

## **TITLE**

**ADHERENCE TO ANTIRETROVIRAL THERAPY AT THE DORA  
NGINZA HOSPITAL ADULT WELLNESS CLINIC, PORT ELIZABETH  
SOUTH AFRICA.**

**BY**

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| <b>Table of Contents</b>                         | <b>Page</b> |
|--|-------------|
| Declaration of originality                       | 3           |
| Acknowledgement                                  | 4           |
| Dedication                                       | 6           |
| Abstract   | 7           |
| Introduction                                     | 8           |
| Literature Review                                | 10          |
| Aim and Objectives                               | 18          |
| Methods  | 19          |
| Ethical Considerations                           | 25          |
| Results / Analysis of Results                    | 28          |
| Discussion of Results                            | 58          |
| Limitations                                      | 62          |
| Conclusion                                       | 63          |
| Recommendations                                  | 63          |
| References                                       | 65          |
| Addendum 1- Questionnaire                        | 68          |
| Addendum 2 – Semi structured interview questions | 81          |
| Addendum 3 – Ethics Committee – PEHC             | 82          |
| Addendum 4 – Ethics Committee – SU.              | 83          |
| Addendum 5 – Informed Consent                    | 84          |
| Addendum 6 – Letter to Medical Superintendent    | 86          |

**Declaration of Originality.**

I Dr. Febisola Ibilola Ajudua hereby declare that this dissertation is my own idea and the result of my own work; that it has not been submitted for any degree or examination at any other University, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

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**Signed**

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**Date**

## **Acknowledgement**

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Dr Brown, the Chairperson Ethics Committee, Port Elizabeth Hospital Complex

Dr Rank, Clinical Governance manager,

**DEDICATION.**

I dedicate this work to my children, Henry, Emmanuella and Ruth.

## **ABSTRACT.**

**Introduction:** Sub Saharan Africa is home to approximately two thirds of the world's population of HIV positive individuals. In view of the socioeconomic challenges of the region governments have provided antiretroviral therapy free to improve chances of survival among patients. However, adherence to antiretroviral therapy is recognised as more important in predicting patient survival.

**Setting:** This study has been conducted among adult patients attending the Dora Nginza Hospital Adult wellness clinic.

**Aim:** The study aimed to describe the prevailing factors that influence adherence to antiretroviral therapy.

**Methods:** The study design was carried out using three methods of data collection. Focus group discussions, semi structured interviews and a questionnaire format.

**Results:** The methods highlighted factors that influence antiretroviral therapy revealing psychosocial factors – lack of family support, not wanting to take medicines in front of people outside the home; patient factors – co morbidities that disturb patient adherence to therapy, a lack of trust in the patient-care giver relationship, fear of the drug side effects; socioeconomic factors – patients' inability to afford food or transport costs to clinic appointments. In the semi structured interviews, 25% of patients self reported on poor adherence while in the questionnaire 5% of patients reported poor adherence. In assessing the effect of adherence to therapy on CD4 count and viral load there was a general increase in CD 4 count and a drop in viral load indicating clinical improvement in patients on therapy.

**Recommendation:** There is a need for clinicians developing a health relationship with patients to facilitate adherence. The interventions designed to help patients in adherence to therapy should involve the patients in question in the designing of these interventions.

**Conclusion:** Adherence monitoring is an important aspect of managing patients on antiretroviral therapy. The factors highlighted are similar to findings of other studies in similar contexts i.e. resource poor settings.

## **INTRODUCTION**

The United Nations Program on AIDS and the World Health Organisation estimated that at the end of 2005, about 40 million people around the world were living with HIV. The majority of these people are believed to live in Sub Saharan Africa, and in this region the Southern African countries are believed to have the highest rates of infection.

Unfortunately, Sub Saharan Africa is the poorest region in the world rendering the devastating effects of the pandemic far reaching for the families of affected patients and the economy of the region. These effects influenced the choice of governments in the region to provide free antiretroviral therapy for indigent citizens of their countries.

However, making the drugs available is only one aspect of a multifaceted problem requiring interventions at many levels to have a positive effect and reverse the trend of increasing numbers of people with HIV infection. It has since been discovered that providing drugs is only solving part of the problem which without adequate supervision creates an even bigger problem, if patients are poorly adherent to therapy. It has been



noted that poor adherence to antiretroviral therapy is associated with a failure of viral suppression and a development of resistant strains which when spread cause increasing difficulty in achieving virologic suppression and improved immunologic status of the patients.

This study was set in the Wellness clinic of the Dora Nginza Hospital where the majority of patients are referred from the clinics or the hospital inpatient wards for management of their HIV status. A large number of these patients were referred from the local clinics for failure of virologic suppression on Regimen 1A or 1B of the Department of Health's protocol for Highly Active Antiretroviral Therapy (HAART). In a number of instances the patients reported poor adherence as the cause of the reason for failure in achieving virologic suppression and persistently low CD4 cell counts. In the experience of the researcher with the patients, non adherence is a common trend and this often results in poor outcome. The effect of poor adherence to antiretroviral therapy has far reaching implications. When the patients deteriorate, it becomes even more difficult for a lot of them who are breadwinners in their families to source basic necessities for their families. The result is that more than one person suffers from the patient's non adherence. Many studies have been carried out in various other centres but no study has been carried out locally. The common factors for non adherence have been described as ranging from poverty, hunger, lack of family support, drug and alcohol abuse to name a few. The extent to which these factors affect the patients at this clinic is not well described in any study. It is essential to have the extent of these factors documented in order to implement proper interventions designed to the specific needs of the patients at this clinic.

## **LITERATURE REVIEW.**

The human immunodeficiency virus (HIV) has come a long way since it was first described in the 1980s and then associated with AIDS and its high mortality. Since the advent of antiretroviral therapy, it is understood that patients can be managed over long periods with antiretroviral therapy once virologic suppression and the improvement of CD4 count are achieved. However, in the light of this development, a new challenge is being faced. It has become increasingly difficult to maintain virologic suppression and immunologic improvement if patients are poorly adherent to therapy. In questioning the amount of adherence to HAART considered optimal, review of the literature<sup>1</sup> reveals it is uncommon to find patients with clinical failure. Bangsberg et al suggest that even with development of resistant strains of HIV there is always residual anti HIV activity in the ARV medication that helps patients stay clinically well in most instances of poor adherence<sup>1</sup>. It however concurred with other studies that the need for strict adherence can not be overestimated as the goal of therapy must remain complete virologic suppression and good immunologic response. Studies have reported that >95% adherence is required to achieve optimal suppression as lesser levels of adherence are associated with treatment failure and poor outcome in the long term<sup>2</sup>.

Poor adherence is common and in a lot of instances reasons for this is related to forgetting to take the doses as required. A study carried out at a private sector disease management program for beneficiaries of contracted medical insurance funds in South Africa set out to confirm that adherence to highly active antiretroviral therapy does in fact influence survival as it is associated with “a three fold decrease in mortality hazard

among HIV 1 infected South African adults”<sup>3</sup>. There is a paucity of studies from Sub Saharan Africa but a systematic review<sup>1</sup> done in 2005 into factors affecting adherence to highly active antiretroviral therapy (HAART) gathered a total of 84 studies, 37 qualitative studies and 47 quantitative studies from developed and developing nations. It revealed that a lot of studies carried out in developed and developing nations had similar factors affecting adherence. Described as barriers to adherence, these factors were grouped into 3 major groups namely: patient related factors; beliefs and daily schedules<sup>3</sup>. The patient related factors included factors such as fear of disclosure, avoiding taking medication in public, depression, drug and alcohol addiction, suspicions of treatment, preferring a natural approach, denial of HIV status, lack of self worth, financial constraints and concurrent illnesses affecting adherence. Factors influenced by beliefs included; adverse effects of medication, complicated regimens, feeling better affected adherence and decreased quality of life. Patients also reported busy schedules preventing them from refilling their prescriptions<sup>4</sup>.

Patient reported facilitators of adherence included, acceptance of status, improved health status in response to HAART, simple regimens, the use of reminder tools and successful positive interpersonal relationships<sup>4</sup>. Another review of the literature which examined adherence to antiretroviral therapy<sup>5</sup> mentioned the predictors of adherence, having grouped them into factors associated with patient variables, factors associated with treatment regimen, factors associated with disease characteristics, factors associated with patient provider relationships and factors associated with the clinical setting. The factors associated with patient variables include socio-demographic factors and psychosocial factors. The psychosocial factors are commonly associated with being good predictors of

adherence e.g. depression, substance abuse, stressful life events, lack of social support, poor knowledge of drug regimens and the relationship between adherence and development of resistance. Factors associated with treatment regimen are associated with how complicated the regimen is and the adverse effect of the antiretroviral therapy. Factors associated with the disease include stage and duration of disease especially number of opportunistic infections; it described how some studies have shown that ill health stokes the desire for good health hence driving the motivation for adherence to therapy. Factors associated with patient provider relationships describe the fact that patients tend to be better adherent when they have a good relationship with the care provider, i.e. physician and other health workers at the health facility. Factors associated with clinical setting include the access to a primary care centre, involvement in an adherence program, convenience of appointments and pleasantness of clinical staff.<sup>5</sup>

An attempt to compare adherence among patients in Sub Saharan Africa a third world setting and North America a first world setting revealed that the problems encountered in Sub Saharan Africa are still not on the scale of poor adherence encountered in North America. In other words, there are still too few cases to make a comparison between both regions but it is well described that in North America adherence to HAART is a big problem<sup>6</sup>. The paper stated that adherence though a big problem in both regions, the differences in living standards of patients does not allow for a justifiable comparison. The paper does agree that adherence is the “single most accurate predictor of good patient outcome in the fight against HIV/ AIDS.”<sup>6</sup> The paper assessed studies with patients who completed the studies and adherence measures were assessed as primary adherence

thresholds. In studies where more than one method was used to assess adherence it chose the most objective in reporting the findings. Again it is important to mention that there is no gold standard for measuring adherence to HAART. This is part of the dilemma investigators face in trying to measure the problem.

Pence BW et al<sup>7</sup> conducted a study to assess the influence of psychosocial characteristics duration of use and the success of HAART, assessed the rate of commencing and discontinuing ART among patients based on psychosocial factors and found that patients with unfavourable psychosocial factors were less likely to be commenced on ART, were more likely to stop ART and have failure of virologic suppression.

In a similar study conducted to assess the effect of adverse life events<sup>8</sup>, Mugavero et al identified factors like depression, drug and alcohol abuse, stress, lower levels of education, physical and / or sexual abuse are associated with higher levels of non adherence among patients. The authors suggested assessing the risks for non adherence prior to commencing HAART and designing interventions to help patients with these factors. The aim will be to aid them in dealing with these issues prior to starting HAART. The expected result is increased adherence to HAART.

Murri et al<sup>9</sup> stated that physicians had poor estimations of adherence in patients with lower levels of education, unemployment and where there were no social workers available at the clinic. Their study suggested that poor concordance in the estimation of adherence between patients and their physicians were likely to be associated to poor clinical decisions by physicians in the management of HAART. It states that to achieve better levels of adherence in these clinics, interventions be designed to improve the

relationship between physicians and patients. Physicians will need to acquire a better understanding of their patients' context.

In the study by Ammassari et al<sup>10</sup> on depressive symptoms and neurocognitive impairment and adherence to HAART, they described how 28 to 100% of patients fall below the required levels of adherence. Their study showed that 50% of patients diagnosed with HIV have depressive symptoms or symptoms of neurocognitive impairment, these individuals are said to develop the accelerated form of HIV independent of virologic suppression or improved CD4 count. It suggested the need to actively manage these patients in order to improve their outcome as depression and neurocognitive impairment also negatively impact on adherence to HAART.

There is a need to assess patients starting HAART for predictors of adequate/inadequate adherence. The guideline<sup>11</sup> lists predictors of inadequate adherence and adequate adherence. The predictors of inadequate adherence include a lack of trust in the patient physician relationship, active drug and alcohol abuse, active mental illness, lack of patient education, inability of patients to recognize their medication and lack of access to primary health care or medication. The predictors of adequate adherence on the other hand include availability of adequate emotional and practical life supports; ability of patient to use medication in their daily routine; understanding the importance of strict adherence; feeling comfortable with taking medication with others present; keeping clinic appointments. The guideline identifies that though there is no gold standard of assessing adherence, a patient's admission of suboptimal adherence is a reliable method of assessing adherence. The clinician's estimation of adherence is considered to be

unreliable. It suggests that having patients bring their diaries of drug ingestion and their left over pills and paying attention to situations where doses were missed with the intent to preventing future occurrences is important. The guideline suggests multi focused strategies of intervention involving the clinician, the patient, the regimen/ doses and directly observed therapy. Suggestions for patient directed strategies include the education of patients. Especially, according to their literacy level and address issues like the goal of therapy, side effects of therapy, education of family and friends. Clinician directed strategies are to include adequate communication with patients in between visits, having a non judgmental attitude, looking out for problems like pill fatigue (a recognized phenomenon in suboptimal adherence especially after taking medication for a prolonged period), shortening follow up intervals, involving the help of social workers and counsellors in patients assessment. Regimens should be simplified and patients be educated to recognize the medication, DOT has not been proven to be of effect in prolonged therapy like HAART<sup>11</sup>.

Hardon et al set out to outline the socio-demographic factors encountered in Africa which influence adherence to antiretroviral therapy<sup>12</sup> it used qualitative methods of assessment (semi structured interviews, focus group discussions and exit interviews) to gather information from ART users and people working with these patients. The factors outlined in the results of the study include poverty as a lot of the patients could not afford food (which was required to regain adequate health after starting HAART) or the cost of transport to the health facility, other factors outlined include stigma as a number reported loosing their jobs after disclosure of their status, a number of these patients reported non disclosure so they had no social or emotional support, a lot of patients skipped doses due

to side effects of the medication. A qualitative study<sup>12</sup> not dissimilar from the one the researcher intends to conduct, was carried out in resource poor settings across three countries of Tanzania, Uganda and Botswana, the findings suggested that patients started on ARVs end up with suboptimal or non adherence often due to patient related or drug related factors, it listed factors like transport costs, inability to get food, non disclosure causing poor social support as those who disclose their status are abandoned by family and friends or lose their jobs as a result of stigma associated with HIV, substance and alcohol abuse are said to also play a role in poor adherence among these patients. The findings revealed that often patients are not adequately counselled about the side effects of medication causing them to become non adherent when they start having the adverse effects of medication also a number found the regimens too complicated with a huge pill burden, the exit interviews conducted during the study revealed that only 21% of patients coming to clinic had counselling. The factors in the resource poor settings have been described as being largely economic related factors among the indigent patients. The study went on to state that the increasing numbers of patients being put on ARV therapy with no increase in the number of health workers is causing a huge burden on the system and may be indirectly associated with poor adherence in these settings.

Recommendations by the study include the provision of transport and food for the very needy, the provision of three monthly medications for the patients who are known to have optimal adherence to avoid recurrent transport costs, provision of good counselling to all patients being commenced on ARV about side effects of medications<sup>13</sup>.



In rural Haiti,<sup>12</sup> a study was based on reviewing how strategies designed to address barriers to adherence to ARVs improved adherence among patients in the community. These strategies were designed against poverty associated barriers and included free health care and medication services including the provision of integrated services for the treatment of tuberculosis, sexually transmitted infections and an ‘opt out’ testing program for all patients with possible HIV related disease. For patients who were largely from the indigent community, provision of small funds for transport to the clinics and food parcels and the use of community health workers in active case finding and psychosocial support among the community, the results reported markedly improved rates of adherence among these patients. The recommendations from this study go on to suggest that all ARV roll out programs must assess the barriers to adherence which may prevent the success of these programs in the long term and should set out to forestall these by having programs that will address these barriers especially the poverty related barriers such as were carried out in rural Haiti. A similar study carried out in Khayelitsha<sup>13</sup>, South Africa’s first Primary care ARV roll out program using triple therapy, revealed that having strategies that address possible barriers to adherence improve the outcome of patients allowing for successful virologic suppression without a subsequent rebound leading to treatment failure due to poor adherence. A study in rural eastern Uganda<sup>15</sup> revealed that home based care and monitoring of patients on ARVs in the rural setting can achieve higher levels of adherence in the short term especially among patients having difficulty with transport costs and food. This study was a longitudinal follow up study that formed part of a bigger study on the effect of ARVs in improving outcome<sup>14</sup>. Another study, suggests

that the problem of missing doses is not the only one to be associated with suboptimal disease control. It stressed the importance of having optimal intervals between doses<sup>16</sup>.

The studies included in this review all confirm that various factors influence adherence and these factors are often patient related, to do with the patient context and other pressing medical problems, which are common among these patients.

### **AIM.**

The aim of this study is to obtain a deeper understanding and describe the prevailing factors that influence adherence to antiretroviral therapy in adult patients attending the Dora Nginza Hospital Wellness clinic.

### **OBJECTIVES.**

- To assess the prevailing factors associated with poor adherence or non adherence among patients at the clinic.
- To obtain a deeper understanding of the factors associated with non adherence in patients at the clinic
- To describe the relationship of poor or non adherence to virologic suppression and clinical status of the patient.
- To describe the prevalence of poor adherence among patients on antiretroviral therapy at the Dora Nginza hospital wellness clinic.

