# ADHERENCE TO ANTIRETROVIRAL THERAPY AND ASSOCIATED FACTORS AMONG HIV AND AIDS PATIENTS AT MNAZI MMOJA HOSPITAL, ZANZIBAR

**FARHAT JOWHAR KHALID**

**MASTER OF SCIENCE**

**(Applied Epidemiology)**

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# Adherence to Antiretroviral Therapy and Associated Factors Among HIV and AIDS Patients at Mnazi Mmoja Hospital, Zanzibar

**FARHAT JOWHAR KHALID**

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# DECLARATION

This thesis is my original work and has not been presented for a degree in any other University.

Signature:…… Date:.....

**Farhat Jowhar Khalid**

This thesis has been submitted for examination with our approval as University Supervisors.

Signature :..... Date:.....

**Dr. Myat Htoo Razak**

Field Epidemiology and Laboratory Training Program, Kenya

Signature: ..... Date:.....

**Dr. Marion Mutugi**

JKUAT, Kenya

Signature:……..... Date: .....

**Dr. Mohammed J.U. Dahoma**

Ministry of Health and Social Welfare, Zanzibar

# DEDICATION

To my beloved parents; my mother whose constant prayers and support are the root of my success and my late father whose dreams for me came true.

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# LIST OF ABBREVIATIONS

| | |
|---|---|
| **AIDS** | Acquired Immuno Deficiency Syndrome |
| **ANC** | Antenatal Clinic |
| **ARVs** | Antiretroviral drugs |
| **ART** | Antiretroviral Therapy |
| **BCC** | Behavioural Change Communication |
| **FGD** | Focused Group Discussion |
| **HCW** | Health Care Worker |
| **HIV** | Human Immunodeficiency Virus |
| **IDU** | Injection Drug User |
| **IEC** | Information, Education and Communication |
| **NACP** | National AIDS Control Programme |
| **NBS** | National Bureau of Statistics |

| | |
|---|---|
| **NNRTI** | Non-Nucleoside Reverse Transcriptase Inhibitor |
| **NRTI** | Nucleoside Reverse Transcriptase Inhibitor |
| **PI** | Protease Inhibitor |
| **PLHA** | People Living with HIV and AIDS |
| **USA** | United States of America |
| **WHO** | World Health Organization |
| **ZACP** | Zanzibar AIDS Control Programm |

## ABSTRACT

HIV and AIDS is a major public health concern in the world with 33.2 million people living with HIV infection by December 2007. Sub-Saharan Africa is the most affected region in the world where more than two thirds (68%) of all HIV positive people live and more than three quarters (76%) of all AIDS deaths in 2007 occurred. Antiretroviral medicines (ARVs) have been documented to delay progression of HIV disease and improve the quality of life in the HIV infected individuals. However, patients need to be on treatment for life. The goals of antiretroviral therapy (ART) are preservation of the immune system, prevention of clinical progression and maximal viral suppression. In order to achieve these goals, adherence to ART is essential with more than 95% ART adherence levels being recommended. Major implication of poor adherence is

the emergence of viral resistance with the accompanying immunological and clinical failure. This study was conducted to determine level of adherence to antiretroviral therapy and investigate its associated factors among adult HIV and AIDS patients at Mnazi Mmoja Hospital's HIV care and treatment clinic in Zanzibar.

A comparative cross-sectional study was conducted from September to November 2008 at Mnazi Mmoja Hospital's HIV care and treatment clinic in Zanzibar. Study population consisted of adult HIV and AIDS patients, receiving ART for the previous six months or more from the date of interview at the clinic. A systematic sampling procedure was used to select the study participants. Data was collected by trained research assistants through: interviews using a semi-structured questionnaire, records review to obtain clinical information and through focused group discussions. Both quantitative and qualitative data analysis was done. In analysis of quantitative data, univariate analysis was done to describe HIV and AIDS patients on ART by socio-demographic characteristics and determine proportions of patients on ART reaching optimal and suboptimal adherence levels. Bivariate analysis was then done to compare adherence levels with CD4 cell counts and factors affecting adherence. Qualitative data was transcribed and summarized using

themes.

A total of 280 adult HIV and AIDS patients on ART for six (6) months or more at Mnazi Mmoja hospital's HIV care and treatment clinic in Zanzibar were enrolled in the study. Majority of the patients i.e. 76.1% (95%CI: 70.6% - 80.9%) were found to be reaching optimal adherence level to ART of 95% and above but a significant proportion of the patients i.e. 23.9% (95%CI: 19.1% - 29.4%) were not. The mean CD4 cell count gain for patients who were reaching optimal adherence levels was 221 (95%CI: 201 - 241) as compared to 171 (95%CI: 135 – 207) for those who were reaching suboptimal adherence levels. The difference between the two means was statistically significant (p=0.02). This study found no association between adherence and studied demographic, social, economic, behavioural, clinical and health service related factors. Findings of this study indicate the need for timely detection of patients not reaching optimal adherence and implementing interventions to improve adherence.

# CHAPTER 1

## 1.0 INTRODUCTION AND LITERATURE REVIEW

## 1.1 HIV and AIDS

Human Immunodeficiency Virus and Acquired Immuno Deficiency Syndrome (HIV and AIDS) has been a major public health concern in the world since it was first recognized in the United States of America (USA) in 1981. Its effects are devastating and it has affected not just health but also social and economic aspects of life. Its profound effects to the health sector include: reduction in child survival, reduction in life expectancy and increased morbidity leading to the impairment of the health system to cope with provision of HIV care and treatment services (UNAIDS, 2008). Its dramatic effects in the social and economic sectors include: increasing number of orphans, a slowdown in economic development and an increase in household poverty due to a reduction in workforce caused by severe illnesses and deaths (UNAIDS, 2008).

The effects of HIV and AIDS are especially severe in Sub-Saharan Africa where more than two-thirds (68%) of all HIV positive people live and more than three quarters (76%) of all AIDS deaths in 2007 occurred (UNAIDS, 2007). In this region, the epidemic has orphaned nearly 12 million children aged under 18 years (UNAIDS, 2008).

### 1.1.1 HIV and AIDS in the world

Estimates show that globally 33.2 million people were living with HIV infection by December 2007 with 2.5 million people having been newly infected in 2007 (UNAIDS, 2007). Estimates also show that 2.1 million people died due to AIDS in 2007 alone (UNAIDS, 2007). Though there is a decline in AIDS deaths partly due to scaling up of antiretroviral therapy (ART) services, AIDS remains a leading course of death worldwide and a primary cause of death in sub-Saharan Africa (UNAIDS, 2007). Global estimates show that HIV is affecting men and women equally whereby 50% of people living with HIV infection by December 2007 were women (UNAIDS, 2008). Worldwide, most (45%) of the new HIV infections are occurring among young people aged 15-24 years (UNAIDS, 2008). In sub-Saharan Africa, the most prevalent mode of HIV transmission is heterosexual but in other regions of the world, injecting drug use and homosexual practices are predominant modes of HIV transmission (UNAIDS, 2008).

### 1.1.2 HIV and AIDS in Africa

Sub-Saharan Africa is the most affected region in the global AIDS epidemic. Estimates show that by the end of 2007, 22.5 million people (68% of all) were

living with HIV in sub-Saharan Africa. However the prevalence in the region varies ranging from less than 2% in some countries such as Madagascar to more than 15% in most countries in southern Africa such as Botswana. A total of 1.7 million people became newly HIV infected in 2007 in sub-Saharan Africa. Although this shows a decline from 2.2 million in 2001, the burden of the disease in sub-Saharan Africa is still high with almost equally high numbers of deaths (1.6 million people) occurring due to AIDS in the same year. The high number of deaths in sub-Saharan Africa demonstrates that they are still high numbers of AIDS patients who need ART but are unable to access it. Sixty one percent of adults living with HIV in 2007 in sub-Saharan Africa are women (UNAIDS, 2007).

### 1.1.3 HIV and AIDS in Tanzania

Overall prevalence of HIV in Tanzania is 5.7% with the prevalence being much higher in Tanzania Mainland (5.8%) than in Zanzibar (0.6%). Prevalence is higher among women (6.6%) than men (4.6%) and it is highest in the age group 30-34 years among women and 35 – 39 years among men. The region which is mostly affected in Tanzania Mainland is Iringa with a prevalence of 15.7% (TACAIDS/ZAC/NBS, 2008).

### 1.1.4 HIV and AIDS in Zanzibar

The first patient with HIV in Zanzibar was identified in 1986. Zanzibar is part of the United Republic of Tanzania and it comprises of two main islands, Unguja and Pemba, located off the eastern coast of Tanzania. Zanzibar has a total population of approximately 1.2 million and an annual growth rate of 3.1% (NBS, 2002). The HIV epidemic in Zanzibar is a concentrated type with HIV prevalence being low in the general population but high in high-risk groups.

Routine antenatal clinic (ANC) surveillance of pregnant women documents an HIV prevalence of less than 1% with the most recent ANC surveillance reporting an HIV prevalence of 0.6%. HIV prevalence is higher in Unguja Island (0.9%) than Pemba Island (0.1%) (ZACP, 2008a). Concurrently, the HIV magnitude validation survey conducted in the general population in 2002 documented an HIV prevalence of 0.6% (ZACP, 2003). The validation survey also documented higher HIV prevalence among women (0.9%) compared to men (0.2%).

High HIV prevalence has been documented in certain sub-populations in Zanzibar. A study conducted in 2005 among substance abusers (injection drug users as well as non-injection drug users), found that the overall prevalence of HIV among substance abusers was 13% with higher HIV prevalence in women (30.7%) compared to men substance abusers (12.0%) (Dahoma *et al.,* 2006). In the same study, 38.9% of the substance abusers were found to be injection drug users (IDUs) and the prevalence of HIV among the IDUs was 26.2%. Heroin, in the form of white and brown sugar, was the substance abused by nearly all participants (98.2%) i.e. both non-IDUs and IDUs. A follow up study conducted in high risk groups in 2007 using another methodology (respondent driven sampling) revealed an HIV prevalence of 15.1% among IDUs, 12.3% among men having sex with men and 10.8% among commercial sex workers (ZACP, 2008c).

### 1.2 Overview of antiretroviral therapy

Antiretroviral drugs (ARVs) delay progression of HIV disease and improve the quality of life in the HIV infected individuals. Combination antiretroviral therapy (ART) has been attributed to a declining morbidity and mortality due to HIV and AIDS in the world (Palella *et al.,* 1998). It has, therefore,

transformed HIV disease into a chronic treatable condition for people living with HIV and AIDS who access treatment. However, there is a need to maintain patients on treatment for life and this calls for a long term perspective of ART. The initial regimen plays an important role in achieving prolonged viral suppression and, therefore, it must be selected with the intent of achieving the following goals: prolongation and improvement of quality of life, suppression of viral load to undetectable levels, having a CD4 cell count in the normal range, reducing HIV transmission and rational sequencing of medicines which maintains future therapeutic options, is relatively free of side effects and has a high probability of adherence (Nischal *et al.,* 2005).

In patients with prior ARV drugs exposure, the desired goals are preservation of the immune system and prevention of clinical progression rather than maximal viral suppression (Bini *et al.,* 2000).

The World Health Organization (WHO) recommends a standardized formulary for first-line and second-line ART. Two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI) are recommended as the first-line regimen; protease inhibitors (PI) class is the mainstay of second-line regimens. Simplified patient management

and standardized laboratory monitoring, particularly measuring of CD4 cell count, to indicate when to initiate ART and when to switch ARV regimen for failure, are recommended (WHO, 2006). It also recommends that ART should be delivered as part of a package of care interventions, including the provision of co-trimoxazole prophylaxis, the management of opportunistic infections and co-morbidities, nutritional support and palliative care (WHO, 2006).

The Tanzania national guidelines for the management of HIV and AIDS are in line with the WHO recommendations for ART. The criteria for ART initiation are based on CD4 cell count and WHO clinical stage (NACP, 2008). The following three classes of patients are eligible to start ART:

All patients in WHO clinical stage 4 (Appendix 1) regardless of CD4 cell count

Patients in WHO clinical stage 3 (Appendix 1) with a CD4 cell count of less than or equal to 350/mL

All patients with a CD4 cell count of equal or less than 200/mL regardless of WHO clinical stage

The Tanzania national guidelines for the management of HIV and AIDS recommends triple therapy both for first line and second line ART (NACP,

2008). The ARV drugs are either administered as three separate drugs or in fixed combinations of two drugs such as Combivir (Zidovudine and Lamivudine) or of three drugs such as Triomune (Stavudine, Lamivudine and Nevirapine). The recommended first line ARV drugs combinations are:

AZT (Zidovudine) + 3TC (Lamivudine) + NVP (Nevirapine)

AZT (Zidovudine) + 3TC (Lamivudine) + EFV (Efavirenz)

d4T (Stavudine) + 3TC (Lamivudine) + NVP (Nevirapine)

d4T (Stavudine) + 3TC (Lamivudine) + EFV (Efavirenz)

TDF (Tenofovir) + FTC (Emtricitabine) + NVP (Nevirapine)

TDF (Tenofovir) + FTC (Emtricitabine) + EFV (Efavirenz)

TDF (Tenofovir) + 3TC (Lamivudine) + NVP (Nevirapine)

TDF (Tenofovir) + 3TC (Lamivudine) + EFV (Efavirenz)

Once on treatment, patients' progress is monitored clinically as well as through CD4 cell count which is measured every six months. Change of treatment to second line ARV drugs can be based on virologic, immunologic or clinical treatment failure. In Tanzania, immunological parameters (30% drop in CD4 cell count from peak value or return to pre ART CD4 cell count or lower) and clinical parameters (disease progression clinically presenting with development of opportunistic infections or malignancies occurring 3 months or more after

ART initiation) are used to identify treatment failure (NACP,2008). The recommended second line ARV drugs in Tanzania are:

ABC (Abacavir) + ddI (Didanosine) + LPV (Lopinavir) boosted by RTV (Ritonavir)

ABC (Abacavir) + ddI (Didanosine) + ATV (Atazanavir) boosted by RTV (Ritonavir)

ABC (Abacavir) + TDF (Tenofovir) + LPV (Lopinavir) boosted by RTV (Ritonavir)

ABC (Abacavir) + TDF (Tenofovir) + ATV (Atazanavir) boosted by RTV (Ritonavir)

Only the first four of the first line ARV drug combinations and the first of the second line ARV drug combinations were available in Zanzibar when this study was being conducted.

