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An Evaluation of determinants of adherence to antiretroviral therapy in AIDS patients in Gert Sibande District, Mpumalanga Province

By

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Declaration

I Laszchenov Muzimkhulu Zungu declare that the work that I hereby submit for the degree Master of Medicine (Community Health) is my own and has not been presented either wholly or in part for any other degree.

Signed

Dr LM Zungu Date:

Dedication

This work is dedicated to my parents especially my father Magagu Zungu for the grounding he gave me while growing up; my wife Unathi Fana-Zungu for all the love, support and inspiration she gives me everyday; and my children Ulwandle and Summer Zungu for making it all worthwhile, ‘Nginithanda ngenhliziyo yami yonke’.

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List of abbreviations

AIDS	Acquired Immuno-deficiency Syndrome
ART	Antiretroviral Therapy
ARVs	Antiretroviral Drugs
DOTS	Directly Observed Treatment Short Course
HAART	Highly Active Antiretroviral Therapy
HDI	Human Development Index
HIV	Human Immuno-deficiency Virus
WHO	World Health Organisation

Abstract

Title: An Evaluation of determinants of adherence to antiretroviral therapy in AIDS patients in Gert Sibande District, Mpumalanga Province

Introduction

An estimated 11.4% of South Africans are infected with HIV. As of 2007, 1.7 million people required antiretroviral therapy (ART) and only 460 000 were reported to be on ART. ART can improve the quality of life and socio-economic status for HIV positive patients. This study aimed at evaluating the role played by the different factors in influencing treatment adherence among HIV patients on ART.

Methods

The study was conducted on patients receiving out-patient ART in two district hospitals (one urban and the other rural) of Mpumalanga Province, South Africa. The study project was approved by the Research and Ethics Committee of the University of Pretoria as well as by the Mpumalanga Provincial Department of Health. This was an analytical, cross-sectional study. The sample size for the study was 490 (245 per site). Facility-based patient appointment registers for the period June-August 2008 were used as the sampling frame. The respondents were selected through systematic random sampling. An interviewer directed standardised questionnaire was administered to the respondents after securing voluntary informed consent. Data were also extracted from the attendance registers in the two facilities. Adherence was measured using the Patient Medication Treatment Adherence Questionnaire. The Pearson chi-square test of association and binary logistic regression analysis were used for identifying significant predictors of non-adherence variables.

Results

Four hundred and twenty nine questionnaires of the 488 returned questionnaires were analysed. Sixty one questionnaires were disqualified due to incompleteness of data. The response rate was 99.7% in both study areas and participants reported adherence was 92.54%. The median age of the respondents was 36 (IQR, 13), gender distribution was 21.13% males and 78.87% females. The median duration of treatment (in months) with ART was 15 months (IQR, 18). Treatment adherence was higher in the urban than in the rural hospital. The variables that were significantly associated with non-adherence were 'urban residence' (OR 0.39 [0.2-0.8]); 'lack of social support' (OR 2.74 [1.3-5.7]);

Discussion

There were also some qualitative variables that had a bearing on quality of healthcare services that could explain differences between the rural and urban sites. Social support and urban residence demonstrated association with treatment adherence.

CHAPTER 1: INTRODUCTION

Introduction

South Africa is among the countries with the highest incidence and prevalence of Human Immunodeficiency Virus (HIV) infection in the world. This has led to the South African government and Department of Health taking the recommendations of the world health organisation to provide antiretroviral therapy to people suffering from Acquired Immunodeficiency Syndrome (AIDS).

The South African government has established the highest decision making body on HIV in the form of the South African National AIDS Council (SANAC). SANAC was established to strengthen the political leadership and inclusion of civil society in the response against HIV[1]. This decision led to the introduction of the strategic plan for HIV and AIDS 2000 – 2005 (and 2007 -2011) and the operational plan for comprehensive HIV and AIDS Care, Management and Treatment for South Africa in 2003.

Since 2004 South Africa has gradually been expanding the number the antiretroviral therapy sites across the country. As a result a large proportion of the health budget is spent on combating the effects of the epidemic. This is also associated with the ever-increasing demand for treatment of AIDS patients who are currently on ART (antiretroviral therapy) and those that are waiting in line to be enrolled into the programme.

The high prevalence of HIV infection suggests that more and more people will, in the late stages of the infection, require treatment with ART. This is due to the fact that, as people are taking ART, they remain on the system and added to them are new patients being enrolled.

Concerns have been raised that notwithstanding the introduction of ART, mortality among those treated has remained high in South Africa, even though the availability of highly active antiretroviral therapy (HAART) has dramatically reduced HIV-related morbidity and mortality in other countries worldwide[2].

The high morbidity and mortality has been, among other things, the result of inequitable access to antiretroviral drugs (ARVs), the late commencement of therapy when organ damage is in the advanced stages and poor adherence to ART. In addition, as the number of patients increase in the different ART sites, the resources utilised, that is, human and material, is increased markedly with minimal returns.

The health care system is faced with the challenge of improving the quality of life, especially health related quality of life, for the patients receiving ART. This becomes an important aspect of the total package as a patient with improved quality of life will either neglect their treatment, because they feel better, or on the other hand, they may maintain adherence, as they will have seen the benefits of the treatment.

Numerous factors play an important part in influencing treatment adherence among patients who are on chronic medication. Understanding these factors is particularly important in those on ARVs as treatment with these drugs is lifelong and costly while failure to adhere to treatment increases the risk of the development of resistant HIV strains.

The purpose of this study is to describe the factors that influence adherence of patients enrolled into the ART programme since its implementation in Mpumalanga Province, at Bethal and Embuleni hospitals of Gert Sibande District.

Literature Review

HIV/AIDS is a pandemic that affects all communities around the globe, especially Sub-Saharan Africa. It is estimated that about 33 million people are infected worldwide; about two thirds of these people live in Sub-Saharan Africa[3]. South Africa has a population of about 48 million, and about 11.4% of the population is estimated to be infected with HIV[4]. South Africa has nine provinces that are affected to varying degrees with HIV, with Mpumalanga ranking in the 2nd place behind KwaZulu Natal[4]. In 2007, there was an estimated 1.7 million AIDS patients requiring ARVs, with only an estimated 460 000 patients receiving ARVs in South Africa[5].

South Africa has made tremendous strides towards the fight against HIV/AIDS through the Strategic Plan for HIV and AIDS, 2000-2005 (2007-2011), and the Comprehensive Plan for the Management, Care and Treatment of HIV and AIDS in South Africa. The plan includes the National Antiretroviral Treatment Guidelines which highlight the fact that adherence to antiretroviral therapy is essential to maintain long-term health benefits and avoid development of drug resistance[6].

Adherence to antiretroviral therapy has been defined by a number of authors using different criteria. These criteria include self reported adherence by patients which is subjective and objective measures such as prescribed tablets counting, biological markers such as viral load, CD4 cell counts and even serum drug levels. In this study, as in others, adherence has been measured using the subjective measure of self reported adherence by patients. Adherence is deemed satisfactory or good adherence if reported by the patients to be greater or equal to 95% of the pills prescribed in a week were taken in accordance with the prescribed regimen[7,8].

Adherence to antiretroviral drugs in the developing world, including South Africa was the subject of debate amongst donors, scientists, pharmaceutical companies, activists and patients over the issue of adherence in resource limited areas towards the beginning of this century. Adherence to antiretroviral therapy is crucial for viral suppression and prevention of resistance to antiretroviral drugs, as HIV is known for its ability to mutate aggressively.

In the late nineties the debate over the provision of antiretroviral therapy in South Africa was top of the agenda when it came to interventions against HIV. The international community and even some within the country were not convinced that the country with its social and demographic background was ready for ART, especially because of the high degree of non-adherence in patients taking Tuberculosis medicines in the presence of Directly Observed Short Course treatment for tuberculosis (DOTS) and other chronic medicines. This was due to the fact that studies in the past had shown that compliance to chronic medications was in the region of 50%[9]. It is estimated that only a third of patients on antiretroviral drugs take their treatment as prescribed[10].

The factors that influence adherence to antiretroviral therapy have been identified by other studies and are grouped into the same dimensions and reported in the same sequence as those used by the World Health Organization: socioeconomic factors, healthcare team and system-related factors, condition-related factors, therapy-related factors and patient-related factors[10].

This resulted in a number of clinical trials concentrating on antiretroviral therapy roll out in Cape Town and Johannesburg in particular. Most of these studies were designed such that they were able to answer if gender, race, low socio-economic status, unemployment and low educational achievement were significantly associated with non-adherence to antiretroviral therapy in resource limited countries.

It was shown that gender, education, low socio-economic status, race and cultural background in Sub-Saharan Africa were not significantly associated with non-adherence to antiretroviral therapy [11, 12, 13]. There are a number of other studies though, that identified barriers to adherence among patients taking antiretroviral therapy. These include young age of patient, number of daily doses greater than two and extent language used, if different from that of the health educator[2], had a negative impact on the treatment adherence of the patient.

This was evidence enough to convince the National Health Department to provide ART in South Africa as now evidence was in place to prove that the conditions were similar to those of the developed countries as long as the treatment is at no cost to the patient. In the preliminary stages the practice appears to have been successful to a degree, this is because of the lack objective measures to determine adherence.

Currently, the system is unable to determine the reasons for adherence and non-adherence of patients. There is a lack of follow up of patients who leave the system due to death or other reason and this creates room for health system research measures looking into the gaps in the system, even though the National Department of Health monitors health programs through the District Health Information System.

To date antiretroviral therapy roll out has been shown to be successful in a number of countries in Sub-Saharan Africa, including Uganda, Senegal and South Africa. The elements of the success have been the provision of ART in the primary care setting, close to patient's environment, simplicity of therapy, careful preparation of patients and the continuity of care with patients being cared for by the same team[14, 15].