## **METHODS**

### **Study design**

This is a study that involved obtaining a deeper understanding of the factors that influence adherence among the patients at this clinic and therefore the most suitable methodology is interpretive with a qualitative study design.

### **Context**

The wellness clinic at Dora Nginza Hospital has about 1200 patients currently on antiretroviral therapy (ART). This study involved the use of focus group discussions and in-depth interviews with both patients and health workers at the clinic in order to assess the prevailing factors that influence adherence to therapy among the antiretroviral users. This clinic serves as a referral clinic to the outlying clinics for patients who have had treatment failure due commonly to poor adherence; it also manages in-patients with HIV related complications requiring a fast paced adherence program but in a number of instances it is a wellness clinic for ART naïve patients just starting therapy. The focus group discussions was set up with the help of health workers at the clinic and aimed to have patients air their views about the problems they faced as they committed themselves to the use of ARV therapy for life. The in-depth interviews were aimed at a sample size of 20 patients who are on the ARV program. These patients were chosen randomly from the population of patients attending the clinic while waiting for their appointment with the health workers. A list of patients in attendance at the clinic were drawn up each day during a two week duration. 2 patients were randomly selected from the patient line up for interview on each of the days from Monday to Friday. A number of questions were

drawn up to help the researcher while conducting the in-depth interviews with directing the interviews so the patients gave the required information in their own language as much as possible but without missing out information relevant to the study. In an attempt to confirm the credibility of the results, the researcher conducted a small quantitative study by handing out questionnaires to a sample of about 200 patients to collect information in this regard. In other words, the researcher used different methods of data collection in an attempt to enhance the credibility of the results.

The strengths of the qualitative study include

- it focuses on the patient as a social being and not as a physiologic system, while giving an accurate reflection of the factors;
- it describes the factors influencing adherence among these patients as they are;
- small numbers are acceptable and the data collected was easier to analyse;

Possible limitations of the interpretive method include the fact that:

- The findings are context specific and transferability to all wellness clinics but this one is restricted.
- The focus group discussion method did not allow for keeping patient confidentiality and this is where it was important that the researcher ensured that all patients being enrolled for the focus group discussions were fully aware of the fact that proceedings were being recorded and were comfortable talking about their HIV status in the presence of other similarly infected patients.

This study made use of method triangulation where different methods of data collection from different paradigms are combined, in an attempt to enhance the credibility of the results and obtain convergent validity.

### **Reflexivity**

In conducting this qualitative research I have had to look inwards to understand what mindsets and biases I bring to the study.

I am a medical professional in my mid thirties, practising now in South Africa for six years and happily married for 7 years. In taking a deeper look I go back further. I am a Nigerian woman born to parents who are themselves medical professionals, my father a medical doctor and my mother a Nurse midwife. I am the first of 5 siblings. I was born to a Christian family and brought up with Christian values and a strong sense of family.

Children outside wedlock is unheard of in my home, fidelity is absolutely not negotiable and everyone is expected to surpass the dreams of our parents. I now work in this community where the family is largely fragmented as a lot of my patients are born to single parents and women do not want marriage. I see young girls opting to have teenage pregnancies not because they can't avoid this but because it is the trend among their peers.

I believe the HIV pandemic could have been avoided, if moral values of fidelity and care for the other person were held higher in the society. Now we have this pandemic and the governments of the Region have helped with the free ARV roll out campaigns, it is time to make the best of the programs and use the opportunities.

I have tried to understand the thinking of the HIV positive individual in the community where I work. When they are started on antiretroviral therapy, they have such zeal and commitment to the use of their medication. They understand the importance of strict adherence to therapy. What happens in between the time they start therapy and when they start defaulting? Why would they risk falling ill with increased chances of mortality? Can't they understand that to miss doses is risking treatment failure? I set out to understand the factors influencing adherence among the population of my patients. In my interactions, I have seen people who have the same dreams of wanting to live, love and be happy. They know the implications of non adherence and tell of their wanting to improve adherence but some describe frustratingly difficult social circumstances. I begin to see that may be the choices they make are largely due to giving up on wanting to achieve their dreams. They just want to get by from one day to the next and may be at some time life will not be so difficult. I have never known poverty and so I can't tell how desperate people can be when faced with the challenges of finding the next meal to survive. Is this why adherence is a problem? The challenge of facing death from hunger, giving up on the choice to take medication as adherence is pointless in the face of not being able to feed. What about the stigma described by these patients? They are rejected by family, ostracized by friends, alienated by community. The quiet whispers of 'she is promiscuous that is why she got HIV' that are spoken when a very pretty young girl walks past on the street are these enough reason to stop taking therapy? Are they enough reasons to give up on the will to live, love and be happy? They default therapy for fear of the new boyfriend finding out about their HIV positive status. She risks his life and engages in unsafe sex with him to be happy, if only for a short while. I have heard the

various reasons given by patients in this study, they seem enough reasons for these patients to give up on love but surely not living. I am challenged however, in the face of all the social problems described by these patients, what can be done to turn the trend? Is there any thing to be done to stop the problem of poverty or non adherence?

### **Piloting the study.**

The initial pilot study involved the use of a short questionnaire highlighting demographic data without the patients' names in an attempt to maintain patient confidentiality. The other facts included questions about the number of doses missed in the preceding week to answering the questionnaire and the reason/reasons for missing the doses. The in-depth interviews were conducted by the researcher and were aimed at asking questions to obtain a deeper understanding and meaning of the factors associated with adherence to antiretroviral therapy. The aim of the pilots was to assess the feasibility of the study design and to introduce any changes required to improve and to make the designs more feasible. The pilot was conducted among 3 patients for the in-depth interviews and 10 patients for the questionnaires. The focus group discussions were not piloted but the questions required for guiding the discussion groups were tested with the questionnaire and the in-depth interviews.

### **Data collection procedure.**

The researcher aimed to collect data over a 4 month period and sampling of the patients was random. Patients were seen at the clinics and had numbers allocated to them in order of arrival. Patients were chosen by randomly selecting the numbers manually on the different clinic dates. The patients were selected for the questionnaire study and the in-

depth interviews on separate days and data collection was done at different times. Staff at the wellness clinic were aware of and fully supported the program. Before each questionnaire was completed, focus groups compiled or in-depth interview conducted, the selected patients signed informed consent forms and there was no coercion of patients to join the study.

### **Data analysis.**

Qualitative and quantitative data analysis was conducted. It is important to state that the objective of the qualitative data analysis is not to interpret data in numerical language but rather to explore ‘conceptual definitions’, group data based on the similarity of responses and meanings, associations and explanations. The method used in analysis was systematic, keeping a focus on the data collected as it is and developed through reflection on the meanings of each statement.

The steps were as described below:

1. Familiarization : This step required that I got to know the data well and this is why it was essential that I collate the information which was verbal on tapes for the focus group discussions, and written in long hand in the in depth interviews. I reflected on the meaning of each statement before putting the findings down.

2. Indexing: This involved identifying the various parts of the data and marking them in some way making them accessible as they held information pertinent to the findings of the study.



3. Grouping data: This involved sorting the data into segments based on the similarity of information they held as to the patients' views. The data when grouped in this way allowed for easier reflection on the various parts of the study.

4. Development of themes: following the last stage, reflection on the data allowed for me to create themes based on the data in the various groups. The data reporting was greatly dependent on the researcher being able to define the theme of each group and reporting reflections and perceived meanings.

The above steps highlight how the researcher analyzed the qualitative data from the focus group discussions and the in-depth interviews.

A Biostatistician was consulted early to assist with sample size, and the analysis of the quantitative data and the excel software package was used. The recommendations made were noted and implemented with the data analysis. The findings of the quantitative study were compared with the findings of the other two methods used. The researcher then discussed the findings, reporting in the context of the study.

### **Ethical Considerations**

This study sought to describe the factors associated with poor adherence among HIV positive individuals to antiretroviral therapy. HIV poses a challenge when it comes to ethics as there is the continuing problem of stigmatization and the fact that a number of patients still have difficulty with disclosure of their status. The study sought to consider

the participants as the primary concern, the culture, language, customs and beliefs of each participant were considered as the researcher tried to gain insight into the issues of adherence that presented during the study. This study is of great relevance to this community as it faces huge challenges regarding patient adherence to antiretroviral therapy and the findings so far will go a long way in helping to design interventions to help the attendants at the wellness clinic with improving adherence. The study was conducted keeping in mind the importance of good methods designed to give answers to the research question. The researcher conducted a review of the literature which is continuing to help with gaining an adequate knowledge of the problem.

The responsibility of the principal investigator in this study was to be compassionate and empathic, ensuring that the study was done abiding by all ethical standards and good clinical practice prescribed for this type of a study. Permission to conduct this study was obtained from the superintendent of the Dora Nginza Hospital, see addendum 6.

#### **Informed consent.**

The study used 3 methods to gather the information required and all the patients involved gave informed consent having been fully briefed of what their participation required, what the study is about and what the results will be used for. They were made aware of the fact that their confidentiality and anonymity is protected at all times. A right thumb print was used in patients who could not write to show their approval and consent for their involvement in the study. See addendum 2.

#### **Confidentiality.**

This was a rather difficult challenge to overcome given that there were focus group discussions aiming to gather data for the study. The facilitator for the group discussions

was the researcher, and all the facts of the study are strictly confidential, no names were used in the course of interactions during the discussions as patients needed to remain anonymous.

### **Protecting the interests of the research participants**

As is protocol for all ethically sound studies the patients were fully aware of their rights to withdraw from the study at any point in time. More so, this study is based on HIV, an area of medicine that is still associated with unfair stigmatization of patients affected by the disease. In the spirit of patient advocacy the participants had all their personal data kept confidential at all times. Anyone involved with the study was directly involved with patients at the clinic and to ensure this, the researcher validated the identities of all staff prior to any data collection exercise started and when looking in patients folders for information to supplement the questionnaires the folders were not removed from the clinic records office.

### **Freedom to draw unbiased conclusions from the results**

The study has been carried out with the aim of helping to design adequate intervention for the management of patients with difficulties associated with adherence. The findings of the study will be reported as they are with no attempts to give an altered picture. There will be no undue external influence to make untrue representation of the results and all findings of the study are subject to peer review.

## **Results**

### **Focus Group Discussion**

Two focus group discussions were held, each one consisted of 20 people including lay counsellors, peer educators and patients. Both discussions were coordinated by the researcher and participants signed informed consent before each session. The sessions were recorded and the focus was to describe the factors that were said to influence adherence to antiretroviral therapy among participants. In analysing the results, the researcher developed themes as they arose from the transcribed script of the discussions proceedings. The themes were then grouped and this formed the basis of the results presented here. The researcher has also attempted to give quotations from the discussions under each factor identified in the course of the discussions.

The instances described include the following:

- The health workers impression of poor or non adherence are sometimes based on inaccurate reports of the number of pills dispensed to patients. As reported by one of the participants, ‘how do the nurses know that I am defaulting my therapy if they do not count my pills at the pharmacy, when they are dispensed because when I receive the bottle it is sealed?’
- Patients often missed doses because they were out of their home environment, some were at work and would often forget to take their medication because they were distracted by their work schedule, and other patients would not take pills outside their home for fear of someone seeing that they were on antiretroviral medication. A participant reported working with sick patients at a hospital in the

metropole, she would dispense the patients' medication when she was due to take her medication and often took her medication late. Some reported being away from their station at work at the time when they were to take medication. This often resulted in taking medication late and on occasion if more than two hours had elapsed they would default that dose and wait for the next dose. A participant who works as a domestic worker, described a very busy schedule at work. She also expressed fear of her boss seeing her taking her antiretroviral therapy so she would often not take her medication to work, she believed she would lose her job if her boss found out about her HIV positive status. A participant said 'I went to visit a friend over the weekend and missed a dose because I did not take enough pills.'

- The use and abuse of alcohol was often a reason to miss doses for some patients because they could not take their medication with alcohol and after binging on alcohol would have the hangover effects so they slept through the time they were to take their medication. One participant reported, 'I went out with friends over the weekend and got very drunk, I missed my dose for that night, the next day I woke up at half past one (past noon the next day), I had missed my dose for the morning by 4 hours so I decided not to take it'.
- Some patients lacked family support and found it very difficult to keep up with therapy without the support of family members. In some instances there was family violence resulting from the disclosure of status which resulted in depression, alcohol abuse and defaulting antiretroviral therapy. A participant reported how he turned to alcohol following rejection by his father on account of

- his HIV status. He was ostracised by his father on account of his HIV positive status which he disclosed to the community.
- Some patients described the challenges of caring for sick children without family support and how this made it difficult to keep up with their personal health. A participant recounted how she had been rejected by the boyfriend on account of not wanting to be associated to her for being HIV positive and rejecting her child who was ill following vertical transmission in pregnancy.
  - Some patients defaulted treatment due to not having support from their partners, this resulted in depression, with suicidal thoughts in more than one participants' report. A patient reported having defaulted her therapy because her partner was not in support of her taking antiretroviral therapy. A peer educator spoke of how she hid her pills from her new boyfriend so he would not know she was HIV positive.
  - Some patients defaulted treatment because of severe financial constraints, they could not afford to buy food to eat so they defaulted treatment if they did not eat. Numerous participants in the group discussions reported not taking pills if they did not have food to eat. The peer educators admitted that this was a common finding among patients they counselled in the wellness clinic. They expressed worries that the government sometimes withdrew social grants from patients who were very dependent on the social grants for sustenance.
  - Some revealed instances of defaulting therapy to drop their CD4 count so they could remain on government social grants. A participant said in reporting a third

- party, 'people are making themselves sick by not taking medication, so they can get the social grant'.
- Some patients defaulted treatment because they dropped their medication on the floor and considered it not safe for consumption after this and would run short of pills before their next appointment because of discarding 'dirty' medication. A patient said he was afraid to tell the nurses that did the pill counting that even though he had the right number of pills left over at his pill counting appointment, he dropped a few on the floor and never got to take them because the pills were too dirty for consumption. The participant admitted that he was afraid because the medical personnel would be very displeased. Another said he 'forgot' to tell the medical personnel that he vomited his pills and so had not been completely adherent as they had thought he was.
  - Some patients felt the government was not concerned with their social distresses and was only concerned with giving out antiretroviral therapy. They expressed discontent that the government stopped some of the social grants after 12 months even if they had no other source of income.
  - Some felt the social workers were not concerned about their social problems rather they were more interested in getting through their work load. They felt the social worker in question expected all HIV positive patients to only want registration for social grants.

## **Results of Semi structured Interviews**

The semi structured interviews were conducted by a single interviewer to prevent observer bias as patients refused to have recorded sessions of their interviews.

All patients interviewed were on either Regimen 1A or IB with the exception of one who had been started on Regimen 2 at another centre and was being referred to the Wellness clinic where this study was conducted. All reported being responsible for taking their own medication and had all disclosed their HIV status to family members, and 5 of the group had disclosed to people outside of their family which in most instances consisted of 1<sup>st</sup> degree relatives. In one case however the patient spoke of how she was ostracized in her community and told she was HIV positive because she was promiscuous, another patient however spoke of how the community had come to her aid following the death of her husband who died of an HIV related disease. Most patients did not disclose their status to anyone outside their family.

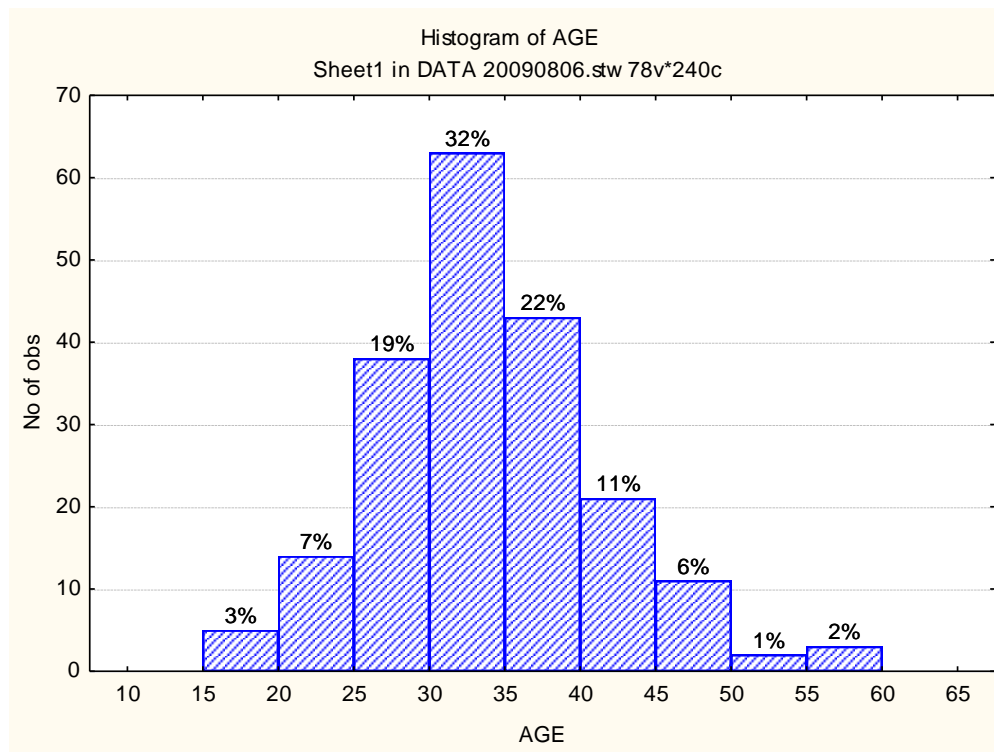
When asked to grade their levels of adherence on a scale of 1 to 10, 6 patients admitted to less than optimal levels of adherence ranging from 0% to 80%. A 7<sup>th</sup> patient admitted to poor adherence but was unable to comprehend the task of grading himself on a scale even though he described poor adherence, an 8<sup>th</sup> patient described poor adherence but would not grade herself on a scale. The patient who graded herself 0% said she had been told to discontinue antiretroviral therapy due to severe hyperlactatemia but she had been 100% adherent to therapy prior to stopping. Therefore 7 of the 20 patients interviewed were poorly adherent to therapy for reasons not due to health intervention.



