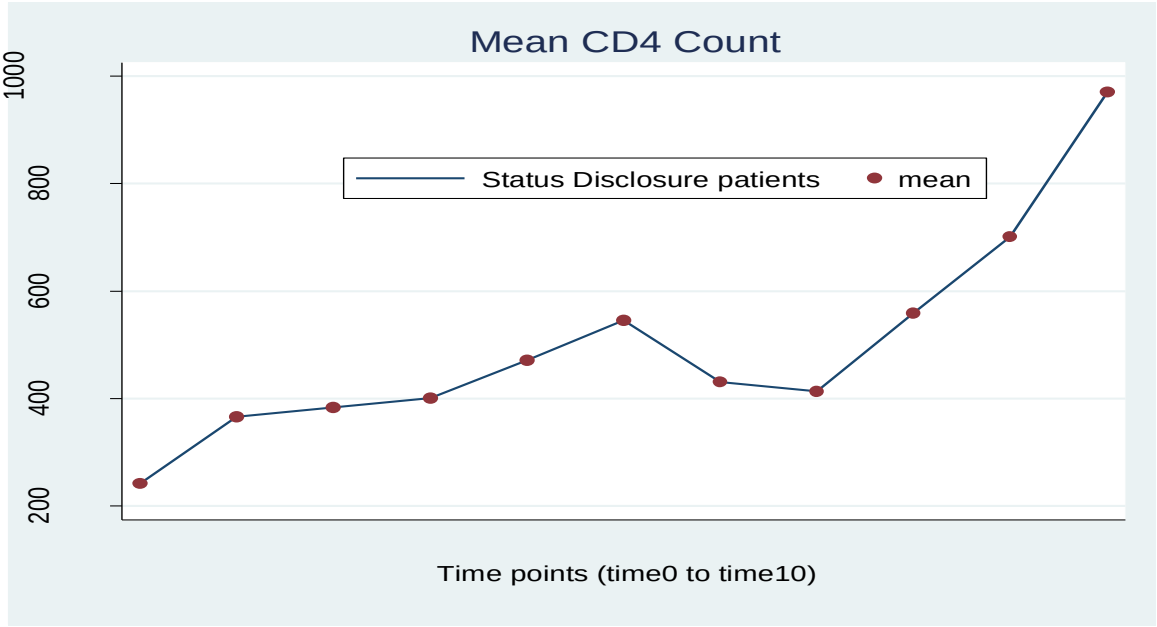

Figure 2: Discriptive analysis of CD4 count measurements over a period of time for participants that disclosed their HIV status. Note that, everyone disclosed their HIV status in this study.

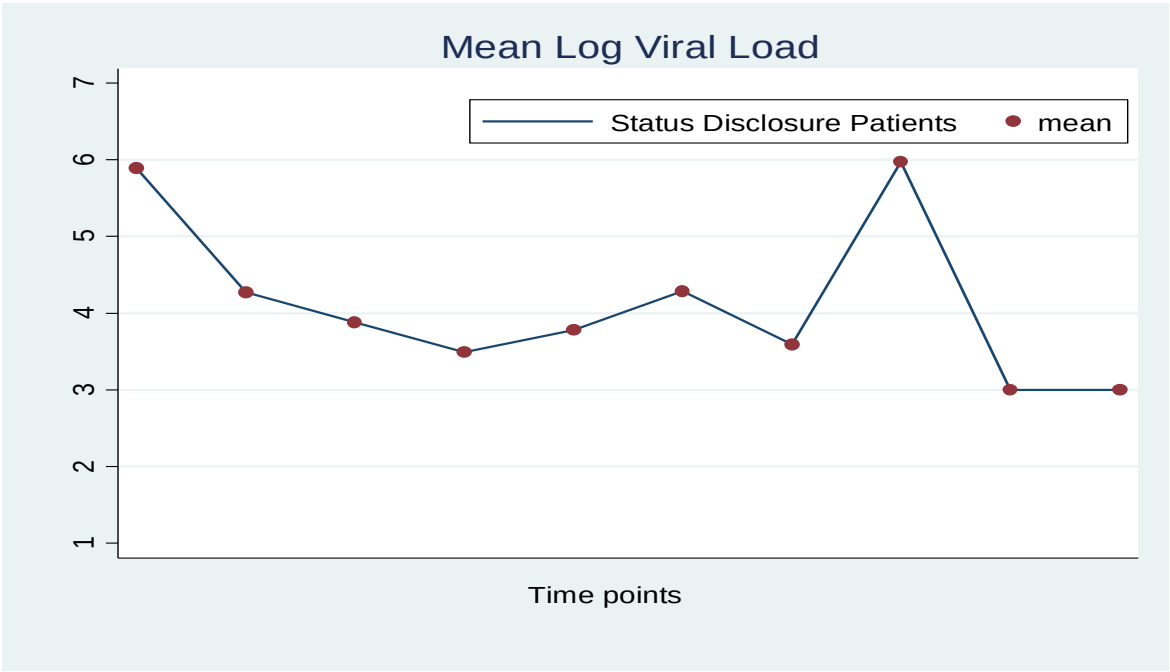

Figure 3: Descriptive analysis of viral load measurements over a period of time for participants that disclosed their HIV status. Note that the average log viral load (VL) count at

baseline (time0) was 5.89495, 4.270039 at time1 (i.e., 1.1 year later), 3.880572 at 2.6 years, 2.995732 after 7 years. Refer to table 3 above for further details.

