PSYCHOSOCIAL CHARACTERISTICS OF AIDS PATIENTS WITH UNSUPPRESSED VIRAL LOAD AFTER SIX MONTHS OF ANTIRETROVIRAL THERAPY

BY

EMMANUEL IKECHUKWU OKOLI

ASSIGNMENT PRESENTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF PHILOSOPHY (HIV/AIDS MANAGEMENT) IN THE FACULTY OF ECONOMIC AND MANAGEMENT SCIENCES AT STELLENBOSCH UNIVERSITY
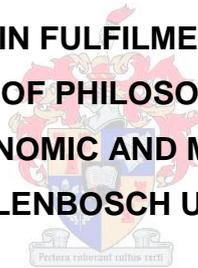
SUPERVISOR: DR GREG MUNRO

MARCH 2013

DECLARATION

By submitting this assignment electronically, I declare that the entirety of the work contained therein is my own original work, that I am the sole author thereof (save to the extent explicitly otherwise stated), that reproduction and publication thereof by Stellenbosch University will not infringe any third party rights and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

Date: March 2013

ACKNOWLEDGEMENT

I am grateful to God for giving me the opportunity to undertake this study. I also thank Him for granting me the strength and resources that enabled me to complete this project.

I also appreciate sincerely my darling wife, Dr Uzoamaka Ijeoma Okoli for her love, assistance and support throughout the duration of the study.

I would also want to thank my study leader, Dr Greg Munro at University of Stellenbosch for his patience, invaluable support and encouragement.

My heartfelt appreciation goes to Dr Ashraf Grimwood (CEO of Khethimpilo), Dr Eula Mothibi (Head of Health Services Cluster, Khethimpilo), The KwaZulu-Natal Provincial Department of Health, Ms Dube (District Manager Ilembe Department of Health), Mr Nathi Shabane (Chief Executive Officer, Sundumbili CHC) and Ms Mtshali (Facility Manager, Isithebe Clinic) for the various forms of authorisations I received from them that enabled me to embark on the study unhindered.

Finally, I would want to thank Dr Mathenjwa, Dr Hlatshwayo, Mr Nevil Braude, Mrs Mkhize and Mrs Bhengu who assisted in conducting the interviews both for the pilot and the main study in addition to Mr Roshan Silochan, the data coordinator for Khethimpilo in Ilembe district.

I also appreciate the support, prayers and unending patience of my family and friends towards the completion of this study. I am very grateful.

ABSTRACT

STUDY AIM

The aim of the study is to explore the psychosocial characteristics of HIV positive clients who are yet to achieve viral load suppression after six months of commencing ARV at Sundumbili CHC in order to plan positive intervention strategies.

RESEARCH DESIGN

Non-experimental quantitative design was used in carrying out the study. The data was collected through retrieval of information from clinic records and completion of questionnaires to clients on ARV who met the inclusion criteria and consented to participating in the study. A total of 51 adults aged more than 18 years that were initiated in 2010/2011 and still access their treatment at Sundumbili CHC were enrolled into the study. They were selected through convenience sampling.

FINDINGS

Psychosocial challenges still exist among research participants whose viral load results were not suppressed after six months on ARV. This affected the adherence of some of them to their antiretroviral treatment.

CONCLUSION

Given the rural nature of Sundumbili and surroundings where the bulk of the patients reside, there are several psychosocial challenges affecting the patients. No known previous study has been undertaken to ascertain the psychosocial characteristics of this group of patients and the impact they may have on viral load suppression after six months of treatment. The study is therefore significant as the findings have provided more insight into the plight of the patients. It is envisaged that the recommendations from the study will assist the relevant management staff in the department in planning and subsequently implementing more positive intervention strategies. The strategies should be targeted at improving the quality of care of the HIV positive clients and attending to their psychosocial needs.

OPSOMMING

STUDIEDOELWIT

Die doel van die studie was om ondersoek in te stel na die psigososiale kenmerke van MIV-positiewe kliënte wie se virustellings ná ses maande van antiretrovirale (ARV) behandeling by die gemeenskapsgesondheidsentrum op Sundumbili steeds nie onder beheer was nie, ten einde positiewe intervensiestrategieë te beplan.

NAVORSINGSONTWERP

'n Nie-eksperimentele kwantitatiewe ontwerp is gebruik om die studie te onderneem. Die data is ingesamel deur die herwinning van inligting uit klinieklêers sowel as die afneem van vraelyste onder kliënte op ARV's wat aan die insluitingsmaatstawwe voldoen en tot deelname aan die studie toegestem het. Altesaam 51 volwassenes bo die ouderdom van 18 wat in 2010/2011 met ARV behandeling begin het en dit steeds by Sundumbili-gemeenskapsgesondheidsentrum ontvang, is in die studie opgeneem. Dié groep is deur middel van geriefsteekproefneming gekies.

BEVINDINGE

Psigososiale uitdagings was steeds te bespeur by navorsingsdeelnemers wie se virustellings nog nie ná ses maande op ARV's onder beheer was nie. Dit het sommige se behandelingsgetrouheid beïnvloed.

GEVOLGTREKKING

In die lig van die landelike aard van Sundumbili en omgewing, waar die meeste van die pasiënte woon, kom pasiënte voor verskeie psigososiale uitdagings te staan. Daar is klaarblyklik nog nooit vantevore 'n studie onderneem om die psigososiale kenmerke van hierdie groep pasiënte, en die moontlike impak daarvan op die onderdrukking van virustellings ná ses maande van behandeling, te bepaal nie. Hierdie studie is dus waardevol, aangesien die bevindinge groter insig in die lot van die pasiënte bied. Daar word beoog dat die aanbevelings uit die studie tersaaklike bestuurspersoneel in die Departement van Gesondheid sal help om meer positiewe intervensiestrategieë te beplan en gevolglik in werking te stel. Die strategieë behoort

daarop afgestem te wees om die gehalte van sorglewering aan MIV-positiewe kliënte te verbeter en in hul psigososiale behoeftes te voorsien.

LIST OF ACRONYMS USED IN THE STUDY:

HIV — HUMAN IMMUNODEFICIENCY VIRUS

AIDS — ACQUIRED IMMUNE DEFICIENCY SYNDROME

UNAIDS — JOINT UNITED NATIONS PROGRAMME ON HIV AND AIDS

WHO — WORLD HEALTH ORGANIZATION

STI — SEXUALLY TRANSMITTED INFECTIONS

SAHR — SOUTH AFRICA HEALTH REVIEW

ART — ANTIRETROVIRAL TREATMENT

STD — SEXUALLY TRANSMITTED DISEASE

MEMS — MEDICATION EVENT MONITORING SYSTEM

DOTS — DIRECTLY OBSERVED THERAPY

DAART — DIRECTLY ADMINISTERED ART

PICT — PROVIDER-INITIATED COUNSELLING AND TESTING

HCT — HIV COUNSELLING AND TESTING

PMTCT — PREVENTION OF MOTHER TO CHILD TRANSMISSION

PLHIV — PEOPLE LIVING WITH HIV

NDOH — NATIONAL DEPARTMENT OF HEALTH

PEPFAR — PRESIDENTIAL EMERGENCY PLAN FOR AIDS RELIEF

USAID — UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT

CHC — COMMUNITY HEALTH CENTRE

eMTCT — ELIMINATION OF MOTHER TO CHILD TRANSMISSION

TB — TUBERCULOSIS

NGO — NON-GOVERNMENTAL ORGANIZATION

RVD — RETROVIRAL DISEASE

NSP — NATIONAL STRATEGIC PLAN

SANAC — SOUTH AFRICA NATIONAL AIDS COUNCIL.

ARV — ANTIRETROVIRAL

VL — VIRAL LOAD

NNRTI — NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR

PI — PROTEASE INHIBITOR

NRTI — NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR

sdNVP — SINGLE DOSE NEVIRAPINE

HIVDR   HIV DRUG RESISTANCE

USA   UNITED STATES OF AMERICA

PMTCT   PREVENTION OF MOTHER TO CHILD TRANSMISSION

POST EXPOSURE PROPHYLAXIS

LIST OF TABLES:

LIST OF FIGURES:

LIST OF ANNEXURES:

CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION

Epidemics are history-changing events. They terminate some lives, incapacitate others and stunt the capabilities of those who have to direct energy and time into care. In the end, sufficient numbers of deaths and illnesses make a society take a part other than that which it would previously have followed (Barnett & Whiteside, 2002:159).

Since the first report on HIV/AIDS was made in 1981 by two Physicians in United States of America, the number of people living with the disease steadily increased and the epidemic moved into a generalized state impacting on many segments of the society.

Sub-Saharan Africa still bears an inordinate share of the global HIV burden (UNAIDS, 2010:25). UNAIDS further indicates that although the rate of new HIV infections has decreased, the total number of people living with HIV in the region continues to rise. In 2009, that number reached 22.5 million which represents 68% of the global total estimated to be 33.3 million at the end of 2009. Recent statistics indicate that there were more people living with HIV in 2011 than ever before due to expanding treatment access and subsequent declining death rates. Globally, this figure was put at 34.2 million in 2011(UNAIDS, 2012:19). UNAIDS further indicates that in sub-Saharan Africa where the need for treatment with antiretroviral therapy is greatest, more than half the people needing treatment were getting it in 2011 and 22% more people were getting the treatment in 2011 than a year earlier.

South Africa has one of the largest ART programmes in the world (Padayatchi, Naidoo, Dawood, Kharsany & Karim, 2010:88) and having unprotected sex with multiple partners is the greatest risk factor for HIV in this region. With an estimated 5.575million PLHIV in 2010, South Africa's epidemic remains the highest in the world (NDOH, 2011). NDOH further indicates that the national HIV prevalence estimate among antenatal women in 2010 was 30.2% while in KwaZulu-Natal, the figure was

put at 39.5%. KwaZulu-Natal province has consistently recorded the highest provincial HIV prevalence since 1990 (NDOH, 2010a:43).

In iLembe district where the study was conducted HIV prevalence was 42.3% making it the district with the highest prevalence of HIV among antenatal women throughout the country alongside uMgungundlovu in 2010(NDOH, 2011). However, recent statistics indicate that the prevalence is now 35.4% (NDOH, 2012:17). The HIV prevalence for the entire iLembe population was 16.6% as at the first quarter of 2011 (Enterprise Ilembe, [Sa]: 13). According to the 2006 national census, the population of iLembe was put at 568498 (iLembe District Municipality, 2011:12). Only about 28% of the population were formally and informally employed at the end of quarter two in 2011 in the district with the not-economically active persons accounting for 64.2% of the district population (Enterprise iLembe, [Sa]:17.)

Viral load monitoring of eligible clients commenced on ART is widely used to assess the success of treatment. Failure of suppression of viral load after six months of commencing ART is almost always due to poor adherence often as a result of poor attention of the Clinicians to drug toxicity or where psychosocial factors have not been addressed. The study seeks to explore the psychological characteristics of clients with unsuppressed viral load after 6 months of commencing ART.

1.2   BACKGROUND OF THE PROBLEM

Sundumbili CHC located in the Mandeni municipality of iLembe District is among the largest HIV management centres in KwaZulu-Natal province. The researcher manages the activities of Khethimpilo, a PEPFAR/USAID-funded nongovernmental organization that supports ART services in the facility. During the course of work, it was noted that majority of the clients who access care at the facility reside in the surrounding largely rural areas. The facility offers a comprehensive ART care and treatment programme ranging from ranging from PICT services, adherence counselling, eMTCT services, adult and paediatric care and management, pharmacy services and TB/HIV care. Clients are provided with the prescribed pre-test counselling prior to testing for HIV. Should a patient test positive to HIV, post-test counselling is carried out immediately by the Lay Counsellors engaged by

Department of Health. Clinical staging is done and blood sample is immediately collected for CD4 count. The outcome of clinical staging and the CD4 count test results is used by the clinician to ascertain the eligibility of the patient for commencing ART. The turnaround time is reasonably quick and most times within five days. The clinical guidelines for the management of HIV and AIDS published by the National Department of Health serves as guidance to the health practitioners at the facility with regard to the comprehensive HIV/AIDS management.

Prior to initiation, the patient undergoes literacy classes where information regarding intake of the medications are passed on to them. The ART regimen, their dosages and possible side effects, sexual and reproductive health issues, early identification of tuberculosis and other opportunistic infections are among the information disseminated to the clients during the classes which usually spans over three sessions. Importance of adherence and ways of achieving and maintaining adherence to the ART medications are also shared. During the course of the classes, the clients are introduced to Patient Advocates who are Community home-based carers recruited by Khethimpilo. The Patient Advocates are specially trained in terms of rendering psychosocial assessments to identify possible factors that could affect adherence. They also undertake home visits for the same reasons and encourage disclosure to at least a treatment supporter, who should preferably reside in the same household with the patient. Aside from the client, the patient advocate offers health education to the remaining members of the household and where indicated, refers them to the health facility where they will access the relevant services. Information regarding TB-related services, contraception, child health and sexually transmitted infections is also shared with the household.

The outcome of the visits and the psychosocial assessment are shared with the clinician managing the client and where the clinical team is convinced that the client is fit for ART, the rest of the clinical assessment including TB screening follows and the client signs treatment contract and is commenced on ART. In some instances, certain factors that will likely affect treatment directly or indirectly like accessing other social services are sorted out prior to initiating treatment or afterwards. These include social grants, identity documentations amongst others.

After initiation on ART, the routine blood monitoring is carried out according to the NDOH guidelines and the viral load test is done six months after initiation. The VL result is expected to be undetectable when the test is carried out after the sixth month of treatment (NDOH, 2010b:19). NDOH further indicates that VL of <400 copies/ml is accepted as suppressed viral load and routine adherence support with regular viral load monitoring is recommended afterwards. However, when the VL is more than 1000 copies/ml on two different occasions despite intensive adherence counselling, the situation is referred to as virological failure and this necessitates changing the medications. Virological failure is almost always due to poor adherence often as a result of poor attention of the Clinicians to drug toxicity or where psychosocial factors have not been addressed.

1.3   RESEARCH PROBLEM

A sizeable number of HIV positive clients who commenced ART at Sundumbili CHC are yet to achieve viral load suppression after six months of treatment. There is a scarcity of documented data regarding the psychosocial characteristics of this group of patients in the environment where the study is being proposed as no known formal study has been carried out on them. There is also paucity of information on the possible psychosocial factors that could lead to poor adherence and subsequent inability to achieve VL suppression after six months on ART. The interventions are individualised at the moment and sometimes occurs long after virological failure has occurred. It is expected that when peculiar characteristics of the patients are known and well documented, measures will be put in place to avert the situation by health workers, the relevant government department and the NGO support partner, Khethimpilo.

1.4   RESEARCH QUESTION

What are the psychosocial characteristics of AIDS patients whose viral load were not suppressed after six months of commencing ART at Sundumbili CHC?

1.5 AIM OF THE STUDY

The aim of the study is to explore the psychosocial characteristics of HIV positive clients who are yet to achieve viral load suppression after six months of commencing ART at Sundumbili CHC in order to plan positive intervention strategies.

1.6 RESEARCH OBJECTIVES

- To ascertain the psychosocial characteristics and social problems of adult   AIDS clients who are yet to achieve viral load suppression after six months of commencing ART.
- To determine how psychosocial characteristics affect adherence to ART.
- To recommend strategies that could be employed to address the psychosocial needs of the clients.

1.7 SIGNIFICANCE OF THE STUDY

Given the rural nature of Sundumbili and surroundings where the bulk of the patients reside, there are several psychosocial challenges affecting the patients. No previous study has been undertaken to ascertain the psychosocial characteristics of this group of patients and the impact they may have on viral load suppression after six months of treatment. The study is therefore significant as the findings will provide more insight into the plight of the patients. It is expected that the outcome of the study will assist the government and Khethimpilo in planning and subsequently implementing more positive intervention strategies.