Patients gave various reasons for poor adherence, the most predominant being that financial constraints and social problems made it impossible to keep up with adherence as required. Patients often described being unemployed, with often no money to buy food and being unable, in a lot of instances to afford transport costs to get to the clinic. One patient missed 7 days of therapy according to her doctor's notes in the folder she confirmed that she had been due to return for therapy the previous week but could not afford transport costs. A lot of the group reported not taking medications if there was no food to eat. In 2 instances, the patients were not taking their medication because they had poorly controlled co morbidities and without family support were unable to keep up with taking their antiretroviral therapy. 2 patients reported adverse effects of the medication actually made them default therapy frequently. A patient described feeling angry, depressed and helpless about the adverse effects of the medication. Another group missed doses because they could not take their medication outside the home as they could not take medication with others present or were too busy working and would miss doses during work hours. In this group of patients 35% of the total number were poorly adherent to their antiretroviral therapy.

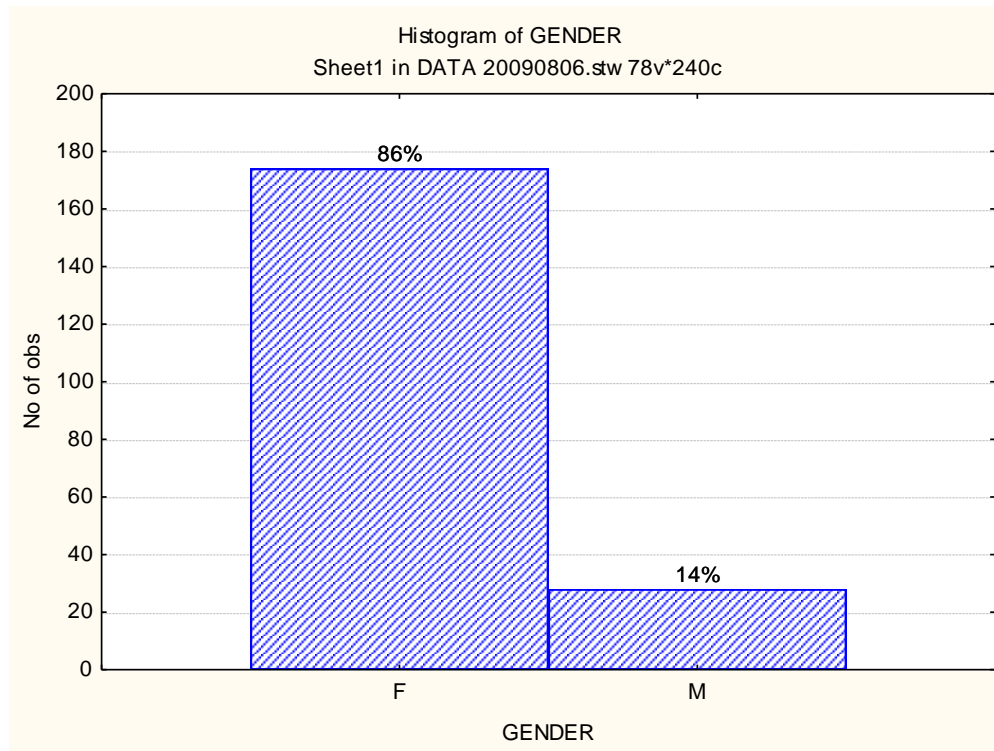
**Results of quantitative study.**

**Figure 1:** Histogram of age distribution of participants.



A large percentage of participants were in the 25 to 40 years age bracket.

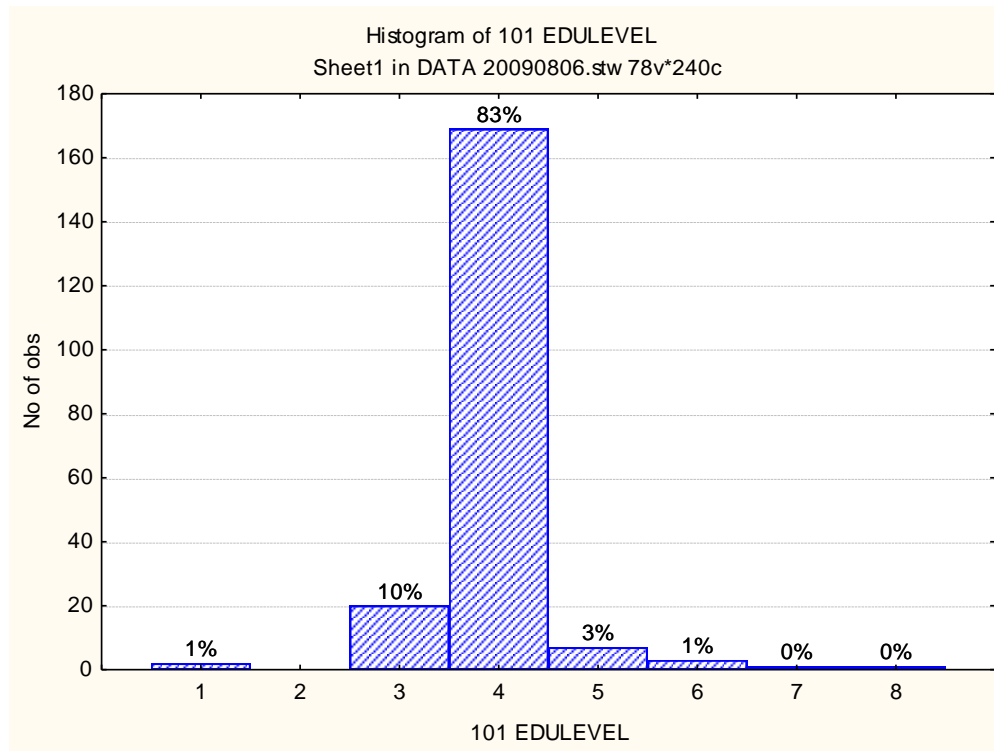
**Figure 2: Histogram of GENDER**



F- Female; M- Male

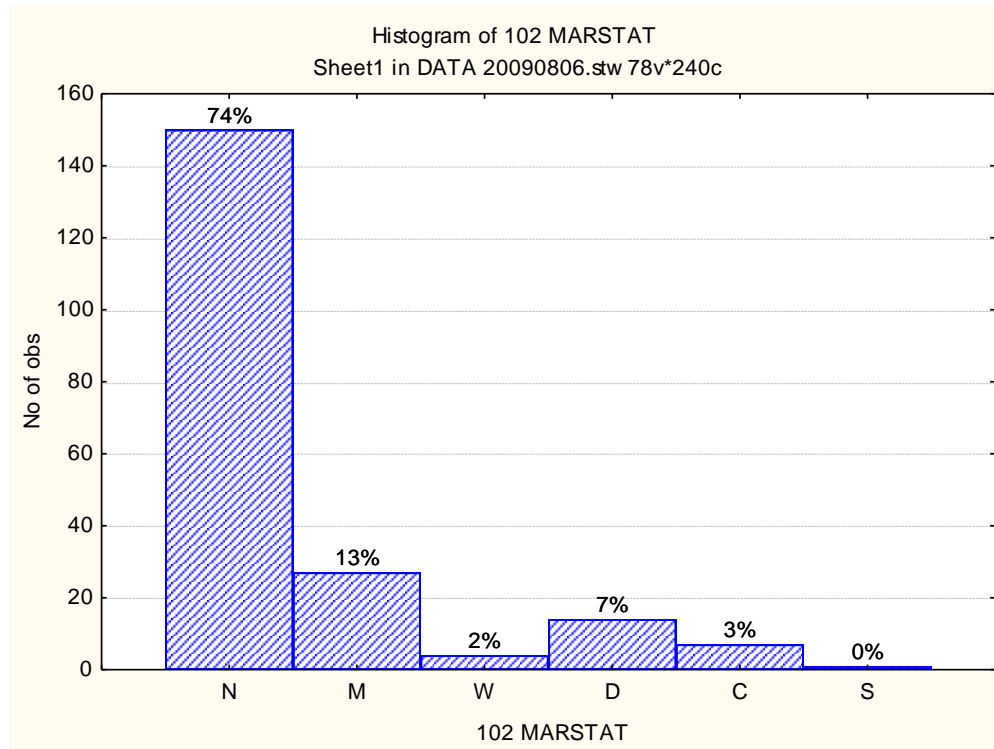
Most participants in the study were female(86%) as is the trend at the clinic, more females are in attendance than males.

**Figure 3:** Histogram of educational level



83%(4) of respondents were secondary school level education, 10%(3) were primary school level, 3%(5) were technical school level education, 1%(6) had diploma level education, 1%(1) had never attended formal schooling.

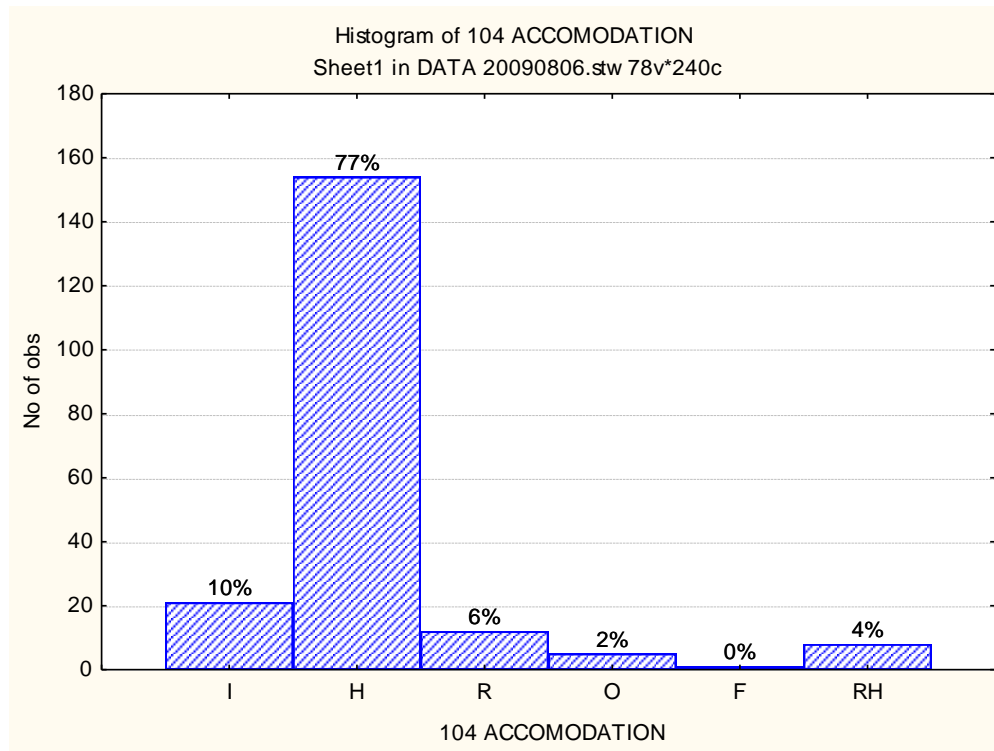
**Figure 4:** Histogram of marital status



N – Never married , M- Married, W – widowed, D – divorced, C- Cohabiting,  
S-Separated

Most respondents(74%) had never been married, 13% were married, 7% were divorced,  
3% were cohabiting and 2% were widowed

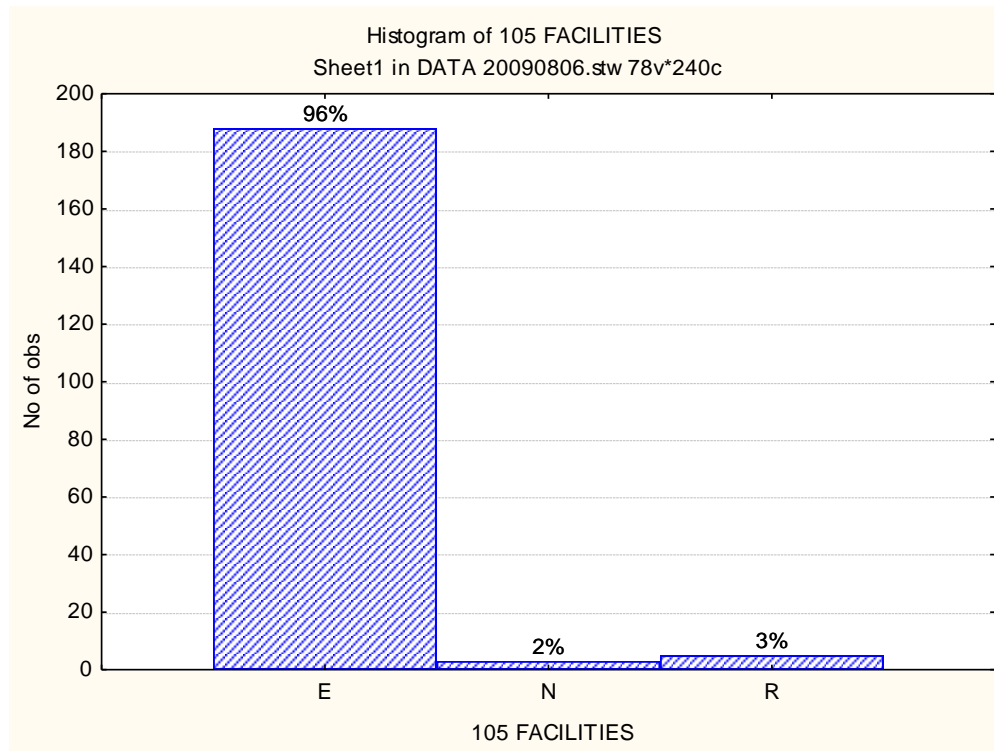
**Figure 5: Histogram of ACCOMODATION**



H-own house, I-Informal housing, R-rented room, O- other accommodation, RH-Rented house.

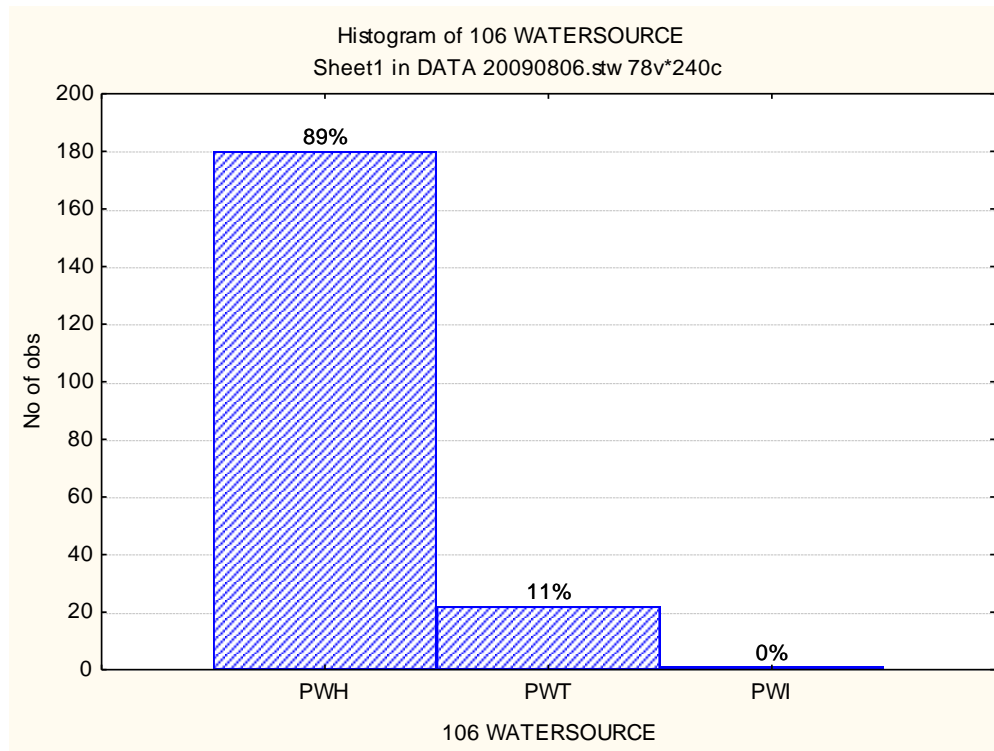
The majority of participants(77%) lived in RDP housing which is reflected here as own independent house (H), 10% of respondents lived in informal housing.