4.3. HIV Status Disclosure

All research participants reported voluntary disclosure of their HIV status. The participants differed in people to whom they disclosed to for various reasons and why they disclosed their HIV status .Table 4 shows the distribution of the people to whom the participants have disclosed to.

Table 4 Frequency distribution of person(s) disclosed to. The difference in treatment outcomes (CD4 count and VL) between persons disclosed to will be done instead of disclosure vs non-disclosure.

To whom disclosed to	Frequency	Percent	Cumulative Percent
Family, friends	14	28.00	28.00
Family, partner	19	38.00	66.00
Family or partner or pastor	7	14.00	80.00
other	10	20.00	100.00
Total	50	100.00	

a) Family or friends or Pastor or partner means a participant has disclosed to only one group of people or one person. **b)** Family/friends means a participant has disclosed to only two groups of people such as one or more members of the family and one or more friends. **c)** Family/partner means a participant has disclosed to only two groups of people such as one or more members of the family and/or a partner. **d)** Others mean that a participant has disclosed to more than two groups of people, which can either be family, friends, partner, employer, pastor and church.

The comparison of the trends of CD4 counts and VL's in five different time points, according to who they disclose to, was done using Analysis of Variance method. The chosen time points had sufficient sample sizes to do this comparison between treatment outcomes and who disclosed to categories in Table 4 above. The P-value of 0.1732 calculated from the test statistics concludes that, there is no statistically significant difference between CD4 counts and to whom disclose over time.

Even for viral load comparison, we couldn't find a statistically significant difference between the viral loads and to who disclosed to categories. Therefore, whether you disclose to your family, friends, pastor or church it does not make one better than the other on outcomes of treatment (drug adherence). Note that every participant in this study disclosed their HIV status therefore the comparison between disclosure and non-disclosure was not possible. Instead we compared the difference between treatment outcomes and the categories of which participants disclosed to. See figure 3 above and 4 below:

Table 5 Mean log viral load count over the 5 time points

Variable	Observation	Time points	Mean	Standard Deviation	Minimum	Maximum
Logvl1	48	0	5.89495	4.059199	2.890372	14.91412
Logvl2	43	1.1	4.270039	2.578309	2.995732	13.03054
Logvl3	33	1.8	3.880572	2.068957	2.995732	10.81122
Logvl4	24	2.6	3.490057	1.703258	2.995732	11.20601
Logvl5	14	3.3	3.781037	1.700146	2.995732	9.191463

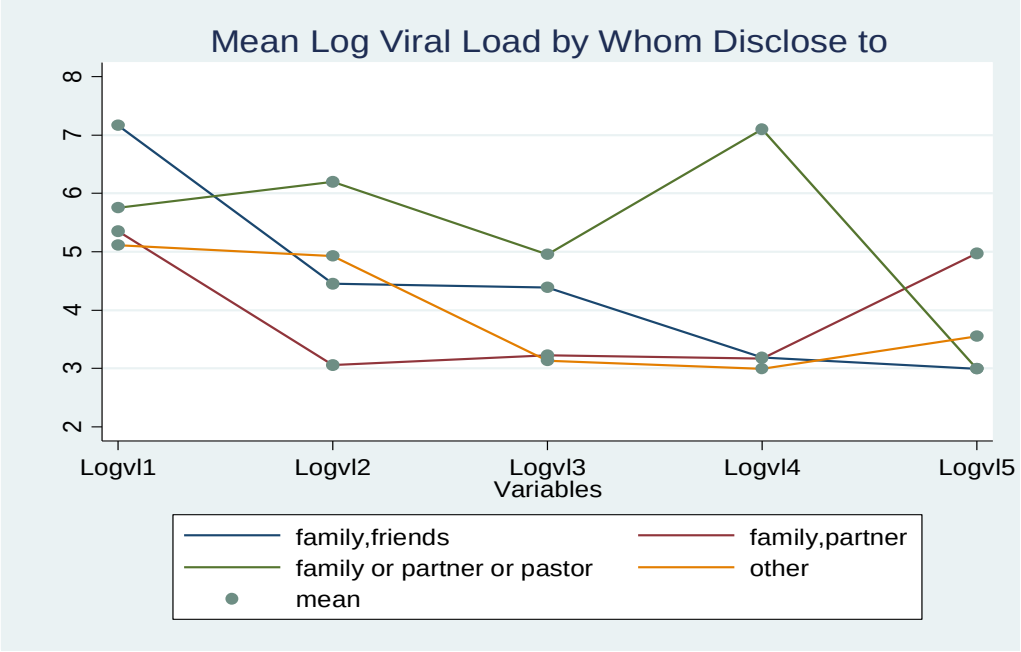

Figure 4: Mean log viral load to whom disclosed to

Table 6 Mean CD4 count over 5 time points

Variable	Observation	Time points	Mean	Standard Dev.	Minimum	Maximum
cd4cnt1	50	0	241.8	226.0201	2	930
cd4cnt2	45	1.1	366.2667	250.3322	14	1307
cd4cnt3	37	1.8	383.6757	216.5191	26	933
cd4cnt4	31	2.6	400.9677	189.4442	31	901
cd4cnt5	20	3.3	471	209.6144	36	831