### 1.2.1 Antiretroviral therapy in the world

Encouraging upward trends are seen in the scale-up of ART in the world. By December 2006, it was estimated that 2 million people living with HIV and AIDS were receiving ART in low- and middle-income countries, representing 28% of the estimated 7.1 million people in need (WHO, 2007). Sub-Saharan

Africa is now estimated to have more than 1.3 million people on ART, with coverage of 28%, whereas three years earlier there were 100,000 on ART and coverage amounted to only 2% (WHO, 2007). About 67% of the people receiving ART in low and middle-income countries live in sub-Saharan Africa, whereas only 25% were doing so in late 2003 (WHO, 2007).

### 1.2.2 Antiretroviral therapy in Zanzibar

Care and treatment services which include ART services for people living with HIV and AIDS in Zanzibar started on 24th of March 2005. Prior to that only care services in the form of counseling, home based care services and treatment for opportunistic infections were provided in Zanzibar. Currently (2009), Zanzibar has seven HIV care and treatment clinics; four in Unguja Island and three in Pemba Island of Zanzibar. The location of these seven clinics is shown on Figures 1 and 2. From the prevalence data of 2008, Zanzibar is estimated to have 7,200 people living with HIV and AIDS, and by September 2008, 2,626 HIV and AIDS clients (36% of all) had been registered in the seven care and treatment clinics existing in Zanzibar. Among the registered clients, 1,201 have been started on ART (ZACP, 2008b).


**Figure 1: Map of Pemba Island showing the location of HIV care and treatment clinics**

Location of HIV care and treatment clinic

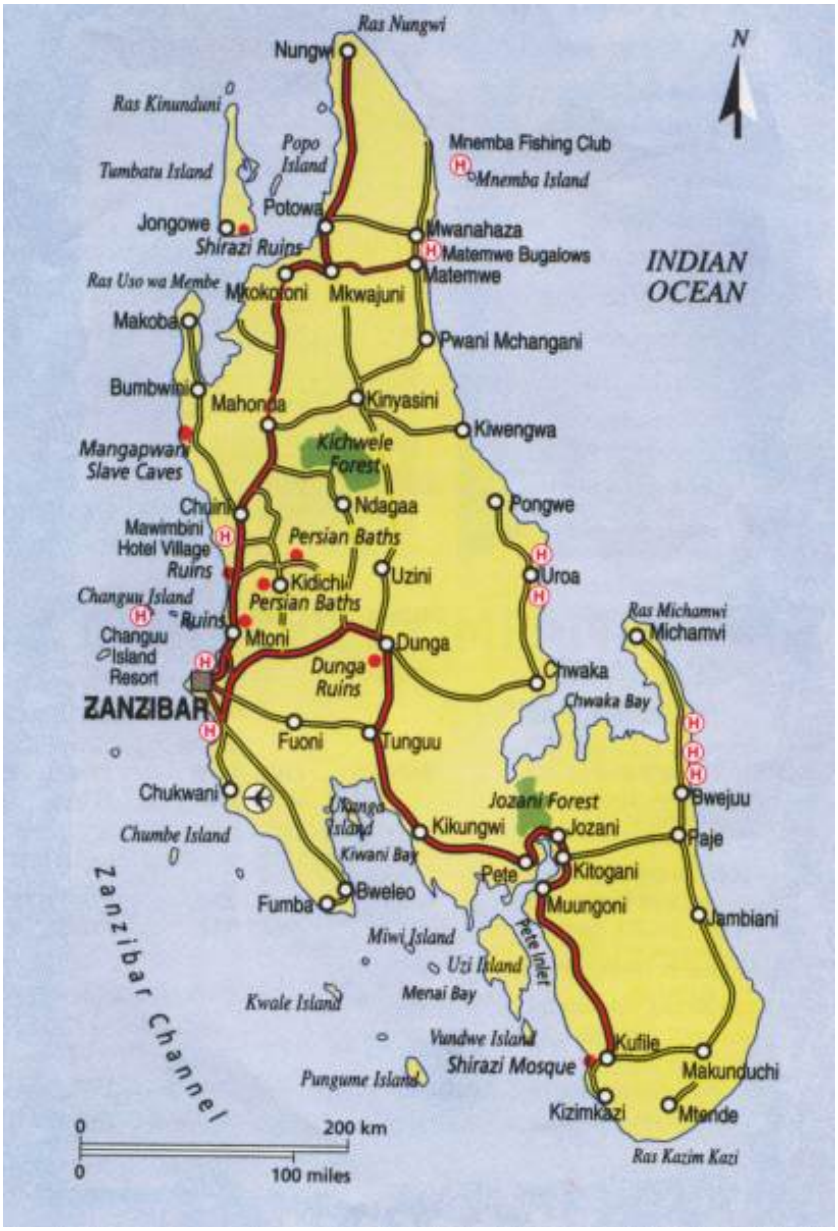


**Figure 2: Map of Unguja Island showing the location of HIV care and treatment clinics and Mnazi Mmoja Hospital**

Location of HIV care and treatment clinic

### 1.3 Adherence to antiretroviral therapy

Adherence to ART is an essential element of successful HIV treatment. A major concern with ART is the emergence of viral resistance, which is mainly due to poor adherence (Bangberg *et al.,* 2006). Other concerns of ART which may have an effect on its outcome are its lifelong duration, serious side effects, the complexity of regimens and the fact that therapy is not curative. The adherence rate varies not just between individuals, but also in the same individual over time, thus making adherence a dynamic rather than a static characteristic of an individual (Amberbir *et al.,* 2008) . Most people will exhibit low adherence at some time during this extended therapy (Nischal *et al.,* 2005).

Optimal adherence is the compliance to ART that achieves a sustained plasma drug concentration that will inhibit viral replication. Studies have indicated that at least 95% adherence to ART regimens is optimal (WHO, 2006). With 95% adherence, viral suppression to below detectable levels occurs in 80% of individuals. However, a fall in adherence to 70% drastically decreases viral suppression to 33%. Also, it has been demonstrated that a 10% higher level

of adherence results in a 21% reduction in disease progression (Nischal *et al.,* 2005).

Implications of suboptimal adherence include failure of the regimen, increase in morbidity and mortality and emergence of resistant strains of virus. For example for NNRTIs, studies have shown that 69% of individuals using them had resistance at 0-48% adherence while resistance was significantly reduced to 13% at 95-100% adherence (Bangberg *et al.,* 2006). For PIs, virologic failures of 22% have been documented in patients with adherence of 95% or more and of 80% in patients with adherence of 80% or less (Paterson *et al.,* 2000). This finding indicates that achieving adherence level of 95% or more is even more important for PIs than NNRTIs based regimens.

For NNRTIs which have been shown to have less probability of virologic rebound even with moderate adherence levels, continuous and sustained treatment interruptions pose a high risk for virologic rebound than interspersed missed doses. Therefore, though near perfect adherence leading to sustained virologic suppression remains the goal of ART, sustained NNRTIs treatment interruptions have to be limited in patients with incomplete adherence (Parienti *et al.,* 2008, Dybul *et al.,* 2004, Dybul *et al.,* 2003).

### 1.3.1 Levels of adherence to antiretroviral therapy

Several studies in different parts of the world have been conducted to investigate on levels adherence. A study done in India found that by using the method of self reporting of adherence to ART, 84% of patients on ART were reaching optimal adherence levels (Sarna *et al.,* 2008). While a meta analysis of studies done in several sub-Saharan African has shown that ART adherence in early treatment programmes are favourable whereby 77% of patients were reaching optimal adherence levels (Mills *et al.,* 2006), a study conducted closer to Zanzibar in Tanzania in the regions of Arusha and Dar es Salaam found that only 21% of clients on ARVs were reaching optimal adherence levels (Irunde *et al.,* 2005).

### 1.3.2 Factors affecting adherence to antiretroviral therapy

In the Indian study mentioned above, free treatment and severe depression were found to be associated with poor adherence (Sarna *et al.,* 2008). In the same study, when interviewees were asked about reasons for missing pills

over a seven day period, reasons given included: being busy with other things, forgetting and being away from home. For longer duration of period, reasons for missing treatment included: financial difficulty, travelling and side effects. This Indian study also demonstrated higher increase in CD4 cell counts in patients with adherence of more than 90% as compared to those below 90% (Sarna *et al.,* 2008).

A qualitative study done in South Africa to determine factors affecting adherence to ART found the barriers to include: denial of existence of HIV or one's own HIV status, use of traditional medicine, alcohol use, being away from home, perceived severity of side effects, long waiting times at the clinic, unavailability of medicines at the clinic, non disclosure of one's HIV status, lack of family or social support, fear of stigma, and anxiety (Dahab *et al.,* 2008). Facilitators of adherence include disclosure of one's HIV status, social support, belief in value of treatment, belief in importance of one's own life to the survival of one's family and ability to fit ART into daily life. Feeling better on treatment was found to be both a barrier and a facilitator of treatment (Dahab *et al.,* 2008).

In the adherence study done in Tanzania, a few patients were not well informed about ART and consequences of suboptimal levels of adherence to ART. Factors which were found to be affecting adherence included cost of traveling to the clinic, lack of food, lack of confidentiality in the clinics, long waiting periods at the clinics and shortages of medicines. Low staff motivation, inadequate training and work overload are other factors found that may have lead to poor adherence by ARV users (Irunde *et al.,* 2005).

## 1.4 Problem statement

Adherence to ART for HIV treatment is of paramount importance in order for it to achieve its goal. Without optimal adherence, immunological and clinical failure of treatment will result leading to an increase in morbidity and mortality of people living with HIV and AIDS (PLHA). Also important is the fact that viral resistance will develop and the effects of viral resistance do not only affect the individual concerned but will also continue to be passed on to the next population which becomes HIV infected. With HIV treatment being lifelong and treatment options being few, the consequences of the viral resistance will be limited alternative treatment options for the affected individual and population.

## 1.5 Justification

Effects of suboptimal ART adherence level which include treatment failure and development of resistance cannot be overstressed because of its implications in the setting of no cure of HIV, the need of lifelong treatment of HIV and few available successful treatment options for suppression of HIV. Despite the vast existing and evolving knowledge on adherence levels and its associated factors in the world and in countries closer to Zanzibar, no published information on the same is available for Zanzibar. Also seen in the literature is the fact that although some of the factors affecting adherence to antiretroviral therapy are recurring, many vary depending on the area one lives due to social and economic differences.

In order to enable Zanzibar improve her ART programme and enable her to achieve her overall goal of improving survival and quality of life of people living with HIV and AIDS, this study aims at investigating adherence levels of patients on antiretroviral therapy in Zanzibar and determine factors which affect adherence either positively or negatively. The information generated from this study will be used by the ART programme in Zanzibar to improve adherence levels of clients by developing appropriate strategies, guidelines and

Information, Education and Communication (IEC) and Behavioural Change Communication (BCC) tools that address issues which are specific to Zanzibar in delivering ART services. The information will also aid in planning and implementing ART services in Zanzibar as well as make a contribution to the overall knowledge on adherence to ART which can be used by other countries in improving their ART programmes.

## 1.6 Hypotheses

### 1.6.1 Null hypothesis

Adherence to antiretroviral therapy is 100% and there are no specific factors associated with adherence to antiretroviral therapy among adult HIV and AIDS patients at Mnazi Mmoja Hospital's HIV care and treatment clinic, Zanzibar.

### 1.6.2 Alternate hypothesis

Adherence to antiretroviral therapy is not 100% and there are specific factors associated with adherence to antiretroviral therapy among adult HIV and AIDS patients at Mnazi Mmoja Hospital's HIV care and treatment clinic, Zanzibar.