**Figure 6:** Histogram of FACILITIES



For feasibility of assessing patients access to basic facilities in housing the access to electricity was noted, some participants who lived in informal housing had a radio. 96% of respondents had access to electricity.

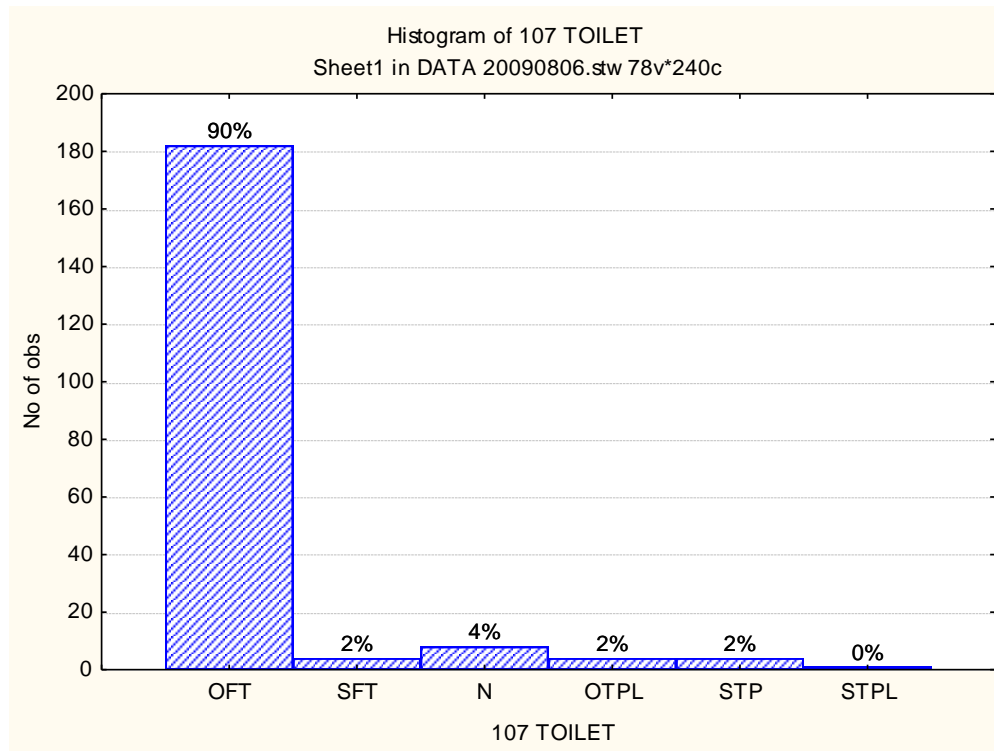
**Figure 7: Histogram of WATERSOURCE**



89% of respondents had access to piped borne water in their homes while 11% had to fetch from the community tap.

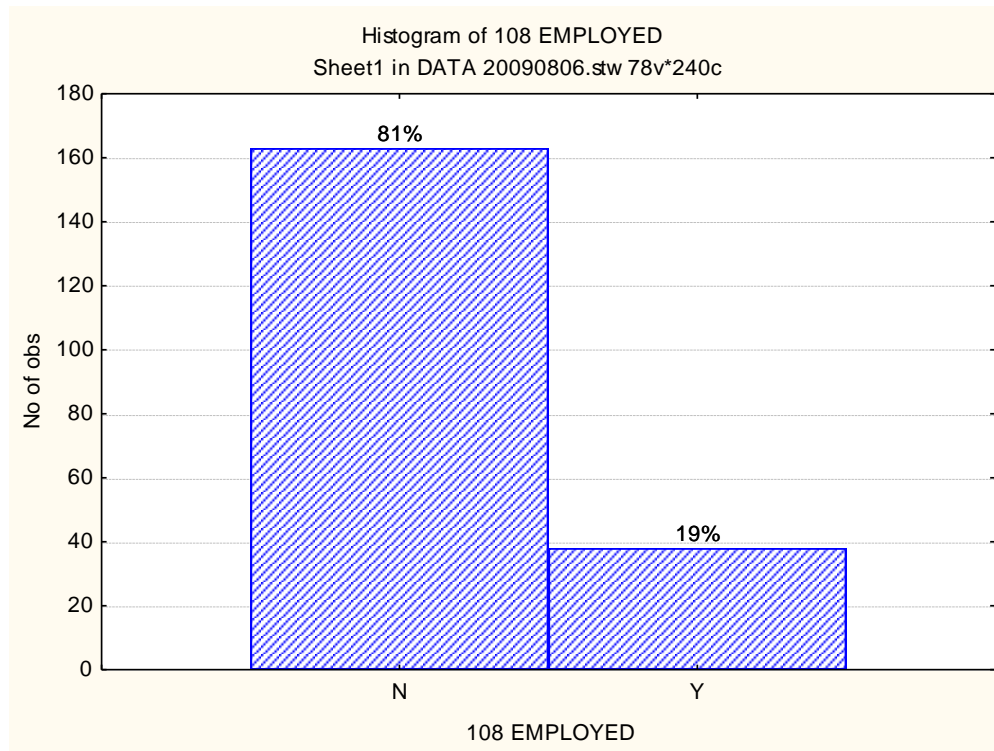


**Figure 8:** Histogram of toilet facilities



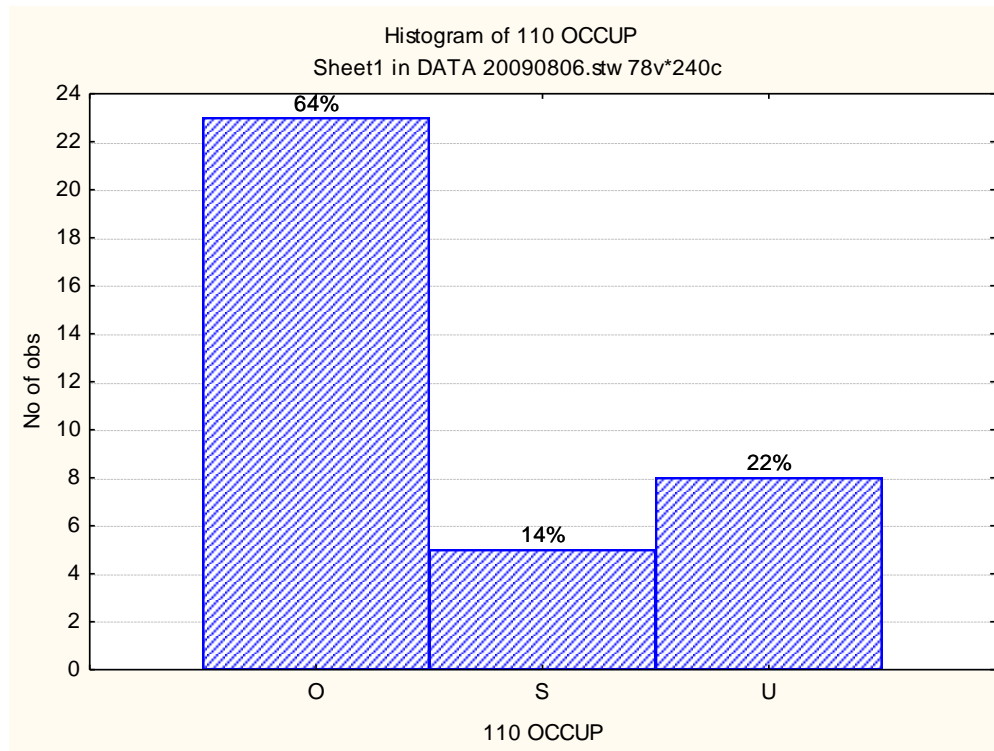
A total of 92% of participants had access to flush toilets, 4% had no toilet facilities and a further 4% had access to traditional pit latrines.

**Figure 9: Histogram EMPLOYED**



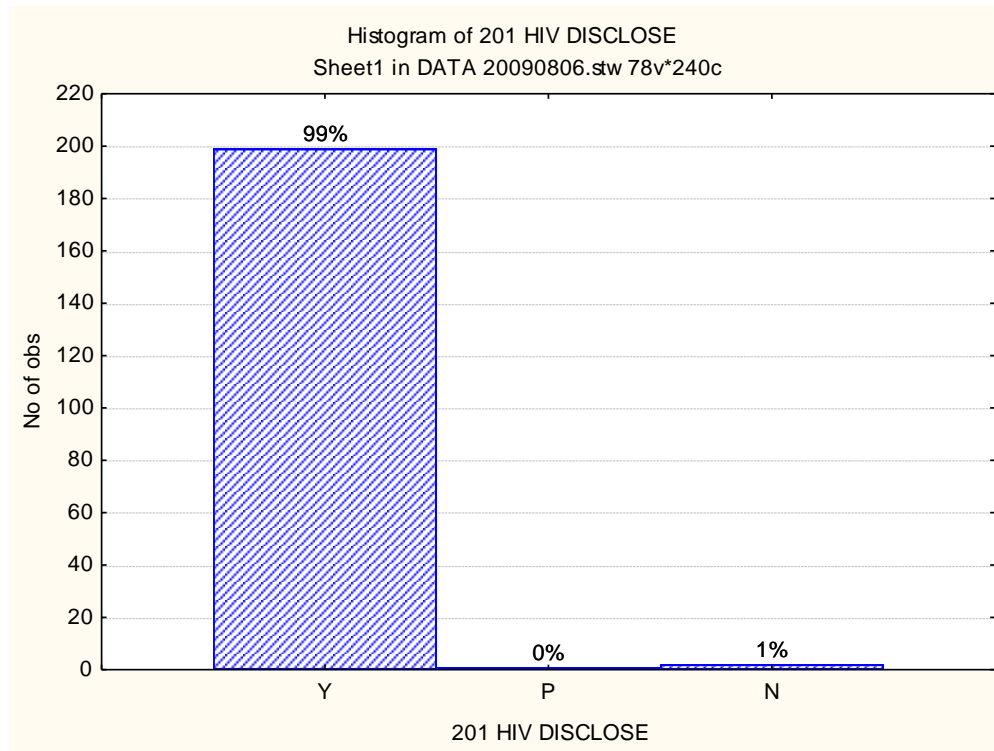
The majority of respondents were unemployed, 81%, only 19% were either full time or part time employed.

**Figure 10:** Histogram of type of occupation



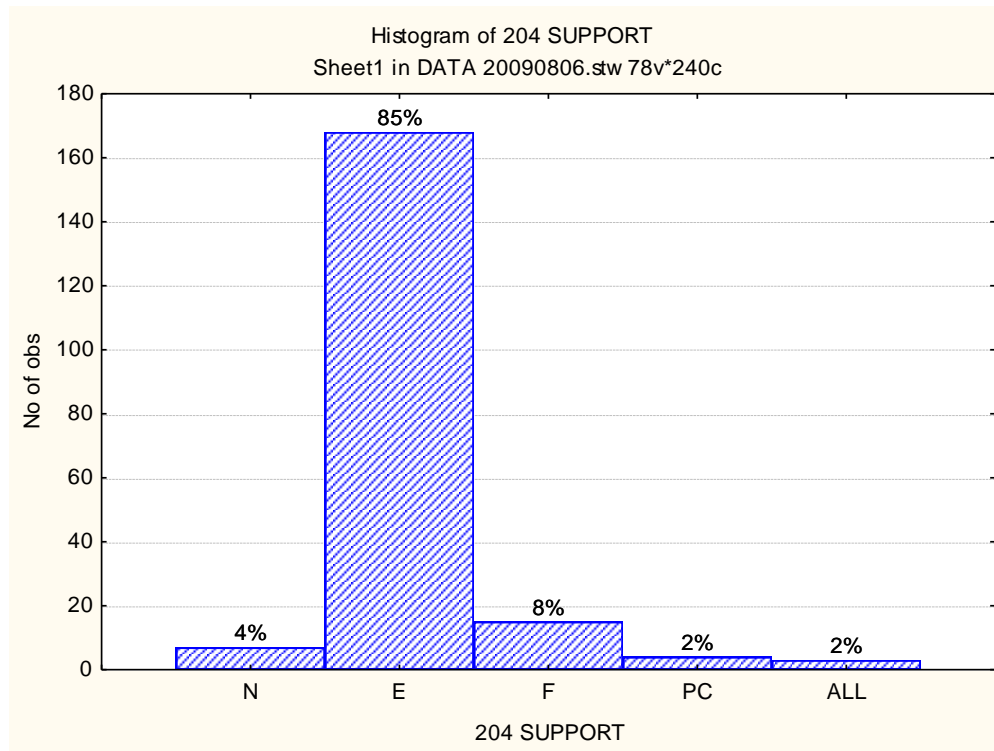
Only 14% of the employed participants were skilled, majority were involved in one form or the other of community work e.g. lay counsellors.

**Figure 11:** Histogram of patients disclosure to family



Only 1% of participants had not disclosed to members of their family.

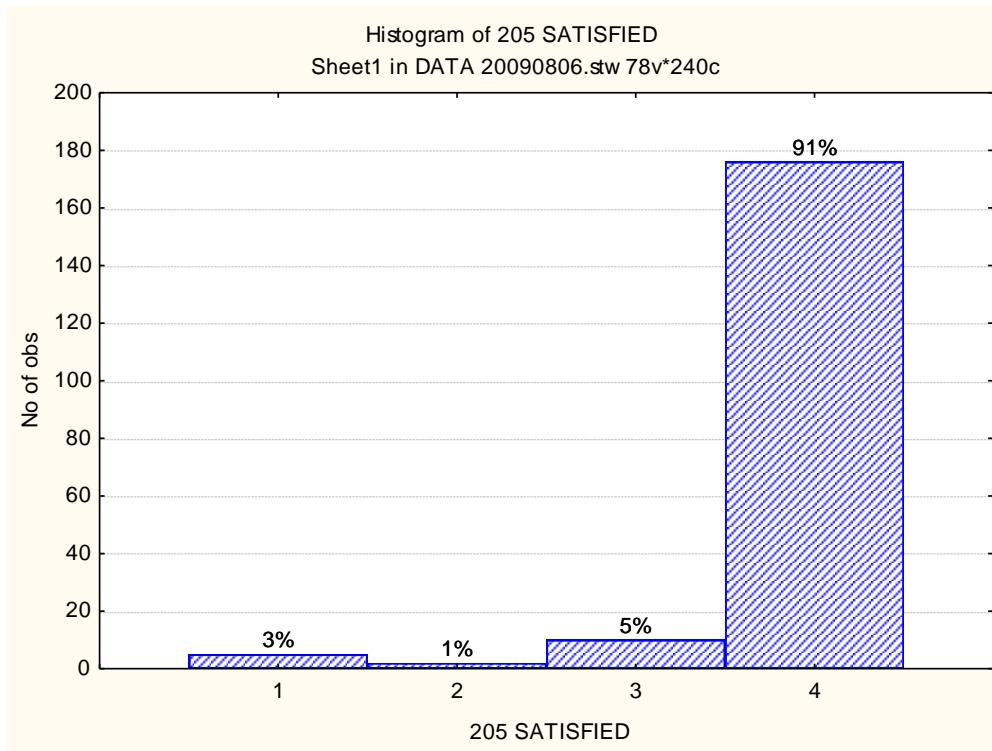
**Figure 12:** Histogram of support received from family.



N- No support, E- Encouragement and psychological support, F- financial support, PC- physical care, ALL- All forms of support.

The majority of patients received some form of support from family members.

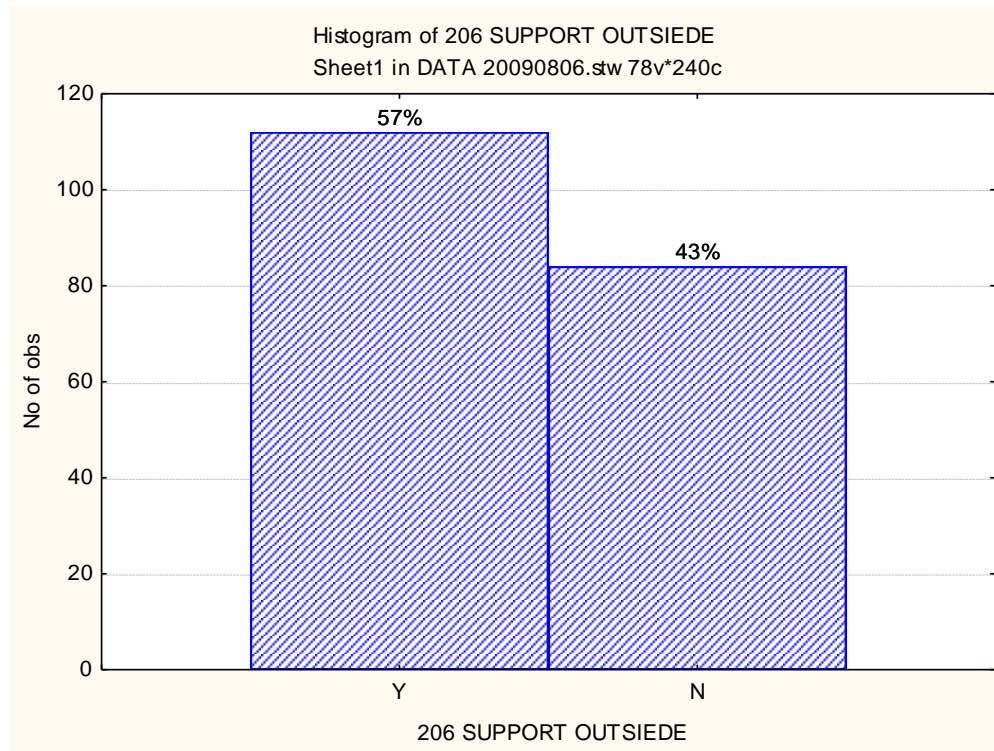
**Figure 13:** Histogram reflecting patient satisfaction with support received



Grade 1- Not satisfied, Grade 2- Not quite satisfied, Grade 3- Moderately satisfied, Grade 4- Very satisfied.