Adherence to ART is a lifetime commitment that will certainly encounter difficulties to maintain. There are some studies that have looked at the factors that are associated with non-adherence to antiretroviral therapy. It was found that younger age, dosing associated with food restrictions, previous history of non-adherence, co-morbidity, relief of symptoms, mistrust of health provider, complex regimen and chronicity of treatment were associated with nonadherence [14, 15, 16, 17].

Antiretroviral therapy is a lifetime commitment and as such adherence for individuals on treatment over time may be subject to variations as the patients experience a number of factors related to his/her health. These are factors such as co-morbidities, side effects of medications, employment and unemployment issues, healthcare practitioner-patient relationships and change in prescribed regimine[16].

The adherence to antiretroviral therapy can be measured subjectively based on self reported adherence and objectively using pill counts, direct measurement of ARV drug levels, rising CD4 cell counts (immune reconstitution measure), the HIV RNA viral load, and observing if viral suppression is achieved as stated earlier in the report.

Viral resistance will result in a detectable viral load amongst patients who are adherent to treatment. The South African government has adopted the management sciences for health (MSH) tool, a multi method tool[18] for adherence assessment and measurement, which measures adherence based on 4 elements: Self report, Visual analogue scale (VAS), Pill identification test (PIT) and Pill count.

It has been found though that self reported adherence is the most feasible and can be replicated by clinic staff[16] even in the more rural of settings. Adherence to antiretroviral therapy has been described to be adequate if it is above or equal to

95%, but studies have shown that the worst acceptable level of adherence with significant viral suppression is 80% adherence[10].

The challenge in the era of ART is to maintain adherence for the patients over a lifetime, which is difficult to achieve. There is evidence that there is less adherence as time progresses. The second problem is making sure that patients continue to receive a good foundation during the scaling up of ART in the presence of increasing workload with less capacity at the treatment centres[6].

The key challenge will be balancing programme quality against coverage[14]. Because of this, there is the anticipation of decreased time spent on each patient, which has the potential to decrease adherence in patients enrolled later in the programme. In South Africa there are backlogs with patients waiting to be started on ART.

Even though adherence is an important aspect of the service delivered by the public health system, there are other questions that are important to the policy makers that may be of use in terms of measuring effectiveness of the programme. Those will be questions around the issue of quality of life of the patients receiving the services. This information can only be provided by patients' themselves[19].

It is a fact also that patient provided information is subjective, and can overestimate or underestimate the nature of a perceived problem; as a result probability sampling will be crucial to increase variability[20]. At the level of the individual caregiver, optimizing quality of life among patients with HIV will be essential to improving adherence to treatment regimens[19].

Rationale for the Study

Antiretroviral therapy has been shown by several studies that, when prescribed, it can improve the quality of life for HIV positive patients. This can only result if there is strict adherence to treatment. In the case of non-adherence to treatment, the result is increased drug resistance to antiretroviral drugs, which will result in a number of complications such as opportunistic infections. The increased number of complications will result in recurrent hospital admissions, poor quality of life and increased contact with health care systems which will increase health care expenditure for the government.

There are a number of studies that show that provision of antiretroviral therapy in areas with limited resources is as successful as in the developed world if patients are properly prepared. The pitfall has been the increasing number of people needing antiretroviral therapy and the shortage of resources to cater for all those in need.

South Africa and in particular the Mpumalanga Province, has a serious shortage of health care workers and the shortage existed even before the HIV/AIDS epidemic became evident. As a result, the implementation of the antiretroviral therapy sites in most areas was depended on resources that were limited from the beginning. With the ever-increasing number of people on antiretroviral therapy it is important to determine the factors that influence adherence to antiretroviral therapy. The determination of the factors that influence adherence to antiretroviral therapy will assist in future programme planning. Programme planning will allow the Department of Health, together with other stakeholders to deal with these factors affecting adherence.

CHAPTER 2: AIMS AND OBJECTIVES

Aim

The aim of the study was to determine the factors that influence treatment adherence in HIV/AIDS patients to antiretroviral therapy

The objectives of the study were:

Primary objective

To determine the factors that influence treatment adherence to antiretroviral therapy at Bethal (urban) and Embuleni (rural) district hospitals of the Gert Sibande District in Mpumalanga province during the period June to August 2008.

Secondary objective

1. To validate the self-reported treatment adherence to ART with objective evidence and response as shown by biological markers (RNA Viral load) in AIDS patients of Bethal and Embuleni district hospitals of the Gert Sibande District in Mpumalanga province, during the period June to August 2008

CHAPTER 3: METHODS AND DATA COLLECTION

Definition of terms

Adherence – is taking all the pills and doses as instructed by the health workers in the last 5 days

Cost of travel – is the cost of traveling to and from hospital in South African Rands

Duration of treatment/or on ART – is the time elapsed since starting ARV drugs

Knowledge of last Saturday's medicines – awareness of the number of pills and doses taken the previous Saturday

Latest CD4 – latest CD4 cell count results available from the laboratory

Regimen type – type of drug regimen according to government specifications

Residence – site of treatment collection, may be rural (Embuleni) or urban (Bethal)

Wellness clinic – is an outpatient clinic offering services for HIV/AIDS and related activities within a hospital.

Settings

The study was conducted in Gert Sibande District, of Mpumalanga Province South Africa (see fig 1). Mpumalanga is a relatively rural province with a land area of about 79 490 km^2, a population of 4 000 000 of which 25% are in Gert Sibande District and a population density of 50 people per km^2. The economy of the province is based mainly on agriculture, travel and tourism and to some extent coal mining[21].

Gert Sibande District has a population growth rate of 1.3%, a Gini coefficient of 0.64 and human development index (HDI) of 0.55[21]. The percentage of people living in poverty is 54.8%, with an unemployment rate of 39.4% based on the

expanded definition[21]. The economically active population as percentage of total population, is 39%[21.]

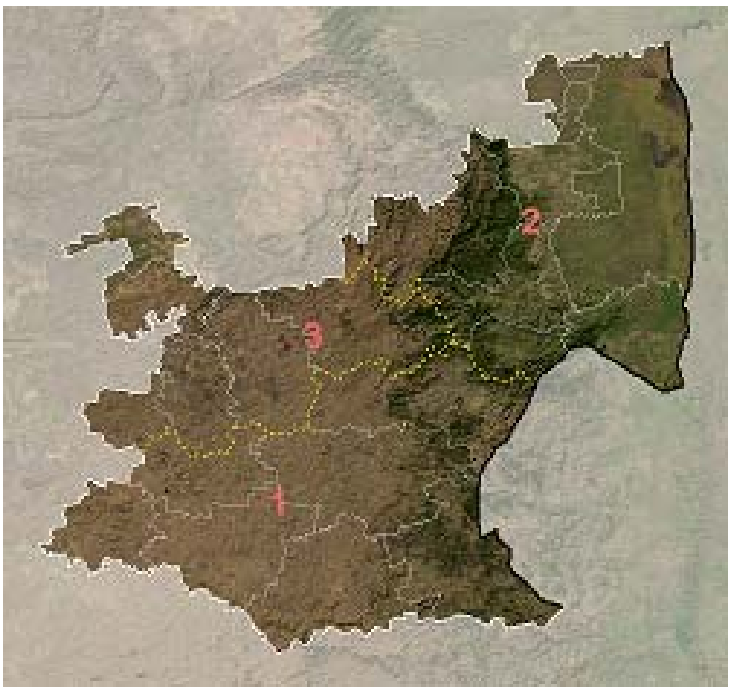

Fig 1: Map of Mpumalanga Province (1 = Gert Sibande, 2 = Ehlanzeni and 3 = Nkangala Districts). Source: www.maplibrary.org

The study sites were chosen from Gert Sibande District. These were Bethal and Embuleni district hospitals. The two hospitals were different in a number of respects including, but not limited to the following:

- Embuleni District Hospital is a rural hospital, serving the rural population of Albert Luthuli Municipality. The nearest town is Nelspruit, which is a distance of 110 km from the hospital. There are a number of villages in the area with the most prominent being Elukwatini. The patients attending this hospital at times have to walk over 20 km to get to hospital.
- Bethal District Hospital is a small town hospital, serving the population of Govern Mbeki Municipality. The town has a relatively good public transport system. Bethal is within 50 km of other neighbouring towns. This would mean that villagers served in Bethal Hospital from the surrounding area

can access public transport with relative ease compared to Embuleni Hospital patients.

- Accessibility
  - Embuleni
    - Poor public transport
    - More expensive travel cost
  - Bethal
    - Readily available public transport
    - Less costly travel cost

The study was conducted in the wellness clinics (outpatient clinic) of both Bethal and Embuleni Hospitals. The two sites were chosen for the following reasons:

- Embuleni hospital was the most rural site in Gert Sibande District and was fully functionally
- Bethal Hospital is in an urban area, it also fully functional
- Bethal Hospital is conveniently located, because it is the closest town in Gert Sibande District, to Pretoria.
- Each of these facilities has an established ART clinic with accreditation since 2004
- Both hospitals have relatively large numbers of patients currently enrolled on ART

The study sites were from the same Province and district, and as such the application of policies was also the same

- At both sites the staff was employed by the Department of Health and Social Development with a few staff coming from the Non Governmental Organisation (Right To Care), these included:
  - For Bethal hospital they provided a data capturer, data manager and a pharmacist dedicated to the wellness clinic

- For Embuleni hospital they provided a clerk, two lay counsellors and the medical doctor

Table 1: Human Resources for Health in the two study sites

	Bethal District Hospital	**Embuleni District Hospital**
Medical officer(s)	1	1
Professional Nurse(s)	2	3
Enrolled Nurse(s)	1	0
Assistant Nurse(s)	2	1
Pharmacist(s)	1	0
Dietician(s)	2	1
Social worker(s)	1	1
Lay counsellor(s)	3	5
Data Manager	1	1
Clerk(s)	1	1

Processes followed prior to enrolment to ART for both sites

- Day 1: All patients are referred from the Primary Health Care clinics with laboratory results of HIV test and their CD4 cell counts. At the facility the following takes place
  - Education about HIV and AIDS
  - Advice on lifestyle modification
  - Assessment of HIV status acceptance
  - Medical doctor screens patient for opportunistic infections including PTB and evaluates liver function tests, urea and electrolytes and the full blood count
  - Dietician gives nutrition advice

    - And the patient is advised to disclose their HIV status to at least one relative or confidant and return with that person in two weeks for further education about HIV and AIDS, ARVs, side effects of ARVs and all other matters pertaining to the ART programme
- Day 2 (two weeks later): Patient gets education again and discusses issues relating to
    - Importance of adherence to ART
    - ARV medications
    - Side effects of medication
    - The social worker counsels them again and assesses the home environment
    - A home visit is scheduled, and the lay counsellors visit patients at home
    - Another two weeks is given to the patient so that they can prepare themselves psychologically for starting ARVs
- Day 3 (four weeks since the first visit): At this visit the patients will start their ART programme including ARVs if all screening test are satisfactorily. If the screening tests are not satisfactorily the doctors will manage accordingly until patient is ready to start ARVs.