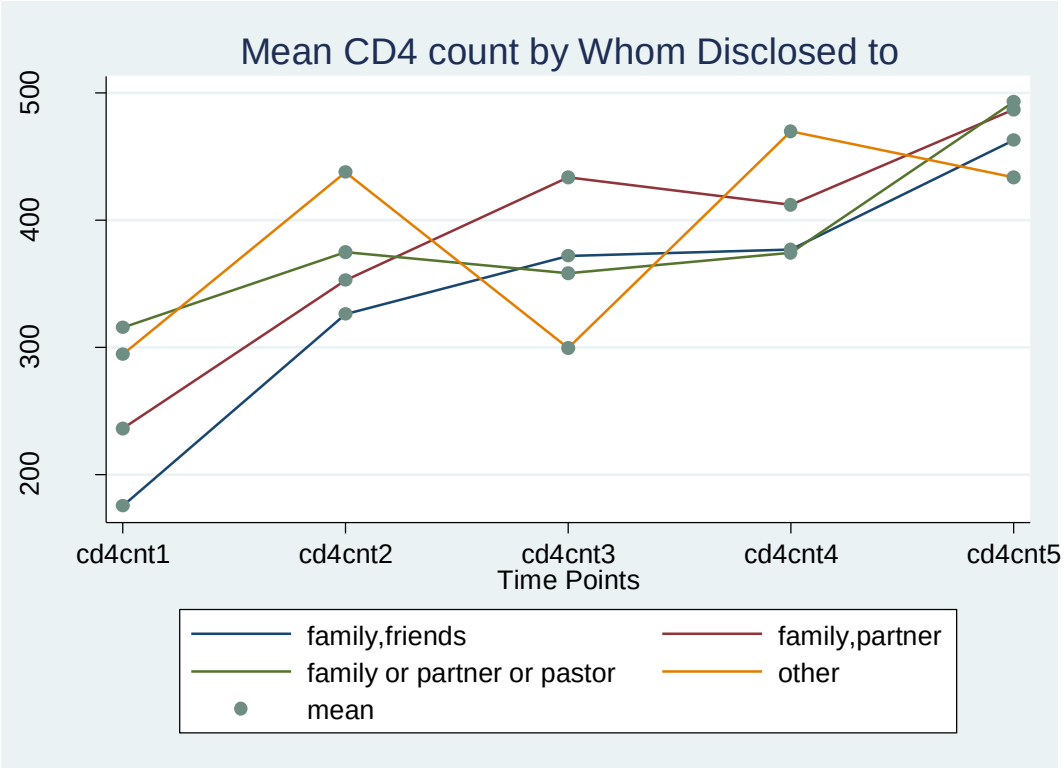

Figure 5: Mean CD4 count to who disclosed to.

The majority of respondents reported they disclosed because they needed support amongst other things. An overwhelming 82% reported they needed support while the remainder reported they disclosed because of counseling, education of others, prevention of transmission to others and their caregivers, encouraged uptake of VCT (voluntary counseling and testing). Some felt that HIV was just like any other disease, their family members died of the disease; saw many people taking HAART successfully. The other participants felt it was

necessary to disclose because their partners died of the disease and therefore it was public knowledge, while others wanted to be free and supported.

The participants have reported varying responses after their HIV status disclosure, from being relieved to being rejected. The majority, about 78% felt relieved, accepted and supported, 8% felt supported, about 12% had mixed feelings, some felt free, hopeful and accepted. Only 2% of participants reported being rejected by a friend.

Most of the respondents, 92%, believed that their families should know about their HIV positive status while only 8% were not comfortable with their families knowing their HIV status. The participants gave different reasons why they believed their families should know about their status. Some of the reasons included the following: 17.38% felt their disclosure would help prevent transmission during their care by family members, educating them about the disease and supporting other family members who were also HIV positive. The remaining 82% believed disclosing their HIV status would earn them the much needed support to pull through their disease and treatment challenges.

Of the 8% that did not disclose to their family members, 25% were not ready and 75% were afraid of stigma and discrimination. Disclosure to friends was accepted by 60% of respondents and the remaining 40% thought it was unimportant and unnecessary for friends to know. Those who responded yes to their friends knowing about their status, 6.66% of them said it was necessary to prevent transmission during care giving by their friends and to educate them about the disease. The 93.34% from this group believed the friends would give them support; they would feel free and felt there was no need to hide their status.

Of those who did not disclose to friends, 5% claimed not to have friends, 10% felt it was not important, 5% thought friends would not help in anyway and 80% were afraid of stigma and discrimination. Regarding disclosure to their employers, 60% agreed that it was important for support so they would be allowed time to go for their treatment at the hospital, while 40% disagreed as they were afraid of stigma and discrimination.

4.4. Antiretroviral Therapy

The range of the participant's initiation of therapy varies from 2002 to 2012. One percent started in 2002, fifty percent in 2010 and by 2012 ninety nine percent were already on treatment. The mean time of the start of treatment for the participants was 2008.96 with a

standard deviation of 2.28 and variance of 5.18. All participants have reported that they felt better since starting treatment.

4.5. Drug Adherence

46% of participants reported that they had skipped taking their medication at least once while 54% of the participants reported that they had taken their medication religiously. Those that have skipped their medication gave various unique reasons why they skipped their medicines. Some participants said they missed their doses due to work related travel, forgot, were arrested for periods varying from three months to one year, some were involved in accidents, some thought they were healed. Other participants said they had medicine fatigue, some ran out of supply and a few have reported they missed their doses because they experienced drug side effects.