91% of respondents were very satisfied with the level of support they received from their families.

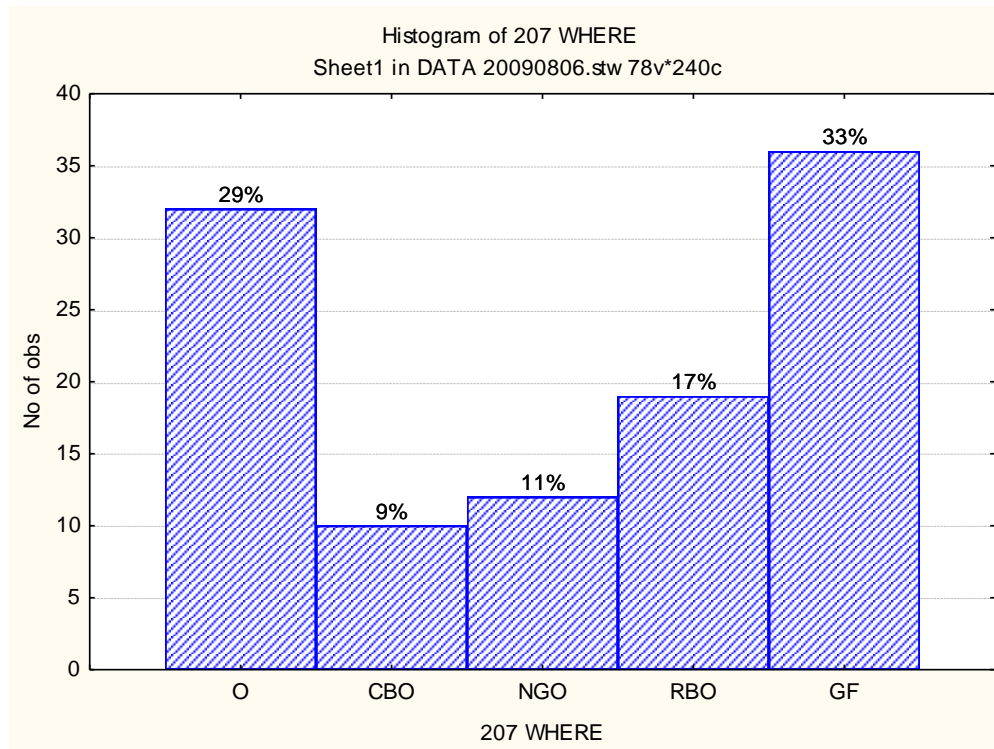
**Figure 14:** Histogram of patients receiving support from outside.



Y-Yes, N- No.

57% responded yes to receiving support from outside the home or their families.

**Figure 15:** Histogram of where patients receive support from outside



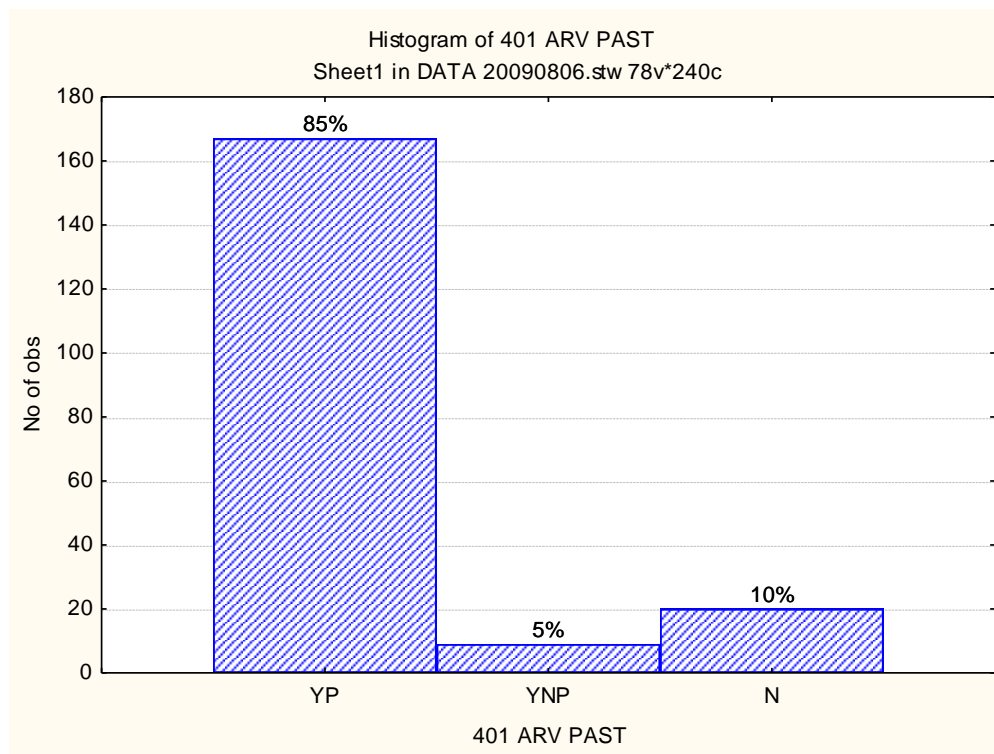
GF- government facility, RBO- Religious based organisation, NGO- Nongovernmental organisation, CBO-Community based organisation, Others – Friends, neighbours etc. 33% received support from government facilities, 17% and 9%received support from religious based organisations and community based organisations respectively, 11% from non governmental organisations and 29% received support from others. 95% of respondents who receive support from outside the home were very satisfied with the kind of support they received which to a large extent (54%) was psychological support followed by physical care in 29% of respondents. 65% of respondents said family and friends always helped them to remember to take their medication. 61% of respondents had HIV positive spouses/partners, 25% had HIV negative partners and 14% had no partners.



44% of respondents answered yes to having other family members who were also HIV positive. Of the number of HIV positive relatives, 73% were also on antiretroviral medication.

12% of respondents gave a history of alcohol use and of these 60% gave a history of using more than 3-4 drinks per episode of drinking. Only 1 patient (<1%) of the whole sample responded yes to the use of recreational drugs (marijuana).

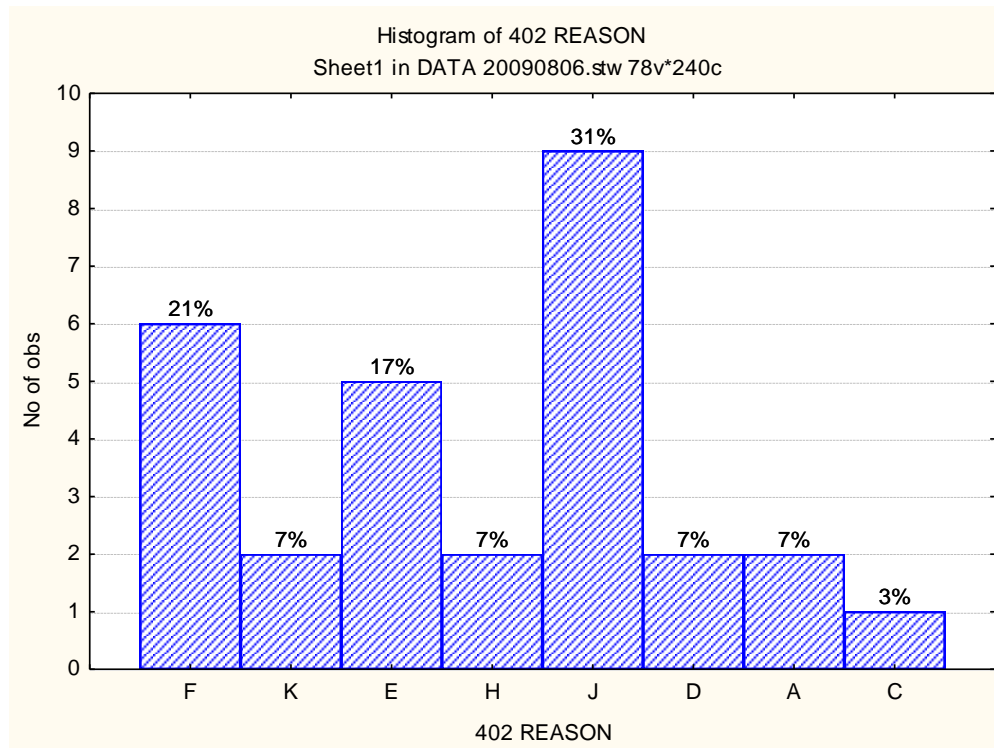
**Figure 16:** Histogram of patients on ARV in the past.



When questioned about antiretroviral therapy 85% of patients were currently on treatment, 5% had stopped therapy for various reasons and 10% had never been on therapy or were commenced on treatment less than 2 weeks before answering the questionnaire. The 5% here had a history of previous antiretroviral therapy that was

stopped for various reasons. 20% of this group of patients showed a rise in their CD4 count, 30% of patients remained within the same level (20% with CD4 less than 50 and 10% over 200). 40% of patients had only one CD4 recording and so it was not possible to comment on the CD4 count although all CD4 counts in this group were less than 250. 10% of these patients had an obvious drop in CD4 count.

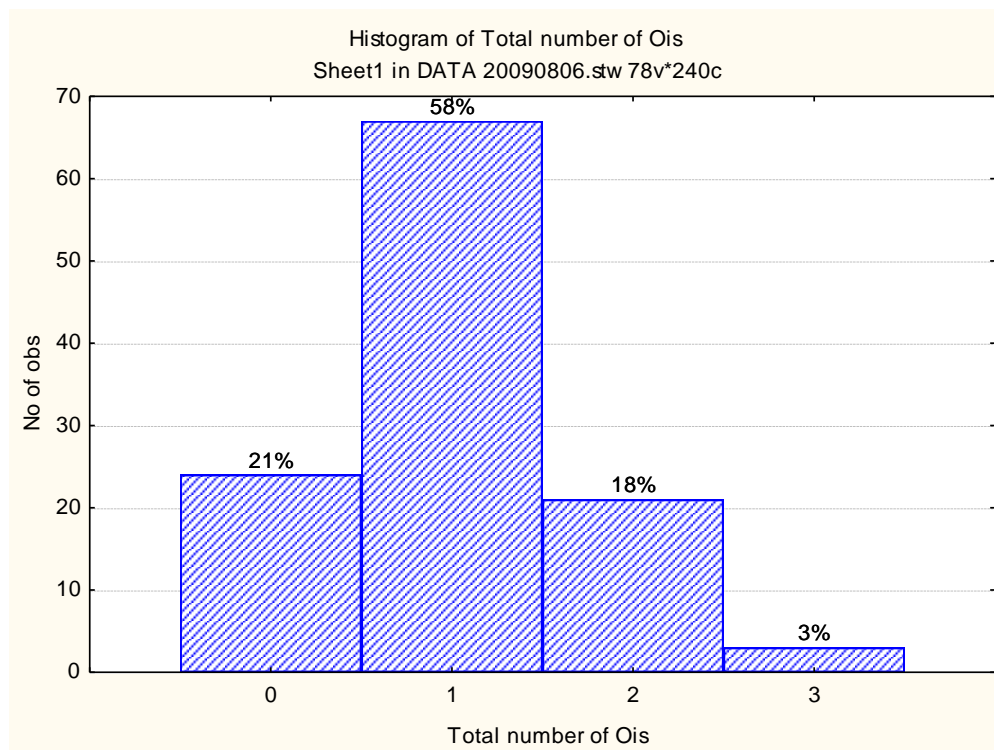
**Figure 17:** Histogram of REASON for defaulting therapy.



Patients were asked to give reasons for stopping their antiretroviral therapy. The following reasons were listed and they could make choices from the list of reasons. A- Financial difficulties, B- ARVs had too many side effects, C- felt sicker with medication, D- Was worried about side effects of drugs, E- Too busy doing other things, F- Travelling so could not keep the routine, G- Did not want anyone to know, H- Felt better

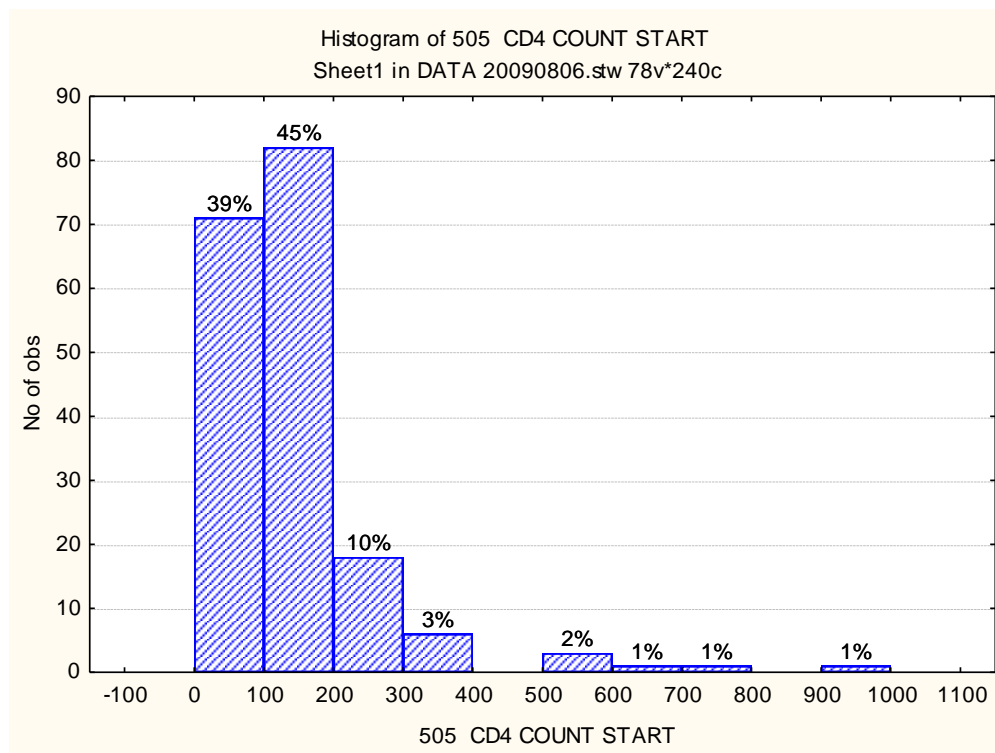
so did not feel the need to continue medication, I- Found it very difficult to take so many pills, J- Health worker told me to stop, K- Other reasons. The histogram as above reflects the reasons patients gave for defaulting therapy. 31% gave a history of stopping on instruction of health workers, 21% said they were travelling and could not keep the routine, 17% were too busy doing other things, 7% stopped because they felt better, 7% stopped because they were worried of the side effects, 7% stopped due to financial difficulties, 3% felt sicker with medication and 7% stopped for other reasons not included in the list. As is seen in the histogram no patients selected the options B,G or I and so these letters are not represented in the histogram.