Both study sites reported that their waiting times for patients average between 1-3 hours everyday depending on the busyness of the wellness clinic and how early the patient was. In terms of loss to follow up to the ART programme, Bethal hospital reports less than 3%, while Embuleni hospital reports just under 20% loss to follow-up. The protocol followed in case of loss to follow up differs slightly between the two institutions.

For Bethal if a patient misses an appointment by three days, they are contacted by telephone, then a community health worker visits patient at home and if still missing then declared lost to follow up. While for Embuleni they claim that it is difficult to trace patients who are not coming for medicines, they usually wait for a

week to 2 weeks before tracing those lost to follow up telephonically through the social worker. Embuleni does not report a home visit to trace those lost to follow up.

Population

The study population was comprised of all the patients who attend the AIDS ART (also referred to as the wellness) clinics of the two district hospitals. The patients had to be on antiretroviral therapy and had to have been on ART treatment for a period of not less than 4 weeks.

Fig 2: Study population and sample

Study design

This was a cross-sectional study in which 490 patients were interviewed in the two sites accredited to provide ART in Gert Sibande District of Mpumalanga Province.

Sample size of study

The sample size was determined using the statistical package nQuery Advisor version 4.0. Based on the following assumptions:

Level of significance = 5%

Two-sided test of proportions (2 independent groups)

Proportion of non adherence in Group 1 = 23%

Proportion of non adherence in Group 2 = 25%

Odds Ratio = 1.889

Power of test = 80%

Using the above assumptions, the sample size of the study per group was equal to 245 respondents.

The sample size was based on the number of patients that were enrolled at the Bethal Hospital (560 patients as of the 27 February 2007) and those enrolled at the Embuleni Hospital (600 patients as of the 27 February 2007). Each of these hospitals attends to about 60 patients per day for antiretroviral therapy in their wellness clinics. As a result the calculated sample size was 245 per hospital.

Sampling techniques

The sampling frame was the batch of patients' hospital records that were filed according to the date when the patient is expected to collect their treatment. The subjects were selected by systematic random sampling of the patients' hospital records on a daily basis for the patients that are expected to collect treatment the following day. The clinic worked from Monday to Friday, so we selected our subjects each afternoon for the next day. Each facility had a file room clerk, whose routine function was to prepare in the afternoon all the patients' hospital records that were due for treatment the next day. The clerk was trained and responsible for the sampling of patients' files each day.

Variables studied

Table 2: List of variables that were studied

Demographic	
	Age
	Sex
	Race
	Residence
Socio Economic	
	Education status
	Employment status
	Marital status
	Declaration to spouse
	Cost of transport
	Have any children
	Social support
Psychological functioning	
	Ability to control irritations
	Stress
	Confidence
Adherence	
	Adherence in the past week
	Ever missed treatment
	Missed treatment in past month
Biological markers	
	CD4 count
	HIV viral load (Suppressed vs. Not Suppressed)

Medication	
	Time since start of antiretroviral therapy
	Type of regimen
	Ever experienced side effects

Inclusion criteria

1. Subjects that were HIV positive and enrolled on antiretroviral therapy for a period of one month or longer.
2. Subjects aged 18 years or older on the day of the interview
3. Subjects, who could comprehend and were able to sign informed consent, after thorough information about the nature and purpose of the study

Exclusion criteria

Subjects not meeting all the above inclusion criteria.

Data collection

All eligible participants who met the inclusion criteria and signed the informed consent were selected for the study. An interviewer directed questionnaire was administered to all participants. Data on routinely collected biological markers (CD4+ cell and viral load) was extracted from the patient's facility-based clinical records.

Interviewers were recruited from the professional nursing staff (nursing assistant, enrolled nurse currently registered with the South Africa Nursing Council) who work in any department within the study sites. The bases for using professional staff from the study facilities was two fold. First the setting for our research was in a relatively rural province and as such there were not enough cadres of human resources for health that could conceptualise the study content and be able to

adequately explain issues related to HIV and AIDS to participants should the need arise. And secondly, due to the sensitive nature of the study, access to patients' clinical records was not possible except through appropriately qualified staff working for the health services.

The data (interviews) were collected in each facility, by a trained health professional. The data collector received at least one day training on the aim of the study, methods applied and the use of the data collection tools. The interviewers were compensated for their time with a token amount of R20-00 (twenty Rands) per completed questionnaire. The reason for the compensation was that all data was collected outside the workings hours (during leave day or days off work) of the hospital staff.

Our data collectors were mostly health professionals who did not live on site and some did not even live in the same area as our study sites, thus they had to travel specifically for the study during their off days. The data collectors were from other areas other than the study site, and therefore they visited their families during time off work. This meant that most of data collectors, were not willing to assist with data collection, outside their normal working hours without adequate compensation and the hospital management of both hospitals did not approve the use of its staff during hospital time and we resorted to compensating them for their time. The researcher directly supervised the collection of data by spending at least one day a week in each of the facilities and indirectly through the facility Nursing Service Managers responsible for patient care at the outpatient ART clinics.

The questionnaire was drawn from similar questionnaires (Adherence Assessment Tool in Clinical Practice[19] and Patient Medication Adherence Questionnaire (PMAQ[25]) and minor changes applied as deemed necessary by the research team.

All interviews were conducted in a local indigenous language IsiSwati or English based on the preference of the participant. Translation and back-translation of the study material i.e. patient information leaflet, questionnaire and informed consent were done through a professional translator. Data on clinical condition of the participants was extracted from the facility-based patient's records. All the instruments of the study were tested through a pilot study, which was done using 5 patients from each site.

Time frame of the study

The study was conducted between June and July 2008 at both sites. The study was conducted over a period of 25 days per site during the same calendar months. The days that were chosen for data collection, coincide with treatment days so that the highest number of patients on treatment could be accessed.

Data capturing and quality assurance

Data editing and data capture on EpiData were initially done on site jointly by the researcher and the research assistants as soon as the questionnaires became available. Double data entry and validation was done by the researcher at the University of Pretoria using the statistical package EpiData.

Data analysis

Data analysis was done in the statistical package STATA version 10:

- The Pearson chi-square test of association was used for identifying categorical variables that were significantly associated with each other.
- Comparison was done between patients in Groups 1 and 2 (unpaired groups) using the Mann-Whitney U-test (a non-parametric test for comparing two independent samples with small sample sizes) with

regards to ordinal variables such as social support, degree of trust in ARV therapy, psychological functioning, etc.

- Frequency tables and bar charts were obtained for discrete variables of the study. The variables were socio-economic, demographic and health-related.
- Summary statistics were obtained for continuous variables of study. The variables were socio-economic, demographic and health related.
- Binary logistic regression analysis was used for identifying significant predictors of non-adherence to medication. This was done because the outcome variable in this study is dichotomous; a variable with only 2 possible values (yes, no).
- Odds ratios were used as an epidemiological measure of effect. Adjustment was done for potential confounding variables.
- The levels of significance of all statistical tests was fixed at the α=0.05 level. Hence, a P-value smaller than 0.05 showed the presence of a significant finding.

Ethical considerations

Approval

The study received ethical approval from the Research and Ethics Committee of the University of Pretoria, and the Mpumalanga Province's Department of Health and Social Development. The participants in the study were requested to participate in the study by the research assistants at the point of collection of their hospital files. The participants were given the assurance that refusal to participate in the study would not affect access to health services, and the quality of services provided to them would not be affected.

Consent Form

The eligible patients were asked for their consent by the researchers. Informed consent was requested after thorough education on the study purpose and objectives. The University's research ethics guidelines, which are based on, among others, Good Clinical Practice and the Helsinki Research Ethics Guidelines[22], were adhered to throughout the study. A copy of the informed consent has been included in appendix 3.

Assessment of adherence

The variable 'adherence in the past week' was used as the proxy outcome variable for adherence. The variable was chosen because it asked patients to answer the question 'what was your adherence in the past week'; the answer was based on an ordinal scale of 0-5 as in table 2 below. Adherence was then defined as 100% self reported adherence; meaning the patient had not missed any of their ARVs in the past week.

The study measures other variables that also can act as proxies for the outcome variable (adherence). These include the following questions asked by the study: do you ever forget to take your medication? When you feel better, do you stop taking your medication? Sometimes when you feel worse do you stop taking your medication? The study also asks patients to identify tablets they take from an attached set of ARVs laminated in paper, including the tablets in the regimen used in the public sector as per department of health guidelines[6]. Patients were also asked about the number of tablets and doses taken each day.

Table 3: Rating of patient reported adherence

Score	Rating of adherence in percentages
0	No
1	20
2	40
3	60
4	80
5	100

Validation of self-reported adherence

To validate self reported treatment adherence to ART, the study used the biological marker 'viral load'. The HIV RNA viral load was classified into a binary variable (suppression if HIV RNA viral load < 400 copies/ml vs. not suppressed if HIV RNA viral load >= 400 copies/ml). For the analysis the study used all the patients irrespective of HIV RNA viral load on entry into the programme, and again only those who were not virologically suppressed on entry into the programme.