## 1.7 Objectives

### 1.7.1 General objective

To determine level of adherence to antiretroviral therapy and investigate its associated factors among adult HIV and AIDS patients at Mnazi Mmoja Hospital's HIV care and treatment clinic, Zanzibar, 2008

### 1.7.2 Specific objectives

To determine level of adherence to antiretroviral therapy among adult HIV and AIDS patients at Mnazi Mmoja Hospital's HIV care and treatment clinic, Zanzibar

To determine association between adherence to antiretroviral therapy and CD4 cell counts over time of adult HIV and AIDS patients at Mnazi Mmoja Hospital's HIV care and treatment clinic, Zanzibar

To determine factors associated with adherence to antiretroviral therapy among adult HIV and AIDS patients at Mnazi Mmoja Hospital's HIV care and treatment clinic, Zanzibar

# CHAPTER 2

## 2.0 MATERIALS AND METHODS

### 2.1 Study site

Zanzibar consists of two main islands: Unguja Island which consists of six districts and Pemba Island which has four districts. The study was conducted at Mnazi Mmoja Hospital's HIV care and treatment clinic which is located in Unguja Island in the Urban district within the Urban West region. This is the main referral hospital for the whole of Zanzibar with a bed capacity of 400. Although it provides specialty care to all people of Zanzibar, it also operates as a primary and secondary level hospital for the people in Urban, West, Central and North B in Unguja which have no cottage or district hospitals.

Mnazi Mmoja Hospital has 19 clinical departments including:

Emergency department

General outpatient clinic

Diabetic and hypertensive clinic

HIV and STI clinic

TB and leprosy clinic

Physical and occupational therapy clinic

Obstetrics and Gynaecology (clinic and ward)

Internal medicine (ward)

Paediatrics (clinic and ward)

Surgery (clinic and ward)

Orthopaedics (clinic and ward)

Ophthalmology (clinic and ward)

ENT (clinic and ward)

Dentistry

Radiology

Laboratory

Intensive care unit

Neonatal unit

Theatre

The HIV care and treatment clinic in Mnazi Mmoja Hospital was established on 24th March 2005. Prior to that it was operating as an HIV care clinic whereby it was providing mainly treatment for opportunistic infections and counseling. Its professional staff include clinicians, nurses, laboratory technicians, and pharmaceutical staff. The daily procedure for patients attending the clinic involves reception by triage nurse who does the initial

physical examination such as weighing, height measurement and blood pressure checking. From the triage nurse, patients are directed to the appropriate service needed (e.g., registration if this is the first clinic visit, mini laboratory for rapid tests needed and for blood drawing if needs any other blood investigations, adherence counseling if patient is to start ART or needs ongoing counseling, consultation with the doctor or dispensing room). The order of going to these different areas will depend on what services are needed by the patient on that day.

The Mnazi Mmoja HIV care and treatment clinic was selected for the study because it has the majority (80%) of all the HIV and AIDS patients registered in care and treatment clinics in Zanzibar. By the end of September 2008, the patients registered in the clinic were 2,088. Among them, 957 patients were on ART (both adults and children).

**2.2 Study design**

A comparative cross-sectional study was conducted for two and a half months starting on 1st September 2008. In the study, HIV and AIDS patients who had been receiving ART for the previous six months or more were enrolled to determine level of adherence, current CD4 cell counts as compared to those

at start of ART and factors affecting adherence. Cross-sectional study design was selected so as to enable one to determine level of adherence, its outcome and explore possible factors which may be affecting adherence in the study population.

### 2.3 Study population

Study population consisted of adult (18 years and above) HIV and AIDS patients receiving ART at Mnazi Mmoja Hospital's care and treatment clinic. Patients who had been receiving ART for the previous six months or more on the date of interview were enrolled so as to determine the level of CD4 cell count after ART has been started.

### 2.4 Selection of study participants

Study participants were selected based on the following criteria:

**Inclusion criteria**

HIV and AIDS patient:

Enrolled in HIV care and treatment clinic

Aged 18 years and above and of any gender

Has been on ART for the previous six months or more so as to determine the level of CD4 cell count after ART has been started

Had a baseline CD4 cell count done as well as follow up CD4 cell count

Willing to participate in the study by giving written informed consent

**Exclusion criteria**

HIV and AIDS patient:

Not meeting the above mentioned inclusion criteria

Too sick to be interviewed

Mentally handicapped

## 2.5 Sampling

### 2.5.1 Sample size

Sample size was calculated using the formula shown below**:**

$$n = \frac{z^2 \times p \times q}{d^2}$$ (Fisher *et al.,*1991)

Where:

n = sample size

z = 1.96 corresponding to 95% confidence level

p = 21% which is the proportion of HIV and AIDS patients reaching optimal levels of adherence to ART in Tanzania Mainland. This was found by Irunde *et al*., in 2005. This proportion was taken under the assumption that with

Tanzania Mainland (especially Dar es Salaam) being close to Zanzibar, some similarities may exist between its people and health service provision maybe similar.

q = 1 - p

d = margin of error set at 5%

Substituting the values:

$$n = \frac{1.96^2 \times 0.21 \times (1-0.21)}{0.05^2} = 255$$

Considering the possibility of non response by 10% then 280 participants were enrolled for the study.

### 2.5.2 Sampling procedure

Systematic sampling procedure was used to select every second patient in the appointment list who met the inclusion criteria. The interval was calculated by taking the number of adult patients on ART by end of March 2008, which was 6 months prior to initiation of this study, and this was 663. This number was then divided by the sample size to get two ($663/280 \approx 2$). This process continued every clinic day until the sample size of 280 was reached.

## 2.6 Pre-test of research tools

Training of interviewers and record reviewers was done one week prior to initiation of data collection. Pre-test of the study tools was then done to determine the feasibility of data collection, applicability of sampling procedure and to evaluate the understanding, length and acceptability of the questionnaire. The results were used to refine and update the questionnaire by adjusting questions and response options which were initially unclear in the questionnaire. All the trained interviewers and record reviewers, together with and under the supervision of the principal investigator, participated in data collection.

## 2.7 Data collection

Data was collected by the principal investigator with the assistance of trained research assistants including two interviewers and three records reviewers for a period of two and a half months from 1st September to 15th November 2008. Both quantitative and qualitative methods were used to collect data. This was done in the following three major ways:

Face to face interviews with study participants using a semi structured questionnaire (Appendix 2)

Records review to obtain information from study participants' files on ARVs taken, other medications taken, ARVs pill count records done by ARVs dispenser, CD4 cell counts and side effects to ARVs (Appendix 3)

Focused group discussions (FGDs) with study participants to obtain information on the underlying causes for adhering to or not adhering to ART and how this adherence is achieved (Appendix 4)

During data collection, the research assistants were closely supervised by the principal investigator. After every clinic day, data auditing was done by the principal investigator by revisiting every questionnaire and record review form to check for completeness and validity of responses. If any other problem arose, the principal investigator discussed it with the interviewers so as to avoid it in the future.

### 2.7.1 Quantitative method

#### 2.7.1.1 Interviews

A semi structured questionnaire was used to interview study participants. This included the following variables:

***Identifiers:***

District

***Demographics:***

Age

Sex

Marital status

Level of education

Occupation

Religion

Number of dependants

***Clinical information***

When was ART started (Duration on ART)

Adherence level:

Pill count – from the last appointment to interview day

Self reported – past 3 days, past one week, past one month, ever

Side effects experienced

***Reasons for missing ARV dose***

***Factors affecting adherence***

Individual factors – alcohol use, drug use, knowledge on ART, etc.

Social factors – disclosure, social support, stigma etc.

Economic factors – income, cost of accessing treatment, etc.

Health system – availability of medicines, provider/patient relationship, etc.

The questionnaire was translated into Kiswahili (native language of Zanzibar) as that is the most commonly used and understood language in Zanzibar and then back translated into English by a different person so as to ensure no loss of meaning. The main challenge faced by the study team during data collection was that on some clinic days, no or only a few patients who were eligible for the study would come to the clinic. Hence, in order to reach sample size, the study period was extended by two extra weeks.

#### 2.7.1.2 Record reviews

Records review was done by the principal investigator with the assistance of clinic nurses to obtain the following information from patient files:

ARV regimen prescribed on the last appointment

ARVs doses taken home on the last appointment

ARVs left on interview day

Other medications prescribed on last appointment

CD4 level:

Baseline

Follow up (Every six months to the latest)

Frequency of side effects

Types of side effects experienced

#### 2.7.1.3 Measurement of ART adherence

ART adherence was measured from the information obtained in records review by applying the steps shown below:

Number of ARV doses taken from the last appointment to date of interview = Number of ARV doses taken home on the last appointment – Number of ARV doses left on the date of interview

Number of ARV doses supposed to have been taken from the last appointment to date of interview =Duration in days from last appointment to date of interview × 2

Adherence level = Number of ARV doses taken from the last appointment to date of interview ÷ Number of ARV doses supposed to have been taken in the same period × 100

NB: All study participants were taking ARVs twice a day for at least one type of ARV

### 2.7.2 Qualitative method

Focused group discussions (FGDs) were used to determine why and how patients adhere to ART and how they thought adherence could be improved.

Two (2) focus group discussions were conducted each having seven to eight study participants. One group comprised of male while the other female study participants. Participants were selected at random during the clinic visits and written informed consent was obtained. Consented participants were asked to come on the following day for the discussion. The FGDs were conducted at ZACP conference room. ZACP is located across the road from Mnazi Mmoja Hospital. During the discussions, a moderator and a note taker were present: the discussions were also tape recorded. The discussed questions were in Kiswahili language (native language of Zanzibar) as that is the most commonly used and understood language in Zanzibar.

**2.8 Data management (processing and analysis)**

Data was entered in Epi-info for windows version 3.3.2**,** cleaned in Microsoft Office Excel 2003 and analyzed using both of the above softwares. Univariate analysis was done to describe HIV and AIDS patients on ART by socio-demographic characteristics and determine proportions of patients on ART reaching optimal and suboptimal adherence levels. Bivariate analysis was then done to compare adherence levels with CD4 cell counts and factors affecting adherence. During comparisons between groups, p value was obtained to determine statistical significance. 95% confidence intervals for the calculated

estimates (proportion or mean) were also determined. Qualitative data was transcribed and summarized using themes.

### 2.9 Ethical considerations

Ethical clearance was sought and obtained from the Zanzibar Health Research Task Force. During the study, the purpose, procedures of the study, measures taken to ensure confidentiality of participants, the voluntary nature of the study and applicability of findings were explained to participants. Participants were assured that their participation in the study is voluntary and they are free to withdraw without any negative impact in their treatment at the clinic. Written informed consent was sought and obtained from the participants. Private rooms were used for interviewing participants whereby only the participant and the interviewer were available in the room during the interview so as to ensure privacy. Confidentiality was maintained by using codes on the questionnaires and forms for record reviews. All records and data were stored confidentially in locked metal cabinets according to good clinical practice (GCP).

# CHAPTER 3

## 3.0 RESULTS

A total of 280 consented adult HIV and AIDS patients on ART for six (6) months or more at Mnazi Mmoja hospital's HIV care and treatment clinic in Zanzibar were enrolled in the study among the 282 patients who were selected. Two patients were excluded because they were not willing to participate in the study. The study findings are presented in the following sections.

## 3.1 Demographic and socio economic characteristics of study participants

The median age of study participants was 38 years with a range of 19 to 76 years and a majority of them being females (71.8%). A high proportion of the patients were between ages 30 to 39 years (45.4%). Majority of the study participants were Muslims (79.3%) and living in Urban and West districts of Unguja (83.9%). A high proportion of the patients were married (47.1%), had attained primary education only (52.5%), were self employed (51.8%) and earned an income of between Tshs 50,000 to 100,000 (46.6%). This is seen in Tables 1 and 2 below.

**Table 1: Demographic characteristics of study participants**

| Characteristic | Frequency | Percent |
|---|---|---|
| **Sex** | | |
| Female | 201 | 71.8% |
| Male | 79 | 28.2% |
| **Total** | **280** | **100.0%** |
| **Age Group (Years)** | | |
| ≤ 29 | 33 | 11.8% |
| 30-34 | 63 | 22.5% |
| 35-39 | 64 | 22.9% |
| 40-44 | 50 | 17.9% |
| 45-49 | 37 | 13.2% |
| ≥ 50 | 33 | 11.8% |
| **Total** | **280** | **100.0%** |
| **Marital Status** | | |
| Single | 29 | 10.4% |
| Married | 132 | 47.1% |
| Divorced | 80 | 28.6% |
| Widowed | 39 | 13.9% |

| | | |
|---|---|---|
| **Total** | **280** | **100.0%** |
| **District of Residence** | | |
| Urban | 124 | 44.3% |
| West | 111 | 39.6% |
| Others* | 45 | 16.1% |
| **Total** | **280** | **100.0%** |
| **Level of Education** | | |
| No formal education | 32 | 11.4% |
| Primary Education | 147 | 52.5% |
| Secondary Education | 97 | 34.6% |
| Higher education | 4 | 1.4% |
| **Total** | **280** | **100.0%** |

* Remaining 4 districts of Unguja Island and Tanzania Mainland

**Table 2: Socio-economic characteristics of study participants**

| Characteristic | Frequency | Percent |
|---|---|---|
| **Religion** | | |
| Christian | 57 | 20.4% |
| Muslim | 222 | 79.3% |

| | | |
|---|---|---|
| None | 1 | 0.4% |
| **Total** | **280** | **100.0%** |
| | | |
| **Employment status** | | |
| Employed in private sector | 39 | 13.9% |
| Employed in public sector | 20 | 7.1% |
| Self employed | 145 | 51.8% |
| None | 76 | 27.1% |
| **Total** | | **100.0%** |
| | | |
| **Income per month (Tshs)*** | | |
| < 50,000 | 62 | 30.4% |
| 50,000 - 100,000 | 95 | 46.6% |
| > 100,000 | 47 | 23.0% |
| **Total** | **204** | **100.0%** |

* 1US$ = 1,300 Tshs

Among female patients, the highest proportion was in the age group 30 to 34 years and the least proportion was in the age group 50 years and above. For male patients, the highest proportion was in the age group 35 to 39 years and the least proportion was in the age group 29 years and below. This is as shown in Figure 3 below.