1.8 RESEARCH DESIGN AND METHOD

1.8.1 Research Design

Research design refers to the outline, plan or strategy specifying the procedure to be used in seeking an answer to the research question (Christensen, 2007:269). Christensen further indicates that it specifies how to collect and analyze the data and also serves to control unwarranted variation.

Quantitative research using a survey was utilised for the study because according to Burns & Grove, (2005:24), structured interviews and questionnaires which are

appropriate for quantitative studies were used. In addition, the data was in the form of numbers and descriptive statistics was utilized to interpret the data.

1.8.2   Population

The target population will be adult RVD clients currently on ART at Sundumbili CHC who have completed at least six months of treatment and had viral load test carried out on them with results retrieved. Adults aged more than 18 years who were initiated on ART in 2010/2011 and still access their treatment at the Siyethemba Clinic of Sundumbili CHC will be enrolled into the study. The inclusion criteria that will be met by each participant include the that the participant will be an adult aged more than 18 years, HIV positive on ART for more than six months, latest viral load carried out in 2011 with the result indicating viral load of more than 400cells/mm^3 of blood. Clients diagnosed of dementia or other significant psychiatric diseases, those that sent proxies to collect their medications during the period the study was carried out and terminally ill clients admitted in referral hospital will be excluded from the study.

1.8.3   Sampling

Purposive sampling will be used to select the participants. Their identity will be sourced from the data maintained at the clinic and they will be approached to complete the questionnaires when they present at the clinic to collect their medications. Three of the Clinicians working at the HIV Clinic were trained for the purpose of assisting participants to complete the questionnaire.

1.8.4   Pilot study

The structured questionnaires designed for the study comprise of both open-ended and close-ended questions that will ascertain the demographic and psychosocial characteristics of the target population. They were piloted at Isithebe PHC among 10 HIV positive clients on ART before the main study. Isithebe PHC is located in the same municipality as Sundumbili CHC. The clients that access ART services at the facility share similar demographics.

1.8.5 Data Collection

The researcher employed face to face method in which a mixture of open and close-ended questionnaire was administered and the research participant chose from the predetermined responses and in some cases clarified their choice of responses. Some of the responses will be retrieved from the clinic records of the patient.

The use of questionnaires as a way of obtaining data from the participants was to pave way for a quick less expensive means of data collection. Contents of the questionnaires include questions that indicate the demographic characteristics of the participants, their social status, sexual behaviour, the psychosocial challenges they experienced during the course of their treatment and how such problems affected their adherence to ART. Efforts were made to avoid any form of bias that could invalidate the results of the study. This is because a biased study result suggests one that does not represent the truth (Joubert, 2007:160). The questionnaires were administered by the trained Clinicians to the clients as they accessed treatment services at the ARV Clinic of Sundumbili CHC.

1.8.6 Data analysis

Descriptive statistics was used to summarize and describe the data in a concise form (Joubert, 2007:137). The data collected from the questionnaires were summarized by tabulating or graphically depicting them using the appropriate program in the computer. The data was analyzed based on the responses received from the research participants as indicated in the completed questionnaires. Summary of the categorical variables include the mean of the ages of participants, percentage of the study participants that are male or female and the extent to which the study participants were spread among the identified psychosocial characteristics will also be calculated.

1.8.7 Ethical consideration

Ethical approval for the study was obtained from the Ethics Committee, Stellenbosch and permission for the study was obtained from the KwaZulu-Natal Provincial Department of Health, Ilembe District Department of Health and from the Management of Sundumbili Community Health Centre. Written informed consent

was also obtained from the participating AIDS clients. Anonymity and confidentiality of the whole exercise including the identity and status of the participants were equally maintained. The details of the study were explained to the research participants and they were offered the option of voluntarily participating in the study. Prior to completion of the study questionnaires, they were informed they could withdraw from the study at anytime without penalty.

1.9   CONCLUSION

Sub-Saharan Africa still bears an inordinate share of the global HIV burden with iLembe District of South Africa where the study was conducted among the districts with the highest prevalence of HIV among ANC women throughout the country.

Despite rendering the full component of primary healthcare level HIV care, a sizeable number of HIV positive clients that commenced ART at Sundumbili CHC between 2010 and 2011 are yet to achieve viral load suppression after six months of treatment.

In this chapter, the researcher proposed a study aimed at exploring the psychosocial characteristics of the aforementioned group of clients in order to plan more positive intervention strategies. The research problem, research objectives, significance of the study, aspects relating to research design and methods in addition to ethical considerations were also elaborated.

The next chapter will consist of literature review on the research topic by the researcher.

CHAPTER 2: LITERATURE REVIEW

2.1   INTRODUCTION

Guided by the NSP, the current national response to HIV in addition to STIs and TB plan addresses the drivers of the HIV and TB epidemics and builds on the achievements of the previous NSPs to achieve its goals (RSA & SANAC, 2011: 12). The NSP 2012-2016 is driven by a long-term vision for the country with respect to the HIV and TB epidemics.

Two years after releasing clinical treatment guidelines by the NDOH in consultation with the Treatment Technical Task Team of SANAC, the 2010 guidelines were updated. These are intended to accelerate ART uptake, improve clinical outcomes, reduce morbidity and mortality due to TB co-infection and delay AIDS disease progression (HST, 2012:1).

Very high levels of patient adherence, (greater than 95%), are required for ARVs to be effective and to prevent the emergence of resistant viral strains. With three quarters of antiretroviral users in Africa adhering successfully, African countries have achieved extraordinary levels of adherence given the levels of poverty in which many ARV users live. Apart from being a good indication of treatment success, suppressed viral load at the individual and community level reduces the spread of HIV. Psychosocial factors which include depression and lack of support from partners were associated with non-adherence to ART. Unlike many other diseases, it is vital that PLHIV consume all doses of the drug to prevent resistance and to improve their chances of survival. Understanding the level of non-adherence and the factors that lead to it are important clinical and public health goals. This information is essential to inform ART programmes and maximise the success of treatment.

2.2   OVERVIEW OF HIV/AIDS MANAGEMENT IN SOUTH AFRICA

South Africa has one of the largest ART programmes in the world (SAHR, 2010:88). The national response to HIV in addition to STIs and TB is guided by the NSP. The plan addresses the drivers of the HIV and TB epidemics and builds on the achievements of the previous NSPs to achieve its goals (RSA 2011: 12). Produced

20

by SANAC, the current 2012-2016 strategic plan aims to inform national, provincial, district and community level stakeholders on strategic directions to be taken into consideration when developing implementation plans. It was also designed to be used by SANAC as the framework to coordinate and monitor implementation by sectors, provinces, district and municipalities. SANAC further indicates that international development partners are also meant to use the NSP to support the country in its effort to turn the tide with respect to the twin HIV and TB epidemics. The NSP is thus aligned with international and regional obligations, commitments and targets related to HIV, STI and TB. It is located within the constitutional framework of the Republic of South Africa and strives towards its ideals of human dignity, non-racialism, non-sexism and the role of law.

2.3   VISION AND GOALS

The NSP 2012-2016 is driven by a long-term vision for the country with respect to the HIV and TB epidemics. The 2016 year vision for South Africa is:

• Zero new HIV and TB infections
• Zero new infections due to vertical transmission.
• Zero preventable deaths associated with HIV and TB
• Zero discrimination associated with HIV and TB.

Also in line with the 2012-2016 year vision, the NSP 2012-2016 has the following broad goals:

• Reduce new HIV infections by at least 50% using combination
   prevention approaches
• Initiate at least 80% of eligible patients on ART, with 70% alive and
   on treatment five years after initiation
• Reduce the number of new TB infections as well as deaths from TB by 50%.
• Ensure an enabling and accessible legal framework that protects
   and promotes human rights in order to support implementation of the NSP.
• Reduce self-reported stigma related to HIV and TB by at least 50%.

## 2.4	CLINICAL TREATMENT GUIDELINES

The recent clinical guidelines for the management of HIV and AIDS in adults and adolescents were developed by NDOH in 2010 in conjunction with SANAC Treatment Technical Task Team (NDOH, 2010b:4). NDOH further indicates that in addition to several goals, the objectives of the programme are to contribute to strengthening of the public and private health sectors' capacity to deliver high quality integrated health and wellness services; to ensure timely initiation of antiretroviral drugs for treatment and prevention according to the Presidential mandates and to minimize unnecessary drug toxicities.

### 2.4.1	National eligibility criteria for starting ART regimens for adult and adolescents

Table 2.1 below indicates the eligibility criteria for commencing ART for adults and adolescents prior to recent adjustments in 2012. HIV positive clients eligible for ART include those with CD4 count ≤200cells/mm³, patients who are pregnant or are co-infected with TB having CD4 count ≤350cells/mm³, those with WHO clinical stage IV irrespective of CD4 count or those diagnosed with MDR/XDR-TB irrespective of CD4 count (NDOH, 2010b:6). NDOH further indicates that pregnant women eligible for lifelong ART, patients with very low CD4 count (<100 cells/mm³), patients adjudged to be in WHO Clinical stage IV and those with MDR/XDR-TB are eligible. Most recently in April 2012, the South African NDOH published changes to the National Antiretroviral Treatment Guidelines, by means of a circular signed by the Director General of Health on 14 April 2012. These were intended to accelerate ART uptake, improve clinical outcomes, reduce morbidity and mortality due to TB co-infection and delay AIDS disease progression. These are intended to be achieved through accelerating access to ART initiation and reducing missed opportunities for provision of early ART to those that are eligible. Table 2.4 below highlight the key differences between the 2010 and 2012 clinical treatment and monitoring guidelines. The updated guidelines are in line with WHO recommendations which indicate that moderate-quality evidence supports strong recommendations for the timing of ART initiation for the critical outcomes of absolute risk of death, disease progression and the occurrence of serious adverse events (WHO, 2010:25).

However, patients who are not yet eligible for ART after clinical and laboratory assessments are transferred to a wellness programme for regular follow-up and repeat clinical assessment/CD4count testing 6-monthly. They are also advised on how to avoid HIV transmission to sexual partners and children, initiated on INH prophylaxis if asymptomatic for TB and offered contraception and pap smears (NDOH, 2010b:6).

Table 2.1 Standardised National ART regimens for adults and adolescents

First Line		
All new patients needing treatment	TDF+3TC/FTC+ EFV/NVP	For TB co-infection EFV is preferred. For pregnant women or women of child bearing age, not on reliable contraception, NVP is preferred.
Currently on d4T-based regimen with no side-effects	d4T + 3TC + EFV/NVP	Remain on d4T if well tolerated. Early switch with any toxicity. Substitute TDF if at high risk of toxicity (high BMI, older, female, TB treatment)
Contraindication to TDF: renal disease	AZT+ 3TC +EFV/NVP	
Second line		
Failing on a d4T or AZT-based 1st line regimen	TDF + 3TC/FTC + LPV/r	Virological failure must be followed by intensive adherence management, as resuppression is often possible. If repeat VL remains >1000 in 3 months despite adherence intervention, switch.
Failing on a TDF-based 1st line regimen	AZT + 3TC + LPV/r	Virological failure must be followed by intensive adherence

		management, as resuppression is often possible. If repeat VL remains >1000 in 3 months despite adherence intervention, switch.
Salvage Therapy		
Failing any 2nd line regimen	Specialist referral	Virological failure on protease inhibitors is almost always due to non-adherence. Intensively exploring and addressing issues relating to causes of non-adherence will most often lead to resuppression. If VL remains high, refer where possible, but maintain on failing regimen

(Source: 2010 Clinical guidelines for the management of HIV & AIDS in adults and adolescents, National Department of Health-South Africa)

2.4.2   Standardized monitoring of clients on ART

Table 2.3 indicates the standardised monitoring procedures for HIV positive patients at initial diagnosis of HIV, at routine follow-up visits and when eligible for ART as outlined in the 2010 Clinical guidelines for the management of HIV & AIDS in adults and adolescents. The whole essence is to ensure the best possible and timely care to the deserving clients. The change in 2012 is the emphasis on early commencement of ART and change in the timing of CD4 count tests. As illustrated in Table 2.4, after initiation on ART, a CD4 count follow-up test will now be done at one year on ART and then every 12 months as opposed to the 2010 guidelines that required CD4 tests to be done at six months, one year post initiation and then yearly afterwards.

NDOH also recommends that viral load monitoring should be done first at six months after initiation where it is expected to be undetectable (NDOH, 2010b:18). Repeat

viral load is also to be done at one year after commencement on ART and yearly after wards should the values remain undetectable. However should the viral load result read between 400-1000 copies/ml, NDOH recommends that adherence should be carefully assessed and the test repeated after six months of providing adherence services to the affected client. As outlined in Table 2.5, intense adherence assessment with repeat viral load in three months is recommended at any time the viral load is more than 1000 copies/ml.

Table 2.2: Standardised national ART and ARV regimens for women who are HIV positive

	Maternal regimens	
Woman	**Regimen**	**Comment**
Eligible for lifelong ART (i.e. CD4 < 350 or WHO clinical stage 3 or 4)	TDF + 3TC/FTC + NVP	Start lifelong ART within 2 weeks
Currently on lifelong ART	Continue ART	Substitute EFV with NVP if in first 12 weeks of pregnancy
Contraindication to TDF (renal disease)	AZT+ 3TC + NVP	
Not eligible for ART i.e. CD4 > 350 and WHO stage 1 or 2	AZT from 14 weeks sdNVP + AZT 3hrly in labour TDF + FTC single dose (stat) after delivery	
Unbooked and presents in labour	sdNVP + AZT 3hrly in labour TDF + FTC single dose post delivery	Assess maternal ART eligibility before discharge

(2010 Clinical guidelines: Prevention of Mother-to-Child Transmission (PMTCT) National Department of Health, South Africa)

Table 2.3: Standardized Monitoring (Pre-ART and on ART)

At Initial Diagnosis of HIV	Purpose
Check HIV result	Ensure that the national testing algorithm has been followed
Clinical staging if HIV positive	To assess eligibility for ART; To assess eligibility for fast-tracking
Ask if pregnant or planning to conceive	To identify women who need ART or ARV for PMTCT
Screen for TB symptoms	To identify TB/HIV co-infected
CD4 count	To identify eligibility for ART or ARVs if pregnant
Hb or FBC if available	To detect anaemia
At Routine Follow-Up Visits	**Purpose**
Check that CD4 has been done in the last 6 months	To see if they have become eligible for ART
WHO clinical staging	To see if they have become eligible for ART
Screen for TB symptoms	To identify TB/HIV co-infection
If Eligible for ART	**Purpose**
Serum creatinine and clearance if starting on a TDF-based regimen	Refer urgently if estimated creatinine clearance is less than

26

	50; if referral not available, start AZT/3TC/EFV (or NVP), but dose adjust AZT and 3TC
ALT if starting on a NVP-based regimen	If ALT raised >100, avoid NVP if possible; if no alternative, closely monitor the patient

(Source: Clinical guidelines for the management of HIV & AIDS in adults and adolescents, National Department of Health-South Africa)

Table 2.4: Outline of the main differences between the 2010 and 2012 ART Guidelines.