CHAPTER 4: RESULTS

4.1 Population

Four hundred and eighty eight (488) study participants were interviewed for the study. Two study participants were not interviewed because one participant from Embuleni hospital refused to give informed consent, while the other study participant from Bethal hospital had not been interviewed by the time we concluded data collection. Both the Bethal and Embuleni hospitals returned 244 completed questionnaires each.

Overall, four hundred and twenty nine questionnaires were analyzed. Of the four hundred and twenty nine analyzed questionnaires, two hundred and twenty six were from Bethal Hospital and two hundred and three were from Embuleni Hospital. Fifty nine questionnaires were excluded from analysis because of incomplete data.

4.2 Characteristics of the participants

The median age of participants was 36 years (IQR, 13), figure 3 displays the different age characteristics of the participants from both Bethal and Embuleni District Hospitals; the two groups were found to be more or less similar. There were 11 study participants who had been on the ART programme for more than 46 months, which was longer than the lifetime of the ART programme at the two study sites as they were both in operation for at least 46 months. After exclusion of these participants, the period since starting ART at the two sites of our study had a median time of 14 months (IQR, 17), but the range since start of ART was 45 months.

The gender of the participants was predominantly female with 21.29% male and 78.71% female. All the participants were African blacks. Two hundred and fifty

five (63.12 %) of the participants had attained at least high school education, but only 8 (1.98%) had achieved tertiary education. Forty seven (11.90%) of the participants were employed. Thirty five (16.20%) of the Bethal participants were employed, while only 12 (6.70%) of the Embuleni participants were employed. Most of the general characteristics of the participants from both Bethal and Embuleni hospitals were similar and are illustrated in table 6 of appendix 1.

Fig 3: Age categories of participants by site

Table 4: Demographic characteristics of the participants

	All participants	**Bethal**	**Embuleni**
Age years (median, IQR)	36 (13)	35 (12)	36 (13)
Gender (female, %)	336 (79)	175 (78)	161 (79)
Education (%)			
• None	4	5	3
• Primary	30	26	34
• Secondary	63	66	60
• Technical	1	1	1
• Tertiary	2	2	2

Eighty seven (20.28%) participants had been on ARVs for 1-5 months, 77 (17.95%) for 6-11 months, 140 (32.63%) for 12-23 months and 125 (29.14%) for 24 or more months. For Bethal Hospital 39 (17.26%) participants had been on ARVs for 1-5 months, 33 (14.60%) for 6-11 months, 75 (33.19%) for 12-23 months and 79 (34.96%) for 24 or more months. At Embuleni Hospital 48 (23.65%) participants had been on ARVs for 1-5 months, 44 (21.67%) for 6-11 months, 65 (32.02%) for 12-23 months and 46 (22.66%) for 24 or more months. Overall, 79.48% the study participants were still on their first regimen. For Embuleni Hospital 88.44% of their participants were still on the first regimen, while only 71.56% of the Bethal participants were on their first regimen.

4.3 Measures of self reported adherence

In view of the fact that some participants in the study had CD4 cell counts greater than 200 cell/mm^3, the analysis below has excluded the 11 patients that the study analysis has been able to determine that they were treatment experienced when they started ART at our two study sites. This was done through calculation of the time while on treatment and then comparing that to the operational period of each study site.

Participant self reported adherence for the study was 92.87% and only 7.13% reported non-adherence as per the definition used in this study (adherence in the past week). Self reported adherence was highest in Bethal Hospital 95.87%, while Embuleni Hospital reported 89.42% adherence as in figure 4 below. Other variables of self reported adherence measured found that only 7 % reported ever forgetting to take their medicines, less than 1% reported stopping medicines when feeling better and again less than 1% reported stopping medicines when feeling worse.

Four hundred and twenty one (98%) of the patients were able to point the correct ARV medicines that they were taking when shown seven ARVs laminated on the

paper, including the one taken by the patient. Only 29 (7%), did not know the correct number of pills and doses they were taking for the last week. And only 64 (15%) reported having missed ARVs in the past month.

Table 5: Concordance between self-reported adherence and proxy measures of adherence (using chi-square test of association p-value)

	Pill identification	Correct identification of dosages	Missing dosages
Adherence	0.000	0.000	0.000
Pill identification		0.000	0.366
Correct identification of dosages			0.675

Table 5 above shows the concordance of self reported adherence with other proxies for self reported adherence. The results shown a strong association between self reported adherence and all the ‘adherence proxies’. There is no association though between pill identification and missing dosages, and between missing dosages and correct identification of dosages.

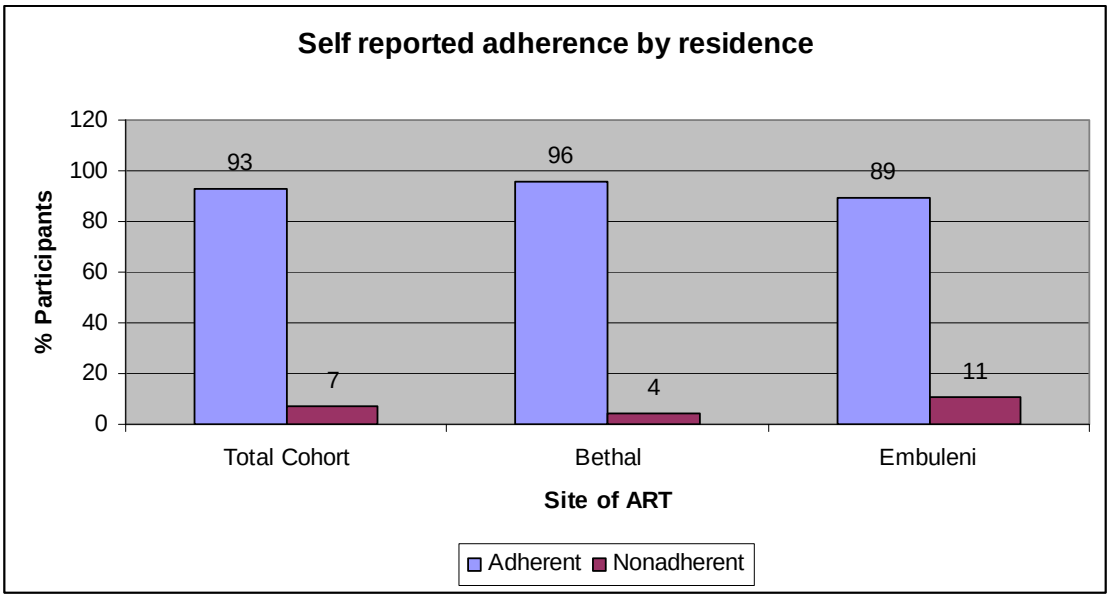

Fig 4: Adherence of study participants by residence

4.3.2: Biological marker and immune reconstitution measures

4.3.2.1: CD4 cell counts

The total number of participants who had laboratory records for both CD4 cell counts at initiation of ARVs and at least six months post ARVs was 296 (71%). Of these 107 (36%) was from Embuleni and 189 (64%) from Bethal. At initiation of ART 170 (58%) of participants had a CD4 cell count of less than 200 cell/mm^3, 72 (24%) had CD4 cell count between 200-349 cell/mm^3 and 54 (18%) had CD4 cell count of 350 cells/mm^3 or more (see fig. 5 below).

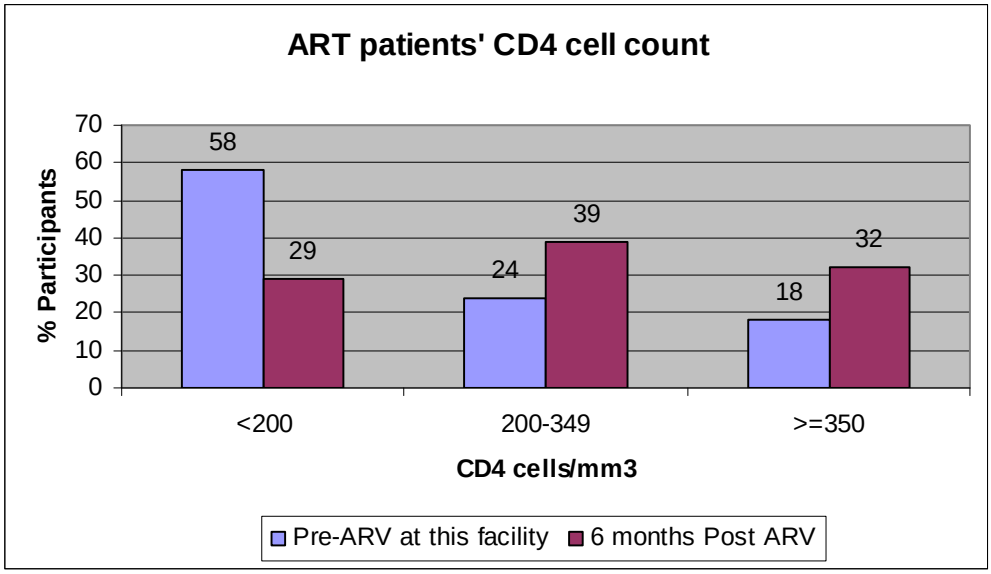

Figure 5: CD4 cell count categories for study participants

At Bethal hospital 100 (53%) of the participants had a CD4 cell count of less than 200 cell/mm^3, 54 (29%) had a CD4 cell count between 200-349 cell/mm^3 and 35 (18%) had a CD4 cell count of 350 cell/mm^3 or more (see fig. 6 below). And for Embuleni hospital 70 (65%) of the participants had a CD4 cell count of less than 200 cell/mm^3, 18 (17%) had a CD4 cell count between 200-349 cell/mm^3 and 19 (18%) had CD4 cell count of 350 cell/mm^3 or more (see fig. 7 below).