**Figure 3: Distribution of study participants by age and sex**

The highest proportion of single study participants is in the age group 29 years and below (24.2%), of married participants is in the age group 45 to 49 years (59.5%), of divorced participants is in the age group 35 to 39 years (31.2%) and of widowed participants is in the age group 50 years and above (36.4%). This is shown in Figure 4 below.

**Figure 4: Distribution of study participants age and marital status**

On the other hand analysis of marital status by sex shows that males have a higher proportion than females among married (57% vs. 47%) and single (14% vs. 9%) while females were 1.5 times higher than males among divorced (31% vs. 22%) and 2 times higher than males among widowed (16% vs. 8%). This is seen in Figure 5.

**Figure 5: Distribution of study participants by sex and marital status**

About 52.5% (147/280), 34.6% (97/280) and 1.4% (4/280) of study participants had attained primary, secondary and higher education respectively. Across age groups, the highest proportion of those with no formal education was in the age group 50 years and above (33.3%), those with primary education was in the age group 30 to 34 years (57.8%) and those with secondary education was in the age group 45 to 49 years (54.1%). This is shown in Table 3 below.

**Table 3: Distribution of study participants by age and highest level of education attained**

| Age Group (Years) | No formal education n (%) | Primary education n (%) | Secondary education n (%) | Higher education n (%) | Total n (%) |
|---|---|---|---|---|---|
| **≤ 29** | 4 (12.1) | 14 (42.4) | 14 (42.4) | 1 (3.0) | **33 (100)** |
| **30-34** | 5 (7.9) | 40 (63.5) | 17 (27.0) | 1 (1.6) | **63 (100)** |
| **35-39** | 3 (4.7) | 37 (57.8) | 23 (35.9) | 1 (1.6) | **64 (100)** |
| **40-44** | 6 (12.0) | 28 (56.0) | 15 (30.0) | 1 (2.0) | **50 (100)** |
| **45-49** | 3 (8.1) | 14 (37.8) | 20 (54.1) | 0 (0.0) | **37 (100)** |
| **≥ 50** | 11 (33.3) | 14 (42.4) | 8 (24.2) | 0 (0.0) | **33 (100)** |
| **Total** | **32 (11.4)** | **147 (52.5)** | **97 (34.6)** | **4 (1.4)** | **280 (100)** |

Fifty two percent (52%) of female participants and 53% of male participants had attained primary education only. A higher proportion of males than females attained secondary education (39% vs. 33%) while females were 2 times higher than males (13% vs. 6%) among study participants with no formal education. This is seen in Figure 6.

**Figure 6: Distribution of study participants by gender and level of education**

More than half of the study participants were self employed (51.8%), 13.9% were employed in private sector while 7.1% were employed in public sector. More than a quarter of the participants were not employed (27.1%). The highest proportion of those employed in private sector is in the age group of 29 years and below (21.2%), of those employed in public sector is in the age group 45 to 49 years (18.9%), of those self employed is in the age group 40 to 44 years (62.0%) and among those not employed is in the age group 50 years and above (45.5%). This is seen in Table 4 below.

**Table 4: Distribution of study participants by age and employment status**

| Age Group (Years) | Employed in private sector n (%) | Employed in public sector n (%) | Self employed n (%) | None n (%) | Total n (%) |
|---|---|---|---|---|---|
| **≤ 29** | 7 (21.2) | 1 (3.0) | 14 (42.4) | 11 (33.3) | **33 (100)** |
| **30-34** | 8 (12.7) | 5 (7.9) | 33 (52.4) | 17 (27.0) | **63 (100)** |

| | | | | | |
|---|---|---|---|---|---|
| **35-39** | 12 (18.8) | 1 (1.6) | 38 (59.4) | 13 (20.3) | **64 (100)** |
| **40-44** | 4 (8.0) | 4 (8.0) | 31 (62.0) | 11 (22.0) | **50 (100)** |
| **45-49** | 7 (18.9) | 7 (18.9) | 14 (37.8) | 9 (24.3) | **37 (100)** |
| **≥ 50** | 1 (3.0) | 2 (6.1) | 15 (45.5) | 15 (45.5) | **33 (100)** |
| **Total** | **39 (13.9)** | **20 (7.1)** | **145 (51.8)** | **76 (27.1)** | **280 (100)** |

Males were nearly twice as high as females in the public sector (11% vs. 6%) and thrice as high in the private sectors (28% vs. 9%). On the other hand, 52% of females and 51% of males were self employed while more than 3 times more females than males were not employed (34% vs. 10%). This is seen in Figure 7 below.

**Figure 7: Distribution of study participants by gender and employment status**

Among study participants who are employed, the median income per month was Tanzania shillings (Tshs) 75,000; with the minimum income per month being Tshs 3,000 and the maximum Tshs 1,000,000. A high proportion of them earned an income between Tshs 50,000 and 100,000 per month (46.6%).

The highest proportion of those earning less than Tshs 50,000 were self employed (39.3%) and of those earning between Tshs 50,000 and 100,000 were employed in public sector (75%). The proportions of those earning more than Tshs 100,000 across types of employment were almost equal. Nobody working in the public sector earned an income of less than Tshs 50,000. This is shown in Table 5 below.

**Table 5: Distribution of study participants by type of employment and income per month**

| Type of employment | Income Group (Tshs) | | | Total |
|---|---|---|---|---|
| | **< 50,000 n (%)** | **50,000-100,000 n (%)** | **> 100,000 n (100%)** | |
| **Employed in private sector** | 5 (12.8) | 24 (61.5) | 10 (25.6) | 39 (100) |
| **Employed in public sector** | 0 (0.0) | 15 (75.0%) | 5 (25.0) | 20 (100) |
| **Self employed** | 57 (39.3) | 56 (38.6) | 32 (22.1) | 145 (100) |

| | | | | |
|---|---|---|---|---|
| **Total** | 62 (30.4) | 95 (46.6) | 47 (23.0) | 204 (100) |

## 3.2 ART adherence levels of study participants

Results in Figure 8 shows that 42% of study participants reported to have missed taking at least one dose of ARVs since they started taking ARVs, 28.6% in the past one month, 15.7% in the past one week while 10.0% reported to have missed taking at least one dose of ARVs in the past three (3) days. The remaining 57.9% reported that they had never missed taking ARVs since they started ART.

**Figure 8: Distribution of study participants according to the reported frequency of missing a dose of ARVs**

Number of doses missed ranged from 1 to 3 for the past 3 days, 1 to 6 for the past one week, 1 to 30 for the past one month and 1 to 180 for those who had ever missed taking ARVs.

By calculating level of adherence to ART using ARV dispenser's records whereby pill counts of remaining ARV doses was done on each day that a

patient comes for ARV refill, 76.1% (95%CI: 70.6% - 80.9%) of the patients were found to be reaching optimal adherence level to ART of 95% and above but a notable proportion of 23.9% (95%CI: 19.1% - 29.4%) were not (Figure 9).

**Figure 9: Percent of study participants with optimal and suboptimal adherence levels**

## 3.3 Analysis of relationship between adherence levels and CD4 cell count gain over time

The mean CD4 cell count gain for patients who reached optimal adherence levels was 221 (95%CI: 201 - 241) as compared to 171 (95%CI: 135 – 207) for those who reached suboptimal adherence levels. Using the Student's t test, the difference between the two means was statistically significant (p value = 0.02).

Stratification of study participants was done into those who had been on treatment for shorter durations of time of less than 24 months compared to those who had been on treatment for longer durations of 24 months and above. Using Student's t test, the difference between the mean CD4 cell count gain

for those who reached optimal adherence as compared to those who didn't for patients who had been on treatment for shorter durations of time of less than 24 months was statistically significant (p value = 0.03) but it was not statistically significant for patients on ART for longer durations (p value = 0.20). See Figure 10 below.

**Figure 10: Comparison of adherence levels with CD4 cell count gain for different durations on ART for patients**

## 3.4 Analysis of relationship between adherence level with various factors

Patients who reached optimal and suboptimal adherence levels were compared on the basis of the following factors:

Demographic

Social

Economic

Behavioural

Treatment related

Health service related

### 3.4.1 Analysis of relationship between adherence level with demographic characteristics

About seventy seven percent (76.6%) of females reached optimal adherence while 74.4% of males reached optimal adherence. Adherence levels were highest in age group 40 to 44 years (82.0%) with proportions of patients reaching optimal adherence levels reducing with decreasing and increasing age. Adherence was highest among widowed (79.5%) and lowest among single (72.4%) participants. Adherence increased with level of education until secondary school. This is as seen in Table 6 below.

**Table 6: Comparison of adherence levels with demographic characteristics of study participants**

| Adherence level | < 95 | ≥ 95 | Total | p value |
|---|---|---|---|---|
| | n (%) | n (%) | n (%) | |
| **Sex** | | | | |
| Female | 47 (23.4) | 154 (76.6) | 201 (100) | |
| Male | 20 (25.3) | 59 (74.7) | 79 (100) | 0.85 |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Age (Years)** | | | | |
| ≤ 29 | 8 (24.2) | 25(75.8) | 33 (100) | |
| 30-34 | 16 (25.4) | 47 (74.6) | 63 (100) | 0.90 |
| 35-39 | 15 (23.4) | 49 (76.6) | 64 (100) | 0.87 |
| 40-44 | 9 (18.0) | 41 (82.0) | 50 (100) | 0.68 |
| 45-49 | 10 (27.0) | 27 (73.0) | 37 (100) | 0.99 |
| ≥ 50 | 9 (27.3) | 24 (72.7) | 33 (100) | 1.00 |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Marital Status** | | | | |
| Single | 8 (27.6) | 21 (72.4) | 29 (100) | |
| Married | 31 (23.5) | 101 (76.5) | 132 (100) | 0.82 |
| Divorced | 20 (25.0) | 60 (75.0) | 80 (100) | 0.98 |

| | | | | |
|---|---|---|---|---|
| Widowed | 8 (20.5) | 31 (79.5) | 39 (100) | 0.69 |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Level of Education** | | | | |
| No formal education | 8 (25.0) | 24 (75.0) | 32 (100) | |
| Primary education | 35 (23.8) | 112 (76.2) | 147 (100) | 0.93 |
| Secondary education | 22 (22.7) | 75 (77.3) | 97 (100) | 0.98 |
| Higher education | 2 (50.0) | 2 (50.0) | 4 (100) | 0.30 |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **District of residence** | | | | |
| Urban | 34 (27.4) | 90 (72.6) | 124 (100) | 0.63 |
| West | 23 (20.7) | 88 (79.3) | 111 (100) | 0.99 |
| Others | 10 (22.2) | 35 (77.8) | 45 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |

### 3.4.2 Analysis of relationship between adherence level with economic factors

Most of the patients reported to be paying less than Tshs 1000 for transportation to the clinic (69.3%). Apart from transport, 29.6% of the patients reported to incur other costs for their treatment of HIV. Eighty two (98.8%) of the 83 patients who incurred other costs reported this to be the cost of buying medicines which were not available in the clinic. The medicines which these study participants had to buy were for opportunistic infections and other diseases and not ARVs.

The highest proportion of those reaching optimal adherence was among those employed in private sector (82.1%). A higher proportion of patients having an income of between Tshs 50,000 and 100,000 per month reached optimal adherence (77.9%) as compared to other groups. Those not incurring other costs for treatment of HIV also had better adherence whereby 77.7% reached optimal adherence. There was no difference in adherence levels between those who spent more than Tshs 1,000/= as cost of roundtrip transport to the clinic as compared to those who spent less than Tshs 1,000/= (p value = 0.98) (Table 7).

**Table 7: Comparison of adherence levels with economic factors of study participants**

| Adherence level | < 95 | ≥ 95 | Total | p value |
|---|---|---|---|---|
| | n (%) | n (%) | n (%) | |
| **Employment status** | | | | |
| Employed in private sector | 7 (17.9) | 32 (82.1) | 39 (100) | 0.64 |
| Employed in public sector | 5 (25.0) | 15 (75.0) | 20 (100) | 1.00 |
| Self employed | 37 (25.5) | 108 (74.5) | 145 (100) | 0.89 |
| None | 18 (23.7) | 58 (76.3) | 76 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Income per month (Tshs)** | | | | |
| < 50,000 | 16 (25.8) | 46 (74.2) | 62 (100) | |
| 50,000 – 100,000 | 21 (22.1) | 74 (77.9) | 95 (100) | 0.73 |
| > 100,000 | 12 (25.5) | 35 (74.5) | 47 (100) | 0.85 |
| **Total** | **49 (24)** | **155 (76)** | **204 (100)** | |

| | | | | |
|---|---|---|---|---|
| **Cost of transport to clinic (Tshs)** | | | | |
| < 1,000 | 47 (24.2) | 147 (75.8) | 194 (100) | |
| > 1,000 | 20 (23.3) | 66 (76.7) | 86 (100) | 0.98 |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Incur other costs for treatment of HIV** | | | | |
| Yes | 23 (27.7) | 60 (72.3) | 83 (100) | |
| No | 44 (22.3) | 153 (77.7) | 197 (100) | 0.41 |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |

### 3.4.3 Analysis of relationship between adherence level with social factors

More than half of study participants revealed to have a back up reminder system for ART uptake. The system is made up people (59.3%) and other reminders (63.2%) such as alarms, radio, adhan (Islamic call for prayers).