Some participants reported experiencing drug side effects: 2% had hallucinations, 4% had lipodystrophy, 4% had pruritus and rash from co-trimoxazole (Bactrim®) and 20% had other unspecified side effects. A remaining 70% of participants were free from side effects. All participants reported not to have had the temptation to stop the medication at any stage of their treatment, regardless of having experienced some side effects.

Table 7: Skipped medication vs to whom disclosed to

Ever Skipped Medication?	To whom disclosed to :				
	Family, Friends	Family, Partner	Family or Partner or Pastor	Other	Total
No	9 64.29	10 52.63	3 42.86	5 50.00	27 54.00
Yes	5 35.71	9 47.37	4 57.14	5 50.00	23 46.00
Total	14 100.00	19 100.00	7 100.00	10 100.00	50 100.00

The participants were asked if they had ever taken medicines in front of other people; 74% responded yes they had, for various reasons, and only 26% reported that they had never taken medicines in front of people. Of the 74% that took their medicines openly, 78.38% said it was

because they had disclosed their HIV status, 2.7% said they did not care, 2.7% thought people should know and 16.22% said because people did not know the medication they were taking. Of the remaining 26% that had not taken their medicines openly, 30.77% of them said it was because they were always at home when taking their medicines, 7.69% indicated that they were afraid of stigma and discrimination while 61.54% said because they did not fully disclose their HIV status to people other than their family and partners

Table 8 Hide taking medication among people vs to whom disclose to

Hide taking medication among people	To whom disclose to:				
	Family, Friends	Family, Partner	Family or Partner or Pastor	Other	Total
No	10 71.43	12 63.16	0 0.00	8 80.00	30 60.00
Yes	4 28.57	7 36.84	7 100.00	2 20.00	20 40.00
Total	14 100.00	19 100.00	7 100.00	10 100.00	50 100.00

Participants were also asked if they were hiding when taking medicines among people, and 60% of participants were free to take their medicines openly while 40% were hiding their medicine when among people. Table 8 above shows that hiding medication among people does not depend on to whom disclose to. The Pearson chi-square p-value of 0.005 supports our conclusion. Table 8 also suggests that disclosing to more than one person helps not to hide taking medication in front of people. All participants have reported that they were taking their medicines regularly. The research participants were also asked to give an opinion about the effect of disclosing the HIV status on taking their medicines, a resounding 98% agreed that disclosing ones HIV status would help improve taking antiretroviral therapy and only 2% disagreed.

CHAPTER FIVE

5.1. Conclusion and Recommendations

Some participants reported to have missed taking their medication; however the majority claimed that they were taking their medication regularly. The CD4count and the Viral load (VL) trends have corroborated the respondent's claims as depicted by figures 1 and 2 respectively. The CD4counts showed an upward trend while the VL showed a downward trend.

The respondents disclosed to different people: family, partner, friends and others. There was no statistically significant differences between to whom disclosed to over time on both the CD4 count and VL as shown in figure 3 and 4.Therefore, whether you disclose to either your family, friends, pastor or church does not make one better than the other on outcomes of treatment (drug adherence).

It is apparent from the results that 82% (41) of the respondents have disclosed primarily because they needed support. 92% (46) believed that their families should know about their positive HIV status while only 8% (4) were not comfortable with their families knowing their HIV status. This is a very significant number and it puts the family at the epicenter of the strategy to improve drug adherence.

Of the 8% that did not disclose to their family members, 25% (1) were not ready and 75% (3) were afraid of stigma and discrimination. 75% is quite significant; it highlights the fact that we still have challenges of stigma and discrimination to deal with. Disclosure to friends was accepted by 60% (30) of participants, and of these, 93.34% (28) believed it was necessary so that they could get support while taking their medication.

Sixty-percent (30) of participants agreed that it was important to disclose to their employers, for support so that they will be allowed time to go for their treatment at the hospital, while the problem of stigma and discrimination has resurfaced again with 40% (20) not willing to disclose to their employers.

Drug side effects played an insignificant role in the drug adherence in this study as 70% (35) of participants were free of side effects, 2% (1) experienced hallucinations, 4% (2) had lipodystrophy, 4%(2) had pruritus and rash from Bactrim (Co-trimoxazole) and 20%(10) had

other unspecified side effects. None of the participants reported any temptation to interrupt their treatment completely, despite having experienced some side-effects.

The majority of participants (54%) 27 reported they had never skipped taking their medication. The participants also reported they had taken their medicine in front of other people and they constituted 74% (37) of the group. Of this 74%, 78.38% (29) said it was because they had disclosed their status. This observation supports the fact that if you have disclosed your HIV status, you are more likely to be adherent to treatment. In Table 7 it was shown that there was no statistically significant difference when you compare the ever skipped medicine by to who disclosed to. This observation further confirms the earlier statement that it does not matter whether you disclose to your family, friends, pastor or church; it does not make one better than the other as far as treatment outcomes (drug adherence) are concerned. The conclusion that one draws from this statement is that, for as long as you have disclosed, your outcomes of treatment adherence will be better. This observation is also supported by studies done by Mills et al, (2006), Nachega et al. (2004) and Nakiyemba et al., (2006) which supports the existence of a relationship between HIV status disclosure and drug adherence.