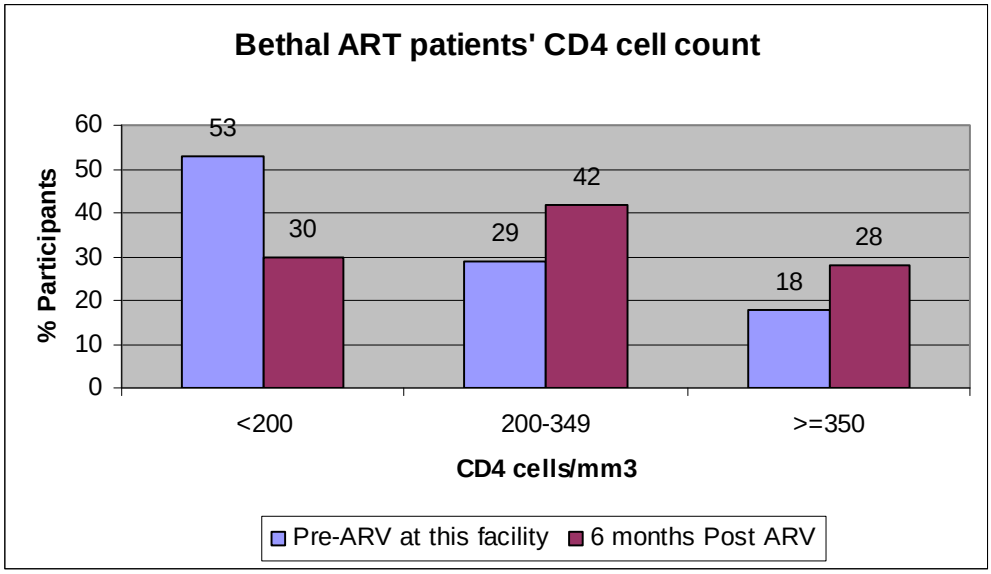

Figure 6: Bethal hospital CD4 cell count categories for study participants

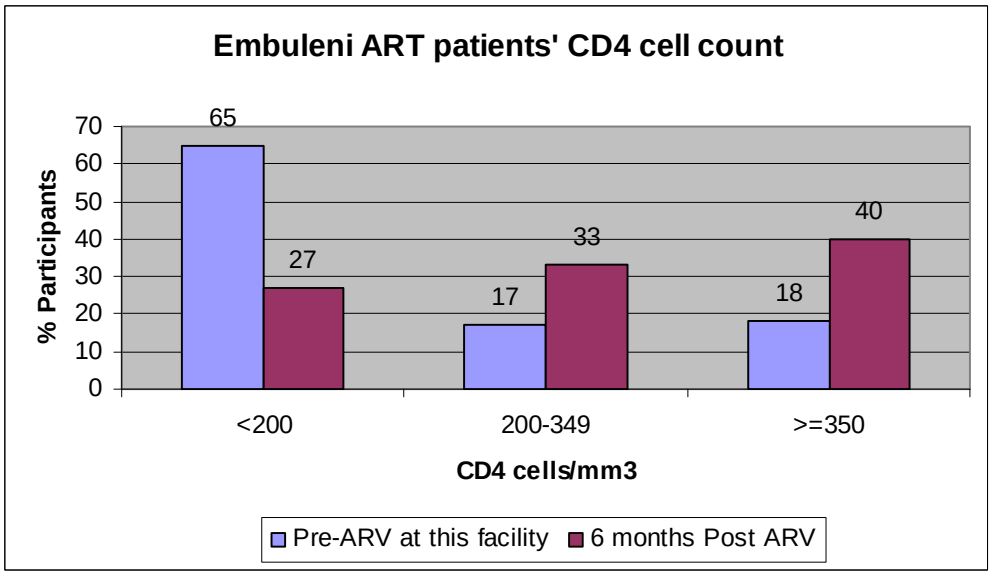

Figure 7: Embuleni hospital CD4 cell count categories for study participants

After at least six months post initiation of ARVs 86 (29%) of the participants had a CD4 cell count of less than 200 cell/mm^3, 115 (39%) had a CD4 cell count

between 200-349 cell/mm^3 and 95 (32%) had a CD4 cell count of 350 cell/mm^3 or more out of the 307 patients who had at least 2 laboratory records (before and at least 6 months post ARVs) of CD4 cell counts (see fig. 5 above). At Bethal hospital 57 (30%) of the participants had a CD4 cell count of less than 200 cell/mm^3, 80 (42%) had a CD4 cell count between 200-349 cell/mm^3 and 52 (28%) had a CD4 cell count of 350 cell/mm^3 or more of the 195 patients who had their CD4 cell counts done (see fig. 6 above). And for Embuleni hospital 29 (27%) of the participants had a CD4 cell count of less than 200 cell/mm^3, 35 (33%) had a CD4 cell count between 200-349 cell/mm^3 and 43 (40%) had a CD4 cell count of 350 cell/mm^3 or more of the 112 patients who had their CD4 cell counts done (see fig. 7 above).

4.3.2.2: Viral Loads

Two hundred and seventy eight participants (67% of the total study population) had at least 2 laboratory records of HIV RNA viral load available, one at initiation of ARVs at the site and again at least 6 months post ARVs. One hundred and five (38%) had an undetectable viral load, 21 (7%) had a viral load of between 50-400 RNA copies/ml and 152 (55%) had an RNA viral load of > 400 RNA copies/ml. After at least 6 months since the start of ARVs 178 (64%) had an undetectable viral load, 50 (18%) had a viral load of between 50-400 RNA copies/ml and 50 (18%) had an RNA viral load of > 400 RNA copies/ml as in figure 8 below. The viral load trends for Bethal and Embuleni hospitals were more or less similar to the trends for the whole group, see figures 12 and 13 in appendix 1.

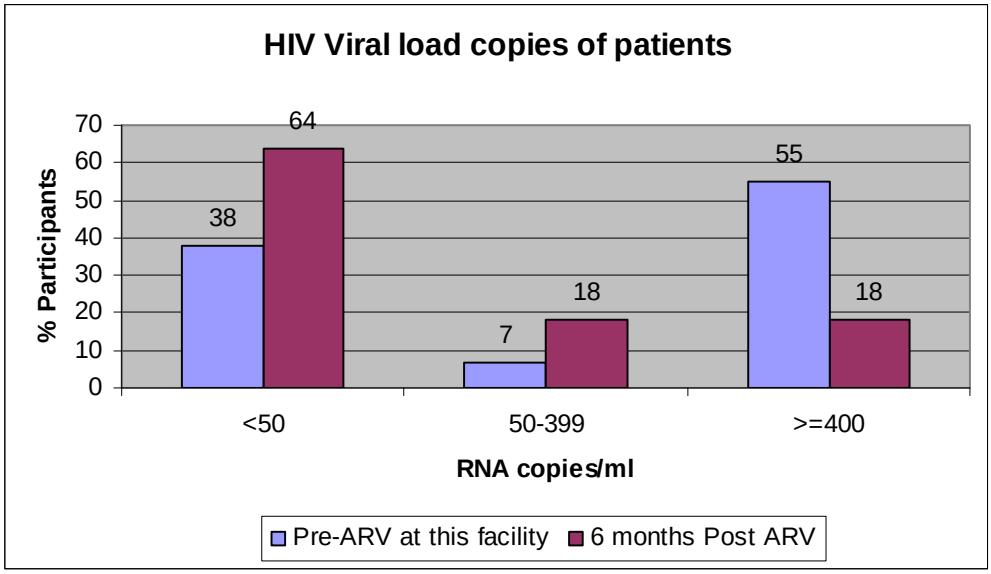

Figure 8: HIV RNA copies (viral load) categories for study participants

4.4 Initial analysis for significant associations

The socio-demographic variables age, gender, educational level, employment status, ever had children, cost of travel and duration on ARVs did not show any significant association with non-adherence, as summarized in table 11 of appendix 1. The only variable that was associated with non adherence was site of treatment collection (urban residence)($p = 0.012$).

The social and psychological factors that were associated with non-adherence included: 'I feel satisfied with the overall support I get from my friends and my family' ($p = 0.001$); 'I feel satisfied with the overall encouragement I get from my friends and my family' ($p = 0.01$) and 'HIV medications will not work if I don't take my treatment exactly as instructed' ($p = 0.001$).

Contrary to the above mentioned variables the following variables did not have an association with non-adherence: 'My friends or family help me remember to take my medication' ($p = 1.00$); 'I believe I will take all or most of my medication' ($p = 1.00$ and 'HIV medications have a positive effect' ($p = 0.47$). All the variables

that measure 'Emotional limitations and psychological functioning in the past month' did show significant association with non-adherence. A summary of these and other social and psychological variables are in table 11 of appendix 1.

Table 6: Summary of variables association with nonadherence to ART

Variable	P-value
Rural residence	0.012
Lack of social support	0.002
Gender	0.914
Employment status	0.805
Age	0.794

**Level of significance = 0.05*

Table 6 shows P-values obtained from Pearson's chi-square tests of association. At the level of significance 0.05; and confidence level of 95%, 2 of the 5 variables were significantly associated with the outcome variable of study, non-adherence. These 2 significant variables of study were used for subsequent binary logistic regression analysis in view of their strong relationship with non-adherence to medication. The other 3 variables of study (gender; employment status and age) were also chosen for table 8, in view of their relevance to adherence based on the literature review conducted for this study.

Table 7 below describes the validity of the self reported adherence measure against the biological marker (viral load) and the immune reconstitution marker (CD4 cell count), which can also be an indirect biological marker for the response to antiretroviral therapy. There is no association between both the viral load and CD4 cell count, and the self reported adherence to antiretroviral therapy.

Table 7: Association of Self-reported adherence to viral load and CD4 cell count for patients not virologically suppressed at initiation of ART

Variable	Chi-square test	Logistic regression analysis		
	P-value	Odds Ratio	P-value	[95% Confidence interval]
Viral Load (six months post ARV)	0.16	0.68	0.32	[0.3 – 1.4]
CD4 cell count (six months post ARV)	0.38	1.6	0.21	[0.7 – 3.2]

4.5 Logistic regression analysis results

The gold-standard model recommended for epidemiological studies by Kleinbaum and Klein (2002) was estimated by applying the hierarchical stepwise backward elimination procedure[23]. Based on findings from the gold standard model, the variables shown below in Table 8 were key predictors of non-adherence to medication.