**Figure 18:** Histogram of Total number of opportunistic infections.



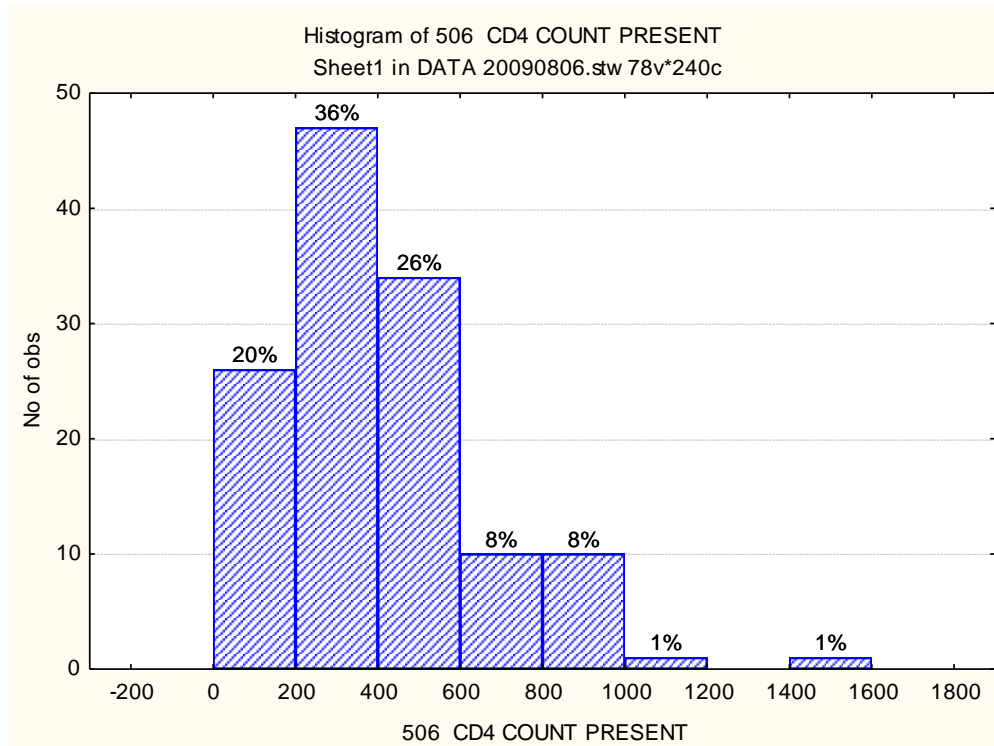
58% of patients had 1 opportunistic infection, 18% had 2 opportunistic infections in the past and 3% had 3 opportunistic infections, 21% of patients had no opportunistic infections.

**Figure 19:** Histogram of CD4 count distribution before starting antiretroviral therapy.



The South African guidelines for starting antiretroviral therapy is used in this clinic, patients who have stage 4 disease sometimes had CD4 count of above 200 and were commenced on therapy. However as reflected by this histogram less than 20% of the study population had CD4 count greater than 200 at the start of antiretroviral therapy.

**Figure 20:** Histogram of distribution - recent CD4 count.



This histogram reflects that about 80% of patients had CD4 count improving to above 200 after commencing antiretroviral therapy compared to the previous histogram where less than 20% of patients had CD4 above 200.

**Figure 21: CD4 before starting therapy**

Summary: 505 CD4 COUNT START

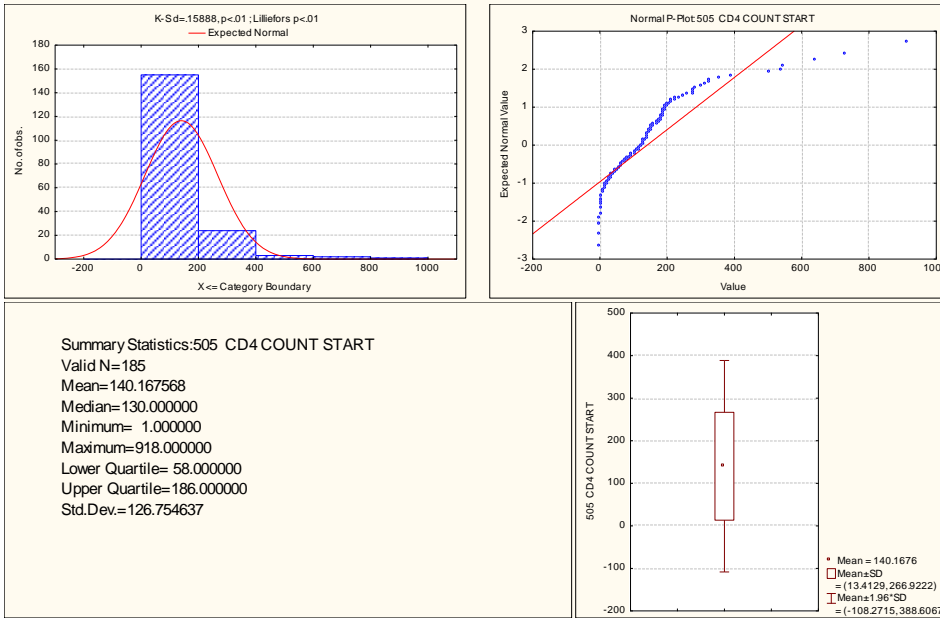
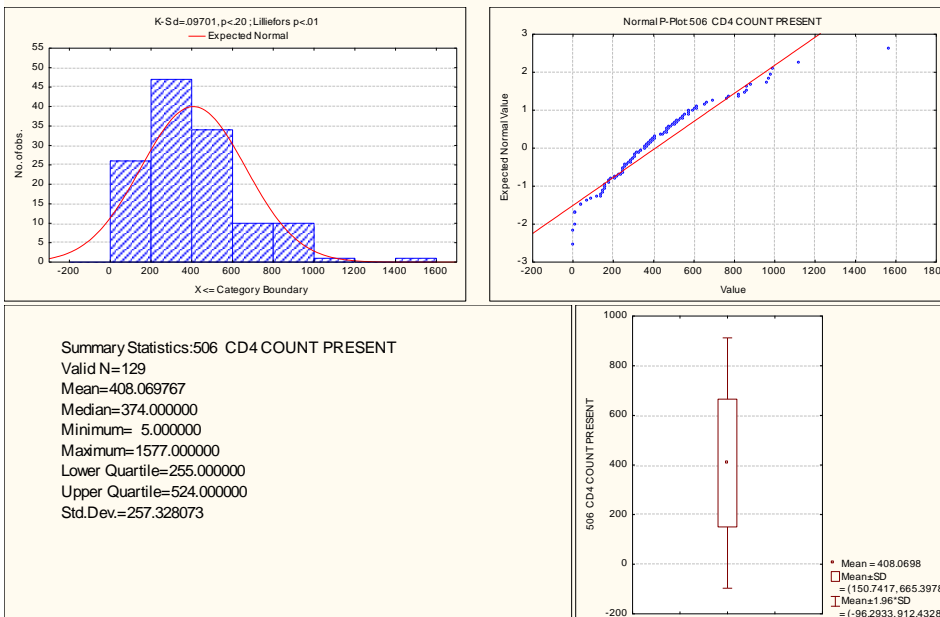


Figure 22: CD4 COUNT RECENT

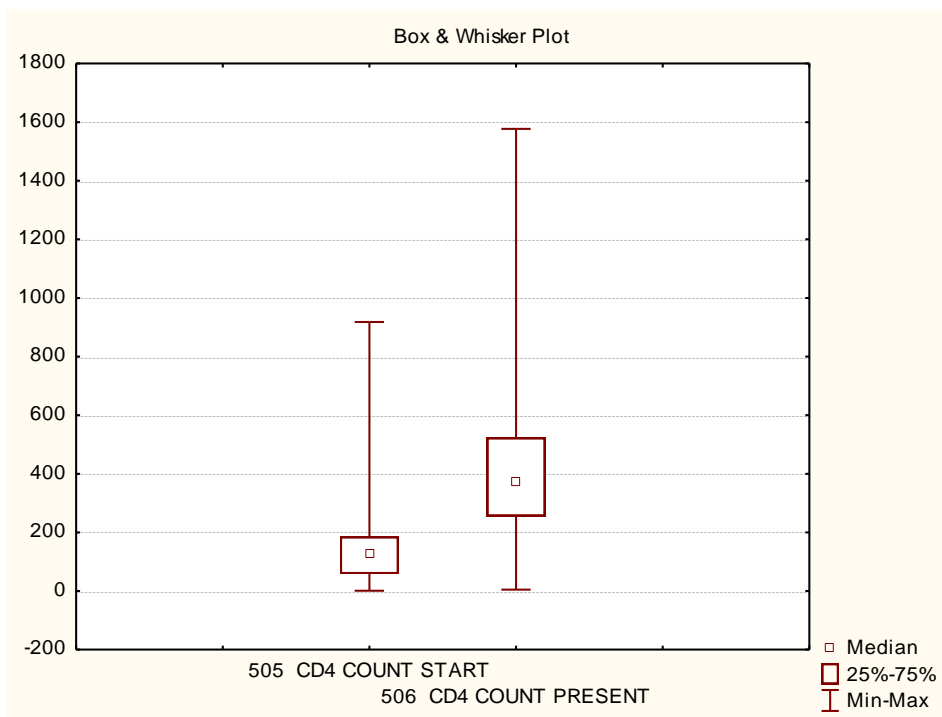
Summary: 506 CD4 COUNT PRESENT



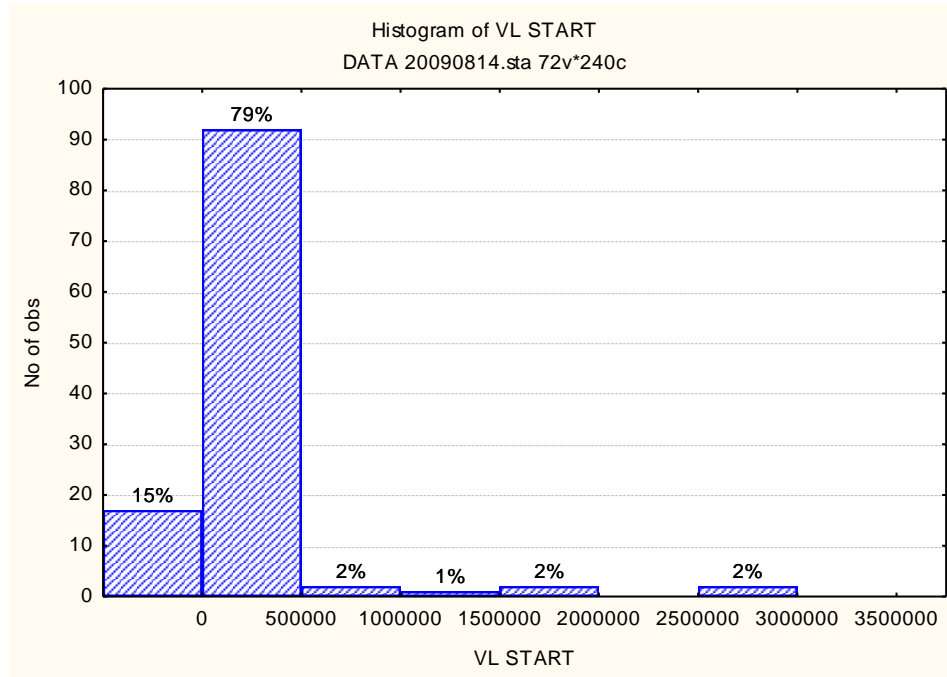
### Wilcoxon Matched Pairs Test (DATA 20090814.sta)

|   |  | Wilcoxon Matched Pairs Test (DATA 20090814.sta) |          |         |         |
|---|--|---|----------|---------|---------|
|   |  | Marked tests are significant at p <.05000       |          |         |         |
| Pair of Variables                         |  | Valid N   | T        | Z       | p-value |
| 505 CD4 COUNT START & 506 CD4 COUNT PRESE |  | 124   | 298.0000 | 8.91988 | 0.00000 |

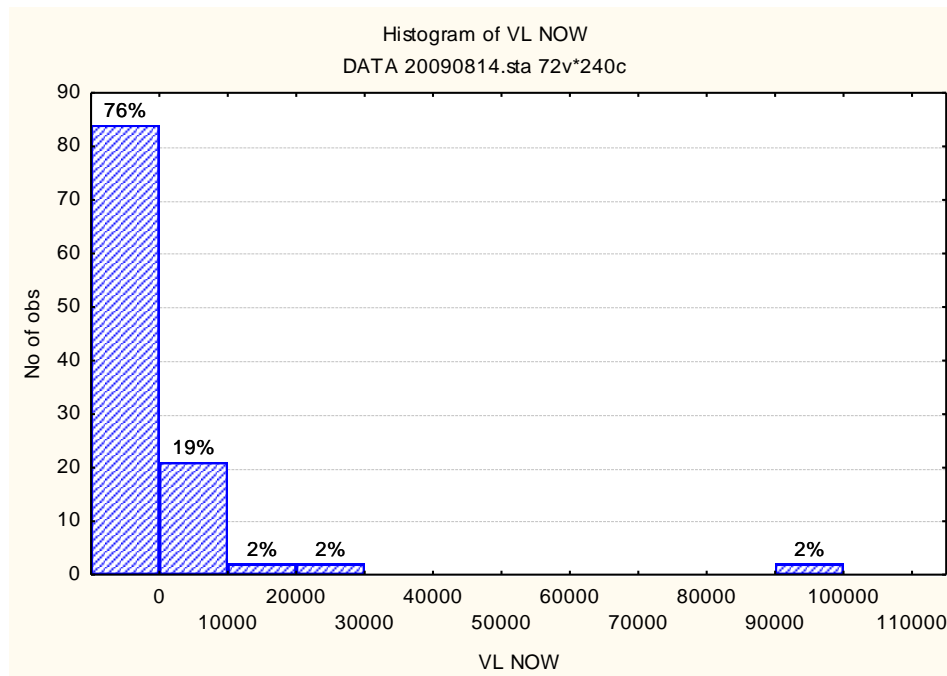
**Figure 23: Box & Whisker Plot**



**Figure 24:** Histogram of VL START



**Figure 25:** Histogram of VL NOW

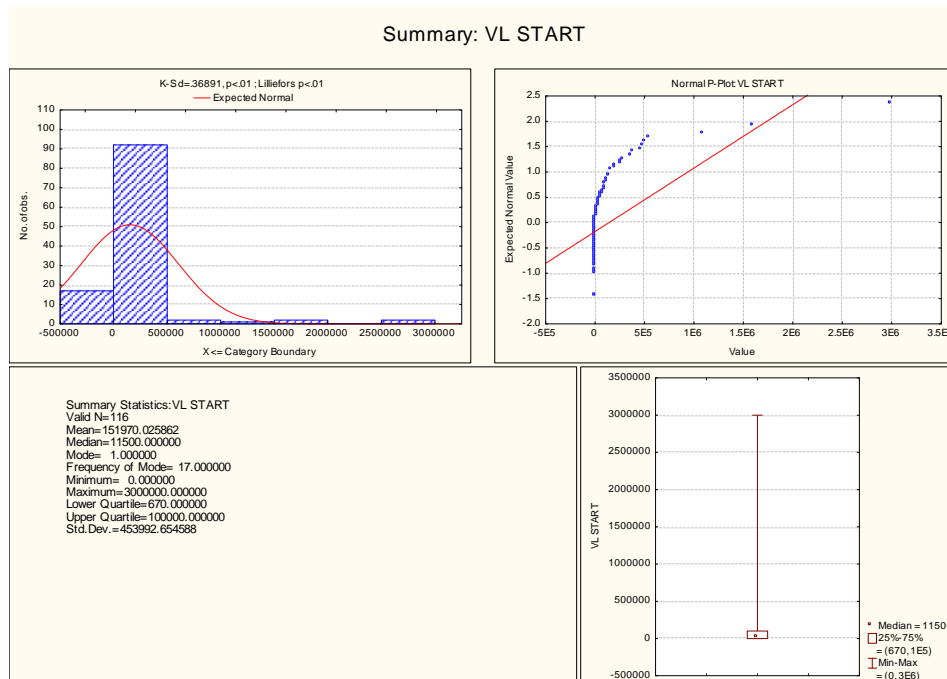




VL – viral load.

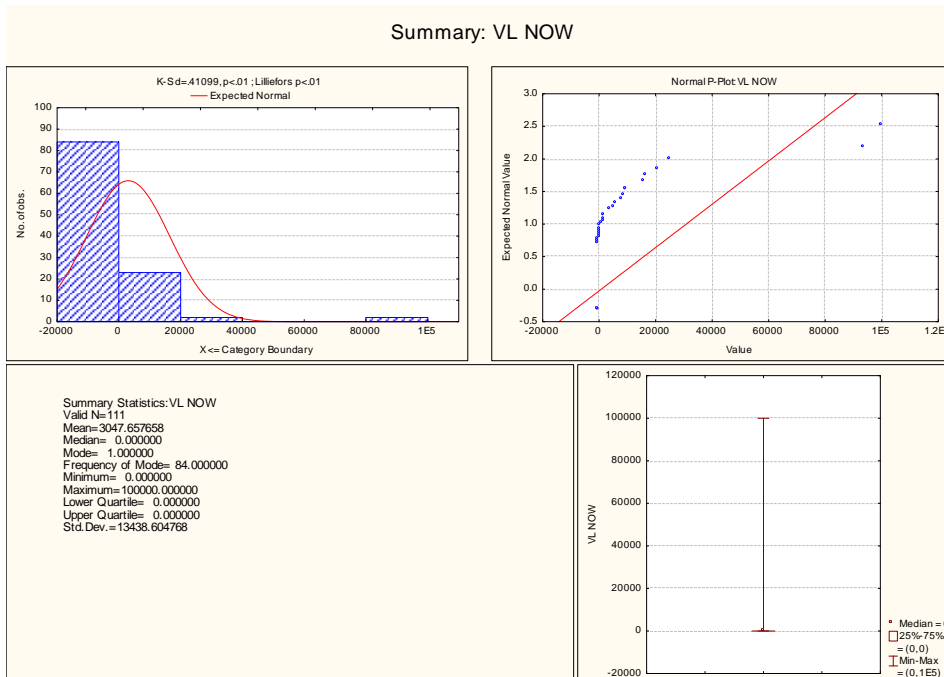
As with the CD4 count the histograms of the viral load at the start of antiretroviral therapy and more recently reflect a drop in viral load. At the start of therapy 79% of patients had viral load in the 0 to 500000 copies per ml range, the recent viral load after patients had been on therapy for a while showed that 76% of patients had undetectable viral loads which is shown here as 0.