Sixty-three percent of study participants belong to an organization of people living with HIV and AIDS (PLHA). Almost all study participants (98.2%) had disclosed their HIV status to at least one person, mostly within the family.

Though small, a notable proportion had also disclosed their HIV status to their employers (42.4%). However only a third (30%) of study participants thought positively about disclosing their HIV status to others.

There was no difference in the proportions of those who had reached optimal adherence among those who had something to remind them to take ART (76.3%) as compared to those who didn't have anything to remind them to take ART(75.7%) and among those who had disclosed their HIV status to their employers (80.0%) as compared to those who hadn't disclosed their HIV status to their employers (79.4%). Patients who had people to remind them to take ART had lower adherence. There is a slight noted difference in adherence between participants who belonged to an organization of PLHA (77.6% reached optimal adherence) as compared to those who didn't belong to a PLHA organization (74.5% reached optimal adherence). A higher proportion of those who thought positively about disclosing one's HIV status reached optimal adherence (79.8%) as compared to those who didn't. Adherence level could not be compared with disclosure of HIV status in general as almost everybody had disclosed their HIV status to at least one person (Table 8).

**Table 8: Comparison of adherence levels with social factors of study participants**

| Adherence level | < 95 | ≥ 95 | Total | p value |
|---|---|---|---|---|
| | n (%) | n (%) | n (%) | |
| **Have people who remind to take ART** | | | | |
| Yes | 43 (25.9) | 123 (74.1) | 166 (100) | 0.42 |

| | | | | |
|---|---|---|---|---|
| No | 24 (21.1) | 90 (78.9) | 114 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Use something to remind to take ART** | | | | |
| Yes | 42 (23.7) | 135 (76.3) | 177 (100) | 0.96 |
| No | 25 (24.3) | 78 (75.7) | 103 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Belong to organization of PLHA** | | | | |
| Yes | 32 (22.4) | 111 (77.6) | 137 (100) | 0.63 |
| No | 35 (25.5) | 102 (74.5) | 143 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Disclosed HIV status to employer** | | | | |
| Yes | 5 (20.0) | 20 (80.0) | 25 (100) | 0.78 |
| No | 7 (20.6) | 27 (79.4) | 34 (100) | |
| **Total** | **12 (20.3)** | **47 (79.7)** | **59* (100)** | |
| **How one feels about disclosure** | | | | |
| It's good for people to know my HIV status | 17 (20.2) | 67 (79.8) | 84 (100) | 0.61 |

| | | | | |
|---|---|---|---|---|
| It's ok for people to know my HIV status | 23 (27.1) | 62 (72.9) | 85 (100) | 0.78 |
| I don't want people to know my HIV status | 27 (24.3) | 84 (75.7) | 111 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |

* Only 59 patients were employed

### 3.4.4 Analysis of relationship between adherence level with behavioural factors

Forty-six percent (46%) of study participants admitted to have ever used alcohol, 6.1% to have ever used drugs of abuse, 16.1% to have ever taken traditional medicine for treatment of HIV and around six percent (5.7%) to have ever taken traditional medicine together with ARVs. Since no patient admitted current use of the above mentioned items, ever use of the above mentioned items was compared with adherence levels.

Higher proportions of those who had never taken alcohol (80.0%) were able to reach optimal adherence as compared to those who had ever taken alcohol (71.5%). For drugs of abuse taking behaviour, the difference in adherence

levels between those not taking and those taking drugs of abuse is even higher (77.2 % vs. 58.8%). However, slightly higher proportions of those who had ever taken traditional medicine either for treatment of HIV or together with ARVs (80.4% and 81.3% respectively) reached optimal adherence levels as compared to those who had never taken (75.2% and 75.8% respectively). This is shown in Table 9 below.

All the patients enrolled in this study were taking ARVs twice a day. Almost all of them (99.3%) reported that taking ARVs does not interfere with their other daily activities.

**Table 9: Comparison of adherence levels with behavioural factors of study participants**

| **Adherence level** | **< 95** | **≥ 95** | **Total** | **p value** |
|---|---|---|---|---|
| | **n (%)** | **n (%)** | **n (%)** | |
| **Ever taken alcohol** | | | | |
| Yes | 37 (28.5) | 93 (71.5) | 130 (100) | 0.12 |

| | | | | |
|---|---|---|---|---|
| No | 30 (20.0) | 120 (80.0) | 150 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Ever taken drugs of abuse** | | | | |
| Yes | 7 (41.2) | 10 (58.8) | 17 (100) | 0.14 |
| No | 60 (22.8) | 203 (77.2) | 263 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Ever taken traditional medicine for treatment of HIV** | | | | |
| Yes | 9 (19.6) | 37 (80.4) | 46 (100) | 0.57 |
| No | 58 (24.8) | 176 (75.2) | 234 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Ever taken traditional medicine together with ARVs** | | | | |
| Yes | 3 (18.8) | 13 (81.3) | 16 (100) | 0.77 |
| No | 64 (24.2) | 200 (75.8) | 264 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |

### 3.4.5 Analysis of relationship between adherence level with treatment related factors

Forty one percent of study participants had been on treatment for the duration of between 12 and 23 months, over three quarters of the participants (77.5%) were taking one (1) pill of ARVs per dose and 76.1% were taking the ARV regimen of combination of Stavudine, Lamivudine and Nevirapine. For most of the patients who were in this study (71.4%), their duration since last visit to the clinic was more than two (2) months.

Most of the study participants had experienced side effects of ARVs (73.6%) with the most prevalent side effect being numbness in hands and feet (37.1%), followed by rash (21.1%) and headache (20.0%) (Figure 11).

**Figure 11: Distribution of study participants by experienced side effects**

On comparison of the different treatment related factors with adherence levels, starting with duration on ART, proportion of study participants reaching optimal adherence levels was highest among those on ART for 12 to 23 months (77.6%). Adherence was lower among participants on ART for shorter duration of less than 12 months (72.2% reached optimal adherence) and after peaking at 12 to 23 months, reduced thereafter among those on ART for 24 to

35 months and 36 months and longer (75.7 % and 75.9% respectively) (Table 10).

Adherence difference was noted among patients whose duration since last clinic visit was less than or equal to 2 months (83.8% reached optimal adherence) compared to patients whose duration since last visit was more than 2 months (73.0% reached optimal adherence).

On comparison of adherence level with pills per dose of ARVs, 76.5% of those taking one pill per dose of ARVs reached optimal adherence while among those taking two pills or more per dose of ARVs 74.6% reached optimal adherence. Though constituting a small percentage of all patients (5.7%), all the patients using Efavirenz based ARV regimen reached optimal adherence. Amongst those using Nevirapine based ARV regimen, those using combination of Stavudine, Lamivudine and Nevirapine had a higher proportion reaching optimal adherence (76.5%) as compared to those using Zidovudine, Lamivudine and Nevirapine (66.0%). Among patients who had never had side effects of ARVs, 82.4% reached optimal adherence while 73.8% of patients reached optimal adherence among those who had ever had side effects of ARVs (Table 10).

**Table 10: Comparison of adherence levels with treatment related factors of study participants**

| Adherence level | < 95 | ≥ 95 | Total | p value |
|---|---|---|---|---|
| | n (%) | n (%) | n (%) | |
| **Duration on ART (Months)** | | | | |
| < 12 | 10 (27.8) | 26 (72.2) | 36 (100) | |
| 12 – 23 | 26 (22.4) | 90 (77.6) | 116 (100) | 0.66 |
| 24 – 35 | 18 (24.3) | 56 (75.7) | 74 (100) | 0.88 |
| ≥ 36 | 13 (24.1) | 41 (75.9) | 54 (100) | 0.88 |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Duration since last visit (Months)** | | | | |
| ≤ 2 | 13 (16.3) | 67 (83.8) | 80 (100) | 0.08 |
| > 2 | 54 (27.0) | 146 (73.0) | 200 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |

| | | | | |
|---|---|---|---|---|
| **Pills taken per ARV dose** | | | | |
| 1 | 51 (23.5) | 166 (76.5) | 217 (100) | 0.89 |
| ≥ 2 | 16 (25.4) | 47 (74.6) | 63 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **ARVs regimen taken** | | | | |
| Stavudine, Lamivudine, Nevirapine | 50 (23.5) | 163 (76.5) | 213 (100) | |
| Stavudine, Lamivudine, Efavirenz | 0 (0.0) | 10 (100.0) | 10 (100) | 0.12 |
| Zidovudine, Lamivudine, Nevirapine | 17 (34.0) | 33 (66.0) | 50 (100) | 0.17 |
| Zidovudine, Lamivudine, Efavirenz | 0 (0.0) | 6 (100) | 6 (100) | 0.34 |
| Abacavir, Didanosine, Kaletra | 0 (0.0) | 1 (100.0) | 1 (100) | 1.00 |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Had side effects of ARVs** | | | | |
| Yes | 54 (26.2) | 152 (73.8) | 206 (100) | 0.81 |

| | | | |
|---|---|---|---|
| No | 13 (17.6) | 61 (82.4) | 74 (100) |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** |

### 3.4.6 Analysis of relationship between adherence level with health service related factors

Most of the patients waited for three (3) hours or less to get services at the Mnazi Mmoja HIV care and treatment clinic (65.4%). Only 18.2% of the patients reported to be receiving food support through the clinic. All patients (100%) reported to have been counseled on ART prior to initiation of ART; however slightly less than half (47.4%) of the patients reported that they continued being counseled on ART even after they had started ART. Almost all patients (98.2%) were having a good relationship with the health care workers (HCWs) at the clinic. When participants were asked why they reported to be having a good relationship with the HCWs, reasons such as the HCWs having a good approach to patients, providing services well, maintaining confidentiality were stated. Also almost all patients (99.6%) reported that there have been no ARV stock outs at this clinic since they started ART.

There was no statistically significant difference in adherence levels among patients who received food support (76.5% reached optimal adherence) as compared to those who didn't receive food support (76.0% reached optimal adherence). The same was true for patients who received adherence counseling after starting ART (76.7% reached optimal adherence) as compared to patients who didn't receive adherence counseling after starting ART (75.8% reached optimal adherence). A higher proportion of patients was able to reach optimal adherence level among those who waited for HIV care and treatment services for three (3) hours or less (77.6%) as compared to those who waited longer for durations of more than 3 hours (73.2%). This is shown in Table 11.

**Table 11: Comparison of adherence levels with health service related factors of study participants**

| **Adherence level** | **< 95** | **≥ 95** | **Total** | **p value** |
|---|---|---|---|---|
| | **n (%)** | **n (%)** | **n (%)** | |
| **Food support** | | | | |
| Yes | 12 (23.5) | 39 (76.5) | 51 (100) | 0.91 |
| No | 55 (24.0) | 174 (76.0) | 229 (100) | |

| | | | | |
|---|---|---|---|---|
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Duration of waiting for services (Hours)** | | | | |
| ≤ 3 | 41 (22.4) | 142 (77.6) | 183 (100) | 0.5 |
| > 3 | 26 (26.8) | 71 (73.2) | 97 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |
| **Continuing counseling on ART after initiation of treatment** | | | | |
| Yes | 21 (23.3) | 69 (76.7) | 90 (100) | 0.99 |
| No | 46 (24.2) | 144 (75.8) | 190 (100) | |
| **Total** | **67 (23.9)** | **213 (76.1)** | **280 (100)** | |

## 3.5 Focused group discussions findings

Two focused group discussions (FGDs) were conducted one for male and one for female participants. Female FGD consisted of 7 participants, the range of duration on ART for the participants ranged from 6 months to 5 years. Male FGD consisted of 8 participants, the range of duration on ART for the participants ranged from 6 months to 4 years.

### 3.5.1 Patients expectations when they started ART

There was a consensus among study participants that when they started ART they expected to have better health, go back to normal life and prolong life. Most reported that their expectations have been met. One participant reported "*When I was diagnosed to be HIV positive I thought it was the end of life for me, but after starting ART, I got better within a week of starting ART, it was even beyond my expectations, now I'm like anybody else who doesn't have HIV, I work, I got married*".

Some, however, were hoping to get cured completely and for them this expectation had not been met. These patients therefore reported that although they were continuing with their ART, they were not very much motivated to take the treatment as they knew they could not be cured completely.

Some of the women reported to have taken ARVs for prevention of mother to child transmission of HIV and for these also their expectations had been met because their children had been tested and they were negative. One participant reported "*I saw the success of ARVs because when I started taking ARVs I was pregnant and I couldn't do my work properly, but after starting ARVs I was able to continue with my everyday activities, and I thank God, I gave birth to*

*my child and breastfed the child for three months and at one and a half years when I took her to be tested, my child was found to be HIV negative*".

### 3.5.2 Patients' experiences with ART

Patients reported that at the beginning of starting ART it was difficult for them to take ART regularly but now it was part of their lives. They carried their ARVs everywhere they went. One participant reported, "*Taking ARVs is like brushing my teeth, you have to do it before doing anything else"*. Most reported to have had one side effect or another but that did not stop them from taking ARVs.