Skhosana et al. (2006) hold a different view, they argue in their study conducted in Johannesburg that there was no direct relationship between disclosure of HIV status and adherence to ART. I believe they are bringing forward a weak case in their argument. They argue that the relationship between disclosure of HIV status and adherence to ART depends on the perception of both the patients and the person the information is disclosed to. This to me is an obvious straight forward case because any information whether related to HIV or not, for it to be interpreted, will depend on perceptions of the subjects involved and therefore you cannot use this argument to determine the relationship between two concepts. I agree with their view that fear of being stigmatized has been reported as a barrier to adherence to medication as this prevented patients from disclosing their HIV status and therefore losing their social support. This in my view confirms the existence of a relationship between HIV status disclosure and adherence to ART.

Of the twenty six percent (13) participants that have not taken their medicines openly in front of other people, 30.77%(4) of them said it was because they were always at home when taking their medicines, 7.69%(1) indicated that they were afraid of stigma and discrimination while 61.54% (8) said because they did not fully disclose their HIV status to people other

than their family and partners. From the above facts, it can be argued that there is a clear relationship between HIV status disclosure and drug adherence.

Sixty percent (30) of the participants said they were not hiding when taking medication among people, while 40% (20) were hiding. In table 8 it was shown that hiding medication among people does not depend on to who disclosed to. The Pearson chi-square p-value of 0.005 supports our conclusion. Table 8 also suggests that disclosing to more than one person helps not to hide taking medication in front of people. All participants in the study have disclosed their HIV status and they all reported taking their medicines regularly. The patient's CD4 count and VL were verified, the CD4 count has shown an upward trend while the VL load showed a downward trend in keeping with patients who are adhering to ART.

These findings further support the argument that HIV status disclosure helps improve antiretroviral therapy adherence. All study participants agreed that disclosing HIV status does help improve their adherence to antiretroviral therapy.

This study has two main shortcomings, the small sample size and the fact that all participants have disclosed their HIV status which makes it impossible to compare the outcomes of drug adherence in the patients who have not disclosed their HIV status. The small sample size of 50 patients used in the study, poses a challenge because you cannot generalize results in confidence to the larger population from which the sample comes from. The lack of adequate resources also influenced the decision to use a small sample size.

The larger significance of this study is to help highlight the importance of pre and posttest counseling. Counseling should also put emphasis on HIV status disclosure and ART drug adherence. Drug adherence counseling should be strengthened in all institutions that provide antiretroviral therapy.

The lessons that were learned from this study would lead one to recommend that more research be done that would put more focus on counseling and drug adherence strategies. One other important recommendation is to resuscitate the almost dying public HIV/AIDS awareness campaigns to sensitize the communities to be more accepting and empathetic to people living with HIV/AIDS. These public awareness campaigns will heighten the fight against HIV/AIDS stigma and discrimination with a resultant effect of promoting HIV status disclosure and improved antiretroviral drug adherence. Voluntary counseling and testing campaigns must also be increased in communities. Mamelodi Hospital ART clinic must

spearhead and lead the public awareness campaigns so that the stigma and discrimination can be reduced leading to increased HIV status disclosure and better drug adherence. All these efforts contribute to the common goal of preventing HIV/AIDS spread and elimination of this pandemic.

5.2. Guidelines

All ART Clinics must put more emphasis on pre and posttest counseling. During counseling, the importance of HIV status disclosure and their relationship to drug adherence should be deliberately emphasized. All patients who seroconvert must be taught more about the coping mechanisms and strategies of how to best deal with stigma and discrimination. The public campaigns must be stepped up, and people must be informed about the plight of people living with HIV both infected and affected. The public must be taught more about the negative impact stigma and discrimination has on the lives of people living with HIV and how this can cause people to lose their lives. Drug Adherence counseling and education should be broadened to include all sectors of the communities even include other chronic illnesses so that HIV can also be taken as just another chronic conditions.

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Appendices

Appendix A: Mamelodi Hospital Approval Letter

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MAMELODI HOSPITAL

Private Bag x 0032 P.O. Rethabile 0122
Tel no. +27 12 841 8300/8301
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Enquiries: Dr L S Adonis
Tel:012 841 8306
Fax: 012 841 8412
Lungiswa.Adonis@gauteng.gov.za
20th January 2014

TO: DR M S PHALAFALA
PO BOX 356
MENLYN
0063
CELL: 0823386032

SUBJECT: APPROVAL TO CONDUCT A RESEARCH STUDY AT MAMELODI HOSPITAL

THE TITLE OF THE RESEARCH STUDY: The effects of HIV status disclosure on antiretroviral therapy adherence.

PROTOCOL NUMBER: P151113

Approval is hereby granted to conduct a research Study in Mamelodi Regional Hospital Anti Retro Viral Treatment Clinic (ART) section.

This study will be limited to patients who are ART-experienced and above 18 years of age.

To be noted

- A written informed consent should be requested from the patients for interviews.
- Leading staff should be asked to consent to data collection and validation.
- Strict confidentiality procedures of the documents and patient files must be followed and observed.