2010 Eligibility	2012 Eligibility
All HIV positive children under 1 year irrespective of CD4 or WHO stage	All children 5 years and under irrespective of CD4 count and WHO clinical stage
All adults and adolescents with CD4 count ≤ 200cells/mm3 irrespective of clinical stage	All adults and adolescents with CD4 count ≤ 350cells/mm3 as soon as diagnosed
All HIV-positive TB patients with CD4 count ≤ 350cells/mm3	All HIV-positive TB patients irrespective of CD4 count
All HIV-positive pregnant women with CD4 count ≤ 350cells/mm3 OR WHO stage 3 or 4	NO CHANGE
WHO clinical stage 4 irrespective of CD4 count	NO CHANGE
MDR or XDR TB patients irrespective of CD4 count	NO CHANGE
Fast-tract (ART initiation within 2 weeks of being eligible)	Fast-tract (ART initiation on same day diagnosis and eligibility confirmed)
All pregnant women eligible for HAART	All pregnant women eligible for HAART

(Highly Active Antiretroviral Therapy)	
Patients with CD4 count ≤ 100cells/mm3	Patients with CD4 count ≤ 200cells/mm3
WHO clinical stage 4, no CD4 count available	NO CHANGE
MDR or XDR TB patients	NO CHANGE
Follow-up for new patients on ART	**Follow-up for new patients on ART**
CD4 count at month 6 on ART, 1 year and then every 12 months	CD4 count at 1 year on ART and then every 12 months
Viral load at month 6 on ART, 1 year and then every 12 months	Viral load at month 6 on ART, 1 year and then every 12 months

(Source: Health Systems Trust, Kwik-Skwiz, Vol 2 Number 4 2012.)

Table 2.5   Viral load monitoring and recommended responses

Viral Load (VL)	Response
<400 copies/ml	6-monthly viral load monitoring and routine adherence support
)copies/ml	Assess adherence carefully Repeat viral load at 6 months
>1 000 copies/ml	Intense adherence assessment **Repeat viral load in 3 months; check hepatitis B status, if not done already** If <1000, return to routine 6-monthly monitoring If > 1000 and adherence issues addressed, switch to second line therapy after hepatitis B status checked

(Source: 2010 Clinical guidelines for the management of HIV & AIDS in adults and adolescents, National Department of Health-South Africa)

2.5 ADHERENCE ASSESSMENT AND MONITORING

2.5.1 Definition of adherence

Adherence could be defined as the act of behaving according to a particular rule or of following a particular set of beliefs or a fixed way of doing things (Oxford Advanced Learner's Dictionary, 2010:17). The most common definition in the healthcare literature is that of Haynes et al which states that adherence can be defined as the extent to which patients follow the instructions they are given for prescribed treatments (Bissonnette 2008: 636). Bissonnette further indicates that other definitions of adherence found in the literature include such variations as the extent to which patients follow instructions, binding themselves to observance, the extent to which a person's actions or behaviour coincides with advice or instruction, a collaboration to achieve mutually derived goals and a voluntary collaborative relationship. Zuurmond (2008:5) defines adherence as taking doses of drugs and sticking to a treatment plan. Zuurmond indicates that adherence means taking the correct dose of drugs at the correct time and in the correct way.

Despite agreement across health disciplines regarding the significance of the phenomenon of adherence, the definition of the concept of adherence is vague and ambiguous, and there is little agreement either within or among disciplines on a conceptual definition of adherence. Authors across all healthcare disciplines frequently consider the terms and phenomena of adherence and compliance as synonymous and use them interchangeably (Haynes as cited in Bissonnette, 2008: 635).

Very high levels of patient adherence (greater than 95%) are required for ART to be effective and to prevent the emergence of resistant viral strains. This means missing no more than three doses a month for a twice daily regime, and maintaining that level of adherence year after year. Though studies found that adherence greater than 95% is needed to achieve virological success, 22% of patients with an adherence level of over 95% experienced virological failure compared to 61% of patients with adherence between 80–94.9%, and 80% of patients with an adherence level of below 80% (Wasti, Simkhada, Randall, Freeman & van Teijlingen, 2012:1).

Self-reported adherence during the past 4 days was adjudged to be the best predictor of detectable viral load (Ferradini et al, 2006:1340). Adherence is dynamic, changing over time with significant proportions of patients not reaching good/high levels of adherence. Average estimates of ART adherence in USA range from 50% to 70% (Falang, Akubaka & Jimam, 2012). Falang et al further indicate that meta-analysis of African studies on adherence to ART in Sub-Saharan Africa in 12,116 patients indicated a pooled estimate of 77% with good adherence.

With three quarters of antiretroviral users in Africa adhering successfully, African countries have achieved extraordinary levels of adherence given the levels of poverty in which many ARV users live (Skovdal, Campbell, Nhongo, Nyamukapa & Gregson, 2011:296). Skovdal et al further indicate that nevertheless, one quarter of ARV users still struggle to adhere and run the risk of experiencing viral replication, clinical progression or even drug resistance. Good adherence has been noted to be associated with disclosure of HIV status to either spouse or family member and with a tenofovir-containing first-line regimen (Charurat, Oyegunle, Benjamin, Habib, Eze, Ele, Ibanga, Ajayi, Eng, Mondal, Gebi, Iwu, Etiebet, Abimiku, Dakum, Farley & Blattner, 2010:5).

Although women are more likely to seek healthcare and initiate ART earlier than men, they may be more likely to show incomplete adherence and discontinue ART during the first year on therapy (El-Khatib, Ekstrom, Coovadia, Abrama, Petzold, Katzenstein, Morris & Kuhn, 2011:2). El-Khatib et al further indicates that women's adherence to ART may be compromised by child-care responsibilities and dependency ratios, economic pressures and lack of partner support. Incomplete adherence to ART increases women's risk of virologic failure and subsequent clinical progression. The association between adherence and virologic outcome is complex.

Apart from being a good indication of treatment success, suppressed viral load at the individual and community level reduces the spread of HIV (UNAIDS & WHO, 2009:18). A recent meta-analysis suggests that the transmission rate from a person on ART is approximately 0.5 per 100 person-years while it is 5.6 per 100 person-years for persons not on ART (Attia et al as cited in UNAIDS & WHO, 2009:18).

UNAIDS & WHO further indicate that improved access to HIV testing and counselling in addition to ART which in turn leads to decreased viral load could significantly reduce infection rates.

Because of the crucial role of ART in slowing clinical progression and increasing survival in HIV-infected individuals, adherence has become a major issue since ART introduction (Carrieri, Leport, Protopopescu, Cassuto, Bouvet, Peyramond, Raffi, Moatti, Chêne, & Spire, 2006: 477). Carrieri et al further indicate that high levels of adherence to ART are associated with its virologic and immunologic success. Good adherence to antiretroviral therapy has also been found to be associated with suppressed viral load that was sustained in most surviving clients during their first year on antiretroviral therapy (Weidle, Wamai, Solberg, Liechty, Sendagala, Were, Mermin, Buchacz, Behumbiize, Ransom, & Bunnell, 2006:1592).

Incomplete adherence to antiretroviral agents can have serious consequences, including loss of plasma HIV suppression that could lead to disease progression, inability to suppress HIV even with very intensive regimens, and development of drug resistant HIV strains (Tiyou, Belachew, Alemseged & Biadgilign, 2010: 2). This can result in the transmission of resistant HIV to others. Markedly increased efficiency of HIV-1 transmission is expected to occur when the concentration of HIV-1 in semen becomes greater (Chakraborty, Sen, Helms, Vernazza, Fiscus, Eron, Patterson, Coombs, Krieger, and Cohen, 2001:626). This could in turn have multiplier effect in the community especially if the individuals have multiple sexual partners.

However, adherence behaviours may change considerably over time. Both high adherence to ART in the initial phase of treatment and at least moderate adherence in the maintenance phase of treatment independently predicted long-term sustained virologic suppression. Although the majority of patients have their viral load suppressed after six months of ART, those whose viral load remained high could potentially transmit the infection to others. The vast majority of people newly infected with HIV in sub-Saharan Africa are infected during unprotected heterosexual

intercourse (including paid sex) and onward transmission of HIV to new-borns and breastfed babies (UNAIDS, 2010:30).

2.5.2   Measuring adherence

Researchers agree that adherence is a complex, multifaceted and challenging patient behaviour (WHO, 2003). WHO indicates that the practical reality of not following a recommended course of treatment, particularly for individuals with chronic illness, is a major cause of poor health outcomes and increased healthcare costs. On the other hand, some authors suggest that optimizing adherence rates could lead to an increase in the rate of adverse medication side effects as patients avoid recognizing serious side effects in an effort to follow recommendations as prescribed (Bissonnette, 2008: 635).

Currently, there are no gold standard methods for measuring adherence (Reda & Biadgilign, 2012: 2). However, Reda and Biadgilign indicate there are different methods for assessing adherence and the level of adherence is specific not only to places and patient groups but also to the method of adherence measurement used. They include direct methods such as biologic markers and body fluid assays, or indirect methods such as self-report, interview, pill counts, pharmacy records, computerized medication caps, and viral load monitoring. While a combination of these methods may be employed, patients self-report is the most widely used given its ease of implementation and use of already existing resources. However, reliability of answers to the adherence assessment questions might get influenced by patients' desires to provide socially acceptable answers or mere forgetfulness on the part of the patients (Sahav, Reddy & Dhayarkar, 2011). Additionally, adherence also depends on patient provider relationship. Sahav et al further indicate that these concerns about reliability of adherence by self-report get attested by several studies that have shown discrepancy between self-reported adherence and biomedical markers.

ART treatment adherence could also be assessed by two self-reported adherence measures - the Adult AIDS Clinical Trials Group (AACTG) adherence instrument and the 30-day visual analog scale (VAS) (Peltzer, 2010:3). Peltzer et al indicate that the

AACTG consists of nine questions that assess adherence from the previous 1-4 days, within the past week, prior to the interview. The instrument also assesses reasons for non-adherence. The 30-day visual analog scale (VAS) provides an overall adherence assessment for a longer time interval (one month). Both have been validated in resource-limited setting. Adherence is calculated as the % of doses taken over those prescribed. Adherence levels assessed from the VAS are defined as follows: full adherence= 100%, partial adherence >/= 95% and < 100%, and non-adherence as < 95% of prescribed doses taken since the last refill.

Dose adherence could then be assessed by asking participants to report on how many days they had missed taking all their doses during the past four days. Dose non-adherence was defined as having missed all doses on at least one day during the past 4 days.

There are other objective measures of adherence generally used in research that have been found to be more sensitive than patients' self-reports for detecting medication adherence. Clinical studies have employed MEMS, pharmacy refill data, providers' estimates and DOT or DAART either alone or in combination to measure ART adherence.

The current national ART programme in India uses pill count method for assessing adherence. However, this method might not give exact adherence calculation as it does not match with number of missed pills (self) reported by patient leading to discrepancies between pill count by provider and self-report by patient. After being on ART for some time, the patient gets habituated to pill count exercise and manages to bring the exact number of pills to the clinic. He/ she may either be throwing away pills every day or removing them from the bottles just before visiting the clinic. It is obvious that being a patient enabled issue, any adherence measure related to patient (report/ pill count) has its own disadvantages owing to the psychosocial need of social desirability or merely to avoid reprimand from health care provider.

To routinely assess the effectiveness of ART at HIV treatment clinics and to minimize preventable HIVDR, WHO recommends using available site-based data from medical and pharmacy records, e.g. on-time adherence to monthly ART drug pick-up and clinic appointment-keeping as an early warning indicator of inconsistent drug exposure (El-Khatib, Katzenstein, Marrone, Maher, Mohapi, Petzold, Morris & Ekström 2011:1). They further indicate that failure to pick up drugs on time serves as a proxy for treatment interruption and suboptimal drug concentrations, which are associated with virologic failure and the evolution of drug resistance.

Use of computerized medication caps and monitoring of surrogate markers seems reliable and less prone to respondent bias. However, the advanced technology, high cost, and logistic requirements have precluded their wider application in sub-Saharan Africa. In developing countries, pharmacy refill reports and self-reports are commonly implemented for adults, while caregiver reports are employed for children. Various studies of ART treated patients show that self-reports tend to estimate adherence as slightly higher than alternative methods of measurement such as unannounced pill counts and electronic medication monitors (Carrieri et al 2006:483). Mills, Nachega, Buchan, Orbinski, Attaran, Sigh, Rachilis, Wu, Cooper, Thabane, Wilson, Guyatt and Bangsberg (2006:686) indicate that studies in North America using MEMS reported a non-significant pooled reduction in ART adherence compared with self-reported studies of 19%, which is in keeping with expectations that self-report may exaggerate adherence.

Other studies also indicate that self-reports correlate well with both viral load and clinical outcomes. A report from Mumbai in India has shown viral suppression to be associated with participant self-reported adherence (Sahav et al, 2011). Carrieri et al also indicate that nevertheless, most studies of ART-treated patients have confirmed that self-reports are reasonably reliable and that self-reports of non-adherence correlate well with undetectable plasma PI levels.

2.6   PSYCHOSOCIAL ISSUES AND ADHERENCE

Several studies have identified treatment-related or psychosocial factors associated with non-adherence during the early phase of treatment that could put into evidence

factors that influence non-adherence during the maintenance phase. Psychosocial factors which include depression and lack of support from partner were associated with non-adherence to ART (Carrieri et al, 2006:481). Reda and Biadgilign (2012:2) identified presence of anxiety; depression; active substance abuse; presence of HIV infection in another family member; fear of disclosure of HIV positivity to the family; family disruptions; belonging to racial minorities or other vulnerable groups of the population as some of the major issues related to family or caregiver that influence adherence.

A growing body of literature provides evidence that livelihood is an all-encompassing socio-behavioural barrier that can reduce adherence to ART and increase gastrointestinal diseases due to lack of much needed food to go along with ART (Sahav et al, 2011). Sahav et al further indicate that in a systematic review of studies in low and middle-income countries, higher education was associated with adherence but some studies reported negative association between education and adherence. Psychological state could be a reason behind such findings. Mental health challenges have been reported as barrier to adherence among Chinese patients (Sabin, Desilva, Hamer, Keyi, Yue, Wen, Tao, Heggenhougen, Seton, Wilson & Gill, 2008). In another study among HIV test seekers, anxiety was shown to be associated with higher education and this could explain negative association of higher education with ART adherence. Such patients may tend to self-medicate. Depressive symptoms are highly prevalent in individuals infected with HIV (Wagner, Goggin, Remien, Rosen, Simoni, Bangsberg & Liu, 2011: 2). Wagner et al indicate that in a large nationally representative probability sample of persons living with HIV in USA, 37% screened positive for depression using a self-report method. Rates of current clinical depression are much lower when diagnosed by clinical structured interviews, but nonetheless are roughly two times greater in people living with HIV than the general population (approximately 10% versus 5%), as determined by a meta-analysis of published studies. Depression has also been shown to be associated with a threefold increase in non-adherence with medical treatment and HIV research has consistently shown depression to be an impediment to ART adherence (Wagner et al, 2011:2). They further indicate that depression is also associated with missed clinic appointments, failure to initiate ART or to enter into HIV

care, virologic treatment failure, and provider reluctance to prescribe ART for fear of it interfering with adherence. While depression is commonly thought of as an antecedent to non-adherence, the relationship between depression and adherence may be bidirectional; depression may impede adherence and other health behaviours, and poor adherence and associated effects on physical health may increase the risk for depression.

Aside poverty, poor patient-clinician relationship, poorly managed depression and substance abuse have been noted as some of the barriers to adherence among impoverished population in North America. (Mills et al, 2006:687). In Southern Africa, study done by Peltzer, Friend-du Preez, Ramlagan and Anderson (2010: 2) identified non-disclosure, alcohol use, traditional medicine use, notion of feeling better on treatment, inadequate knowledge about the disease and ARVs, stigma, transport costs, lack of social support, discrimination as barriers to adherence. They further indicate that depression and hopelessness, unavailability of food adequate, service-related factors, pill burden and drug side-effects are also common barriers to treatment.