Table 8 below shows that non-adherence to ART was significantly associated with rural residential area and lack of social support in a decreasing order of strength. The logistic regression analysis did not shown any significant association between adherence and both the 6 months post ARV CD4 counts and viral loads, as shown above in table 8.

Table 8: Odds ratio of non-adherence to ART

Adherence	Odds Ratio	Std. error	Z	P value	[95% Confidence interval]	Rank
Urban residence	0.28	0.15	-2.28	0.022	[0.1-0.8]	1
Lack of social support	3.0	1.68	1.97	0.049	[1.0-9.0]	2
CD4 Count 6 months post ARV	1.1	0.37	0.26	0.793	[0.5-2.1]	Not applicable
Viral load 6 months post ARV	1.1	0.40	0.48	0.631	[0.6-2.3]	Not applicable
Period since on ART	1.0	0.01	0.51	0.610	[0.9-1.1]	Not applicable

Table 9: ART adherence predictor variables

Variable	Unadjusted odds ratios and [95% Confidence interval]	*Adjusted odds ratios and [95% Confidence interval]
Urban residence	0.28 [0.1-0.8]	0.39 [0.2-0.8]
Lack of social support	3.0 [1.0-9.0]	2.74 [1.3-5.7]

**Adjustment was done for age, gender and employment status,*

Odds ratios estimated from binary logistic regression analysis were adjusted for three potential confounding variables (age, gender and employment status). The estimates shown in Table 9 above show that adjusted odds ratios do not differ significantly from unadjusted odds ratios, thereby showing that none of the three variables used for adjustment could be confounding variables.

4.5.1 Interpretation of odds ratios

The odds ratio of the variable ‘urban residence’ is 0.39. The odds ratio is less than 1, thereby showing that urban patients are protected in comparison to rural patients by a factor of 1-0.39=0.61=61%. This shows that urban patients are less likely to be non adherent in comparison to rural patients by a factor of 61%.

The odds ratio of the variable “lack of social support” is 3.0. This shows that a patient who lacks social support is 3.0 times more likely to fail to adhere in comparison to a patient who does not lack social support.

To assess the adequacy of our fitted model on STATA, we used the classification table (lstat), the Hosmer-Lemeshow goodness of fit test (lfit), lroc and lsens. The fitted model is poorly sensitive (the fitted model works very well on patients who adhere to their medication, but does not do the same with non adherent patients) and is highly specific. This is a minor limitation of study

CHAPTER 5: DISCUSSION

The study measured patients' self reported adherence to ART in two ART outpatient clinics of Mpumalanga's Gert Sibande District. The study found that 92.54% of all our participants reported 100% adherence to the prescribed ART regimen in the last week. There was a higher report of adherence in the urban (Bethal hospital) site clinic (95.58%) compared to the rural (Embuleni hospital) site clinic (89.16%).

The high level of self reported adherence to ART was consistent with, though slightly higher than that found in other studies assessing patients' self-reported adherence, these other studies reported ART adherence rate of 81%[24]. The high level of adherence should be taken with caution as the objectivity of the patients self-reported ART adherence has not been evaluated against other more objective measures of ART adherence of biological markers, for example the viral load in serum and even plasma drug levels which often show low levels of adherence.

In this study, the chi-square test of association between self reported adherence and viral load six months post ARVs (for those not immunologically suppressed at initiation of ARVs) had a p-value of 0.16, while that of the CD4 cell count six months post ARVs (for those not immunologically suppressed at initiation of ARVs) was 0.38. Also the logistic regression tests as shown in table 6 of the results section did not find any association between viral load and CD4 cell count with the high level of self reported adherence.

Based on these findings, the study was not able to validate the high level of patients' self-reported adherence with the biological markers. The study did not find any significant association between self-reported adherence and the biological marker (viral load as a measure of adherence), based on the chi-square test of association and the logistic regression model of our analysis.

The failure of the study to show significant association between self-reported adherence and the biological markers was not an overall marker of failure of the ART programme. This was because the study in both the study sites found that viral load measurements demonstrated a decreasing trend with time on ARVs. The initial viral load done prior to the commencement of ARVs showed that about 46% of the participants had virological suppression with viral load of <400 copies/ml, which subsequently showed an increase after at least six months of ARVs to about 82% of participants showing virological suppression.

When the viral load measurements were analysed separately for the two study sites, a similar trend as in the whole study group was shown. For Bethal the initial viral load done prior to the commencement of ARVs showed that about 51% of the participants had virological suppression with viral load of <400 copies/ml, which subsequently showed an increase after at least six months of ARVs to about 77% of participants showing virological suppression.

While for the Embuleni participants, the initial viral load done prior to the commencement of ARVs showed that about 35% of the participants had virological suppression with viral load of <400 copies/ml, which subsequently showed an increase after at least six months of ARVs to about 91% of participants showing virological suppression. See figures 12 and 13 of appendix 1, for the viral loads of the Bethal and Embuleni hospitals respectively.

Another encouraging finding about the decline in viral loads was that at both sites the viral load improved such that at least 78% of their participants had an HIV RNA viral copies of < 400 copies/ml six months post ARVs. This finding has been found to correlate to a greater than 95% self-reported adherence[6]. This would suggest that the study sites are well within the department of health's objectives of maintaining a high level of adherence, so as to minimize ARV drug resistance from developing.

This finding is supported by the other measures of self-reported adherence reported on the results, that is: 'if you feel worse do you stop taking your treatment'; 'if you feel better do you stop taking your treatment'; and 'do you remember the number of tablets and doses for the past week' can be used to support the high level of self-reported adherence in the study.

The above mentioned findings would on the whole suggest treatment success for most of our participants, based on the biological marker (HIV RNA viral load copies). However, it is worth noting that when the biological marker's results were individually interrogated, there was about 17 (6%) of participants who had results that were consistent with treatment failure. Most of the 6% had their viral load measurement increasing with time on ARVs. Of interest in this group was that the median duration on ART was 22 months, which suggest that this group had been on treatment for longer compared to the median of the study cohort.

The study did not find any significant association between self-reported adherence and the measures of immune reconstitution (CD4 cell count, which can be used as an indirect biological marker of adherence), based on both the chi-square test of association and the logistic regression model of our analysis as shown in table 6 of the results section.

The study in both the study sites found that at initiation of ART about 57% of patients had a CD4 cell count less than 200 cells/mm^3, and after at least six months on treatment the CD4 cell count had improved for most patients, such that only 29% of patients had a CD4 cell count less than 200 cells/mm^3. When the analysis of the CD4 cell counts were done separately for the two study sites, they followed a similar trend as shown in Figures 6 and 7.

Even though not all the study participants had both the pre ARV and the post ARV CD4 cell counts, it is worthwhile mentioning that for those who had their

CD4 cell count after treatment initiation there was a median CD4 cell count of 283 cells/m^3 (IQR, 206), which is suggestive of a positive response in terms of immune reconstitution post treatment with ARVs.

The department of health's national antiretroviral treatment guidelines[6] stipulate that patients should ideally, be started on ARVs if their CD4 cell count is less than 200 or are diagnosed to be WHO's stage IV AIDS-defining illness, and the patient must expresses willingness and readiness to take ART adherently. This was important for this study as I found that about 43% of the participants allegedly started ARVs, while their CD4 cell counts were above 200 cells/mm^3.

There could be a number of explanations for this including that there were participants who started ART and ARVs before the implementation of the two study sites as shown by the range of 46 months since enrolment to ART and as such not all the participants were ART naïve; and that some patients could have transferred in from the private sector or other previously established sites. The possibility of the sites starting patients with CD4 cell counts > 200 cell/mm^3 on ART also exists and may need to be established.

This study found 2 main variables to be predictors of non adherence to ART. The only demographic variable that was significant was the area of residence of the participant; urban (Bethal hospital) patients are protected in comparison with rural (Embuleni hospital) patients by a factor of 1-0.39=0.61. This shows that urban patients are less likely to be non-adherent in comparison with rural patients by a factor of 61%.

This was an interesting finding as Bethal hospital had more or less the same resources in terms of human resources for health. The difference could be explained by access to the facility, the fact that Bethal hospital was more readily accessible in terms of public transport; also the average cost to get to hospital in Bethal was 18.33 South African Rands (ZAR) compared to Embuleni's 39.60

ZAR. It could also be explained by other healthcare related factors such as patient-health worker relationship which were not measured in this study.

The second variable that was a determinant of adherence was social support. Participants who lacked social support were 2.74 times as likely to fail to adhere in comparison with a patient who has social support. Social support was measured based on four variables. Of these, three were associated with non-adherence. The measures of social support included 'feeling satisfied with the overall acceptance, encouragement and support that they got from their friends and families'. This could be attributed to the fact that, with social support, patients are likely to have disclosed their status to their friends and families and as such were openly taking their treatment.

In this study, I did not find any significant impact between treatment adherence and duration on treatment with ARVs ($p = 0.610$). This finding, however does not entirely exclude a difference in adherence between those who have been on ARVs for a long period of time and those who have only been on ARVs for a much shorter period. This is because our study did not measure simultaneously the objective measures of adherence with the self reported adherence.

There were no other significant associations between adherence and the demographic variables other than that of residence. This was consistent with many other studies that assess adherence. There are however a few studies that have reported significant association between adherence and age; and between adherence and gender. These studies suggested that younger age groups, complex treatment regimen, lack of continuity of treatment staff, payment at the point of treatment collection and male patients on ART are more likely to be non-adherent[14, 15, 16, 17].

Of interest with the demographic profile of this study group, was the finding that the median age of patients on ART is 36 years and that the majority of patients

on ART were females (about 78.8%). This illustrates the fact that the participants in this study are in the age group of economically active people, and also that they are likely to be members of young families or couples. This is a major concern should the programme fail to improve their health and wellbeing.