Thank you

Dr Lungiswa Adonis

CEO: Mamelodi Hospital

- 1 -

Appendix B: Gauteng Health Department Approval Letter

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

OUTCOME OF PROVINCIAL PROTOCOL REVIEW COMMITTEE (PPRC)

Researcher's Name (Principal investigator)	Dr M S Phalafala
Organization / Institution	The Department of Economic and Management Science – Africa Centre for HIV/AIDS at Stellenbosch University.
Research Title	The effects of HIV status disclosure on Antiretroviral Therapy Adherence
Protocol number	P151113
Date submitted	23 November 2013
Date reviewed	13 December 2013
Outcome	**APPROVAL**
Date resubmitted	N/A
Date of second review	N/A
Final outcome	

It is a pleasure to inform that the Gauteng Health Department has approved your research on "The effects of HIV status disclosure on Antiretroviral Therapy Adherence"

The Provincial Protocol Review Committee kindly requests that you to submit a report after completion of your study and present your findings to the Gauteng Health Department.

Dr Bridget Ikalafeng :
Provincial Protocol Research Committee (PPRC), Chairperson

Date 16/01/2014

Appendix C: Stellenbosch Approval Notice

UNIVERSITEIT•STELLENBOSCH•UNIVERSITY
jou kennisvennoot • your knowledge partner

Approval Notice
Stipulated documents/requirements

20-Feb-2014
PHALAFALA, Mathatho Samuel

Proposal #: HS987/2013
Title: **The effects of HIV status disclosure on Antiretroviral Therapy Adherence.**

Dear Dr Mathatho PHALAFALA,

Your **Stipulated documents/requirements** received on , was reviewed by members of the **Research Ethics Committee: Human Research (Humanities)** via Expedited review procedures on **04-Feb-2014** and was approved.
Sincerely,

Winston Boukes
REC Coordinator
Research Ethics Committee: Human Research (Humanities)

Appendix D: Consent Form

Consent to participate in research

TITLE OF THE STUDY: The effects of HIV status disclosure on antiretroviral therapy adherence.

You are asked to participate in a research study conducted by DR MS PHALAFALA –BSc, MBCHB, PGDip (HIV/AIDS Management), from the Department of Economic and Management Science – Africa centre for HIV/AIDS management at Stellenbosch University. The results of the study will contribute to my research paper for my Master's degree MPhil HIV/AIDS management. You were selected as a possible participant in this study because you are over 18years of age, and have been on antiretroviral therapy for over 2years, which are the inclusion criteria for the study.

1. PURPOSE OF THE STUDY

The study is designed to establish the relationship and effects of HIV status disclosure to adherence to the antiretroviral therapy at Mamelodi Hospital.

2. PROCEDURES

If you volunteer to participate in this study, we would ask you to do the following things:

You are going to be interviewed about the disclosure of your HIV status and how that affected your adherence to your antiretroviral medication.

3. POTENTIAL RISKS AND DISCOMFORTS

There are no risks expected during the study but you may suffer from the discomfort, as we will be asking you about your personal and private things regarding your HIV illness and how you are taking your medicines. If the levels of your discomfort become too high, you will be referred for counselling.

4. POTENTIAL BENEFITS TO SUBJECTS AND OR TO SOCIETY

Subjects may or may not benefit directly from this study. The study may benefit patients by empowering them with the new knowledge that will be obtained to assist in creating the necessary support structures for patients to adhere to antiretroviral therapy. The overall benefit to patents is improved quality of life while on antiretroviral therapy. The information

gathered from the study will contribute to the pool of knowledge that is available to prevent and treat HIV disease effectively.

5. PAYMENT FOR PARTICIPATION

Subjects or participants in the study will not be receiving any payment for their participation in the study.

6. CONFIDENTIALITY

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by Law. Confidentiality will be maintained by means allocating participants with a study code number and the original coding list with participant's name will be kept under lock and key by the researcher who will be the only person with access to the information. If information will be released to any other party for any reason, it will be my study supervisor Mrs Riana Dippenaar, Stellenbosch University ethics review comity who will be assessing whether the study was done in accordance with the research ethics. Stellenbosch University staff who will be marking my research study for purposes of my Master's degree research paper.

The results of the study will be published and all the information relating to the identity of the participants will be omitted on the publication.

7. PARTICIPATION AND WITHDRAWAL

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any question you do not want to answer and remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so, for example if during the interview the subject becomes emotionally disturbed and becomes hysterical.

8. IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about the research, please feel free to contact:

Principal Investigator: DR M.S PHALAFALA. (012) 805 8080, Cell: 082 338 603, Email samp2@telkom.sa.net.

Supervisor: Mrs Riana Dippernaar, Email: riana.dippenaar@gmail.com

University of Stellenbosch, Africa Centre for HIV/AIDS management, Administrative Assistant: Arlene Willets, Tel: 021 808 3405, Email: awillets@sun.ac.za

9. RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, contact Ms Malene Fouche [mfouche@sun.ac.za, 021 808 4622] at the Division for Research Development.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

The information above was described to [me/the subject/the participant] by _____ in Sotho/English/Zulu/Other] and [I am/the subject is / the participant is] in command of this language or it was satisfactorily translated to [me/him/her.]. [I /the participant/the subject] was given the opportunity to ask questions and these questions were answered to [my/his/her]. [I/the answered to [my/his/her] satisfaction.

[I hereby consent voluntarily to participate in this study/I hereby consent that the subject/participant may participate in this study.] I have been given a copy of this form.