### 3.5.3 Factors reported to be affecting adherence (individual, family, work and community related)

Participants of the FGDs reported that several reasons were causing patients to take ARVs optimally but most were related to the added value of treatment i.e. one knowing that treatment could help.

Knowing that without ARVs one would become sick again as the viruses would attack was what motivated most participants to take ARVs optimally. One participant reported "*It is better for me to miss taking food but not to miss*

*taking my ARVs*". Patients were aware that stopping ARVs could make health deteriorate and could cause viral resistance.

Fear of stigma if one became sick again also made patients adhere well to treatment. One patient reported *"Parents are discriminating against me, so if I become sick who will I depend on? That makes me work harder at taking my ARVs".* Having a goal in life was another factor that assisted one to take ARVs well, e.g. the women mainly reported that wanting to live in good health so as to be able to take care of their children enabled them adhere to ART. Also looking at where one came from i.e. having had bad health while now one was doing well motivated patients to take ARVs well. Having a partner, family or co-workers to support one to take ARVs, having something to remind one to take ARVs, good counseling given by the adherence counselors were the other factors that helped in adhering well to treatment. "*My partner is very close to me and reminds me to take ARVs, even when I am asleep, he wakes me up to remind me to take my ARVs*", one FGD participant reported.

Factors which made patients not take ARVs properly were reported to be forgetting, traveling, lack of food, alcohol, drugs getting finished, number of pills per dose, frequency of taking ARVs, getting tired of taking ARVs,

alcohol, and feeling that one was well. One patient who had been using ARVs for five years reported "*I don't know maybe because I have been on treatment for long, when I started I was really eager to take ARVs well as I wanted to be like people who are HIV negative, but now I keep forgetting because I'm well*".

Most families supported one to take ARVs but in places of work and in the community there were problems of stigma and discrimination. This negatively affected adherence to ART among PLHA. Both men and women participants agreed that women sometimes did not disclose their HIV status to their husbands for fear of getting divorced and this made them not adhere to treatment well as they had to take their ARV drugs in hiding. However, most patients thought that one should disclose their HIV status anyway because by not doing so one was self stigmatizing himself or herself. Therefore, they thought that they should disclose their HIV status and face the consequences as that was the best way to face stigma and discrimination and with time people would get used to living with PLHAs normally.

### 3.5.4 Relationship with health care workers

Most health care workers in HIV care and treatment clinic were reported to be treating the patients well. "*They are very patient, the doctors can spend up to*

*half an hour with you so at make sure you don't leave before they know what your problem is*", one participant reported.

However, stigma and discrimination existed in hospital wards as all participants had some bad experiences to report on how they were handled in hospital wards by the health care workers. This happened both for themselves and for their children if admitted. They reported incidences of being put in isolation wards for diarrhea patients even when they didn't have diarrhea. Also they were not taken care of by the nurses and had to wait for relatives or fellow PLHAs to come and take care of them. One patient reported "*My child was discharged although she was not well once she was diagnosed to be HIV positive*".

### 3.5.5 Quality of adherence counseling provided

The system of counseling on adherence together with a partner or any other treatment buddy was reported to be good. Also study participants reported that having peer counselors do adherence counseling was good as it motivated the patients to adhere to treatment when they saw fellow PLHAs doing well on treatment. The peer counselors also had experiences to share on their use of ARVs which health care workers would not have. One FGD participant

reported "*I see a difference in the adherence counseling being given before by health care workers and the one given now by peer counselors, the peer counselors counsel you on ARVs and then tell you that like you I'm HIV positive and I'm also using ARVs, before I was sick but now I'm well*". The participant went on to say "*Peer counselors know how to help you, they explain to you well, you just get motivated*". It was reported by FGD participants that quring adherence counseling given by both HCWs and peer counselors, all the important aspects of adherence counseling were covered including how to take the ARV drugs, side effects of drugs, avoiding alcohol and cigarettes, prevention of new infections and implications of stopping ARVs including development of viral resistance. From the discussions, however, it seemed that adherence counseling was done only before starting ART and was not ongoing.

### 3.5.6 Suggestions for improving adherence

Participants thought that adherence would be much better if the frequency of taking ARVs could be decreased. They also thought that the current ARV drugs which were white in colour and looked like paracetamol tablets improved adherence as one could take them anywhere without fear of stigma and discrimination. Other factors that emerged during FGD include getting

food support and getting a loan to start an income generating activity once one is well. One participant said that something should be done for children who were being stigmatized while attending school. Disclosure of one's HIV status was also reported to be a factor that improved adherence and hence those who had not disclosed should be supported to do so.

Participants also suggested that it would be good to have regular meetings of people using ART in the clinics to discuss their experiences as a group. In order to empower peer counselors more and be able to give them more responsibilities, peer counselors should be given further training on how to follow up patients on ART particularly be given further counseling and negotiation skills. Women also thought that partners should be encouraged to test and if found negative should be counseled on how to live with an HIV positive partner without divorcing them. "*Training should be provided to male partners because immediately they are told they are HIV negative while their female partners are HIV positive, they divorce their wives. They don't even wait to repeat the test after three months. I know many such cases. The man just sees you as being promiscuous*", a female FGD participant reported.

# CHAPTER 4

## 4.0 DISCUSSION

This study found that majority of the patients attending the Mnazi Mmoja hospitals' HIV care and treatment clinic are women. This finding is consistent with the HIV infection patterns in Zanzibar whereby women are 4 times more HIV infected than males (ZACP, 2003). The distribution of the study participants by other demographic characteristics such as age, district of residence and level of education are also consistent with HIV infection patterns in Zanzibar. However, the fact that HIV infection in Zanzibar affects high risk groups such as IDUs more is not reflected among these study participants whereby only 6.1% of study participants were substance abusers (injection and non-injection drug users). This indicates that most of those HIV infected

among high risk groups such as IDUs may not be accessing HIV care and treatment services.

The study found that majority of the patients who had been on ART for six (6) months or more at Mnazi Mmoja hospitals' HIV care and treatment clinic were reaching optimal adherence. However, almost a quarter of the patients were not reaching optimal adherence. Although this proportion is relatively small as compared to those who were reaching optimal adherence; consequences of suboptimal adherence which include treatment failure and development of viral resistance are severe (Bangsberg *et al.,* 2006, Peterson *et al.,* 2000), and therefore this proportion needs to be addressed.

The proportion of patients who were reaching optimal adherence at this clinic (76%) was comparable to that found by a meta analysis of studies done in 12 sub-Saharan African countries among patients in early treatment programmes (77%) (Mills *et al.,* 2006). However, it is much higher than that found by a study done in Tanzania in the regions of Arusha and Dar es Salaam which found only 21% of patients were reaching optimal adherence (Irunde *et al.,* 2005). The good adherence levels documented in Zanzibar might have been as a result of several factors including all patients receiving adherence counseling

prior to initiation of ART, disclosure of HIV status to at least one person, the good relationship between patients and health care workers of this clinic, having no ARV drug stock outs and ability of the patients to fit the twice a day ARV doses into their daily activities. Lack of these factors have been documented in previous studies to affect adherence to ART negatively (Gifford *et al.,* 2000, Miller *et al.,* 2003, Schneider *et al.,* 2004, Irunde *et al.,* 2005, Dahab *et al.,* 2008).

The outcome of optimal and suboptimal adherence was clearly demonstrated when comparison of CD4 cell count gain was done for patients who were adhering optimally to ART and those who were not. Those who were adhering optimally to ART were able to gain a much higher CD4 cell count as compared to those who were not. This observation is consistent with findings of other studies (Sarna *et al.,* 2008). An interesting observation is that this finding is statistically significant for patients who had been on ART for less than 24 months but not for those who had been on ART for longer durations. From this, one may speculate that ART is much more effective within the first two years and over longer durations whether one adheres well to treatment or not, the effectiveness of ART on CD 4 count seems to wane. This finding warrants further investigation to ascertain its existence.

Analysis of relationship between adherence level and different factors which may have a possibility of affecting it either negatively or positively was done. These included demographic, social, economic, behavioural, treatment and health service related factors.

On comparison of demographic characteristics with adherence, a higher proportion of those female, widowed, and aged between 40 and 44 years reached optimal adherence as compared to their counterparts. Increased level of education also caused higher proportions of patients to reach optimal adherence but these findings were not statistically significant. Therefore, adherence could not be associated with demographic characteristics in this study. Some previous studies have documented an association of some demographic characteristics with adherence; this includes level of education whereby formal education is documented to cause a better understanding of the medication dosing (Pinheiro *et al.,* 2002, Golin *et al.,* 2002, Miller *et al.,* 2003). Another demographic characteristic which is associated with adherence in previous studies is age (Sullivan *et al.,* 2007). Consistent with the findings of this study, no other study has documented an association of sex and marital status with adherence.

On comparison of adherence with economic factors, adherence was not significantly associated with employment status, income per month, incurring other costs for treatment of HIV which in the case of this study was mostly buying medicines which were not available in the HIV care and treatment clinic and cost of transport to the HIV care and treatment clinic. The probable reason for this finding was that with majority of the study participants coming from Urban and West districts (83.9%) which are near Mnazi Mmoja hospital, they did not incur a high cost for transport to and from the clinic and, therefore, there was no difference in this characteristic among study participants. Also it was not associated with income per month probably because ARVs are provided free of charge to everybody attending the clinic. Previous studies conducted in the USA suggest that income affects adherence (Miller *et al.,* 2003, Golin *et al.,* 2002).

The quantitative findings of this study documented that having somebody to remind one to take ART, using something to remind one to take ART, belonging to an organization of PLHA, thinking positively about disclosing one's HIV status to others were not significantly associated with adherence. However, the FGD findings of this study highly recommended the idea

of having somebody to remind one to take ART as causing a significant contribution towards optimal adherence. In the same findings, lack of disclosure because of stigma and discrimination is thought to hinder adherence. Social support and use of a reminder to take ART has been documented to affect adherence positively in previous studies conducted in Ethiopia and USA. (Amberbir *et al.,* 2008, Golin *et al.,* 2002).

This study was not able to find anybody who admitted current use of alcohol, drugs of abuse or traditional medicine and therefore comparison was made between adherence and ever use of the above three items. However, a statistically significant association between adherence and ever use of alcohol, ever use of drugs of abuse and ever use of traditional medicine could not be demonstrated. The study of Golin and others conducted in the USA also could not demonstrate an association between ever use of drugs of abuse and adherence (Golin *et al.,* 2002).

Patients who were just starting ART were more likely to be poor adherers but after one year on treatment, adherence improves. Though this finding is not statistically significant, it is consistent with some of the reasons given by patients on why they missed doses of ARVs whereby many said that they used

to forget a lot at the beginning of starting ART. Also when patients were asked about their experience of using ART during focused group discussions (FGDs), they reported that it was very difficult at the beginning but with time they got used to taking ARVs. However, after two years on treatment, adherence wanes again. This observation could be explained by two possible explanations; one is that pill fatigue may have started and another is that at this time, one may have improvement in one's health and this has been documented to sometimes have a negative effect on adherence (Dahab *et al.,* 2008). Both these reasons were also reported by study participants in FGDs. Similar observations have also been documented in previous studies (Amberbir *et al.,* 2008)

The number of pills taken per dose of ARVs, ARV drug regimen taken by the patient and experiencing side effects was not statistically significantly associated with adherence in this study. The same was also found in the USA where number of pills taken per dose could not be associated with adherence (Golin *et al.,* 2002). Previous studies have also not documented an association between experiencing side effects and adherence (Sarna *et al.,* 2008, Amberbir *et al.,* 2008).

Patients whose last clinic visit was more than two months prior to date of interview were poor adherers as compared to those whose last clinic visit was less than two months ago. Although this finding was not statistically significant, it had a borderline statistical significant (p value 0.08) and therefore this relationship warrants further investigation in future studies. This is because if an association is determined, it could have an implication on how patients' appointments to the HIV care and treatment clinic are scheduled.

From the qualitative findings of this study, the patients thought that receiving food support would improve adherence to ART. Previous qualitative studies have also documented the same (Irunde *et al.,* 2005). However, analysis revealed that there is no association between receiving food support and ART adherence. This may be explained by the fact that the qualitative finding was based on patient's perception but when an association between food support and adherence is determined objectively, none is found. Another possible explanation is that receiving food support at Mnazi Mmoja Hospital has made the recipients' food status be the same as patients who didn't receive food support and hence no difference in ART adherence could be observed between the receipients as compared to non-recipients of food support. Therefore in the future a clinic which is providing food support could be compared to one

which is not to ascertain this association.

This study also found no association between waiting period at the clinic and adherence. This factor was documented to affect adherence in previous qualitative studies (Irunde *et al.,* 2005). However, the range of time of waiting for services in the study conducted in Dar es Salaam and Arusha was longer (1 to 8 hours) than for this study (1 to 6 hours). The longer waiting hours in Arusha and Dar es Salaam could have caused some patients to leave without receiving services and hence causing poor ART adherence.