Many other studies have identified other patient's characteristics, pre-ART health, and health literacy (educational level and knowledge about HIV/AIDS and ART) as predictors of ART outcome and sustainable retention in the programme (Sahav et al, 2011). Retention actually is a function of direct and indirect treatment costs. Most commonly reported obstacles to adequate health-seeking behaviour of the poor for obtaining prompt and adequate treatment is the indirect cost. Even if direct costs are affordable, or if medical services are free, indirect costs (for transport, special food and special investigations) limit access to treatment, or lead patients to interrupt therapies. To a great extent, visit to an ART centre depends on patient's family's capacity and possibility at a specific moment to mobilize resources, both in material and social or symbolic terms. Ultimately, poverty emerges as the structural barrier to retention. Many factors, including complicated therapeutic regimens, depression, alcohol and drug use, and changes in daily routines may reportedly impact a patient's ability to adhere to these medications (Nozaki, Dube, Kakimoto, Yamanda & Simpungwe, 2011:831). Other barriers like inhibiting clinic attendance, poor diet

and inability to afford absence from work have also been identified as hindrance to treatment regimen. Temporary seasonal migration for generating more money is also a major cause of follow up failures in the environment where the study was conducted especially for the unskilled clients working in the farm and the migrant population from neighbouring countries.

2.7   VIRAL LOAD SUPPRESSION

VL refers to the amount of HIV RNA per unit of blood plasma. It indicates how much HIV there is in the blood, how quickly it is replicating, and how quickly a patient is progressing towards AIDS and subsequent death. Earlier reports from resource-limited settings have defined virologic failure as a VL of .400, .1, 000 or .5, 000 copies/ml at one or two repeated visits (El-khatib et al, 2011:1). El-khatib et al further indicate that drug resistance mutations can emerge at lower VL levels and in high-income countries, monitoring guidelines recommend using VL of 50 copies/ml as an indicator of virologic failure for patients on ART. As more robust, sensitive and lower cost assays are developed, ART programmes in low- and middle-income may be able to adopt lower threshold values for virologic failure. NDOH (2010:19) defines virological failure as VL >1000copies/ml on two occasions, despite intensive adherence counselling. NDOH accepts VL<400 copies/ml as undetectable and recommends yearly viral load monitoring and routine adherence support after VL at months 6 and 12 on ART are deemed undetectable. More than 80% of patients remaining in care after 6 months of ART have been found to have undetectable viral load (Ferradini, Jeannin, Pinoges, Izopet, Odhiambo, Mankhambo, Karungi, Szumilin, Balandine, Fedida, Carrieri, Spire, Ford, Tassie, Guerin, & Brasher, 2006:1340). Similarly, high proportion of patients with viral load results of <400 copies per ml in the first year of treatment were also noted in a study carried out in Khayelitsha and this further affirms the fact that adherence rates achieved in resource-limited settings are comparable to those in rich countries (Coetzee et al, 2004:893).

2.8   ADHERENCE AND VIROLOGIC SUPPRESSION.

Earlier, unboosted protease inhibitor- based ART regimens required more than 95% adherence to ensure virologic suppression (El-Khatib et al, 2011:2). El-Khatib et al

further indicate that with today's NNRTI and boosted protease inhibitor-based regimens a moderate adherence level (70-90%) may be adequate to achieve virologic suppression. Bangsberg and co-workers found, using a medical electronic assessment (MEMS), that >75% adherence may be sufficient to achieve virologic suppression among men receiving an NNRTI-based regimen in San Francisco. However, for optimal outcomes and to avoid disease progression, maximum level of adherence (100%) should always be the patient's goal and the provider's recommendations. An additional factor for women that may jeopardize ART success is prior receipt of sdNVP for prevention of mother-to-child transmission which can select drug resistance and jeopardize the efficacy of ART. Little is known about the association between adherence level and virologic suppression among women exposed to sdNVP.

Poor adherence can lead to the virological failure of cheap first-line treatment regimens and the spread of multi-drug resistant forms of the virus, resulting in a public health calamity (Wasti et al, 2012:1). Unlike many other diseases, it is vital that PLHIV consume all doses of the drug to prevent resistance and to improve their chances of survival. Understanding the level of non-adherence and the factors that lead to it are important clinical and public health goals. This information is essential to inform ART programmes and maximise the success of treatment. However, the relationship between adherence and the development of resistance differs by regimens; for example resistance to non-nucleoside reverse transcriptase inhibitors is significantly higher at low levels of adherence than that for protease inhibitors.

Although nearly perfect adherence to ART is critical for successful HIV treatment, some patients remain suppressed despite poor adherence. The ability to achieve and sustain virological suppression despite suboptimal adherence could result from host genetic and/or pharmacological factors (Glass et al, 2012:2).

2.9   CONCLUSION

In conclusion, Chapter 2 provides an overview of HIV/AIDS management in South Africa which has one of the largest ART programmes in the world. The clinical

guidelines which were updated in 2012 provides for accelerated quality of care for clients diagnosed with HIV/AIDS.

Viral load assessment is a vital investigation used in monitoring clients on ART as it indicates how much HIV there is in the blood, how quickly it is replicating and how quickly a patient is progressing towards AIDS and subsequent death.

Thus for optimal outcomes and to avoid disease progression, maximum level of adherence should always be the patient's goal and the provider's recommendations. However, psychological factors including depression have been shown to be associated with poor adherence to ART.

CHAPTER 3: RESEARCH METHODOLOGY

3.1   INTRODUCTION

This chapter will identify the research design, method, and the instruments used to collect the data and how the data was analysed and interpreted to draw conclusions from the study. The pilot study conducted prior to collecting the data and the ethical considerations observed and implemented while undertaking the study are also discussed in this chapter.

3.2   RESEARCH DESIGN

Research design refers to the overall structure or plan of the research (Bowling, 2009:158). It is the blueprint for the conduct of a study that maximizes the researcher's control over factors that could interfere with the validity of the desired outcomes (Grove, Burns & Gray, 2013: 214). A descriptive study design was utilised for the study. The descriptive study design serves to provide a picture of situations as they naturally happen without manipulation of the variables and the study was devoid of treatment or intervention (Grove et al, 2013: 215).

3.3   RESEARCH METHOD

Non-experimental quantitative research using a survey was used for the study. Quantitative research study refers to a form of scientific study where some form of numerical data is utilised to answer a research question (Christensen, 2004:32). Christensen further indicates that it is a descriptive type of research in which the goal is to attempt to provide an accurate description or picture of a particular situation or phenomenon. The use of structured interviews as the method of measurement affirms the choice of quantitative research (Burns & Grove, 2005: 24). In addition, the data was in the form of numbers and statistical analysis was utilized in interpreting the data.

The survey utilised as the research technique refers to a method of collecting standardised information by interviewing a representative sample of some population (Christensen, 2004: 44). In other words, it represents a probe into a given state of

affairs existing at a given time that involves direct contact with the individuals whose characteristics were relevant to the study.

3.4   RESEARCH SETTING

The research setting is the location where a study is conducted (Gray et al, 2013:373). A natural (field) setting where the environment was uncontrolled under real-live situation was chosen for the study. Thus the researcher did not manipulate the environment for the study. The research took place at the Siyethemba Clinic of Sundumbili Community Health Centre (CHC) located in Mandeni Municipaility, Ilembe health district of KwaZulu-Natal Province in the Republic of South Africa. With over 6000 clients receiving various ART regimens, Sundumbili CHC provides the full complement of HIV/AIDS management to mostly the inhabitants of Mandeni Municipality. Services rendered include Provider-initiated Counselling and Testing (PICT; HCT; wellness clinic; PEP; Adult and Paediatric ART; PMTCT services; adherence support, assessment and monitoring; TB/HIV care; family planning and other related services. The catchment area for the health facility is the surrounding Sundumbili and Mandeni environs which are largely rural area inhabited by middle and low income earners.

3.5   POPULATION AND SAMPLING

The target population for the study were adult RVD clients currently on ART at Sundumbili CHC who have completed at least six months of treatment and had viral load test carried out on them with the latest results retrieved and indicating more than 400 copies/ml at the time of conducting the study.

Fifty one adults aged more than 18 years that were initiated on ART in 2010/2011 and still access their treatment at the Siyethemba Clinic of Sundumbili CHC were enrolled into the study. The inclusion criteria that were met by each participant include the fact that the participant would be an adult aged more than 18 years, HIV positive on ART for more than six months, latest viral load carried out in 2011 with the result indicating viral load of more than 400 copies per ml of blood. Clients diagnosed of dementia or other significant psychiatric diseases and terminally ill clients admitted in referral hospital were excluded from the study. Also, clients who

met the criteria but sent proxies to collect their medications on their behalf were excluded from the study.

Convenience sampling also known as accidental sampling was used to select the participants. The sampling method is the process of selecting a group of people, events, behaviours or other elements that represent the population being studied (Grove et al, 2013: 357). Grove et al further indicates that convenience sampling refers to a non-probability (non-random) type of sampling where research participants are included in the study because they happened to be at the right place at the right time. It entails using the most conveniently available people as participants (Polit & Beck, 2012: 276). The Clinicians trained to collect the data simply enrolled available research participants into the study until the end of the period set out for data collection. Though considered a weak approach due to the increased likelihood for bias, the researcher was in close contact with the Clinicians to reduce bias. The minimal bias noted was that the Clinicians avoided enrolling adult ARV clients who are part of the target population when the clinic is considered very busy. Also some of the patients send in proxies to collect their medications. This practice is acceptable to the management of the facility as it minimises loss to follow up and enhances adherence to the medications. Unfortunately, they were excluded from the study. However, the researcher chose convenience sampling because of cost implications and the fact that the participants were readily accessible and required less time to enrol into the study. Thus the type of sampling used was not considered as having an appreciable negative impact on the representativeness of the sample.

On presentation at the clinic during the months of June to September 2012 when the data was collected, the Clinicians working at the ARV Clinic that were properly trained on the contents of the questionnaire used as the measuring instrument identified the adult ART clients that met the inclusion criteria. They were then requested to enrol into the study as the accessible population. Accessible population refers to the portion of the target population that the researcher had reasonable access to during the data collection period (Grove et al, 2013: 351). Once they agreed and gave a written consent by completing the consent form, they were

guided to complete the questionnaire. Where the participant was not literate enough to write legibly, the Clinician translated the questions into the local language and completed the data collection instrument on their behalf. A total of 51 research participants were enrolled on the study. They all met the eligibility criteria.

3.6   DATA COLLECTION

Data collection is the process of selecting research participants and gathering data from them (Grove et al, 2013: 523). Both the clinicians that collected the data and the study participants were constrained during the process. The consistencies in what were asked and how the questions were answered and reported enhanced objectivity, reduced bias and facilitated analysis (Polit & Beck, 2012: 293). The data collection plan made for the study was intended to yield accurate, valid and meaningful data.

The data collection instrument was designed to describe the sample characteristics (Polit & Beck, 2012: 293). A combination of hospital records and face to face structured interviews were utilised during the data collection. Structured interviews refers to verbal interactions with research participants that allow the researcher to exercise increasing amounts of control over the contents of the interview in order to obtain essential data for the study (Grove et al, 2013: 422). The choice of the aforementioned data collection method was due to the limited availability of financial and physical resources, the purpose of the study and the fact that it provides the best way of gaining access to the research participants in the opinion of the researcher. The researcher designed the questions, specifying the order of the questions, and got them approved by the relevant authorities before commencing the data collection.

The dates when ART was started, recent viral load result, recent CD4 result and whether there was any recorded drug resistance were the questions in the data collection instrument that were sourced from the hospital records (patients' folders). The rest were structured interview questions that comprised of both open-ended and close-ended questions that sought to ascertain the psychosocial characteristics of the target population. The questionnaires included questions that indicate the

demographic characteristics of the participants, their social status, sexual behaviour, the psychosocial challenges they experienced during the course of their treatment and how such problems affected their adherence to ART. Efforts were made to avoid any form of bias that could invalidate the results of the study. This is because a biased study result suggests one that does not represent the truth (Myer & Karim, 2007:160).

The Clinicians (2 Medical Officers, 1 Pharmacist and 1 Professional Nurse) working in the ARV clinic were trained by the researcher to assist in the data collection. During the period the data was collected, any patient from the target population that met the inclusion criteria for the study was transferred to the trained clinicians if they presented to any other clinician in the facility who was not directly involved in the study. The contents of the participant's information sheet that was prepared both in English and IsiZulu languages were brought to their attention and they are asked to participate in the study.

Once the patient agrees to participate, written consent is secured by the Clinician collecting the data. The purpose of the study, procedures, potential risks and discomforts and benefits of the study are some of the contents of the document used in securing the written consent. The fact that there was no payment for participation, confidentiality and the right of the research participant to withdraw consent and discontinue participation without penalty were also explained to the research participants. The Clinician then proceeded to complete the various sections of the data collection instrument after which they were handed over to the researcher. The data was entered on an excel spread sheet specifically designed for the purpose by the researcher. During the entire data collection period, no adverse event was reported.

3.7   PILOT STUDY

A pilot study is a run-through of the study with a small number of the participants (Christensen, 2004:364). The pilot study was conducted at Isithebe Clinic on subjects similar to the individuals that participated in the study. This was after satisfactorily developing the research protocol and prior to data collection (Groves et

44

al, 2013: 424). The pilot study was carried out on 18 adult RVD clients receiving ART at Isithebe Clinic whose viral load were not suppressed after six months on treatment. The Professional Nurse working at the ARV Clinic was trained and assisted in conducting the interview from the clients who consented to participating in the pilot study. Approval was secured from the Management of the clinic. The choice of Isithebe Clinic for the pre-test study is because the attendees to the clinic which is located in the same municipality as Sundumbili CHC share similar demographic and psychosocial characteristics. The study provided a great deal of information. It allowed the researcher to identify problems with the design and sequencing of the questions and the procedures for recording responses. These were sorted thus enhancing the reliability and validity of the interview instrument.

3.8   DATA ANALYSIS

After collection of the data, they were carefully checked by the researcher. All the data collection instruments were found to be complete and appropriate for analysis. They were entered on an excel spread sheet installed in the researcher's personal laptop computer. The entries were backed up using an external hard drive.

Descriptive statistics were used to summarize and describe the data in a concise form (Joubert, 2007:137). The purpose of data analysis is to use the data collected in a sample to make inferences about the population from which the data came (Tilling, Peters & Sterne, 2005: 498). A summary of the categorical variables included the percentage of the study participants that are male or female. Variable refers to a quality or characteristic that varies (Cramer, 2003:1). It is a measure of a single characteristic that can vary (Jekel, Katz, Elmore & Wild, 2007: 139). The arithmetic mean of the age, marital and employment status, income, residential status and other psychosocial characteristics of the research participants were also illustrated and analysed. The data analysis also included the impact of the reported characteristics on adherence to ART by the research participants. Various forms of graphs were used in the data analysis.

3.9   ETHICAL CONSIDERATION

The researcher obtained letter of support to conduct the study from the Chief Executive Officer (CEO) of Sundumbili Community Health Centre and the District Manager of iLembe Health District. The letters indicated that the Management at the facility and the District were satisfied with the researcher conducting the study and that service delivery will not be compromised during the entire process especially the data collection stage. These were forwarded with other relevant documents to the Ethics Committee, Stellenbosch University for approval. The approval secured from the University in addition to the research proposal, informed consent forms, information sheet budget and timeline of the study with the letters of support from the facility and the district were forwarded to the Health Research & Knowledge Management Unit of the Provincial Department of Health. In line with the Provincial Department of health protocols, approval was secured from the Provincial Health Research committee and the facilities were informed prior to commencing the study. Permission was also sought and secured from, Khethimpilo, the PEPFAR-funded Non-governmental Organisation supporting the district DOH as they maintain the data base ARV records of the patients where some of the entries were retrieved from.

Written informed consent was obtained from the participating AIDS clients. This was after explaining to them the purpose of the research the procedures, potential risks and discomforts that could arise from the study. It was anticipated that due to the sensitive nature of the questi9ns, there could be need for intervention from the counsellors and Social workers at the facility should there be psychological trauma. However, no such adverse event was reported by the research participants. The research participants were then allowed to voluntarily agree to participate in the research. They were also informed that they could withdraw from the study at any time without consequences of any kind. The anonymity and confidentiality of the whole exercise including the identity and status of the participants was maintained at all times during the study. All documents relating to the study were kept away from the public. The entries on the computer are password protected with access to only the researcher.