_____

Name of Subject/ Participant

_____

Name of Legal Representative (if applicable)

_____ _____

Signature of Subject/Participant of Legal Representative Date

SIGNATURE OF INVESTIGATOR

I declare that I explained the information given in this document to _____ [name of the subject/participant] and or [his/her] representative _____ [name of the representative. [He/she] was encouraged and given ample time to ask me any questions. This conversation was conducted in [Sotho/English/Zulu/Other] and [no translator was used/this conversation was translated into _____by _____].

_____

Signature of Investigator_____ Date

Appendix E: Interview Protocol

TITLE OF STUDY**:** The effects of HIV status disclosure on antiretroviral therapy adherence

Participants No:

Demographic Information

Race:

Gender: Male/Female

Age:

Sexual Orientation:

HIV STATUS

1. When you were first diagnosed with HIV?
2. How were you diagnosed? –Voluntary/Involuntary
3. Were you given Pre and Post-test counselling?
4. Was Pre and Post Test counselling helpful?

STATUS DISCLOSURE

1. Have you disclosed your HIV status to anyone? Yes/No
2.
    a. If yes, above to whom did you disclose to?
    b. Why did you disclose?
    c. Was the disclosure voluntary or involuntary?
    d. How did you feel after disclosure of your HIV status?
3. If no at 1. above:-
    a. Are you planning to disclose? Yes/ No
    b. Why are you not disclosing?

    (Fear of discrimination, Stigma, Isolation).
4. Do you think your family should know about your illness? Yes/No

If yes, why?

If no, why?

5. Do you think your friends and should know about your illness? Yes/No

If yes, why?

If no, why?

6. Do you think your school/employer should know about your illness? Yes/No

ANTIRETROVIRAL THERAPY

1. When did you start taking antiretroviral medication?
2. Do you feel better on medication? Yes/No
3. Have you ever suffered any drug side effects?
   - If yes, have you ever felt the need to stop taking your medication? Yes/No
   - If no, have you ever felt the need to stop taking your medication? Yes/No
4. Have you ever skipped your medication? Yes/No
   - If yes, why did you skip the medication?
5. Have you ever taken your medicine in front of other people? Yes/No
   - If yes, why?
   - If no, why?
6. Do you hide taking your medication when among people?
7. Do you take your medicine regularly?
8. Do you think disclosing your HIV status will help improve taking your medication?

Appendix F: Revised Who Clinical Staging of Hiv/Aids for Adult and Adolescents

(Interim African Region version for persons aged 15 years or more with positive HIV antibody test of other laboratory evidence of HIV infection)

Table1. Revised WHO CLINICAL STAGING OF HIV/AIDS AND ADOLESCENT

Primary HIV Infection

Asymptomatic

Acute retroviral syndrome

Clinical stage 1

Asymptomatic

Persistent generalized lymphadenopathy (PGL)

Clinical stage 2

Asymptomatic

Persistent generalized lymphadenopathy (PGL)

Clinical stage 3

Severe weight loss (>10 % of presumed measured body weight)

Unexplained chronic diarrhoea for longer than one month

Unexplained persistent fever (intermittent of constant for longer than one month)

Oral candidiasis

Oral hairy leukoplakia

Pulmonary tuberculosis (TB) diagnosed in two years

Server presumed bacterial infections (e.g. pneumonia, empyema, pyomosistis, bone or joint infection, meningitis, bacteraemia)

Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

Conditions where confirmatory diagnostic testing is necessary

Unexplained anaemia (<8 g/dl), and or neutropenia (<500/mm3) and or thrombocytopenia (<50 000/ mm3) for more than one month

All clinical events or conditions referred to all described in the Annexes. The UN defines adolescents as persons aged 10 – 19 years but, in the present documents, the category of adults and adolescents comprises people aged 15 years and over for surveillance purposes.

Clinical stages 4

Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations

HIV wasting syndrome

Pneumocystis pneumonia

Recurrent severe or radiological bacterial pneumonia

Chronic herpes simplex infection (oralabial, genital or anorectal of more than one month's dration)

Oesophageal candidiasis

Extrapulmonary TB

Kaposi's sarcoma

Central nervous system (CNS), toxoplasmosis

HIV encephalopathy

Conditions where confirmatory diagnostic testing is necessary:

Extrapulonary cryptococcosis including meningitis

Disseminated non- Mycobacteria turberculous infection

Progessive multifocal leukeoncephalopathy (PML)

Candida of trachea, bronchi or lungs

Cytomegalovirus (CMV) infection (retinitis or of an organ other than liver, spleen or lymph nodes)

Any disseminated mycosis (e.g. histoplasmosis , coccidiomycosis, penicilliosis)

Recurrent non-typhoidal salmonella septicaemia

Lympnoma (cerebal or B cell non-Hodgkin)