**Figure 26: VL START**



VL – viral load

**Figure 27: VL NOW**

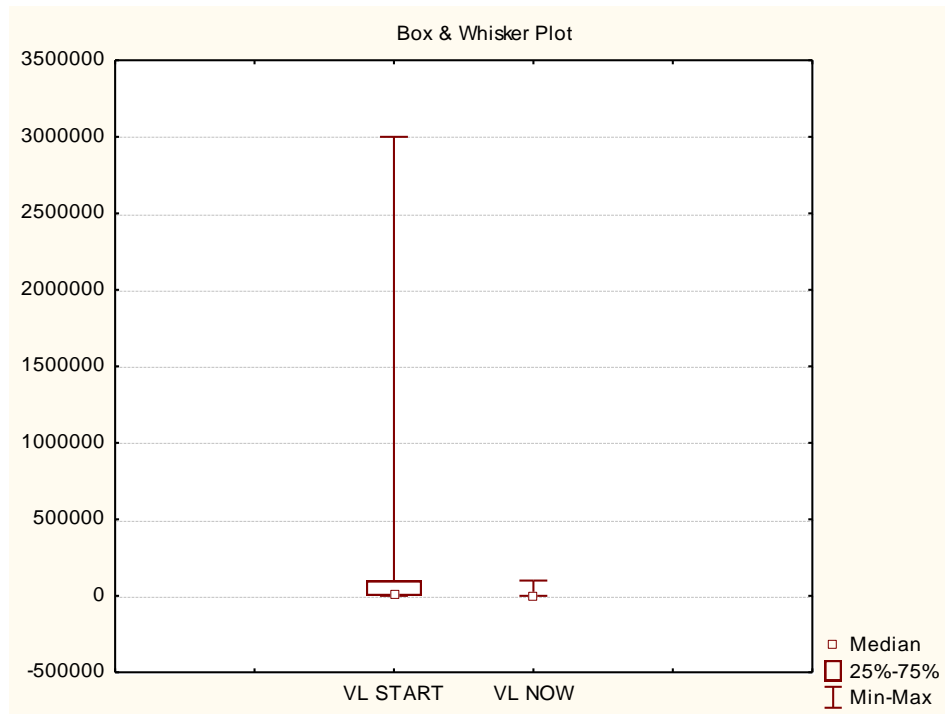


VL – viral load

**Wilcoxon Matched Pairs Test (DATA 20090814.sta)**

| Wilcoxon Matched Pairs Test (DATA 20090814.sta) |         |         |         |         |
|---|---------|---------|---------|---------|
| Marked tests are significant at p <.05000       |         |         |         |         |
| Pair of Variables                               | Valid N | T       | Z       | p-value |
| VL START & VL NOW                               | 68      | 173.000 | 6.11035 | 0.00000 |

**Figure 28: Box & Whisker Plot**



Statistic calculations reflecting a significant rise in CD4 count and drop in viral load variables when comparing levels at start of therapy and recent levels in patients on antiretroviral therapy.

### **Discussion of Results.**

This study has attempted to define the factors that influence adherence at the clinic under study. The factors defined in the different arms of the study reveal that socioeconomic factors play a large role in patient adherence.

In the course of the focus group discussions, patient factors revealed included psychosocial factors that influence patients' emotional stability and directly influence their adherence to antiretroviral therapy. A factor that featured quite prominently in the

course of the discussions is the need for family support. A lot of patients defaulted therapy on account of not having adequate family or partner support, the need to be accepted without having to hide their status from family and friends. A number revealed how the negative stigma in the community influenced how they were shut out by family and close friends. The guideline<sup>10</sup> of patient adherence highlights the role of emotional and practical life supports in patient adherence to antiretroviral. The problems of neglect by family were associated with depression and alcohol abuse in some patients. The use and abuse of alcohol by patients in resource poor settings is also associated with poor or non adherence among patients on antiretroviral therapy.

They also highlighted the need to have better health worker and patient relationships. This is widely recognized in many studies as a good way of encouraging adequate adherence among patients<sup>8</sup>. The clinician needs to understand the context of the patients and avoid a judgemental approach in discussing adherence to medication among patients. There is a need to foster strong relationships with patients, relationships based on trust. Patients in this study highlighted their dissatisfaction with the judgemental attitude often taken by health workers in the course of discussing issues relating to adherence. Clearly revealed in the discussions is the fact that patients understand fully the implication of poor adherence. They also know when they are not adhering to therapy as most were quite to the point in agreeing to being poorly adherent to their medication. They pointed out in some instances their use and abuse of alcohol and how it influenced their adherence to medication. The use of alcohol in the resource poor setting is an accepted norm and patients admitted episodes of abuse that led to defaulting therapy as they did not want to use alcohol and the antiretroviral therapy together.

The semistructured interviews revealed similar causes of poor adherence, patients highlighted the lack of family support, the difficulties experienced in not being able to take their medication in the presence of people outside their home environment for fear of being identified as HIV positive, they expressed the fears of family neglect, the difficulties of dealing with other comorbidities that directly influenced their adherence to antiretroviral medication. 25% of the patients interviewed revealed they were poorly adherent to medication. They cited reasons that varied from the lack of family support structures to fear of the side effects and the difficulties of their comorbidities. A fear of disclosure in the community ranked high among the group of patients in the semistructured interviews and in the course of both focus group discussions. Some mentioned the challenges of financial constraints, not being able to afford food or transport costs to the clinic appointments. This is similar to findings of other qualitative studies that highlight patient related factors as the main factor influencing poor or non adherence.

The quantitative study used a questionnaire that asked about sociodemographic features and then went on to ask about family support systems, community support and issues concerning drug therapy and disease control. The majority of patients were secondary school level educated (see fig.3) and this could negatively impact the understanding of the pharmacodynamics of medication and their side effects. A large number had access to electricity (see fig. 6) and pipe borne water(89%) (see fig.7) in their homes revealing that they were not all indigent. This said however, patients in the majority were unemployed (86%) (see fig. 9), showing that there is a high rate of financial constraints. 99% had disclosed to family (see fig. 11) and 57% to community members. When asked about

satisfaction with family support only 65% were very satisfied with the support they receive from family members (see fig. 13). Very few compared to the whole number were poorly adherent to medication and the major factor influencing poor or non adherence was due to work related commitments or travelling and an inability to keep up with drug schedule (see fig. 17). These are similar to the findings of a study carried out in Soweto (Nachega et al)<sup>13</sup> among patients on antiretroviral therapy where patients listed among the reasons for poor adherence as being away from home, difficulty with dosing schedules and running out of pills.

The assessment of CD4 levels at the start of treatment (mean CD4 - 185) and currently (mean CD4 - 408) among these patients revealed an improvement in CD4 cell levels (see fig. 24). There was also a general decline in viral load levels among these patients (see fig. 28). From studies done so far clinical failure secondary to adherence is rare but patients especially in the 80 -90% adherence bracket are very likely to develop resistant strains of the virus which is cause for worry as this limits the therapeutic options for patients.

### **Limitations**

The focus group discussions were carried out in groups of 20 people per episode the patients may have had reservations in disclosing fully all the factors that influence their adherence to therapy.

The findings of this study are context specific and may not be transferable to other studies elsewhere.

## **CONCLUSION.**

Adherence is dynamic and can not be judged by one measurement, it should be measured as part of an ongoing clinical assessment of patients during clinic visits. The factors highlighted in this study show that the need for emotional support plays a large role in patient adherence to therapy, also important is the need to address the fear of disclosure among patients which deters them from taking medication outside the home.

Socioeconomic factors like lack of food, inability to afford transport to appointments, alcohol abuse which seems to be an accepted norm in the community, the need for strong patient – caregiver relationships are also highlighted as in other studies similar to this one. These factors should serve as a guide in developing interventions aimed at improving the adherence to therapy among patients on antiretroviral therapy.

Unfortunately the stigma of HIV is not one that can be easily removed. However, developing strategies that will aid patient and community awareness through continued education of the community will go a great length in taking the first few steps required to move away from the present predicament.

## **Recommendations.**

- The problem of adherence should be assessed in every patient attending the clinic at regular intervals as every patient is a potential poorly adherent patient.
- All patients should get regular psychologist review to assess the social stressors they have and what can be done to allay their difficulties
- The community served by Dora Nginza hospital is a resource poor community. It needs community development initiatives that will aid the people to draw strength

from one another as a collective. The ideas for this intervention should be developed with direct input from those most affected by the problem i.e. patients and community members.

- The social welfare system has developed grants to help patients, it is important to get their input in building a project that addresses HIV positive individuals directly. The aim is not to give money to these patients but to get them involved in self improvement initiatives.



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**QUESTIONNAIRE - ADDENDUM 1**

Instructions

- To be administered once per patient and each patient is assigned a code.
- To be administered by the Adherence Counselor nurse
- The adherence nurse counselor should have obtained informed consent for the study prior to administering this questionnaire. Signed consent form to be stored in the Master file.

**SUBJECT CODE** -----

---

**DATE:**

[\_\_\_/\_\_\_/\_\_\_] DD/MM/YY

**TREATMENT SITE:** \_\_\_\_\_

**AGE:**

\_\_\_\_\_

**SEX:**

\_\_\_\_\_

**Adherence Nurse Counselor Code:**

\_\_\_\_\_

**Research Interviewer code:**

\_\_\_\_\_

**Informed Consent obtained:**

**Yes**

**1**

**No**

**2**

**Date of Informed consent:**

[\_\_\_/\_\_\_/\_\_\_] DD/MM/YY

**The signed Informed Consent Form for the patient should be collected and placed in the Master file by the Research coordinator.**

| <b>Section I - Demographic information</b> |  | <b>Responses</b>  |
|--|--|---|
| <b>Questions and Filte</b>                 | <b>Coding categories</b>   |   |
| <b>101</b>                                 | What is your highest educational level?<br><br>(Completed years)   | Never attended school 01<br>Preschool 02<br>Primary school (Grade...) 03<br>Secondary school (Grade...) 04<br>Vocational / Technical school 05<br>Diploma 06<br>University level 07<br>Adult literacy 08  |
| <b>102</b>                                 | What is your current marital status?   | Married 01<br>Cohabiting 02<br>Never married 03<br>Divorced or separated 04<br>Widowed 05   |
| <b>103</b>                                 | Who do you currently live with?<br><br>(Multiple responses possible.<br>After respondent answers,<br>probe by asking for any others)<br><br>Do NOT read out answers. | M= Mentioned<br>NM= Not Mentioned<br><br>a) By your self <u>M</u><br>b) Partner/spouse <u>NM</u><br>c) Parents 1 2<br>d) Siblings 1 2<br>e) Children 1 2<br>f) Relatives 1 2<br>g) Friends / Roommates 1 2<br>h) Other (specify)_____ 1 2<br>_____ 1 2<br>_____ 1 2 |
| <b>104</b>                                 | What type of accommodation do you live in?   | Own independent house /flat 01<br>Rented independent house / flat 02<br>Informal housing 03<br>Hostel for students 04<br>Rented room 05<br>Homeless 06<br>Others (specify)_____ 88  |

|            |   |  |   |
|------------|---|--|---|
|            |   |  |   |
| <b>105</b> | Are the following facilities available at your home?<br><br><b>Read out</b> | Y= Yes<br>N= No<br><br>a) Electricity<br>b) Refrigerator<br>c) Radio<br>d) Television<br>e) Bicycle<br>f) Motorcycle<br>g) Car   | Y<br>N<br>1 2<br>1 2<br>1 2<br>1 2<br>1 2<br>1 2<br>1 2 |
| <b>106</b> | What source of water do you use at home?                                    | Piped water to your house/plot<br>Piped water from community tap<br>Well / bore water<br>Purchased water<br>Others (specify)_____  | 01<br>02<br>03<br>04<br>88                              |
| <b>107</b> | What kind of toilet do you use at home?                                     | Own flush toilet<br>Shared flush toilet<br>Own traditional pit latrine<br>Shared traditional pit latrine<br>Own ventilated improved toilet (VIP)<br>Shared VIP<br>No latrine facilities<br>Others (specify)_____ | 01<br>02<br>03<br>04<br>05<br>06<br>07<br>88            |
| <b>108</b> | Are you employed?   | Yes<br>No  | 01<br>02<br><br><b>If no skip to 112</b>                |

|                                  |   |  |  |
|----------------------------------|---|--|--|
| <b>109</b>                       | Do you work on full time or part time basis?  | Full time work<br>Part time work   | 01<br>02                                 |
| <b>110</b>                       | What is your occupation?  | Professional (e.g. teacher, doctor, engineer etc)<br>Skilled (e.g. clerk, welder etc)<br>Unskilled (e.g. cleaner, gardener etc)<br>Others (specify)_____ | 01<br>02<br>03<br>88                     |
| <b>111</b>                       | What is your home district?   | Specify) _____   | 88                                       |
| <b>112</b>                       | How long have you lived in P.E.?<br><br><b>Instruction: enter only 1 category: Weeks, Months, or Years.</b> | Weeks<br>Months<br>Years<br><br>Does not live in P.E.  | [ ][ ]<br>[ ][ ]<br>[ ][ ]<br><br>99     |
| <b>Section 2: Social support</b> |   |  |  |
| <b>201</b>                       | Have you disclosed your HIV status to anyone?   | Yes<br>No  | 01<br>02<br><br><b>If no skip to 204</b> |



|                   |  |  |   |
|-------------------|--|--|---|
| <p><b>202</b></p> | <p>If yes, whom have you disclosed your status to?<br/> <b>Multiple responses possible.</b><br/> <b>After respondent answers, probe by asking for any others)</b></p> <p><b>Do NOT read out answers.</b></p>                     | <p>M= Mentioned<br/> NM= Not Mentioned</p> <p>a) Partner / spouse<br/> b) Parent<br/> c) Sibling<br/> d) Other Relatives<br/> e) Friends<br/> f) Neighbours / community members<br/> g) Friends / Roommates<br/> h) Other (specify)_____</p> | <p><u>M</u><br/> <u>NM</u></p> <p>1 2<br/> 1 2<br/> 1 2<br/> 1 2<br/> 1 2<br/> 1 2<br/> 1 2<br/> 1 2</p>        |
| <p><b>203</b></p> | <p>Why did you disclose your HIV status to these persons?</p>  | <p><b>Open ended answer</b></p>  |   |
| <p><b>204</b></p> | <p>What kind of support do you get from your family and friends?<br/><br/> <b>(Multiple responses possible.</b><br/> <b>After respondent answers, probe by asking for any others)</b></p> <p><b>Do NOT read out answers.</b></p> | <p>M= Mentioned<br/> NM= Not Mentioned</p> <p>a) Encouragement / psychological support<br/> b) Financial support<br/> c) Physical care and support<br/> d) No support<br/> e) Other (specify)_____</p>                                       | <p><u>M</u><br/> <u>NM</u></p> <p>1 2<br/> 1 2<br/> 1 2<br/> 1 2<br/> 1 2</p> <p><b>If none skip to 206</b></p> |
| <p><b>205</b></p> | <p>In general, how satisfied are you with the overall support (help) you get from your family?</p>   | <p>Not satisfied<br/> Not quite satisfied<br/> Moderately satisfied<br/> Very satisfied</p>  | <p>01<br/> 02<br/> 03<br/> 04</p>   |

|     |  |   |  |
|-----|--|---|--|
| 206 | Do you receive support from outside your home or family members?   | Yes<br>No   | 01<br>02<br><br><b>If no skip to 210</b>                 |
| 207 | From where do you get support?<br><b>Multiple responses possible.</b><br><b>After respondent answers, probe by asking for any others)</b><br><br><b>Do NOT read out answers.</b>                                 | M= Mentioned<br>NM= Not Mentioned<br><br>a) NGO<br>b) Community based organization<br>c) Religious based organization<br>d) Government facility<br>e) Other (specify)_____  | <u>M</u><br><u>NM</u><br>1 2<br>1 2<br>1 2<br>1 2<br>1 2 |
| 208 | What kind of support do you get from these organizations?<br><br><b>(Multiple responses possible.</b><br><b>After respondent answers, probe by asking for any others)</b><br><br><b>Do NOT read out answers.</b> | M= Mentioned<br>NM= Not Mentioned<br><br>a) Psychological support<br>b) Financial support<br>c) Physical care and support<br>d) Income generating activities<br>e) Nutritional support<br>f) Legal support<br>g) Other (specify)_____ | M<br>NM<br>1 2<br>1 2<br>1 2<br>1 2<br>1 2<br>1 2<br>1 2 |
| 209 | In general, how satisfied are you with the overall support you get from outside your home?   | Not satisfied<br>Not quite satisfied<br>Moderately satisfied<br>Very satisfied  | 01<br>02<br>03<br>04                                     |
| 210 | To what extent do your friends or family members help you to remember to take your medications?  | Never<br>Occasionally<br>Sometimes<br>Always  | 01<br>02<br>03<br>04                                     |