This has social and economic implications not only for the families but the entire community, which without the effective ART programme will suffer from child headed house-holds with no income. The high number of females raises questions about the utilization pattern of health services by males. This pattern probably arises from the fact that men could have migrated to look for work in other large cities of the country or the fact that they have died owing to AIDS itself, thus leaving behind widows running single parent households.

Even though the study participants were from a generally poor district and province, they also had a relatively low literacy rate. Just over 60% of the study subjects had high school education. The effect of the low educational standard achieved among the majority of participants had a low rate of employment of 11.4% for Bethal the urban site and an even lower rate of 6.25 for Embuleni the rural site.

The low level of employment might affect the patients in terms of traveling expenses to and from the hospital as travel expenses averaged 18.33 ZAR and 39.60 ZAR for Bethal and Embuleni participants respectively. A number of studies have found that even in the presence of free ART, other costs including food and traveling costs to treatment sites, may adversely affect the adherence levels. This was not significantly associated with nonadherence in this study, but is an important aspect for consideration when planning health services and programmes, including ART programme.

The criteria for starting patients on antiretroviral drugs in South Africa, are based on national antiretroviral treatment guidelines of 2004, which include a CD4 cell

count of < 200 cells/m^3 as stated above. It is encouraging to note that the median CD4 cell count for the patients on this study was 283 cells/m^3 and only about 29% of patients had a CD4 cell count of less than 200 cells/m^3 after at least 6 months of ARVs at the study sites. In essence there was a percentage increase of 49% to above 200 cells/mm^3.

Previous studies have found that the number of daily doses greater than two, dosing associated with food restrictions, previous history of non-adherence, co-morbidity, relief of symptoms, mistrust of health provider, complex regimen and chronicity of treatment were associated with non adherence [14, 15, 16, 17]. In this study similar conclusions can not be made as the abovementioned variables did not show significant association with non-adherence.

Previous studies have found elements of success for an ART programme to be the provision of ART in primary care settings, close to patient's environment, simplicity of therapy, careful preparation of patients and the continuity of care with patients cared for by the same team[14, 15]. This study did not measure health team and healthcare system related factors and as a result it is not feasible to make inferences with respect to these variables. Nonetheless, we can say that the above mentioned factors were observed at both our study sites.

The study had some opportunities as well in that we were able to observe that pill counts were used to assess adherence to antiretroviral therapy. Patients were expected to bring their pill containers at every visit and the lay counsellors would count the tablets and record the number of remaining tablets on the patients' hospital notes. There was no assessment of patient reported adherence to compliment the pill counts as means of adherence assessment.

The positive outcome of the current system was the use of the lay counsellors (community workers). It was clear that these counsellors contributed positively to the programme and to some extent the programme was depended on the lay

counsellor for adherence counselling and general information provision to the patients and communities.

Study limitations

The study has a number of limitations, starting with the areas that were chosen for the location of the study. Both Embuleni and Bethal Hospitals were selected out of convenience as they were the most stable and well functioning sites in Gert Sibande District. The study also used hospital staff as data collectors, this has the potential to cause bias, and thus lead to over-reporting of adherence by study participants, who will fear victimisation at the hands of the health care provider if they reported poor adherence.

The findings of the study would have been strengthen to the South African context had we used the South African government adopted MSH tool, a multi method tool[18] for adherence assessment and measurement, which measures adherence based on 4 elements: Self report, Visual analogue scale (VAS), Pill identification test (PIT) and Pill count. Unfortunately at the conception of the study in 2007, the tool had not been recommended or widely available.

The issue of language is also a limitation of the study. Even though translations to local indigenous languages for the Patient Information Leaflet and the questionnaires were done, some of the data collectors were not fluent in the local languages as there are a number of other languages that are spoken by the communities in the two study sites.

The study would have produced better results, if a cohort study had been conducted. This was not practical for our study because of lack of resources, such time, money and infrastructure. Also, a larger sample size would have produced better results and increased the confidence of the researcher in the outcome. Also the sample size calculation was done much earlier than when the

study commenced, due to delays with administrative procedures. The sample size calculation could have produced better power had I used assumptions based on literature for level of adherence other than other assumptions.

The study did not study variables that were related to healthworker-patient relationships, healthcare and health system factors. We were also not able to totally disprove selection bias since it was possible that some patients, who are not adherent, did not come to the clinic at all and thus were not in the group we interviewed. Poor adherence for some of the participants may be attributed to poor health, poverty (lack of food, shelter, family structure and job hunting) and stigma. All such confounders were not catered for in the study.

Reliance on routinely collected clinical data for the record review caused the lack of consistency of recorded data e.g. six monthly biological markers (HIV RNA viral loads and CD4 cell counts). This was a weakness in the system as it would be difficult for the health workers (nurses and medical doctor) to readily pick up non-adherence. The other observation from the sites was the poor quality of data. The clinical notes were not linked from one visit to the next. There was a lot of discontinuity in the patient's notes such that if a new staff member was to start managing patients they would have to take their own history to follow the management of the patients. Record keeping is relatively poor as well, with some results from the laboratory missing. This observation supports the idea that it is difficult for the health workers to fully assess the adherence of the patients.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

Conclusion

In conclusion it is important to acknowledge that there were generally high levels of self reported adherence in both rural and urban treatment sites. There should not be blind acceptance of these findings (self reported adherence) as the gold standard in the study sites, other parts of the Mpumalanga Province and South Africa in general. Self-reported adherence to antiretroviral therapy is a poor measure of adherence compared to the more objective adherence measures such as pill counts and drug levels monitoring.

The biological marker (HIV viral loads) investigated in this study, did not show a statistically significant association with the self-reported adherence. Despite the lack of statistically significant association between self-reported adherence and the biological marker, the biological marker did show a marked improvement in both sites, from the time of initiation of ART at the study sites to at least six months post ARVs on average the was a net improvement in HIV viral loads and immune reconstitution as measured by CD4 cell counts.

Findings from other studies, especially studies evaluating adherence based on objective measures of adherence and case reports from service providers, will provide stronger evidence regarding assessment of adherence in ART programmes. ART service providers with adequate training in adherence assessment as per the department of health's national antiretroviral treatment guidelines may have more data that can be analysed in real time together with biological markers for valid association assessment between self-reported adherence and biological markers.

This study has found that being a resident of Bethal or collecting your ARVs in Bethal had a protective effect towards non-adherence. In fact if you stayed in

Bethal you are 61% less likely be non-adherent to your ARVs. This means that there are factors between the two health care facilities studied that are different and need to be explored so that institutions can share in best practices for the greater good of the communities that they serve.

The study was able also to show that the study participants had high level of knowledge of the treatment tablets, number of tablets taken each day and the number of doses to be taken for each medication. This is suggestive of the fact that participants who know their medication and doses could be more motivated or even that by merely remembering their medication and doses that could be an indicator of that they are familiar with the medication and have been taking it. This also reflects on the lay counsellors who are mainly responsible for teaching patients about the medicines, dosing times and the side effects. As such the role of counsellors in the ART programme is a valuable one since they teach patients their treatment.

The belief on ART of the participants has the importance of adherence to treatment is a reflection of the patients' attitude to ARVs (and hence a belief on their effectiveness and in the importance of adherence to ART) is dependant on their knowledge and understanding of the etiology, progression, pharmacological and control of HIV associated disease. Education of all newly diagnosed patients and of their significant members of the family is therefore necessary to ensure effective treatment adherence.

As for the role of the communities, it has been shown by this study that social support is an important factor in ART adherence. The implications of this finding are in line with the ALMA ATA principles of 1978, which emphasized the primary healthcare approach. This essentially talks to involvement of communities in the management of diseases especially diseases of public health importance.

This study suggests to some extent that the conditions that lead to adherence or non-adherence to ART vary from one region to another. For this study in particular non-adherence has been predicted by lack of social support and rural residence. The were other variables that supported a high level of adherence, such as knowledge of your medicines and failing to take medicines as instructed; but these findings could only explain some other root cause of adherence such as motivation for treatment adherence.

The study has not been able to validate the patients' self reported ART adherence with the biological marker (HIV RNA viral loads). This could to a large extent, be attributed to the lack of consistency by the institution oo collecting biological markers, poor data capturing and poor record keeping. The study failed to show a statistical significant association between the duration of ART treatment and adherence.

Recommendations

To conclusively determine the factors that affect ART treatment adherence levels and to improve ART treatment adherence in Gert Sibande district, the researcher recommends the following:

- A follow up, more comprehensive study to assess all the processes that affect adherence to ART, including patient factors, disease factors, patient - health worker relationships, health system factors, community factors and societal factors. The follow-up study to use more objective measure of adherence such as biological markers taken during the period of study for comparison with other adherence measures such as pill counts.
- Service providers should implement a standard format for history taking, examinations and investigations of patients receiving ART. This means that the attending health worker should on a regular basis have a set of minimum data they will collect on any particular visit. The elements of the minimum data set should include clinical condition of patient, information about level of adherence, basic investigations, pill counts, CD4 cell count, and HIV RNA viral copies. This form will serve as a guide to the healthcare workers in the ART programme, while also making available the crucial data to inform policy.
- Improve record keeping and documentation, especially patients's results from laboratories. The returned results should be filed safely with the file, the results transcribed onto a summary sheet and the attending doctor comment on the results.
- Improvement of human resources for health:
    - There was a general observation that most of the ART treatment adherence and information provision was done by the counsellors. Most of these counsellors are either not permanently employed by the district or are volunteers. This is a risk to the programme as

many of these counsellors are actively looking for employment elsewhere.

- Pharmacist are a very scarce resource but an important resource for quality of care as they assist in assessment of adherence and both sites do need a dedicated pharmacist.
- The doctor is getting over loaded as the number of new patients on ART increase. This leads to poor clinical assessment and thus poor management of patients, therefore employment of more doctors is recommended.
- The staff problems indicate that the should be a plan to increase staff with increasing workload.
- The human resource related recommendations for the ART programme may require that we be flexible and revert to a vertical programme only at the sites of ART. This is because of the prevalence of HIV and the number of those expected to take ART with time. Also the programme is very labour intensive and complex and as such will require dedicated trained staff for until we uncover a more user friendly programme.