Invasive cervical carcinoma

Visceral leishmaniasis

Appendix G: Antiretroviral Therapy Guidelines

4. Adults and Adolescents

4.1 Standardised national eligibility criteria for starting ART regimens for adults and adolescents

Eligible to start ART
▪ CD4 count ≤350 cells/mm3 irrespective of WHO clinical stage **OR** ▪ Irrespective of CD4 count ○ All types of TB (In patients with TB/HIV drug resistant or sensitive TB, including extra pulmonary TB) ○ HIV positive women who are pregnant or breast feeding **OR** • Patients with Cryptococcus meningitis or TB meningitis (defer ART for 4-6 weeks) ▪ WHO stage 3 or 4 irrespective of CD4 count
Require fast track (i.e. ART initiation within 7 days of being eligible)
▪ HIV positive women who are pregnant or breast feeding **OR** ▪ Patients with low CD4 <200 **OR** ▪ Patients with Stage 4, irrespective of CD4 count **OR** ▪ Patients with TB/HIV co morbidity with CD4 count < 50
Patients with CD4 above 350, Not yet eligible for ART
▪ Transfer to a wellness programme for regular follow-up and repeat CD4 testing 6-monthly. ▪ Advise on how to avoid HIV transmission to sexual partners and children ▪ Initiate INH prophylaxis if asymptomatic for TB ▪ Provide counselling on nutrition and contraceptive and do annual pap smear

The South African Antiretroviral Treatment Guidelines 2013

4.2 Standardised national ART regimens for adults and adolescents

1st Line		
All new patients needing treatment, including pregnant women	TDF + FTC (or 3TC) +EFV FDC preferred	Replace EFV with NVP in patients with significant psychiatric co-morbidity or intolerance to EFV and where the neuro-psychiatric toxicity of EFV may impair daily functioning, e.g. shift workers.
Contraindications to EFV	TDF + (FTC or 3TC) + NVP	Use NVP based regimen: In patients with significant psychiatric co morbidity or intolerance to EFV and where the neuro-psychiatric toxicity of EFV may impair daily functioning, e.g. shift workers.
Contraindication to TDF	AZT+ 3TC +EFV or (NVP)	Renal disease or the use of other nephrotoxic drugs e.g. aminoglycosides
Contraindication to TDF and AZT	d4T + 3TC+ EFV (or NVP)	Renal disease and anaemia or the use of other nephrotoxic drugs, aminoglycosides
Contraindication to TDF, AZT and d4T	ABC + 3TC + EFV (or NVP)	Renal disease, anaemia, peripheral neuropathy, the use of other nephrotoxic drugs
Currently on d4T-based regimen	TDF + FTC(or 3TC) + EFV FDC preferred	Mandatory if patients experience toxicity and patients who are at high risk of toxicity (high BMI or pregnant). Switch to TDF if virally suppressed and the patient has normal creatinine clearance, even if well tolerated.
2nd Line		
Management of virological failure		If plasma HIV RNA >1000 copies, Check for adherence, compliance, tolerability and drug- drug interaction and assess psychological issues. Repeat VL test 2 months later. If plasma VL confirmed >1000copies change regime to second line therapy
Failing on a TDF-based 1st line regimen	AZT+3TC+ LPV/r	Patients with anaemia and renal failure switch to ABC
Failing on a d4T-based 1st line regimen	TDF+3TC (or FTC) and LPV/r	
Dyslipidaemia or diarrhoea associated with LPV/r	Switch LPV/r to ATV/r	
Third line		
Failing any 2nd line regimen	Specialist referral	
Should be expert and genotype resistance testing based decision and supervised care Patients failing on second line therapy will be managed by an expert panel. The drugs for third line will be managed centrally. More discussion is required to deal with the modalities	Most likely regimen would be Raltegravir/Darunavir/ /Etravirine adjusted according to genotype Interpretation. Should be by expert and take into account prior exposure and predictable mutations	

4.3 Standardized National Monitoring for Adults and Adolescents with HIV

At initial Diagnosis of HIV	Purpose
Confirm HIV result with rapid antibody test	Ensure that national testing algorithm has been followed
Do CD4 count if HIV positive and WHO clinical staging	To assess eligibility for ART To assess eligibility for fast-tracking
Screen for pregnancy or ask if planning to conceive	To identify women who need ART for life or ARV prophylaxis for PMTCT (see section 6)
Screen for TB symptoms using the WHO questionnaire	To identify TB/HIV co-infected
Do the CD4 count on the same day	To identify eligibility for ART or ARVs for prophylaxis if pregnant
Do HB or FBC if requires AZT Creatinine if requires TDF For patients initiated on Nevirapine based regime do ALT	To detect anaemia or neutropenia, To detect renal insufficiency To exclude liver disease

On ART	Purpose
CD4 at 1 year on ART	To monitor immune response to ART
VL at month 6, 1 year on ART and then every 12 months	To identify treatment failures and problems with adherence
ALT only if on NVP and develops rash or symptoms of hepatitis	To identify NVP toxicity
FBC at month 3 and 6 if on AZT	To identify AZT toxicity
Creatinine at month 3 and 6, 1 year then every 12 months if on TDF	To identify TDF toxicity
Fasting cholesterol and triglycerides at month 3 if on LPV/r	To identify LPV/r toxicity

At Routine Follow-Up Visits for those not yet eligible for ART	Purpose
Repeat CD4 count at 6 months	To see if they have become eligible for ART
WHO clinical staging at every visit	To see if they have become eligible for ART
Screen for TB symptoms to identify TB suspects Offer IPT if no TB symptoms	To identify TB/HIV co-infection To prevent TB activation
Offer prevention for HIV positives	To prevent HIV transmission and re-infection To prevent STIs

4.4 Indications for urgent up-referral prior to initiation or when on therapy

- eGFR less than 60 ml/min
- Hb less than 8 g/dl
- BMI less than 18.5 kg/m2
- In a patient with TB, poor response to TB treatment