3.10   CONCLUSION

The research method, research setting, population and the type of sampling undertaken for the study were discussed in this chapter. This is in addition to the data collection strategy, details of the pilot study, data analysis and the ethical considerations relating to the study. The next chapter will discuss the results obtained from the data analysis.

CHAPTER 4: RESULTS AND DISCUSSION

4.1   INTRODUCTION

The results of the study and subsequent discussion are included in this chapter.

4.2   RESULTS

A total of 51 HIV positive adult clients that met the inclusion criteria participated in the study. Their completed data collection instruments were received from the Clinicians that assisted in carrying out the structured interviews. The responses were checked before and after they were entered on an excel spread sheet by the researcher. This was to ensure that problems were corrected as anything that alters the rhythm of the data increases errors. No major problem was noticed and the researcher ensured that there was no data capturing error.

The number of males that participated in the study was three. This represented 5.9% of the study population. The remaining 94.1% were adult female ART clients aged more than 18 years.
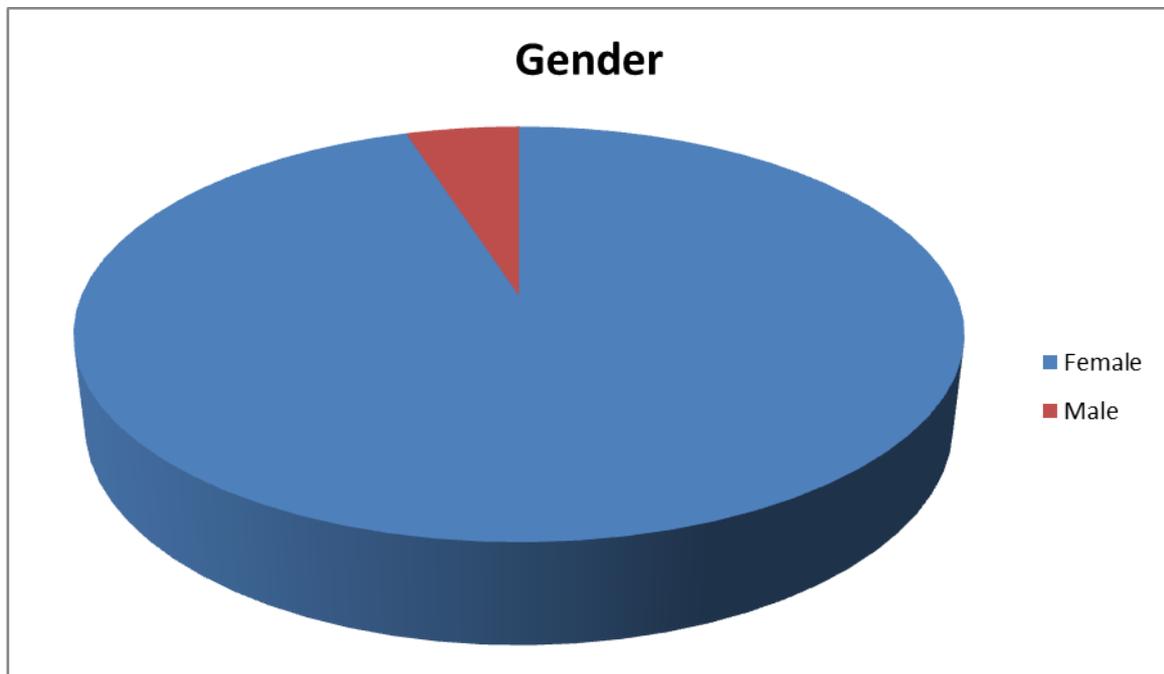

Figure 4.1 Gender of research participants

This is graphically illustrated in Figure 4.1. The youngest aged research participant was 18 years of age while the oldest was aged 53. They were both females. The arithematic mean of the research population is 33.25 years while the standard deviation is 7. Figure 4.2 below depicts the distribution of marital status of the research participants. Four of the participants representing 7.8% of the total numbers were married while 2% were widowed. The remaining 90.2% were single at the time the interviews were conducted.
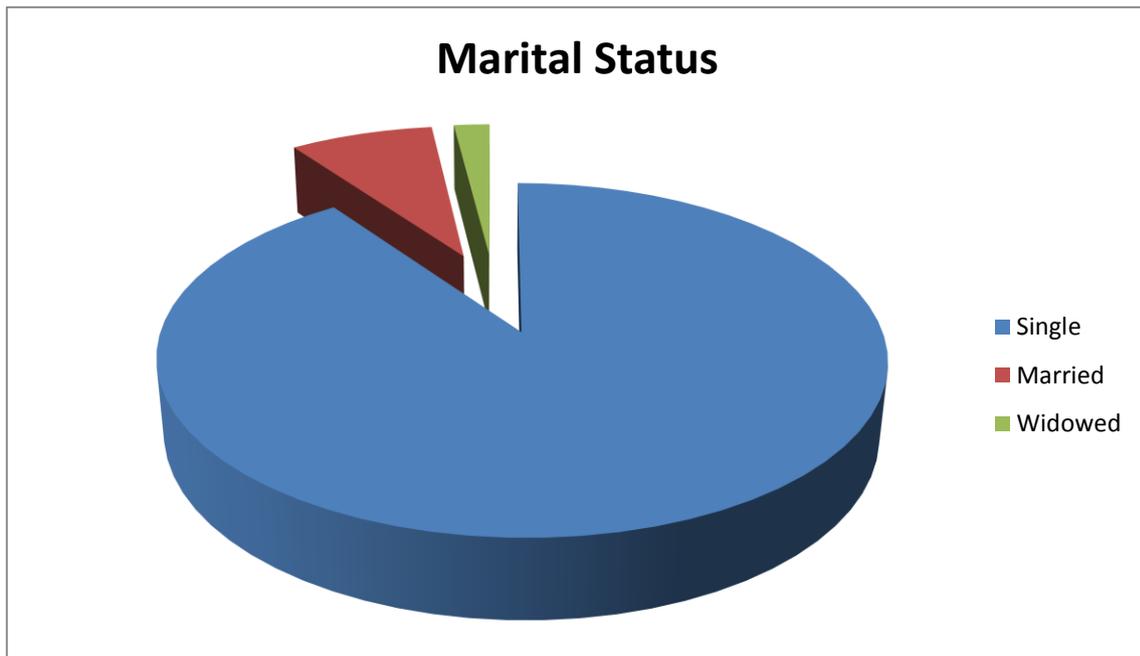

Figure 4.2 Marital status of research participants

A total of 11 or 21.6% of the research participants reported that they were employed on a full-time basis while four or 7.8% were employed on part-time basis. The remaining 36 subjects reported that they were unemployed. Figure 4.3 illustrates this in a graphical manner. Of the 36 subjects that reported that they were unemployed, 21 of them indicated that their unemployment status did not affect their adherence. Nine participants representing 25% reported that unemployment affected their adherence sometimes while 16.7% of them disclosed that the fact that they were not employed affected their adherence to ART always.11 indicated that being unemployed left them with no funds to buy food sometimes. Of those that were employed full-time, one individual indicated that the nature of her job which requires her to work nightshifts affected her adherence sometimes.

The average monthly income of the research participants also varied considerably. 41.2% of them reported average monthly income ranging from R1-1000 while 12 representing 23.5% admitted that their average monthly income is between R1001-5000. There was no recorded response for 35.3% of them. These responses are depicted in Figure 4.4. Only one participant employed full time did not disclose her average monthly income. The rest of those that did not report any monthly income were not employed.
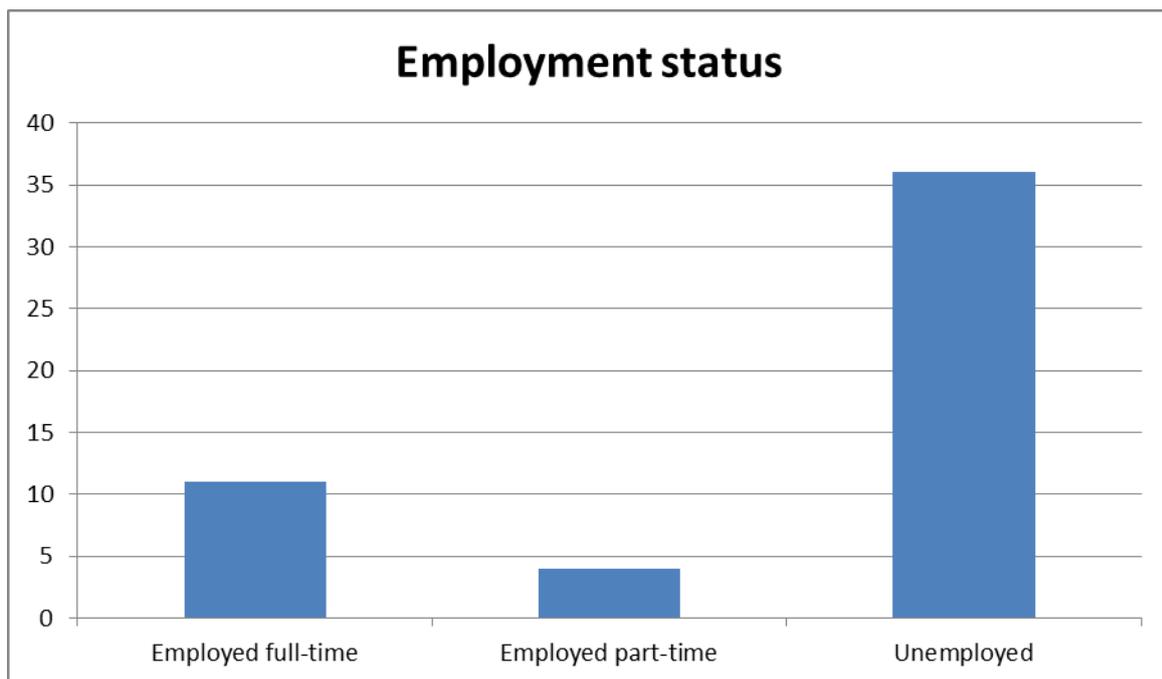
Figure 4.3 Employment status

The research participants were enrolled on ART in 2010 and 2011. The viral load results of the clients recorded after six months of commencing ART ranged from 1106-2003277 copies per ml. The average viral load result was 177350.59 copies/ml. The lowest recorded CD4 count result was 10.61 cells/mm^3 while the highest was 550.75 cells /mm^3. The average CD4 count for the participants was 206.33 cells /mm^3. Of the 51 research participants, seven reported previously recorded drug resistance. One admitted that her treatment has changed with Stavudine substituted by Tenofovir while the remaining six did not provide further details regarding the reported drug resistance.

50
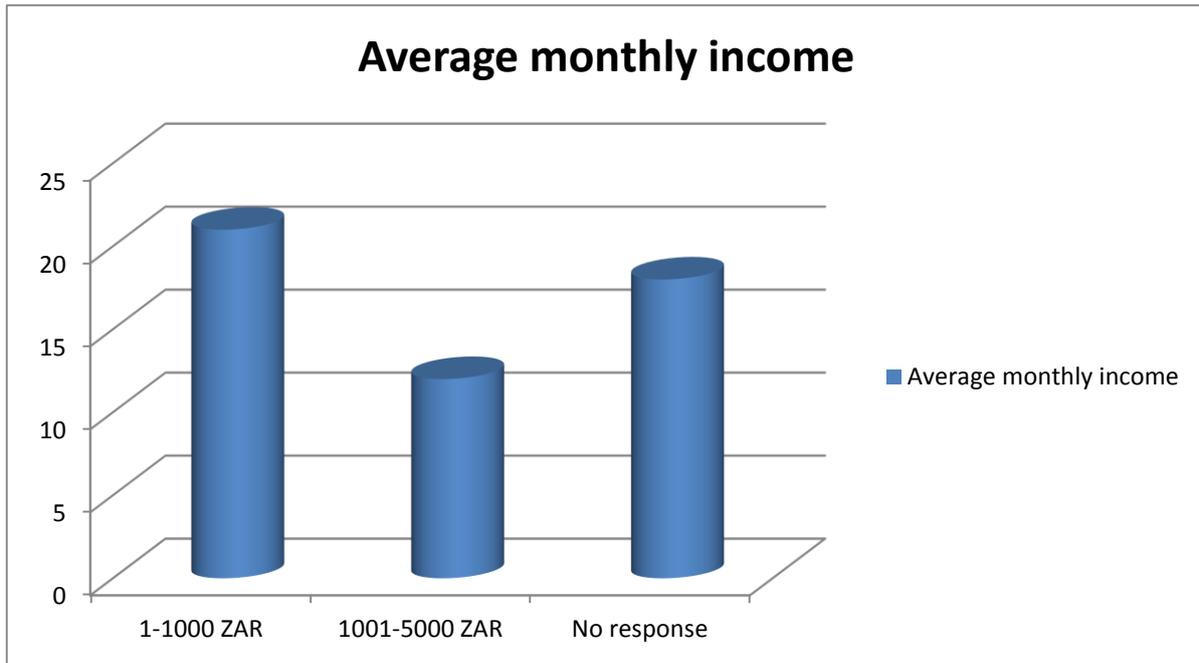
Figure 4.4 Average monthly incomes of research participants (in ZAR)

The number of the subjects that indicated that they reside in rented apartments was 13. This represented 25.5% of the entire research subjects. 38.5% of them indicated that they share the rented apartments with their partners as illustrated in Figure 4.5. This residency arrangement affects the adherence of one of them who incidentally was unemployed. According to her, she did not have funds to buy food if her partner refused to give her some money. This made her skip her medications sometimes. The rest revealed that the living arrangement with their partners did not affect their adherence. Only one of the research participants admitted sharing a rented apartment with another person aside family member, partner or friend. 23% of them reported that they share apartments with their family members. One of them admitted that this arrangement affected her adherence to medications sometimes as she skipped her medications when there was no food in the house. The remaining 30.8% indicated that they stay in rented apartment without sharing with anyone. They indicated that this did not affect their adherence to the ART dispensed to them at Sundumbili CHC. None of the participants admitted sharing a rented apartment.
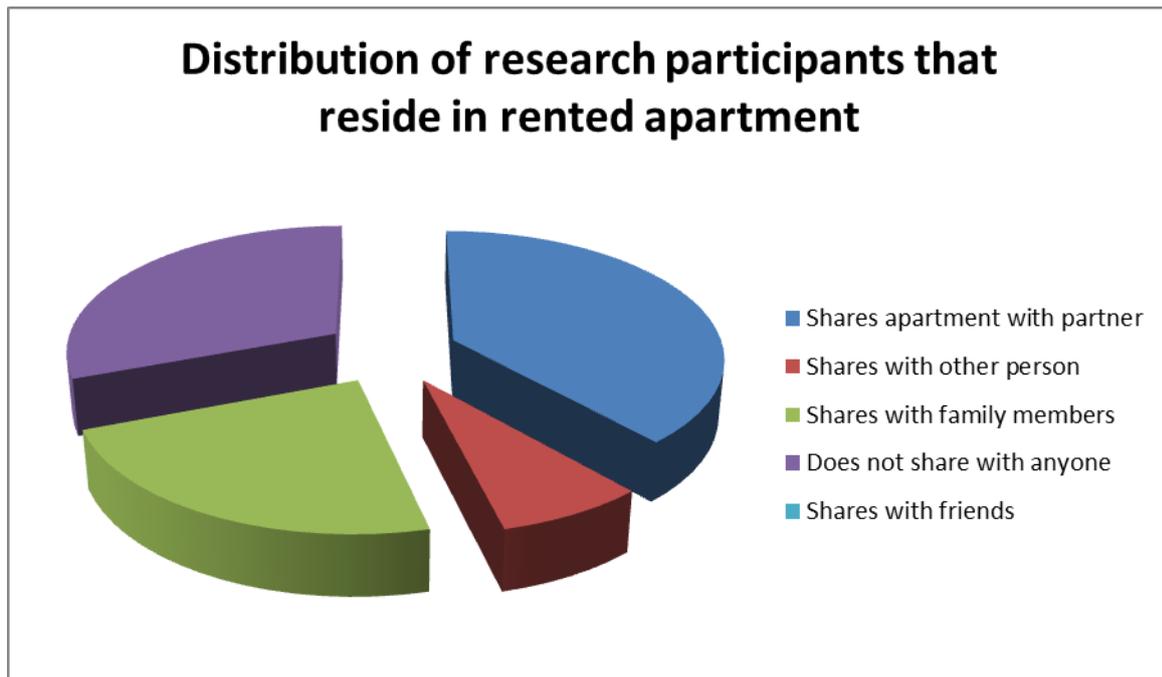
Figure 4.5 Distribution of research participants that reside in rented apartment

The remaining 35 subjects representing 74.5% of the entire research participants revealed that they reside with their family members in a building that was not rented. One of them admitted that this arrangement affected her adherence to ART sometimes because none of her family members was aware of her HIV positive status while no response was recorded for one of the participants.