|     |  |  |   |
|-----|--|--|---|
| 211 | Do you know your spouse's / partner's HIV status? If yes, what is your partner's status?   | Yes positive<br>Yes negative<br>Don't know<br>Not applicable   | 01<br>02<br>03<br>04                      |
| 212 | Is there anyone else in your family who is HIV infected?   | Yes<br>No  | 01<br>02<br><br><b>If No, skip to 301</b> |
| 213 | How many persons are HIV infected?   | Number of persons infected<br>Don't know   | [__ __]<br>[__]                           |
| 214 | Who are they?<br><br><b>(Multiple responses possible. After respondent answers, probe by asking for any others)</b><br><br><b>Do NOT read out answers.</b> | M= Mentioned<br>NM= Not Mentioned<br><br>a) Spouse<br>b) Children<br>c) Sibling<br>d) Other (specify)_____ | M<br>NM<br>1 2<br>1 2<br>1 2<br>1 2       |
| 215 | Is there anyone else in your family taking ARV medications?  | Yes<br>No  | 01<br>02<br><br><b>If No, skip to 301</b> |
|     |  |  |   |
| 216 | Who are they?<br><br><b>(Multiple responses possible. After respondent answers, probe by asking for any others)</b><br><br><b>Do NOT read out answers.</b> | M= Mentioned<br>NM= Not Mentioned<br><br>a) Spouse<br>b) Children<br>c) Sibling<br>d) Other (specify)_____ | M<br>NM<br>1 2<br>1 2<br>1 2<br>1 2       |

| <b>Section 3 Alcohol and drug use</b> |   |               |               |   |
|---------------------------------------|---|---------------|---------------|---|
| <b>301</b>                            | How often have you had an alcoholic drink in the last 30 days?  |               |               | Never 01<br>Once a month 02<br>2-3 times a month 03<br>Once or twice a week 04<br>3-4 times a week 05<br>Nearly every day 06<br>Daily 07<br><br><b>If never skip to 304</b> |
| <b>302</b>                            | On the days when you drank any alcoholic drinks in the past 30 days, how many drinks did you usually have altogether on an average day?<br>Drink = <ul style="list-style-type: none"> <li>○ One 300ml glass or bottle of beer</li> </ul> <b>Or</b> <ul style="list-style-type: none"> <li>○ 45 ml (1.5 oz) of liquor</li> </ul> |               |               | 1-2 / day 01<br>3-4 / day 02<br>5-6 /day 03<br>7-8/ day 04<br>9-11/day 05<br>12 or more/ day 06   |
| <b>303</b>                            | During the past 30 days, how often have you had 5 or more drinks of alcohol within a couple of hours?   |               |               | Never 01<br>Once a month 02<br>2-3 times a month 03<br>Once or twice a week 04<br>3-4 times a week 05<br>Nearly every day 06<br>Daily 07                                    |
| <b>DRUG USE</b>                       |   |               |               |   |
| <b>304</b>                            | <i>Have you ever used recreational drugs?</i><br>Have you used these in the last 6 months?  | 1 Yes<br>2 No | 1 Yes<br>2 No | 01 Once a month<br>02 2-3 times a month<br>03 Once or twice a week<br>04 3-4 times a week<br>05 Nearly every day<br>06 Daily  |

| <b>Section 4 Past use of ARVs</b> |  |  |  |
|-----------------------------------|--|--|--|
| <b>401</b>                        | Have you ever taken ARV medications in the past? | Yes, taking presently<br>Yes, not taking presently<br>No<br>Don't know | 01<br>02<br>03<br>99<br><b>If no<br/>           skip to<br/>           501</b> |

|  |  |   |   |   |
|--|--|---|---|---|
| <p><b>402</b></p> <p>If yes, <b><u>but not taking them presently</u></b>, please give the names and doses of the medications you were taking in the past and for how long (date started / date stopped)?</p> <p><i>In case the respondent does not recall the names of medications please fill in DR</i></p> <p><b>(Multiple responses possible. After respondent answers, probe by asking for any others)</b></p> <p><b>Do NOT read out answers.</b></p>  | <p><b>Name &amp; dose</b></p> <p>Eg AZT 300 mg</p> | <p><b>Date started</b></p> <p>MM/YR</p> | <p><b>Date stopped</b></p> <p>MM/YR</p> | <p><b>Reasons for stopping Tmt with ARVs</b></p> <p>(See codes below)</p> |
|  |  | [ ]/[ ]                                 | [ ]/[ ]                                 |   |
|  |  | [ ]/[ ]                                 | [ ]/[ ]                                 |   |
|  |  | [ ]/[ ]                                 | [ ]/[ ]                                 |   |
|  |  | [ ]/[ ]                                 | [ ]/[ ]                                 |   |
|  |  | [ ]/[ ]                                 | [ ]/[ ]                                 |   |
|  |  | [ ]/[ ]                                 | [ ]/[ ]                                 |   |
| <p><i>Please select reasons for stopping from the following:</i></p> <p><i>Reasons for stopping treatment</i></p> <p>01 Financial difficulties</p> <p>02 ARVs had too many side effects</p> <p>03 Felt sicker with medications</p> <p>04 Was worried about side effects/toxicities</p> <p>05 Too busy doing other things</p> <p>06 Traveling so could not keep the routine</p> <p>07 Did not want anyone to know</p> <p>08 Felt better so did not feel the need to continue medication</p> <p>09 Found it very difficult to take so many pills</p> <p>10 Health worker told me to stop</p> <p>88 Others (specify)_____</p> |  |   |   |   |

|     |  |  |  |
|-----|--|--|--|
| 403 | <p>If you stopped treatment due to financial difficulties, please tell me;</p> <p>(a) How much you were paying for these medications every month?</p> <p>(b) How many months in total did you take them for?</p> | <p>A) Average Cost per month [ ][ ][ ][ ][ ][ ] R c</p> <p>B) Duration medications taken for [ ][ ] months</p> |  |
| 404 | <p>If yes and <b>continuing to take treatment presently</b>, please tell me the doses and names and when started</p>   | <p>Name &amp; dose</p> <p>Eg AZT 300mg one tablet two times/day</p>  | <p>Date started</p> <p>Month/year</p> <p>[ ]/[ ]</p> <p>[ ]/[ ]</p> <p>[ ]/[ ]</p> <p>[ ]/[ ]</p> <p>[ ]/[ ]</p> |

| <b>Section 5 Disease characteristics (to be collected from Study subjects and Medical records.</b> |                                   |   |  |
|--|-----------------------------------|---|--|
| 501  | WHO Clinical stage of HIV disease | <p><b>Stage</b></p> <p>Stage I</p> <p>Stage II</p> <p>Stage III</p> <p>Stage IV</p> | <p><b>Date</b></p> <p>[ ]/[ ]/[ ]</p> <p>[ ]/[ ]/[ ]</p> <p>[ ]/[ ]/[ ]</p> <p>[ ]/[ ]/[ ]</p> <p>[DD/MM/YY]</p> |

|  |   |   |   |  |
|--|---|---|---|--|
| <b>502</b>                               | List OIs (Opportunistic Infections) and number of episodes<br><br><b>Data to be collected from medical records</b>  | Time  | Names of OIs (Opportunistic Infections) | Date of admission/ got medial attn<br>MM /YR |
|  |   | 1   |   |  |
|  |   | 2   |   |  |
|  |   | 3   |   |  |
|  |   | 4   |   |  |
|  |   | 5   |   |  |
| Total number of OIs [__ __]              |   |   |   |  |
| <b>503</b>                               | Please tell me how many times have you been hospitalized—and the reasons why—for HIV related illnesses over in the past 12 months.<br><br><b>Based on patient history or discharge slips)</b> | Time  | Reason for hospitalization              | Date of admission<br>MM /YR                  |
|  |   | 1   |   |  |
|  |   | 2   |   |  |
|  |   | 3   |   |  |
|  |   | 4   |   |  |
|  |   | 5   |   |  |
| Total number of hospitalizations [__ __] |   |   |   |  |
| <b>504</b>                               | Date of first HIV test<br><b>(Ask patient)</b>  | Date of test [__/__/__]<br><b>[DD/MM/YY]</b>                                    |   |  |
| <b>505</b>                               | CD4 counts at start of treatment/Date of test<br><br><b>(Collect from patient –first visit records)</b>   | CD4 count [__ __ __][__ __]<br><br>Date of Test [__/__/__]<br><b>[DD/MM/YY]</b> |   |  |
|  | CD4 count presently/ Date of test<br><b>(Collect from patient records)</b>  | CD4 count [_____<br>Date of Test [__/__/__]<br><b>[DD/MM/YY]</b>                |   |  |
| <b>506</b>                               | VL (Viral load) at start of treatment / Date of test  | Initial VL count [_____<br><br>Date of Test [__/__/__]<br><b>[DD/MM/YY]</b>     |   |  |
|  | VL(Viral load) currently / Date of test   | Current VL count [_____<br>Date of Test [__/__/__]<br><b>[DD/MM/YY]</b>         |   |  |
| <b>507</b>                               | Height / date   | Height [__]Feet [__ __] Inches<br>Date [__/__/__]<br><b>[DD/MM/YY]</b>          |   |  |



|     |               |  |  |
|-----|---------------|--|--|
| 508 | Weight / date | Weight     [ ][ ][ ][ ] . [ ][ ][ ] Kg<br>Date        [ ][ ] / [ ][ ] / [ ][ ]<br>[DD/MM/YY] |  |
|-----|---------------|--|--|

**End Time** [ ][ ][ ] : [ ][ ][ ]

**THANK YOU FOR YOUR TIME!!**

ADDENDUM 2.

Questions for Semi structured Interviews

1. Semi structured interview questions. Sourced from AETC National Resource centre clinical manual of adherence, questions to ask patients on antiretroviral therapy.

1. Do you manage your own medication? If not, who manages them for you?
2. What HIV medication do you take and what is their dosage? When do you take these?
3. How do you remember to take your medication?
4. How many doses of your medication have you missed in the last 3 days, in the last 1 week, in the last 2 weeks, in the last month?
5. On a scale of 1 to 10, where would you say you are with adherence to your medication 1 is that you don't take it all and 10 is that you take every dose at the same time every day.
6. If you are not a 10 what is the reason(s) you are not a 10?
7. When are you most likely to miss doses?
8. Do you have side effects to your antiretroviral therapy? If so what are they?
9. Are you comfortable taking medication in front of others?
10. What is the most difficult problem you have taking your medication?
11. What is your current CD4 count, when was it tested?
12. What is your most recent viral load?
13. What was your previous CD4 count?
14. Do you have family/social support in your fight against this disease?

Interviewer will then evaluate patient's pharmacy refill records which are available in folder and record details of records for preceding 3 months.

ADDENDUM 3

MEDICAL RESEARCH ETHICS COMMITTEE  
PE HOSPITAL COMPLEX

Chairperson: Dr B.G.Brown  
Phone: 041 3923265  
Fax : 0413923329  
Email: [basil.brown@unipib.acprovgva](mailto:basil.brown@unipib.acprovgva)

29 August 2008

Dr El Ajala  
Dora Ngwenya Hospital

Dear Dr Ajala

**RE: STUDY TO EXAMINE THE MAIN FACTORS INFLUENCING ADHERENCE TO ANTI-RETROVIRAL THERAPY BY PATIENTS ATTENDING THE WELLNESS CLINIC AT DORA NGWENYA HOSPITAL**

The committee hereby gives its approval for you to perform this study, as set out in your research proposal submitted to us, on patients attending the Wellness Clinic at Dora Ngwenya Hospital.

We wish you all the best for the successful performance of this study.

Yours sincerely



.....  
Dr B.G.Brown

ADDENDUM 4



UNIVERSITEIT-STELENBOSCH-UNIVERSITY  
UNIVERSITY OF STELENBOSCH

17 February 2009

**MAILED**

Dr FI Ajudua  
Department of Interdisciplinary Health Sciences  
Division of Family Medicine and Primary Care  
Faculty of Health Sciences  
Tygerberg  
7505

Dear Dr Ajudua

"What are the main factors influencing adherence to anti-retroviral therapy at the Dora Nginza Adult Wellness Clinic"

ETHICS REFERENCE NO. N08/10/275

RE : RATIFICATION

At a meeting that was held on 4 February 2009, the Committee for Human Research ratified the approval of the above project by the Chairperson.

Yours faithfully

**MRS ELVIRA ROHLAND**  
RESEARCH DEVELOPMENT AND SUPPORT  
Tel: 021 938 9677 / E-mail: elr@sun.ac.za  
Fax: 021 931 3352

17 February 2009 14:24

Page 1 of 1



FAKULTeit Gesondheidswetenskappe - Faculty of Health Sciences



Verbind tot Optimale Gesondheid - Committed to Optimal Health  
Afdeling Navorsingsontwikkeling en -steun - Division of Research Development and Support  
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## **ADDENDUM 5 – Informed Consent.**

### **Informed Consent.**

**Title of Research Project:** What are the main factors influencing adherence to antiretroviral therapy at the Dora Nginza Hospital Adult Wellness Clinic?

Reference Number:

Principal Investigator: Dr Febisola I Ajudua.

Address: Eastern Cape Department of Health  
Dora Nginza Hospital.

Contact Number: 0832694029

You are being invited to take part in a research project. Please take time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you clearly understand what this research entails and how you could be involved. Also, your participation is entirely voluntary and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the Committee for Human Research at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines For Research.

This study is to be conducted at the Dora Nginza Hospital Wellness clinic and a total number of 250 patients are to be recruited for the various aspects of the study. The study is aiming to describe the prevalent factors influencing adherence to antiretroviral therapy among patients at this clinic. Three methods will be used to gather information in depth interviews which will be conducted by the medical staff of the clinic with participating patients, focused group discussions which will be conducted among patients with the help of a facilitator who is a member of staff at the clinic and the principal investigator and a questionnaire of not more than 25 questions that will be filled by patient answering questions relevant to the topic of this study. The sampling of patients for this study has been conducted randomly and so not all patients attending this clinic will participate in the study only patients selected by the random sampling process.

You have been invited to join in the study as you have been randomly selected among the patients to be included in this study.

Your responsibility will include participating in the study as you have been counseled by the medical staff. This will involve you answering questions in an indepth interview/ participating in a focused group discussion/ answering he questionnaire with the help of the member of staff explaining this procedure to you.

It must be explained clearly to you at this point that there will be no personal benefits to you aside of the general benefits to be gained from the knowledge of the results of this study that will enable us to make recommendations to assist patients in improving their adherence to the antiretroviral therapy. There are no personal risks involved in your participation in this study. The results and the findings of the study are strictly confidential and access to the records of the study is only accessible to the principal investigator and no one else. You will not be required to personally identify yourself at any point in the whole proceedings. There is no monetary remuneration for your involvement in this study and there are no costs to you as a participant in the study. You can contact the Wellness clinic staff if you have any further queries about this study at this number 041 406????

You will receive a copy of this consent form for your own records.

By signing below, I ----- agree to take part in a research study entitled ‘What are the prevalent factors influencing adherence to antiretroviral therapy at the Dora Nginza Hospital Wellness Clinic?’

I declare that

- I have read OR had read to me this information and consent form and it is written in a language with which I am fluent and comfortable
- I have had a chance to ask questions and all my questions have been adequately answered
- I understand that taking part in this study is voluntary and I have not been pressurized to take part
- I may choose to leave the study at any time and will not be penalized or prejudiced in any way
- I may be asked to leave the study before it has finished, if the study Doctor or researcher feels it is in my best interests, or if I do not follow the study plan as agreed to

Signed at ----- on -----2009.

-----  
Signature or thumbprint of participant

-----  
Signature of witness

Declaration by investigator.

I Dr F.I. Ajudua declare that:-

- I explained the information in this document to -----
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a translator.

Signed at ----- on -----2009.

-----  
Signature of investigator

-----  
Signature of witness.

## **ADDENDUM 6**

The Medical Superintendent,  
Dora Nginza Hospital,  
Port Elizabeth Hospital Complex.  
Port Elizabeth.

Dear Sir,

### **LETTER FOR PERMISSION TO CONDUCT RESEARCH**

I hereby apply for permission to conduct research in the Adult Wellness clinic of the Dora Nginza hospital

I am currently a third year post graduate student of the Division of Family Medicine and Primary Care, Faculty of Health Sciences, Stellenbosch University and the topic of my Thesis is: ‘Adherence to antiretroviral therapy at the Dora Nginza hospital adult wellness clinic, Port Elizabeth South Africa ‘ The study is set in the wellness clinic of Dora Nginza Hospital.

I would be much obliged if you would grant me permission to go ahead with this project.

In addition please find copies of ethics approval from the university of Stellenbosch Ethics committee as well as a copy of the research protocol attached for your perusal..

Kind regards and best wishes.

-----  
Dr Febi Ajudua.