An important component of adherence is proper preparation of patients by being given adherence counseling prior to initiation of ART and ongoing while receiving ART (Miller *et al.,* 2003). As previously stated Mnazi Mmoja hospital's HIV care and treatment clinic is doing well in this in that all patients reported to have received at least one session of adherence counseling prior to initiation of ART. Ongoing adherence counseling, however, was only reported by about a half of the patients on ART. But the patients who received ongoing adherence counseling and those who did not were reaching the same adherence levels. With this finding, several questions are raised including:

Is there a need of ongoing adherence counseling for everybody or should it be targeted to those who need it i.e. poor adherers?

Is the quality of ongoing adherence counseling equally good as compared to that given at the initiation of ART?

Are we addressing treatment expectations, if not then they are negatively affecting adherence

One may not be able to answer all the questions above in the setting of this study. But when patients were asked for the durations that adherence counseling before initiation of ART took and that of ongoing counseling, the mean time for the former was much higher (1.5 hours vs. 0.5 hours). Although a long session of ongoing adherence counseling may not be necessary for everybody, it is certainly necessary for poor adherers and, therefore, ongoing adherence counseling at this clinic needs to be targeted and its quality improved.

**Limitations of the study**

Adherence was assessed by ARVs dispensers' records of ARV doses dispensed and counts of pills left on subsequent visit to the clinic. Although this method can estimate adherence better than self report, it can still be

inaccurate because patients know that their pills will be counted when they go to the clinic and, therefore, if they realize that they have too many pills left they may decide to leave some pills at home. This kind of study, therefore, could benefit from a more objective measure of adherence in the future such as checking of serum drug levels. My study findings may also not be generalizable to other HIV care and treatment clinics in Zanzibar as it has several special characteristics such as being located in a referral hospital, in town and its clients were mainly coming from the surrounding districts. Patients who have stopped treatment or have dropped from the programme were also not included while they may be having information pertinent to this study.

# CHAPTER 5

## 5.0 CONCLUSIONS AND RECOMMENDATIONS

## 5.1 CONCLUSIONS

This study found that majority of patients attending Mnazi Mmoja hospitals' HIV care and treatment clinic had optimal adherence to ART. However, a significant proportion of the patients i.e. 24% were not reaching optimal adherence. The outcome of optimal and suboptimal adherence was clearly demonstrated by use of CD4 cell count gain whereby patients who reached optimal ART adherence had significantly higher CD4 cell count gain as compared to those who had suboptimal ART adherence. Factors which were reported by all study participants and which may, therefore, be causing the high ART adherence include all patients receiving adherence counseling prior to initiation of ART, disclosure of HIV status to at least one person, the good relationship between patients and health care workers of this clinic, having

no ARV drug stock outs and ability of the patients to fit the twice a day ARV doses into their daily activities. Other positive observations which may have an impact of causing optimal ART adherence include the use of treatment buddy and peer counselors providing adherence counseling which occurs at Mnazi Mmoja hospital's HIV care and treatment clinic. This study found no association between adherence and studied demographic, social, economic, behavioural, clinical and health service related factors but there was an almost statistically significant finding of association between duration in between clinic visits and ART adherence.

## 5.2 RECOMMENDATIONS

### 5.2.1 Policy

The Ministry of Health and Social Welfare should develop and ensure implementation of a policy which will protect patients against stigma and discrimination in health care settings. Such a policy should ensure that a person is not denied of his/her right to receive medical care based on her/his HIV status. Relevant bodies should also develop policies which will protect patients against stigma and discrimination in the work setting, in schools and in the community.

### 5.2.2 Health service related

The notable proportion of patients who are having suboptimal adherence need immediate attention but currently it is difficult to detect these patients unless they fail clinically. This is because although records of ARVs remaining and dispensed for each patient are kept, calculation of adherence needs mathematical calculations which are not easy to do manually for every patient. In order to detect patients who are not adhering well timely and take necessary action, it is recommended that the ARV dispensers' records should be computerized to enable instant calculation of adherence from last visit to the present when a patient attends the clinic. This information generated can be used to target interventions such as more intensive ongoing adherence counseling, more frequently scheduled clinic appointments and planning home visits for poor adherers.

The quality of ongoing adherence counseling also needs to be improved and this counseling should be provided regularly with the intensity of the counseling based on the client's needs. In order to support this process it is recommended that more training on adherence counseling should be provided for the health care workers. It is also recommended that provider-patient ratio

should be increased so as to reduce waiting hours and also facilitate the process of providing quality ongoing adherence counseling. Interventions should also be designed to reach out to high risk groups such as IDUs, who may be infected with HIV, and provide them with HIV care and treatment services.

### 5.2.3 Research

Factors affecting adherence need further investigations using a larger sample size and if associations are determined, an analytic study should be conducted to better inform the HIV care and treatment programme in Zanzibar. In further studies, other HIV care and treatment clinics should be included as adherence levels and factors associated with it in different settings could be different. Specific areas which need further exploration in future studies include:

The relationship between adherence and CD4 cell count gain for patients who have been on treatment for durations longer than 24 months

The relationship between duration in between clinic visits and its effect on ART adherence.

The relationship between food support and ART adherence

Impact of disclosure to spouses especially among women

# REFERENCES

**Amberbir A, Woldemichael K, Getachew S, Girma B and Deribe K (2008).** Predictors of adherence to antiretroviral therapy among HIV-infected persons: a prospective study in Southwest Ethiopia. *BioMed Central Public Health*. **8**:265

http://www.biomedcentral.com/1471-2458/8/265 (Downloaded on 11th August 2008)

**Bangberg D, Acosta E, Gupta R, Guzman D, Riley E, Harrigan P, Parkin N and Deeks S (2006)**. Adherence – resistance relationships for protease and non-nucleoside reverse transcriptase inhibitors explained by virological fitness. *AIDS*. **20**:223-231

**Bini T, Testa L, Chiesa E, Adorni F, Abeli C, Castelnuovo B, Melzi S, Sollima S, Bongiovanni M and Monforte A (2000).** Outcome of a Second-Line Protease Inhibitor-Containing Regimen in Patients Failing or Intolerant of a First Highly Active Antiretroviral Therapy. *Journal of Acquired Immune Deficiency Syndromes*. **24**:115-122

**Dahab M, Charalambous S, Hamilton R, Fielding K, Kielman K, Churchyard G and Grant A (2008).** "That is why I stopped the ART": Patients' & providers' perspectives on barriers to and enablers of HIV treatment adherence in a South African workplace programme. *BioMed Central Public Health*. **8**:63

http://www.biomedcentral.com/1471-2458/8/63 (Downloaded on 23rd January 2009)

**Dahoma M, Salim A, Abdool R, Othman A, Makame H, Ali A, Abdalla A, Juma S, Yahya B, Shaka S, Sharif M, Seha A, Mussa M, Shauri O, Nganga L and Kibuka T (2006).** HIV and substance abuse: The dual epidemics challenging Zanzibar. *African Journal of Drug and Alcohol Studies.* **5**(2):130-139

**Dybul M, Nies-Kraske E, Daucher M, Hertogs K, Hallahan CW (2003).** Long-cycle structured intermittent versus continuous highly active antiretroviral therapy for the treatment of chronic infection with human immunodeficiency virus: effects on drug toxicity and on immunologic and virologic parameters. *Journal of Infectious Diseases*. **188**: 388–396

**Dybul M, Nies-Kraske E, Dewar R, Maldarelli F, Hallahan CW (2004).** A proof-of-concept study of short-cycle intermittent antiretroviral therapy with a once-daily regimen of didanosine, lamivudine, and efavirenz for the treatment of chronic HIV infection. *Journal of Infectious Diseases*. **189**: 1974–1982

**Fisher A, Laing J, Stoeckel J and Townsend J (1991).** Handbook for Family Planning Operations Research Design. *Population Council, New York*. **Second Edition**: 43-46

http://www.popcouncil.org/pdfs/frontiers/Capacity_Bldg/HbkFPOR.pdf

(Downloaded on 16th June 2009)

**Gifford A, Bormann J, Shively M, Wright B, Richman D and Bozzette S (2000).** Predictors of Self-Reported Adherence and Plasma Concetrations in Patients on Multidrug Antiretroviral Regimens. *Journal of Acquired Immune Deficiency Syndromes.* **23**:386-395

**Golin C, Liu H, Hays R, Miller L, Beck C, Ickovics J, Kaplan A and Wenger N (2002).** A Prospective Study of Predictors of Adherence to Combination Antiretroviral Medication. *Journal of General Internal Medicine*. **17**:756-765

**Irunde H, Temu F, Maridadi J, Nsimba S and Comoro C (**2005). A study on antiretroviral adherence in Tanzania: a pre-intervention perspective. http:// mednet3.who.int/prduc/Book/Tanzania_ FINAL.pdf (Downloaded on 9th March 2008)

**Miller L, Liu H, Hays R, Golin C, Ye Z, Beck C, Kaplan A and Wenger N (2003).** Knowledge of Antiretroviral Regimen Dosing and Adherence: A Longitudinal Study. *Clinical Infectious Diseases.* **36**:514-8

**Mills E, Nachega J, Buchan I, Orbinski J, Attaran A, Singh S, Bachlis B, Wu P, Cooper C, Thabane L, Wilson K, Guyatt G and Bangsberg D (2006).** Adherence to Antiretroviral Therapy in Sub-Saharan Africa and North America. *Journal of the American Medical Association*. **296**(6):679-690

**NACP (2008).** National guidelines for the management of HIV and AIDS, Tanzania

**NBS (2002).** Population and Housing Census, Tanzania

**Nischal KC, Khopkar U and Saple DG (2005).** Improving adherence to antiretroviral therapy. *Indian Journal of Dermatology, Venereology and Leprology.* **71**:316-20.

**Palella F, Delaney K, Moorman A, Loveless M, Fuhrer J, Satten G, Aschman D, Holmberg S and the HIV Outpatient Study Investigators (1998)**. Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. *The New England Journal of Medicine.* **338**(13):853-860.

**Parienti J, Das-Douglas M, Massari V, Guzman D, Deeks S, Verdon R and Bangsberg D (2008).** Not all missed doses are the same: Sustained NNRTI Treatment Interruptions Predict HIV Rebound at Low-to-Moderate Adherence levels. *PLoS ONE*. **3**(7):e2783

**Paterson D, Swindells S, Mohr J, Brester M, Vergis E, Squier C, Wagener M and Singh N (2000).** Adherence to Protease Inhibitor Therapy and Outcomes in Patients with HIV infection. *Annals of Internal Medicine*. **133**:21-30

**Pinheiro C, de-Carvalho-Leite J, Drachler M and Silveira V (2002).** Factors associated with adherence to antiretroviral therapy in HIV and AIDS patients: a cross sectional study in Southern Brazil. *Brazilian Journal of Medical and Biological Research*. **35**:1173-1181

**Sarna A, Pujari S, Sengar A, Garg R, Gupta I and van Dam J (2008)**. Adherence to antiretroviral therapy and its determinants amongst HIV patients in India. *Indian Journal of Medical Research.* **127**(1):28-36

**Schneider J, Kaplan S, Greenfield S, Li W and Wilson I (2004).** Better Physician-Patient Relationship Are Associated with Higher Reported Adherence to Antiretroviral Therapy in Patients with HIV Infection. *Journal of General Internal Medicine*. **19**:1096-1103

**Sullivan P, Campsmith M, Nakamura G, Begley E, Schulden J and Nakashima A (2007).** Patient and Regimen Characteristics Associated with Self-Reported Non Adherence to Antiretroviral Therapy. *PLoS ONE*. **6**:e552

http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1891091&blobtype=pdf

(Downloaded on 9th March 2008)

**TACAIDS/ZAC/NBS (**2008). Tanzania HIV and AIDS and Malaria Indicator Survey.

**UNAIDS (2008).** Report on Global AIDS Epidemic. August 2008

**UNAIDS (2007)**. AIDS Epidemic Update. December 2007

**WHO (2006)**. Antiretroviral therapy for HIV infection in adults and adolescents: Recommendations for a public health approach. 2006 Revisions

**WHO (2007)**. Towards universal access. Scaling up priority HIV and AIDS interventions in the health sector. Progress Report: WHO; 2007 April 7

**ZACP (2003)**, Community based HIV magnitude validation survey

**ZACP (2008a)**. ANC Surveillance Report

**ZACP (2008b)**. Annual Progress Report

**ZACP (2008c)**. Respondent Driven Sampling Report

# APPENDICES

## Appendix 1: WHO Clinical Staging of HIV Disease in Adults and Adolescents

**Clinical Stage 1**

Asymptomatic

Persistent generalized lymphadenopathy

**Clinical Stage 2**

Moderate unexplained weight loss (under 10% of presumed or measured body weight)

Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, paryngitis)

Herpes zoster

Angular cheilitis

Recurrent oral ulceration

Popular pruritic eruptions

Seborrhoeic dermatitis

Fungal nail infections

**Clinical Stage 3**

Unexplained severe weight loss (over 10% of presumed or measured body weight)

Unexplained chronic diarrhea for longer than longer than one month

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

Persistent oral candidiasis

Oral hairy leukoplakia

Pulmonary tuberculosis

Sever bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)

Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

Unexplained anaemia (below 8 g/dl), neutropenia (below 0.5 x 109/1) and/or chronic thrombocytopenia (bleow 50 x 109/1)

**Clinical Stage 4**

HIV wasting syndrome

Pneumocystis pneumonia

Recurrent severe bacterial pneumonia

Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site)

Oesophageal candidiasis (or candididasis of trachea, bronchi or lungs)

Extrapulmonary tuberculosis

Kaposi sarcoma

Cytomegalovirus infection (retinitis or infection of other organs)

Central nervous system toxoplasmosis

HIV encephalopathy

Extrapulmonary cryptococcosis including meningitis

Disseminated non-tuberculous mycobacterial infection

Progressive multifocal leukoencephalopathy

Chronic cryptosporidiosis

Chronic isosporiasis

Disseminated mycosis (extrapulmonary histoplasmosis, conccidiomycosis)

Recurrent septicaemia (including non-typhoidal Salmonella)

Lymphoma (cerebral or B cell non-Hodgkin)

Invasive cervical carcinoma

Atypical disseminated leishmaniasis

Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy

## Appendix 2: Questionnaire on adherence to antiretroviral therapy and associated factors among HIV and AIDS patients at Mnazi Mmoja Hospital, Zanzibar, 2008

Questionnaire number: _____ Interview Date: _____

Interviewer name: _____ Patient's CTC number: _____

**Socio-Demographic information:**

Sex:

Female

Male

Date of birth:_____ Age at last birthday: _____ (Years)

Marital status:

Single

Married

Cohabiting

Separated

Divorced

Widowed

District of Residence: _____

Religion:

Muslim

Christian

Hindu

Others (Please mention) _____

Education level:

No formal education

Some primary education

Completed primary education

Some secondary education

Completed secondary education

Higher education (Advanced secondary education/College/University)

Occupation:

Employed in public sector

Employed in private sector

Self employed

None [ Go to question 10]

What is your average income per month? Tshs _____

How many dependants do you have? ____ [ Go to question 11]

If not employed, how do you support yourself?