The distribution of the type of housing inhabited by the research participants is illustrated in Figure 4.6. A total of seven representing 13.7% of the research participants both reported that they reside in flats and shacks. However while two of those residing in shacks reported that it affected adherence, one provided what was not considered as a valid reason as she indicated that she did not have enough money. The remaining participant did not indicate any reason. For the seven subjects that resided in shacks, five of them admitted that their abode did not affect their adherence to ART while there was no recorded response by the remaining two participants. There was no influence on adherence reported by those that resided in town houses. Of the 68.6% of the research participants that resided in houses, one did not respond as to whether it affected adherence, one indicated that occasionally there was no food in the house and that affected adherence to ART sometimes. One

52

participant however reported that sharing bedroom in the house affected the way she took her medication which resulted in poor adherence.

The response to whether the subject had a treatment buddy revealed that 45 or 88.2% of them had treatment partners. The remaining 11.8% admitted that they do not have a treatment buddy. It was not further ascertained if this affected adherence to treatment.

The study revealed that all the research participants have disclosed their HIV positive status to someone else. While 29.4% of them revealed their status to their
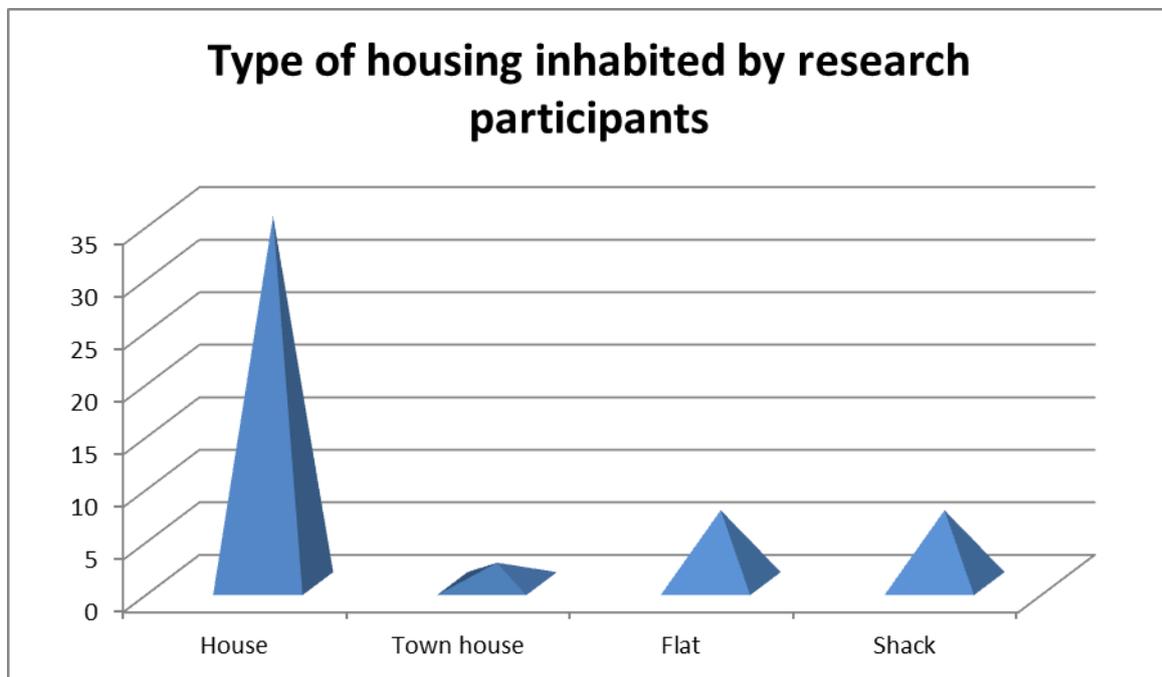
Figure 4.6   Type of housing inhabited by research participants

partners, 34 of them representing 66.7% of the research participants disclosed to at least one family member. The remaining 3.9% revealed their status to another person aside their friend or boss. This is applauded considering the fact that non-disclosure has been associated with non-adherence and subsequent non-suppression of viral load. Table 4.7 illustrates disclosure status of the participants in a graphical manner.

Enquiries surrounding stigmatisation revealed that 19.6% of the research participants have been stigmatised as a result of their HIV positive status. The remaining 80.4% indicated that they did not feel that they have ever been stigmatised as a result of their HIV positive status. Of the 10 participants that reported stigmatisation, five were mildly affected, two were not affected, and one was severely affected while no response was recorded for two participants. The exact ways stigmatisation affected the subjects included scolding by mother, unwillingness by friends to be with her anymore and being chased away by boyfriend who told others that he would be infected by HIV. Also, one research participant reported that she lost her job because of stigma associated with HIV.
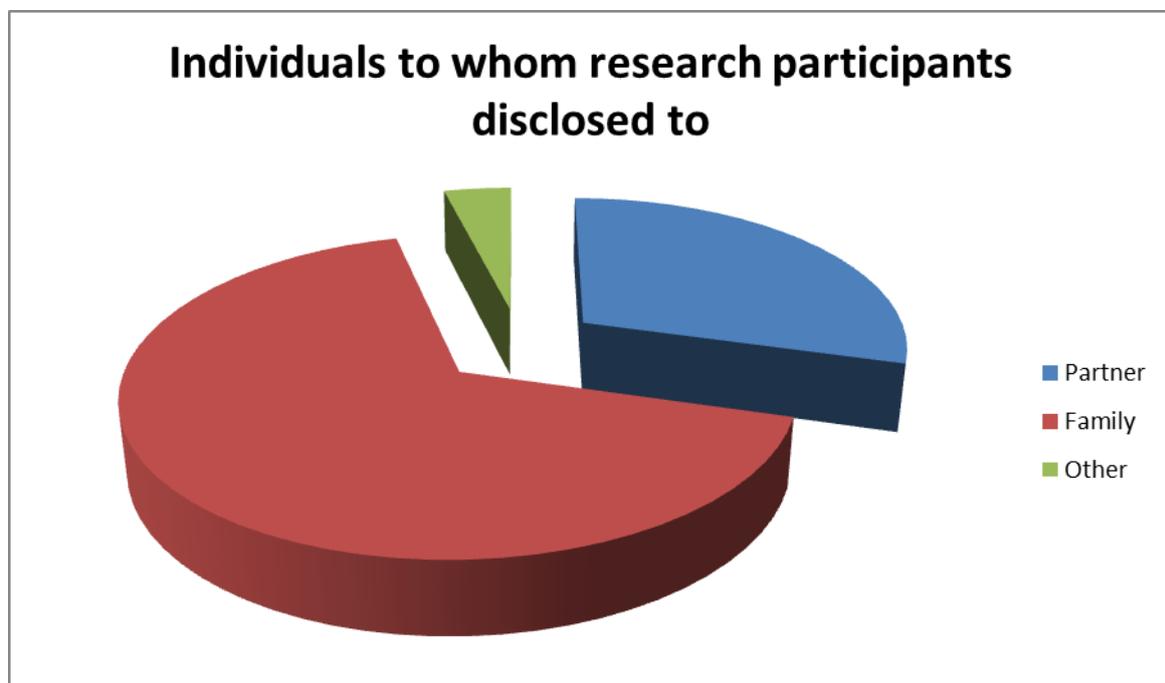
Figure 4.7 Individuals to whom research participants disclosed to

Only three clients representing 5.9% of the research participants admitted that they drink any form of alcohol. While two of them drink beer, the remaining person drinks wine. However, none of them reported any influence on adherence. Also, one of those that drink beer is a male research participant. The rest reported that they do not take any form of alcohol.

When asked whether they smoke, two patients representing 3.9% of the research participants responded on the affirmative. When asked further, none of them

indicated that smoking affected their adherence. The remaining 96.1% of the research participants indicated that they do not smoke.

A total of seven patients representing 13.7% of the study population admitted that they no longer enjoy food since they were commenced on ART. While this did not affect adherence for three of them, the remaining four subjects responded that the fact that they no longer enjoy food while on ART affected adherence to their medications sometimes. Two of the patients reported losing their appetite to food, one felt nauseous while the remaining reported pain during swallowing. The remaining 86.3% reported no loss of appetite since commencement on ART.

Existence of longer than usual sleep was one of the questions that the researcher sought to establish from the research participants. While 32 participants reported that they have not been sleeping longer than usual, the remaining 19 subjects equivalent to 37.3% of the research participants admitted that they have been sleeping longer than usual. Among those sleeping longer than usual, 3.9% of them reported that their adherence was affected sometimes, 5.9% did not respond while the remaining 14 participants reported that the phenomenon of sleeping longer than usual did not affect their adherence. These responses are depicted in Figure 4.8.
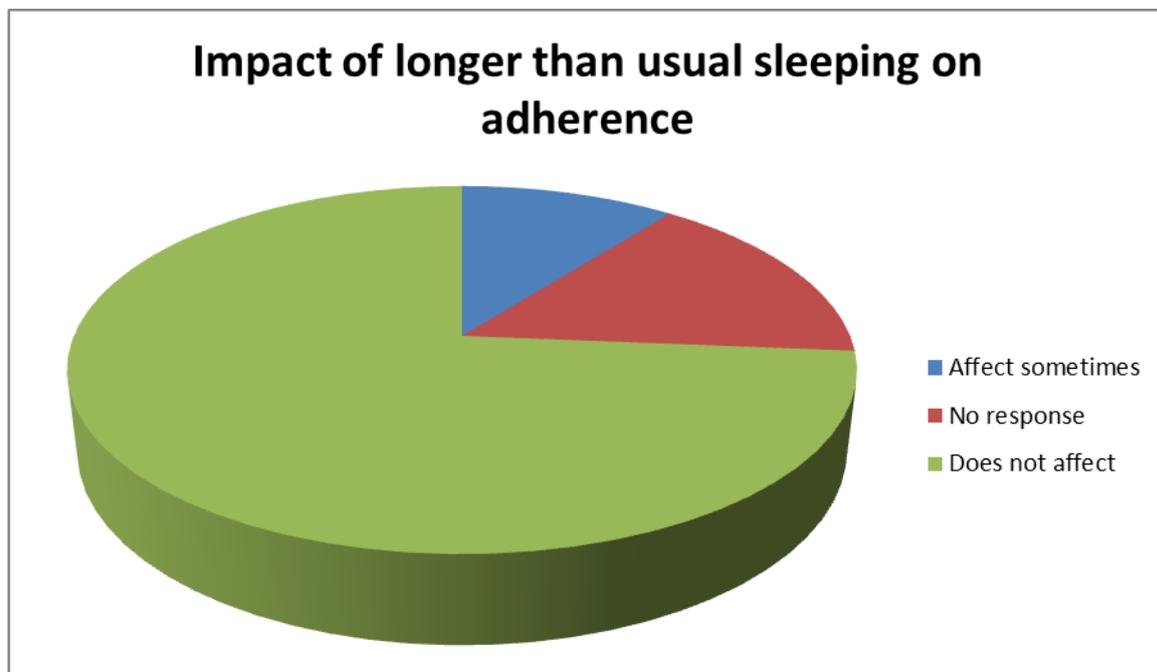
Figure 4.8   Impact of longer than usual sleep on adherence.

More than usual displays of anger among the research participants were also assessed by the researcher. All the research participants responded to the question. 52.9% of them reported that they did not have more than usual displays of anger since they were on ART while the remaining 47.1% revealed that they have more than usual display of anger since they were enrolled on ART. Out of this later group as depicted in Figure 4.9, 79.1% of them indicated that though they experienced more than usual display of anger since being on ART, it did not affect their adherence to ART. 4.2% of them reported that it affected her adherence always as she had social problems, stressed up and did not have enough money to support family. The remaining 16.7% indicated that their adherence to ART was affected sometimes by their more than usual display of anger. When asked further how this affected adherence, reasons given by each of the four of them were that they did not take medication when angry, forgot to take medication until treatment buddy reminded her, slept and forgot to take her medication and decided to default treatment.
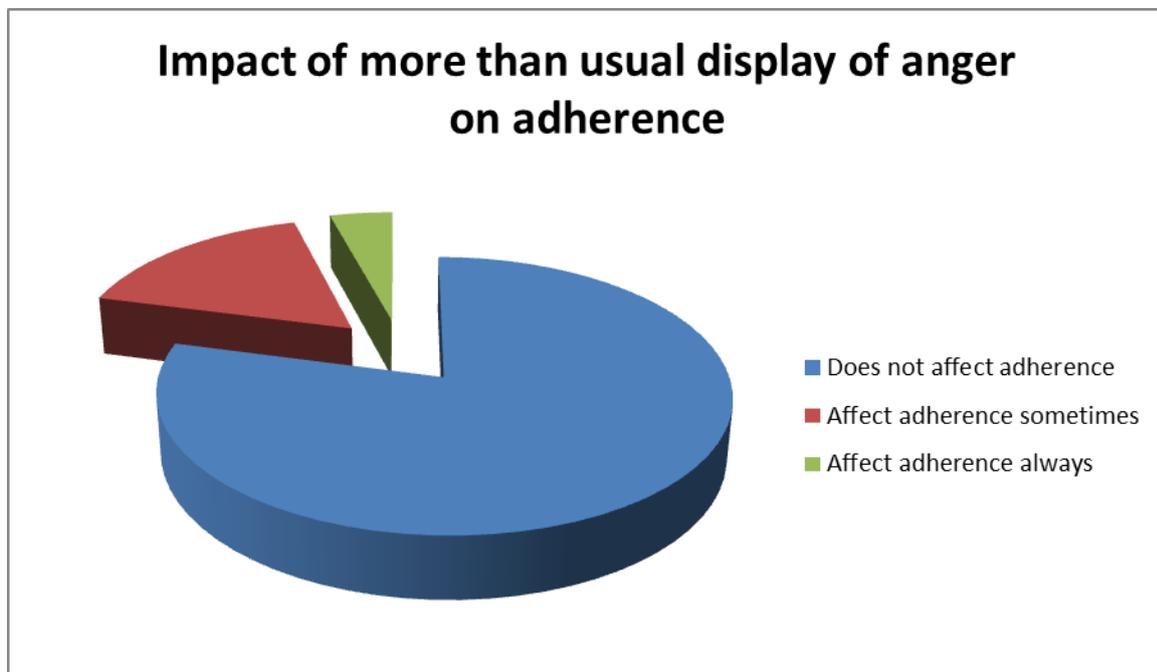
Figure 4.9 Impact of more than usual display of anger on adherence

One of the symptoms of depression is the heaviness and leaden feeling of arms and legs. Thus, this was one of the questions the researcher sought answers to. All but

one of the research participants responded to the question. A total of 34 participants responded that they did not feel leaden and heavy while on ART. No response was recorded for one respondent while the remaining 31% responded on the affirmative that their arms and legs feel leaden and heavy.

Figure 4.10 illustrates the impact of feeling heavy on the limbs on adherence of patients to ART. While 12 of the respondents that earlier admitted to feeling heavy indicated that there was no impact on their adherence, four of them admitted that their adherence was affected sometimes. No one reported that adherence was affected all the time by feeling of heaviness on the arms and legs. Also none of the four subjects that earlier indicated that their adherence to ART was affected sometimes clarified the exact way the feeling of heaviness over the limbs affected adherence.
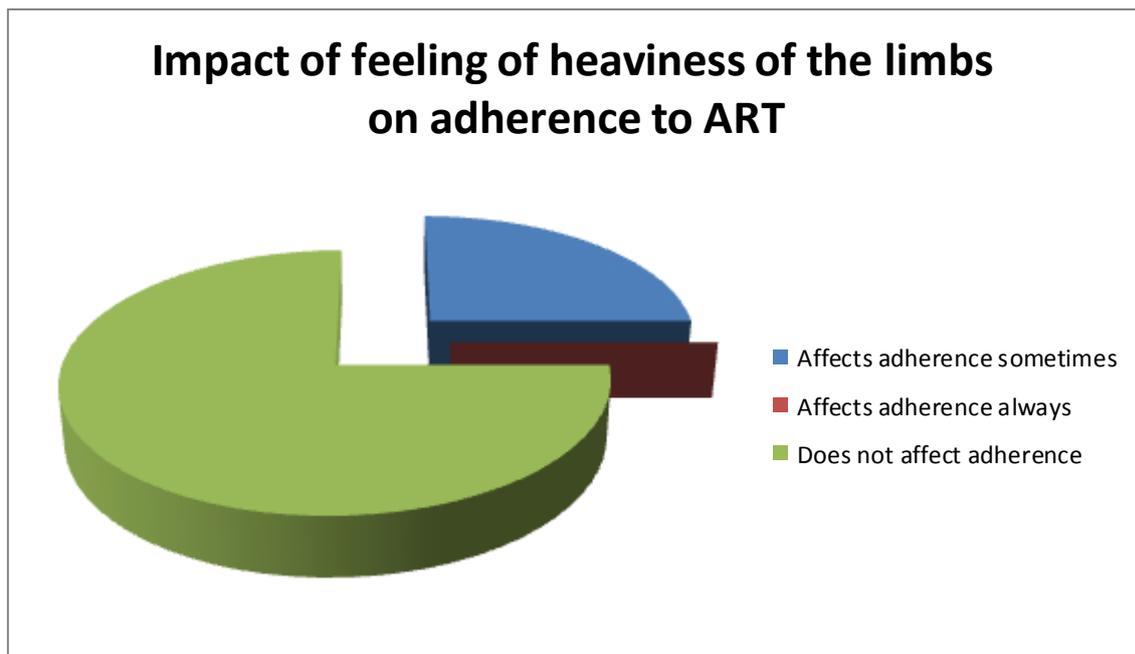
Figure 4.10 Impact of feeling of heaviness of the limbs on adherence

Depressed individuals have been shown to be more sensitive to criticism. How this affects adherence to medication among the ART clients that are yet to achieve viral load suppression after six months on ART was sought by the researcher. All but one of the research participants responded to the question. 29.4% of the research participants responded on the affirmative that they have become more sensitive to

criticism since being on ART while 68.6% of them reported that they have not become more sensitive to criticism. No response was recorded for two of the participants. When probed further, becoming more sensitive to criticism did not affect adherence to ART of 60% of those that admitted to becoming more sensitive to criticism since being on ART. No client had his or her adherence affected all the time by becoming more sensitive to criticism while no response was recorded for two representing 13.3% of the group. However, four of the research participants admitted that becoming more sensitive to criticism affected their adherence to ART sometimes. They indicated that this occurs by making them feel isolated, they desire to stop medications, are afraid of the stigma that could result and of being judged. This is illustrated in Figure 4.11.
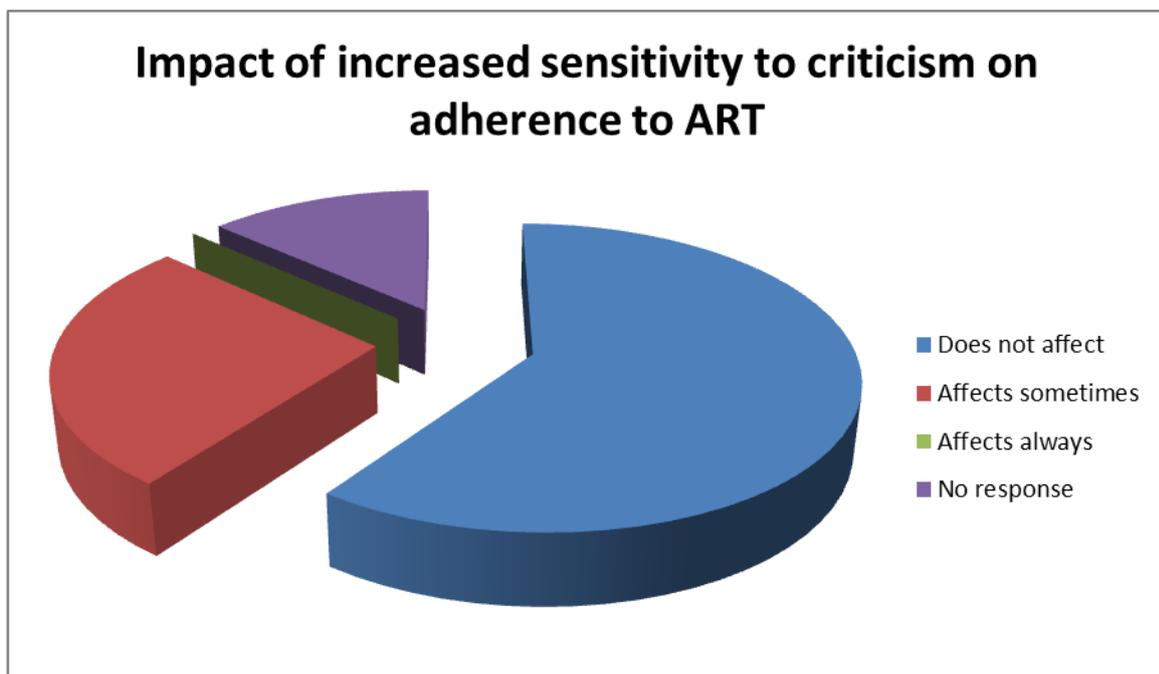
Figure 4.11   Impact of increased sensitivity to criticism on adherence to ART.

The last question the researcher asked was whether there are other things in the opinion of the research participant which affected his or her adherence to treatment that has not been discussed. Responses received include not having money for food sometimes, husband refusing to use condom and not yet on treatment, risky behaviours like unprotected sex and multiple sexual partners, need for a full-time job

in order to get more funds to support family, feeling like not taking medication when pregnant, being unemployed and afraid of unaware family members.

4.3   DISCUSSION

The choice of impact of the various psychosocial characteristics identified by the researcher on adherence to ART was because adherence has been shown by various scientific studies as the major cause of viral load suppression. El-Khatib et al indicate that more than 95% adherence is required to ensure virologic suppression. Maximum level of adherence should always be the patients' goal and the health providers' recommendation. Poor adherence can thus lead to the virologic failure of ART and the emergence of multi-drug resistant strains of the virus.

The majority of the research participants were unemployed. However, while this did not affect adherence to ART for some of the participants, 25% of them revealed that unemployment affected their adherence sometimes while 16.7% disclosed that the fact that they were unemployed affected their adherence to ART always. For a good number of them, unemployment affected adherence because of unavailability of food to eat. This collaborates the finding by Nozaki et al that poor diet is a hindrance to good adherence for the ART regimen.

Accommodation arrangement only affected the adherence of one research participant who did not disclose her HIV positive status to her family member that she shared the accommodation with. Disclosure has been identified by Peltzer et al as one of the barriers to adherence in Southern Africa. However, the study revealed that 88.2% of the research participants have disclosed to someone and had a treatment buddy.

The majority of the respondents resided in houses (68.6%). This did not clearly affect adherence except in the case of one respondent that reported that sharing same bedroom in the house with someone else affected her adherence to her medications negatively. This suggested that the participant was yet to disclose her status to her family members.

Patients on ART are still stigmatised. Peltzer et al report that stigma is a barrier to adherence. Six of the 10 participants that reported stigmatisation indicated that it affected their adherence to ART. One participant actually revealed that she lost her job because of the stigma associated with her HIV positive status.

Though the majority of the patients neither drink nor smoke, none of the 5.9% of the participants that admitted that they drink and the 3.9% that smoke, reported that the behaviour affected their adherence.

13.7% of the participants responded in the affirmative when asked whether they no longer enjoy food. However, only four of them reported that their adherence was affected by the fact that they no longer enjoy food. Longer than usual sleeping is one of the clinical features of depression. 37.3% of the participants admitted that they have been sleeping longer than usual. Only 3.9% of them reported that their adherence was affected sometimes. Though the response cannot diagnose depression in isolation, depression has been identified as one of the barriers to good adherence. (Mills et al, 2006:287).

Other features of depression which is a major psychosocial challenge assessed by the researcher is more than usual display of anger, feeling of heaviness of the legs and arms and increased sensitivity to criticism. Some research participants reported that the afore-mentioned features affected their adherence to their ART. 20.9% of those that reported more than usual display of anger indicated that it affected their adherence to ART. Also, four of the participants reported that the feeling of heaviness noted over the limbs affected their adherence to ART out of the 31% of the entire research participants that responded on the affirmative when asked whether their arms and legs feel leaden and heavy. Increased sensitivity to criticisms was reported by 29.4% of the subjects. Four of them admitted that becoming more sensitive to criticism affected their adherence to intake of their ART sometimes.

4.4   CONCLUSION

This chapter outlined and illustrated the responses received by the research participants. The ART start dates, recent viral load and CD4 results were highlighted. The demographic features of the research participants were also indicated. This was

followed by the various psychosocial characteristics identified by the researcher during literature review. For each of them, their relationship with adherence to ART was sought from each of the respondents. Those that answered on the affirmative that the listed factors affected their adherence were further asked to clarify how the various factors affected adherence.

The following chapter presents the limitations, recommendations made from the findings and the conclusion of the study.

CHAPTER 5: LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

5.1 INTRODUCTION

The chapter reflected back on the aim and objectives of the study with further discussions around the limitations noted while carrying out the study. The aim of the study is to explore the psychosocial characteristics of HIV positive clients who were yet to achieve viral load suppression after six months of commencing ART at Sundumbili CHC in order to plan positive intervention strategies. The objectives set out to be achieved on concluding the study were to ascertain the psychosocial characteristics and social problems of adult AIDS clients who were yet to achieve viral load suppression after six months of commencing ART, to determine how psychosocial characteristics affected adherence to ART and finally to recommend strategies that could be employed to address the psychosocial needs of the clients.

The chapter will conclude the study by providing recommendations and positive intervention strategies that could be implemented by various stakeholders aimed at attending to the psychosocial needs of clients on ART with particular reference to those with unsuppressed viral load after six months on ART. Stakeholders who in the opinion of the researcher should utilise the recommendations include the Provincial and iLembe District Department of Health, Department of Social Development, Management of Sundumbili CHC and Khethimpilo, the PEPFAR supporting partner of the District.

5.2 LIMITATIONS

Limitations refer to challenges noted in a study that may decrease the generalizability of the findings to a larger population or from the situation studied to a larger situation (Grove et al, 2013:598).

Non-representativeness of the sample has been identified by the researcher as one of the limitations of the study. Convenience sampling was used for the study. This is non-random and is relatively homogenous with respect to ethnicity, geographic location and socio-economic status. There is therefore the possibility that self-selection bias occurred while choosing the sample population.

62

The study occurred at Sundumbili CHC. This is a single setting that renders services to mainly HIV positive clients of low socio economic status who reside mainly in Sundumbili Township and surrounding environs. The majority of the residents of same area who are skilled and meaningfully employed utilise various forms of health insurance. Those that are HIV positive among them tend to access ARV services at private hospital settings in the district and beyond. Therefore replication of the study in such settings will highlight their psychosocial challenges especially those on ART whose viral load results were not suppressed after six months on ART. This will improve the generalizability of the research findings.

Clients that sent in proxies to collect their medications on their behalf were excluded from the study. This was noticed as a limitation on concluding the study because of the likelihood that those that sent in proxies were having various forms of psychosocial challenges. Though the Clinicians insist on meeting with the clients at least once in six months, the period utilised for data collection for the study was restricted thereby excluding the clients from participating in the study. With the availability of more resources and extended period of time, the researcher would have arranged visits to such clients at their homes to conduct the structured interviews.

5.3   RECOMMENDATIONS

The researcher recommends replication of the study with larger sample in both government and private health facilities that render ARV care in the district. This will accommodate a broader socio-economic class of research participants. The result after such study will be more generalised to the broader population.

The researcher identified the psychosocial characteristics of clients on ART for more than six months without viral load suppression. Further research with an appropriate research design aimed at evaluating the impact of positive psychosocial interventions on the viral load results of the research participants after a specified period of time is recommended.

The researcher also recommends closer care for clients with unsuppressed viral load. The DOH guidelines recommends intense adherence assessment with adequate counselling and repeat of the viral load test after three months where the viral load result was not suppressed and read more than 1000 copies/ml after six months on treatment (NDOH, 2010:20). The adherence counselling should be thorough and should involve the community healthcare workers known as Patient Advocates and Community Care givers by Khethimpilo and Department of Health respectively. The Lay Counsellors that attend to the counselling needs of the clients and the various community healthcare workers should be continuously trained and supervised in order to enhance the quality of their work.

A sizeable number of the research participants were not employed and this affected the adherence of some of them to ART. Self-sustainability measures like formation of support groups that maintain vegetable gardens, skills transfer and other measures that will provide more jobs to the populace and ultimately provide more funds that will enable the HIV positive clients afford good nutrition.

The researcher also recommends stronger ties between the Clinicians at the ARV clinics and the Department of Social Development. This can be achieved by wider involvement of all stakeholders in the Premier's multi-disciplinary approach towards tackling HIV/AIDS and other related illnesses. This will afford more support and timely interventions on the patients who have psychosocial challenges and also assist in de-stigmatisation of HIV.

It was noted while conducting the study that some clients were yet to access their results despite conducting them while others were yet to have their viral load tests done long after six months on treatment. The researcher recommends an active triaging system before the affected clients are able to access the services at the ARV clinic on a daily basis. Where this triaging is done by a well-trained and motivated nursing staff, the results of the tests done prior to the visit should be retrieved and filed while those that are due for the test are encouraged to do so before visiting the clinicians.

64

The researcher recommends thorough screening for depression on all clients on ART at the various health facilities. This could be made easier by designing a tool that will simplify the process which must be completed by the attending clinicians on an on-going basis. Those adjudged to be depressed should be referred for appropriate management by qualified cadre of staff.

5.4   CONCLUSION

The study focused primarily on ascertaining the psychosocial characteristics and social problems of adult AIDS clients who are yet to achieve viral load suppression after six months of commencing ART and also determining whether and how the psychosocial characteristics affect adherence to ART and finally to recommend strategies that could be employed to address the psychosocial needs of the clients. The afore-mentioned objectives were achieved through this study.

Given the rural nature of Sundumbili and surroundings where the bulk of the patients reside, there are several psychosocial challenges affecting the patients. No known previous study has been undertaken to ascertain the psychosocial characteristics of this group of patients and the impact they may have on viral load suppression after six months of treatment. The study is therefore significant as the findings have provided more insight into the plight of the patients. The outcome of the study will be communicated to the Provincial and District Department of Health and Khethimpilo NGO. It is envisaged that the recommendations will assist the relevant people in the department in planning and subsequently implementing more positive intervention strategies. The strategies are targeted at improving the quality of care of the HIV positive clients and attending to their psychosocial needs.