_____

**Clinical information:**

When did you know your HIV status? _____ (Please mention the month and year)

How did you know your HIV status?

Voluntary Counseling and Testing (VCT)

Provider Initiated Testing and Counseling (PITC)

HIV counseling and testing for Prevention of Mother To Child Transmission of HIV (PMTCT)

Medical check up for employment/studies

Diagnostic testing (Had TB)

Others (Please mention) _____

When did you start ART? _____ (Please mention the month and year)

How many pills of ARVs are you taking per dose? _____

**Adherence levels:**

In the past 3 days:

Have you missed taking your ARV drugs?

Yes

No

If yes, how many doses did you miss? _____

Have you been late in taking your ARV drugs?

Yes

No

If yes, by how long? _____ ( Hours/Minutes)

In the past 1 week:

Have you missed taking your ARV drugs?

Yes

No

If yes, how many doses did you miss? _____

Have you been late in taking your ARV drugs?

Yes

No

If yes, by how long? _____ ( Hours/Minutes)

Have you missed taking ARVs in the past 1 month?

Yes

No

If yes, when did you miss? _____ (Weeks ago)

How many doses did you miss? _____

Since you started ART, have you ever missed taking ARVs?

Yes

No

If yes, when did you miss? _____ (Months ago)

How many doses did you miss? _____

If you have ever missed taking ARVs, why did you miss?

_____

_____

Count remaining number of pills from the last prescription given that the patient has come to the clinic with: _____ (Doses)

**Factors associated with adherence**

**Knowledge on ART**

What are ARVs?

Drugs to reduce effects of HIV

Drugs to reduce HIV viruses in the body

Others (Please mention)_____

Why does one take ARVs?

To reduce HIV viruses in the body

To reduce effects of HIV

To prevent opportunistic infections

To increase immunity/CD4 in the body

Others (Please mention)_____

From whom did you first learn about ARVs?

Doctor

Nurse

Pharmacist

Counselor

PLHA

Friend

Relative

Media

Others (Please mention) _____

What are the important things to consider when one is taking ARVs?

Side effects

Time of taking ARVs

Avoiding alcohol/drugs of abuse/cigarettes

Avoiding unsafe sex

Attending HIV care and treatment clinic as per the appointment given

Others _____

Do you believe that it is important to take ARVs as prescribed?

Yes

No

Why?

_____

_____

What can make you stop taking ARVs?

If I no longer have opportunistic infections

If I get tired of swallowing pills

If I'm told to stop taking by a doctor/nurse/pharmacist

Drinking alcohol

Unplanned travelling

Nothing can make me stop taking ARVs

Others _____

If you forget to take a dose of ARVs, what do you do?

I wait for the time of the next dose to take the next dose only

I wait for the time of the next dose to take two doses

If I remember within 2 hours of the time I'm supposed to take the dose, I take it

Others _____

**Treatment support**

Do you have people who remind you to take ARVs?

Yes

No [Go to question 32]

How many are they? _____

Who are they?

Spouse

Sibling

Parent

Child

Friend

Housemate

Workmate

Others (Please mention) _____

For how long have they been reminding you? _____ (Give duration in months)

Do you use anything to remind you when to take ARVs?

Yes

No [Go to question 34]

What do you use?

Clock/Watch alarm

Phone alarm

Radio

Sunrise and sunset

Others (Please mention) _____

Do you belong to any organization of people living with HIV and AIDS or any other organization providing social or psychological support?

Yes

No [Go to question 38]

For how long have you been a member of this organization? _____ (Give duration in months)

Which organization is it? _____

What support do you get from this organization?

Food

Money

Counselling on use of ARVs

Mosquito nets

Mattresses

Others (Please mention) _____

**Cost of accessing ART**

How much do you spend for transport to the hospital for each clinic visit?

Tshs _____

Do you incur any other costs for your treatment for HIV?

Yes

No [Go to question 42]

What are these costs? _____

How much cost do you incur? Tshs _____

**Health service related factors**

Are you currently under the food support given through the clinic?

Yes

No [Go to question 45]

If yes, is the food you are getting enough?

Yes [Go to question 45]

No

If no, why?

_____

How long do you wait to be seen by the doctor at this clinic?

_____ (Hours/Minutes)

Were you counseled on ARVs prior to initiation of treatment?

Yes

No [Go to question 49]

How many times were you counseled prior to initiation of treatment?

_____

How long did each of the counseling session take? __ (Hours/Minutes)

Are you counseled on ARVs after initiation of treatment?

Yes

No [Go to question 52]

How often are you counseled on ARVs after initiation of treatment?

Every week

Every 2 weeks

Every month

Every 2 months

Every 3 months

Every 6 months

Others (Please mention) _____

How long does each counseling session take? _____ (Hours/Minutes)

What is included in the counseling session on ARVs?

What are ARVs

How ARVs work

Importance of adherence to ARVs

How ARVs should be taken (Dose and time)

How to store ARVs

Food requirements of ARVs

Side effects of ARVs

What to do when one gets side effects of ARVs

Others (Please mention) _____

Who is giving the ARVs counseling?

Doctor

Nurse

Pharmacist

PLHA

Others (Please mention) _____

If you have problems with your treatment, who do you ask for help?

Doctor

Nurse

Pharmacist

PLHA

Others (Please mention) _____

How is the help you get from this person?

Excellent Good Fair Poor

Have you ever had side effects of ARVs?

Yes

No [Go to question 61]

Which side effects did you experience?

Nausea and vomiting

Diarrhoea

Rash

Headache

Dizziness

Fatigue

Numbness/pain in hands or feet

Abdominal pain

Back pain

Muscle pain or weakness

Chills/fever

Insomnia

Nightmares

Anxiety

Depression

Others (Please mention) _____

When you had side effects what did you do?

I told a doctor/nurse/pharmacist

I persevered because I had already been told that they can occur

Others (Please mention)_____

What happened or was done?

I was counseled on side effects of ARVs

I was given medicine to reduce the side effects of ARVs

The side effects disappeared without any intervention

Others (Please mention)_____

For how long did the side effects last? _____ (Days)

Have there been any ARV drug stock outs at this clinic since you started ART?

Yes

No [Go to question 64]

How many times since you started ART? _____

When there was stock out, what did you do?

_____

How would you rate your relationship with the staff at this clinic?

Excellent Good Fair Poor

Why did you rate the relationship as you did above?

Staff have a good approach

Staff provide services well

Staff maintain confidentiality

Staff like us i.e. their clients

Staff teach us a lot of things

Others (Please mention) _____

**Individual factors**

Have you ever taken alcohol in your life ?

Yes

No [Go to question 69]

If yes, are you currently taking alcohol?

Yes [Go to question 69]

No

If no, when did you stop taking alcohol?_____ (Weeks/months ago)

Have you ever taken any drugs of abuse in your life?

Yes

No [Go to question 74]

If yes, which drugs of abuse?

Marijuana

Miraa

Cocaine

Heroin

Others (Please mention) _____

How do you take the drugs of abuse?

Ingestion

Inhalation

Smoking

Injection

Others (Please mention) _____

Are you currently taking any drugs of abuse?

Yes [Go to question 74]

No

If no, when did you stop taking drugs of abuse?_____ (Weeks/Months ago)

Have you ever taken a traditional medicine for treatment of HIV?

Yes

No [Go to question 76]

If yes, what traditional medicine did you take? _____

Have you ever taken a traditional medicine together with ARVs?

Yes

No [Go to question 79]

If yes, what traditional medicine did you take? _____

For what reasons did you take the traditional medicine?

_____

Are you currently taking any traditional medicines?

Yes

No [Go to question 82]

What traditional medicine are you taking? _____

When did you start taking the traditional medicine? _____(Weeks/

Months ago)

Does taking ARVs interfere with your everyday activities?

Yes

No [Go to question 84]

If yes, how does it interfere with your everyday activities?

_____

**Disclosure, Stigma and Discrimination**

Who knows your HIV status?

Spouse

Sibling

Parent

Child

Friend

Housemate

Workmate

Others (Please mention)_____

How did they know?

I told them

They were told by health care worker

Others (Please mention) _____

How do you feel about people knowing that you are HIV positive?

It's good for them to know

It's ok

I don't want them to know

Others (Please mention)_____

Those who know that you are HIV positive how are their reactions?

They stigmatize against me

They discriminate me

They talk badly about me

They spread the news of my HIV status to others

They treat me as well as they used to treat me before

Others (Please mention) _____

If other people found out that you are HIV positive, how would they react?

They will stigmatize against me

They will discriminate me

They will talk badly about me

They will spread the news of my HIV status to others

They will treat me as well as they used to treat me before

Others (Please mention)_____

Does your employer know that you are HIV positive? (N/A for for self employed and unemployed participants)

Yes [Go to question 91]

No

If no, would you tell him/her that you are HIV positive?

Yes

No

Why?_____

**General opinions from patient**

What are the main facilitators for adherence to ART?

_____

_____

_____

What are the main barriers for adherence to ART?

_____

_____

_____

What are your suggestions to overcome the barriers for adherence to ART you mentioned above?

_____

_____

_____

This is the end of the interview

Thank you very much for your cooperation and for using your time

## Appendix 3: Records review form on adherence to antiretroviral therapy and associated factors among HIV and AIDS patients at Mnazi Mmoja Hospital, Zanzibar, 2008

Questionnaire number: _____Record review Date: _____

Record reviewer's name: _____Patient's CTC number: _____

**From clinical records check:**

Baseline CD4 cell count:_____ Date checked: _____

CD4 cell count after 6 months: _____ Date checked: _____

CD4 cell count after 12 months: _____ Date checked: _____

CD4 cell count after 18 months: _____ Date checked: _____

CD4 cell count after 24 months: _____Date checked: _____

CD4 cell count after 30 months: _____ Date checked: _____

CD4 cell count after 36 months: _____ Date checked: _____

The ARVs that the patient is taking (Check in the last visit):

Stavudine, Lamivudine, Nevirapine

Stavudine, Lamivudine, Efavirenz

Zidovudine, Lamivudine, Nevirapine

Zidovudine, Lamivudine, Efavirenz

Abacavir, Didanosine, Kaletra

Other medications that the patient is receiving (Check in the last visit):

_____

_____

_____

How many times the patient has experienced side effects since s/he started ART: _____

Please mention the side effects that the patient has ever experienced:

Nausea and vomiting

Diarrhoea

Rash

Headache

Dizziness

Fatigue

Numbness/pain in hands or feet

Abdominal or back pain

Muscle pain or weakness

Chills/fever

Insomnia

Anxiety

Depression

Others (Please mention) _____

In the last visit was the patient experiencing any side effects?

Yes

No

Check and record the following from ARV dispensers records:

Date of last visit: _____

Duration since last visit: _____ (Days) (*)

Number of doses of ARVs taken home on the last visit: _____

Number of remaining ARV doses patient is expected to have today: __ (*)

Number of ARV doses that the patient actually has today (Pills left) :

_____

Missed doses = e-d = _____ (*)

**Please Note:**

**Do not fill the items with a star (*)**

## Appendix 4: Focused group discussion guide with ARV users

Introductory remarks, explain purpose of the study, reassurance about confidentiality.

**Questions for FGD with ARV users**

What were your expectations when you started ART? Were the expectations met or not? Why?

What is you experience with ART? (Probe about adherence, side effects)

What makes you adhere to ART? What makes you not adhere to ART?

How do you think you are being handled by the health care workers? (Probe about confidentiality, respect, being listened to, time spent with patient, waiting time, payment for services)

What do you think about the counseling that you receive? (Probe on importance of adherence)

What support is available in the family, in the workplace, in the community? (Probe about stigma and discrimination)

What do you think could be done to help people adhere to ART?

**Mnazi Mmoja hospital is located here**