REFERENCES

Barnett, T & Whiteside, A. (2002). *AIDS in the Twenty-first Century: Disease and Globalisation.* South Africa: Palgrave Macmillan.

Bissonnette, J.M. (2008). Adherence: A concept analysis. *Journal of Advanced Nursing* 63(6): 634-643. Retrieved 10 April 2012 from http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2648.2008.04745.x/pdf

Bowling, A. (2009). *Research Methods in Health: Investigating Health and Social Sciences.* 3rd edition. New York: McGraw-Hill

Burns, N & Grove, SK. (2005). *The practice of nursing research; conduct, critique and utilization*; 5th edition. St Louis: Elsevier/Saunders.

Carrieri MP., Leport, C., Protopopescu, C., Cassuto, J., Bouvet, E., Peyramond, D., Raffi, F., Moatti, J., Chêne, G., & Spire, B. (2006). Factors associated with nonadherence to highly active antiretroviral therapy: A 5-year follow-up analysis with correction for the bias induced by missing data in the treatment maintenance phase. *Journal of Acquired Immune Deficiency* . Vol41(4) 2006.

Chakraborty, H., Sen, PK., Helms, RW., Vernazza, PL., Fiscus, SA., Eron, JJ., Patterson, BK., Coombs, RW., Krieger, JN. & Cohen, MS. (2001). Viral burden in genital secretions determines male –to-female sexual transmission of HIV-1: a probabilistic empiric model. *AIDS* 2001:15(5): 621-627.

Charurat, M., Oyegunle, M., Benjamin, R., Habib, A., Eze, E., Ele, P., Ibanga, I., Ajayi, S., Eng, M., Mondal, P., Gebi, U., Iwu, E., Etiebet, M., Abimiku, A., Dakum, P., Farley J., & Blattner, W. (2010). Patient retention and adherence to antiretrovirals in a large antiretroviral therapy program in Nigeria: A longitudinal analysis for risk factors. PLoS ONE 5(5): e10584.doi: 10.1371/journalpone.0010584.

Christensen LB. (2004). *Experimental methodology:* 9th edition. Boston: Pearson

Coetzee, D., Hildebrand, K., Boulle, A., Maartens, G., Francoise, F., Labatala, V., Reuter, H., Ntwana, N., & Goemaere, E. (2004):893). AIDS 2004: 18: 887-895.

Cramer, D. (2003). *Advanced Quantitative Data Analysis*. Maidenhead: Open University Press.

El-Khatib, Z., Katzenstein, D., Marrone, G., Maher, F., Mohapi, L., Petzold, M., Morris, L. & Ekström AM. (2011). Adherence to drug-refill is a useful early warning indicator of virologic and immunologic failure among HIV patients on first-line ART in South Africa. PLoS ONE 6(3): e17518 doi: 10.1371

Enterprise Ilembe (2011). *Ilembe Municipality: Quarterly economic indicators and intelligence report. Second quarter April-June 2011*. Ballito: Enterprise Ilembe

Falang, KD., Akubaka, P. & Jimam, NS. (2012). Patient factors impacting antiretroviral drug adherence in a Nigerian tertiary hospital. *Journal of Pharmacology & Pharmacotherapeutics*. 2012 April-June; 3(2): 138-142.

Ferradini, L., Jeannin, A., Pinoges, L., Izopet, J., Odhiambo,D., Mankhambo, L., Karungi, G., Szumilin, E., Balandine, S., Fedida, G., Carrieri, MP., Spire, B., Ford, N., Tassie, J., Guerin, PJ., & Brasher, C. (2006). Scaling up of highly active antiretroviral therapy in a rural district of Malawi: an effectiveness assessment. Lancet 2006 ; 367:1335-42).

Glass, TR., Rotger, M., Telenti, A., Decosterd, L., Csajka,C., Bucher, HC., Günthard, HF., Rickenbach, M., Nicca, D., Hirschel, B., Bernasconi, E., Wandeler, G., Battegay, M. & Mazotini. (2012). Dterminants of sustained viral suppressin in HIV-infected patients withself-reported poor adherenceto antiretroviral therapy. *PLoS ONE* 7(1):e29186.

Grove, SK., Burns, N. & Gray, JR. (2013). *The Practice of Nursing Research: Appraisal, Synthesis, and Generation of Evidence*. 7th edition. St. Louis: Elsevier:

Health Systems Trust. (2012) Kwik-Skwiz, Vol 2 Number 4 2012.

Ilembe District Municipality. (2011). Draft integrated development plan: Annual review 2011/2012. Retrieved 09 March 2012 from http://www.ilembe.gov.za/Downloads/ILEMBE_DM_DRAFT_2011_12_DP_2503201 1.pdf

Jekel, JF, Katz, DL., Elmore, JG., Wild, DMG. (2007). *Epidemiology, Statistics and Preventive Medicine.* 3rd edition. Philadelphia: Saunders Elsevier

Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO) (2009) *2009 AIDS Epidemic Update* Retrieved December 02, 2009 from http://data.unaids.org/pub/Report/2009/2009_epidemic_update_en.pdf
Joint United Nations Programme on HIV/AIDS (UNAIDS) (2010). *Global Report: UNAIDS Report on the Global AIDS Epidemic 2010.* Retrieved May 10, 2011 from http://www.unaids.org/globalreport/Global_report.htm

Joint United Nations Programme on HIV/AIDS (UNAIDS) (2012). *Global Report: UNAIDS Report on the Global AIDS Epidemic 2012*. Retrieved December 10, 2012 from http://www.unaids.org/en/media/contentassets/documents/epidemiology/2012/gr201 2/20121120_UNAIDS_Global_Report_2012_en.pdf

Joubert, G. (2007) Exploring, summarising and presenting data In G. Joubert & R. Ehrlich (Eds) with contributing editors J. Katzenellenbogen & S.A. Karim (2007). *Epidemiology. A research manual for South Africa* (2nd ed., pp126-140). Cape Town: Oxford University Press.

Mills, EJ., Nachega, JB., Buchan, I., Orbinski, J., Attaran, A., Singh, S., Rachilis, B., Wu, P., Cooper, C., Thabane, L., Wilson, K., Guyatt GH., and Bangsberg, DR. (2006) Adherence to antiretroviral therapy in Sub-Saharan Africa and North America. Journal of American Medical Association (JAMA) 2006: 296-679-90 [Pubmed:

168961111].   Retrieved   10   April   2012   from
http://jama.jamanetwork.com/data/Journals/JAMA/5031/JRV60008.pdf

National Department of Health (NDOH). (2010a). *National antenatal sentinel HIV and syphilis prevalence survey in South Africa, 2009.* Pretoria: The National Department of Health.

National Department of Health (NDOH). (2010b). *Clinical guidelines for the management of HIV & AIDS in adults and adolescents.* Pretoria: The National Department of Health.

National Department of Health (NDOH). (2011). *National antenatal sentinel HIV and syphilis prevalence survey in South Africa, 2010.* Pretoria: The National Department of Health.

National Department of Health (NDOH). 2012. *National antenatal sentinel HIV and syphilis prevalence survey in South Africa, 2011.* Pretoria: The National Department of Health.

Nozaki, I., Dube, C., Kakimoto, K., Yamanda, N., & Simpungwe, TB. (2011). Social factors affecting ART adherence in rural settings in Zambia. *AIDS Care* vol. 23(7), July 2011, 831-838.

Oxford Advanced Learner's Dictionary. Sv "adult". 8th edition. Oxford: Oxford University press

Peltzer, K., Preez, NF., Ramlagan , S & Anderson, J.(2010). Antiretroviral treatment adherence among patients in KwaZulu-Natal South Africa. BMC Public Health 2010, 10:111. Retrieved 04 October, 2012 from http://www.biomedcentral.com/1271-2458/10/111

Polit, DF. & Beck, CT. (2012). *Nursing Research: Generating and Assessing Evidence for Nursing Practice.* 9th edition. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins.

Padayatchi, N., Naidoo, K., Dawood, H., Kharsany, A.B.M. & Karim, Q.A. (2010) A Review of Progress on HIV, AIDS and Tuberculosis In: S. Fonn & A. Padarath (Eds). *South African Health Review 2010* (pp. 87-99). Durban: Health Systems Trust; 2010. Retrieved May 22, 2011 from http://www.hst.org.za/uploads/files/SAHR2010.pdf

Reda, AA & Biadgilign, S. (2012). Determinants of adherence to anti-retroviral therapy among HIV infected patients in Afica. *AIDS Research and treatment* Vol 2012. Retrieved 04 October, 2010 from http://www.hindawi.com/journals/art/aip/574656.

Republic of South Africa (RSA) & South Africa National AIDS Council (SANAC). (2011). *National strategic plan on HIV, STI and TB 2012-2016.* Retrieved 12 May 2011 from http://www.doh.gov.za/docs/stratdocs/2012/NSPsum.pdf

Sabin, LL., Desilva, MB., Hamer, DH., Keyi, X., Yue, Y., Wen, F., Tao, L., Heggenhougen, HK., Seton, L, Wilson IB., & Gill, CJ. (2008) Barriers to adherence to antiretroviral medications among patients living with HIV in southern China: a qualitative study. Retrieved 10 May 2012 from http://www.tandfonline.com/doi/abs/10.1080/09540120801918651

Sahav, S., Reddy S., & Dhayarkar, S. (2011) Optimizing adherence to antiretroviral therapy. *Indian Journal of Medical Research* 2011 December:; 134(6): 835-849.

Skovdal, M., Campbell, C., Nhongo, K., Nyamukapa C., & Gregson, S. (2011) Contextual and psychosocial influences on antiretroviral therapy adherence in rural Zimbabwe: towards a systematic framework for programme planners. *International Journal of Health Planning and Management* 2011; 26: 296-318

Tilling, K., Peters, T and Sterne, J. (2005). Key issues in the statistical analysis of quantitative data in research on health and health services In G. Bowling, A & Ebrahim, S (Eds) (2005). *Handbook of Health Research Methods* (pp497-514). Maidenhead: Open University Press.

Tiyou, A., Belachew, T., Alemseged, F., & Biadgilign, S. (2010). Predictors of adherence to antiretroviral therapy among people living with HIV/AIDS in resource-limited setting of southwest Ethiopia. *AIDS Research and Therapy*, 2010:7(139).

Wagner, GJ., Goggin, K., Remien, RH., Rosen, MI., Simoni, J., Bangsberg, DR., & Liu, H. (2011). A closer look at depression and its relationship to HIV adherence. *Ann Behav Med* 2011 December; 42(3): 352-360. Doi: 10.1007/s12160-011-9195-8.

Wasti, SP., Simkhada, P., Randall, J., Freeman JV., & van Teijlingen, E. (2012). Factors influencing adherence to antiretroviral treatment in Nepal: a mixed methods study [Electronic version]. *PLoS ONE.* Retrieved 10 April 2012 from http://dx.plos.org/10.1371/journal.pone.0035547

Weidle, PJ., Wamai, N., Solberg, P., Liechty, C., Sendagala, S., Were, W., Mermin, J., Buchacz, K., Behumbiize, P., Ransom, RL., & Bunnell (2006). Adherence to antiretroviral therapy in a home-based AIDS programme in rural Uganda. *Lancet* 2006; 368: 1587-94.

World Health Organization (WHO). (2003). *Adherence to long-term therapies: Evidence for action.*

World Health Organization (WHO). (2010). *Antiretroviral therapy for HIV infection in adults and adolescents: Recommendations for a public health approach.* 2010 Revision. Retrieved 10 January 2013 from http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf

Zuurmond M. (2008). Adherence to ARVs-Challenges and successes. CAFOD. Retrieved April 29, 2010 from

http://www.cafod.org.uk/content/download/77210/803422/version/3/file/ART+adhere
nce+-+research+report.pdf

health
_____

Department:
Health
PROVINCE OF KWAZULU-NATAL

Health Research & Knowledge Management sub-component
10 – 103 Natalia Building, 330 Langalibalele Street
Private Bag x9051
Pietermaritzburg
3200
Tel.: 033 – 3953189
Fax.: 033 – 394 3782
Email.: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference	**: HRKM42/12**
Enquiries	**: Mrs G Khumalo**
Telephone	**: 033 – 3953189**

23 March 2012

Dear Dr E I Okoli

<u>**Subject: Approval of a Research Proposal**</u>

1. The research proposal titled '**Psychosocial characteristics of AIDS patients with unsuppressed viral load after 6 months of antiretroviral therapy**' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at Sundumbili CHC.

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facility before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mrs G Khumalo on 033-3953189.

Yours Sincerely
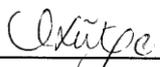
Dr E Lutge
Chairperson, Health Research Committee
KwaZulu-Natal Department of Health
Date: 27/03/2012

uMnyango Wezempilo . Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope

QUESTIONNAIRE FOR THE STUDY ON THE PSYCHOSOCIAL CHARACTERISTICS OF AIDS PATIENTS WITH UNSUPPRESSED VIRAL LOAD AFTER 6 MONTHS OF ANTIRETROVIRAL THERAPY.

Dear Research participant,

Kindly answer the following questions to the best of your ability.

1. ART start date...

2. Recent viral load result...

3. Recent CD4 result...

4. Any recorded drug resistance?

Yes	No

5. If yes to the above question, provide details..

6. Age...

7. Gender..

8. Marital status...

9. Are you presently employed?

Not employed	Employed part time	Employed full time

10. If not employed, do you think it affects adherence to ART?

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

How does it affect

adherence……..

11. What is your average monthly income in SA rand?

1-1000	1001 – 5000	5000 – 10000	ABOVE 10000

12. Is your home your own?

OWNER	RENT

13. If you are sharing, with whom?

FAMILY MEMBER	PARTNER	FRIEND	OTHER

14. Does this affect your adherence to your ART?

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

How does it affect

adherence……………………………………………………………………………………………………..

15. What type of house do you live in?

SHACK	FLAT	TOWN HOUSE	HOUSE

16. Does this affect your adherence to ART

DOES NOT EFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

How does it affect

adherence…………………………………………………………………………………………………..

17. Do you have a treatment buddy?

YES	NO

18. To whom have you disclosed your status?

PARTNER	FAMILY MEMBER	FRIEND	BOSS
OTHER			

19. Do you feel you have ever been stigmatised as a result of your status?

YES	NO

20. If yes, did this affect your adherence to ART?

DID NOT AFFECT	MILDY AFFECTED	SEVERELY AFFECTED

How does it affect

adherence…………………………………………………………………………………………………..

21. Do you drink any form of alcoholic beverage?

YES	NO

22. If yes to the above question, please state the type of drink:

BEER	WHISKY	LOCAL BREW	WINE	OTHER

23. Does this affect your adherence to ART?

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

How does it affect

adherence…………………………………………………………………………………………………..

24. Do you smoke?

YES	NO

25. If yes, does this affect your adherence to ART?

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

How does it affect

adherence…………………………………………………………………………………………………..

26. Since you commenced ART, do you still enjoy food?

YES	NO

27. If no does, does this affect your adherence to ART?

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

 How does it affect

adherence…………………………………………………………………………………………………..

28. Have you been sleeping longer than usual?

YES	NO

29. If yes, does this affect your adherence to ART?
How does it affect

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

adherence…………………………………………………………………………………………………..

30. Do you have more than usual displays of anger?

YES	NO

31. If yes, does this affect your adherence to ART?

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

How does it affect

adherence………..

32. Does your arms and leg feel leaden and heavy?

YES	NO

33. If yes, does this affect your adherence to ART?

How does it affect

adherence………..

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

34. Have you become more sensitive to criticism?

YES	NO

35. If yes, does this affect your adherence to ART?

DOES NOT AFFECT	AFFECT SOMETIMES	AFFECT ALWAYS

How does it affect

adherence………..

36. Are there any things in your opinion which affects your adherence to treatment which have not been

discussed?……