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8. Appendices

Appendix 1: Summary of other figures and tables from study

Fig 9: Selection of study participants

Fig 10: Gender of the study participants

Fig 11: Participant duration on ARVs by site

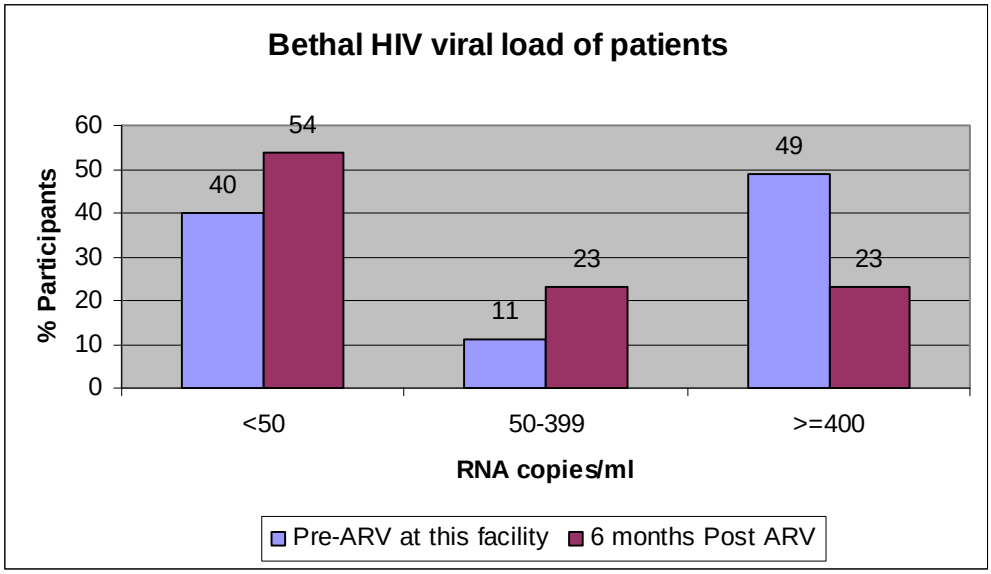

Figure 12: Bethal viral loads for study participants

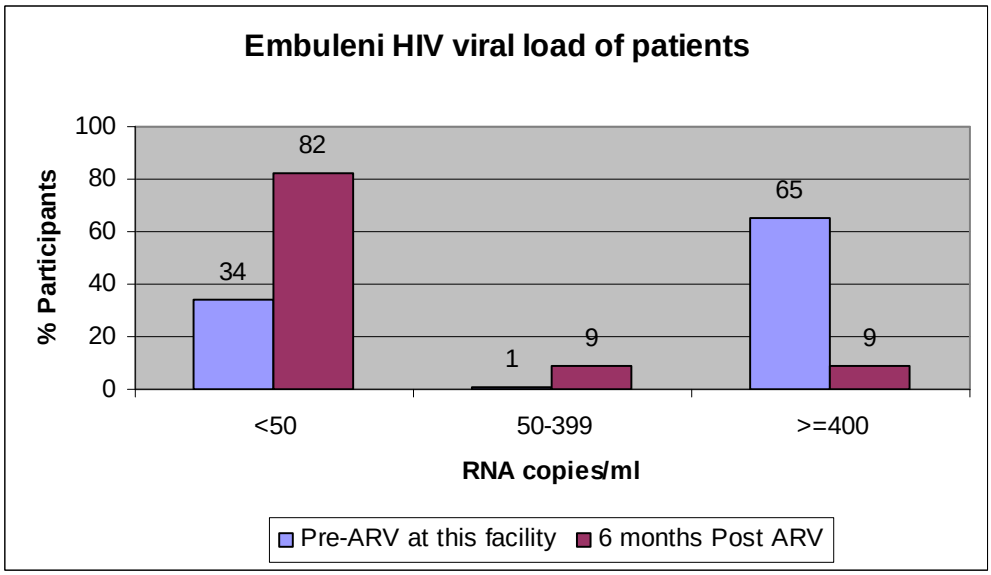

Figure 13: Bethal viral loads for study participants

Table 10: Demographic variables and adherence

	All study participants			Bethal			Embuleni		
variable	Adherent n = 397(%)	Non-adherent n = 32(%)	p-value	Adherent n = 216(%)	Non-adherent n = 10(%)	p-value	Adherent n = 181(%)	Non-adherent n = 22(%)	p-value
residence									
Bethal	216 (50.35)	10 (2.33)							
Embuleni	181 (42.19)	22 (5.13)	0.01						
Age in years									
< 25	22 (5.13)	1 (0.23)		10 (4.42)	0 (0.0)		12 (5.91)	1 (0.49)	
25-35	159 (37.06)	7 (1.63)		88 (38.94)	4 (1.77)		71 (34.98)	3 (1.48)	
35-45	142 (33.10)	14 (3.26)		78 (34.51)	4 (1.77)		64 (31.53)	10 (4.93)	
45-55	58 (13.52)	7 (1.63)		34 (15.04)	2 (0.88)		24 (11.82)	5 (2.46)	
> 55	16 (3.73)	3 (0.70)	0.12	6 (2.65)	0 (0.0)	0.96	10 (4.93)	3 (1.48)	0.06
Gender									
Male	83	7		47	1		36	6	

	(19.48)	(1.64)		(21.08)	(0.45)		(17.73)	(2.96)	
Female	311 (73.00)	25 (5.87)	0.91	166 (74.44)	9 (4.04)	0.36	145 (71.43)	16 (7.88)	0.42
Education									
Not at all	16 (3.76)	2 (0.47)		11 (4.87)	1 (0.44)		5 (2.51)	1 (0.50)	
Primary	115 (27.06)	12 (2.82)		57 (25.22)	2 (0.88)		58 (29.15)	10 (5.03)	
Secondary	254 (59.76)	15 (3.53)		142 (62.83)	7 (3.10)		112 (56.28)	8 (4.02)	
Technical	3 (0.71)	0 (0.0)		2 (0.88)	0 (0.0)		1 (0.50)	0 (0.0)	
Tertiary	8 (1.88)	0 (0.0)	0.45	4 (1.77)	0 (0.0)	0.69	4 (2.01)	0 (0.0)	0.27
Employment									
Yes	44 (10.58)	4 (0.96)		35 (15.63)	1 (0.45)		9 (4.69)	3 (1.56)	
No	341 (81.97)	27 (6.49)	0.77	179 (79.91)	9 (4.02)	1.00	162 (84.38)	18 (9.38)	0.13
Have child/ren									
Yes	359 (83.68)	30 (6.99)		193 (85.40)	9 (3.98)		166 (81.77)	21 (10.34)	
No	38	2	0.7	23	1	1.0	15	1	1.0

	(8.86)	(0.47)	5	(10.18)	(0.44)	0	(7.39)	(0.49)	0
Cost of travel in Rands									
< 20	251 (58.51)	18 (4.20)		169 (74.78)	8 (3.54)		82 (40.39)	10 (4.93)	
20 or more	146 (34.03)	14 (3.26)	0.43	47 (20.80)	2 (0.88)	0.89	99 (48.77)	12 (5.91)	0.99

Table 11: social and psychological factors

variable	Adherent n = 397(%)	Non-adherent n = 32(%)	p-	Adherent n = 216(%)	Non-adherent n = 10(%)	p-value	Adherent n = 181(%)	Non-adherent n = 22(%)	p-value
Social									
I feel satisfied with the overall acceptance I get from my friends and my family									
0	7 (1.63)	1 (0.23)		6 (2.65)	0 (0.0)		1 (0.49)	1 (0.49	
1	13 (3.03)	2 (0.47)		12 (5.31)	2 (0.88)		1 (0.49)	0 (0.0)	
2	8 (1.86)	3 (0.70)		5 (2.21)	2 (0.88)		3 (1.48)	1 (0.49	
3	33 (7.69)	3 (0.70)		31 (13.72)	2 (0.88)		2 (0.99)	1 (0.49	
4	26 (6.06)	6 (1.40)		13 (5.75)	1 (0.44)		13 (6.40)	5 (2.46)	
5	310 (72.26)	17 (3.96)	0.01	149 (65.93)	3 (0.33)	0.01	161 (79.31)	14 (6.90)	0.01

I feel satisfied with the overall encouragement I get from my friends and my family									
0	3 (0.70)	1 (0.23)		2 (0.88)	0 (0.0)		1 (0.49)	1 (0.49)	
1	7 (2.10)	3 (0.70)		9 (3.98)	1 (0.44)		0 (0.0)	2 (0.99)	
2	7 (1.63)	1 (0.23		3 (1.33)	1 (0.44)		4 (1.97)	0 (0.0)	
3	26 (6.06)	3 (0.70)		23 (10.18)	2 (0.88)		3 (1.48)	1 (0.49)	
4	19 (4.43)	4 (0.93)		13 (5.75)	1 (0.44)		6 (2.96)	3 (1.48)	
5	333 (77.62)	20 (26.30)	0.01	166 (73.45)	5 (2.21)	0.09	167 (82.27)	15 (7.39)	0.00
I feel satisfied with the overall support I get from my friends and my family									
0	3 (0.70)	2 (0.47)		2 (0.88)	0 (0.0)		1 (0.49)	2 (0.99)	
1	14 (3.26)	1 (0.23)		12 (5.31)	1 (0.44)		2 (0.99	0 (0.0)	
2	6 (1.40)	2 (0.47)		1 (0.44)	1 (0.44)		5 (2.46)	1 (0.49)	
3	23 (5.36)	2 (0.47)		21 (9.29)	2 (0.88)		2 (0.99)	0 (0.0)	
4	25 (5.83)	6 (1.40)		14 (6.19)	2 (0.88)		11 (5.42)	4 (1.97)	
5	326 (75.99)	19 (4.43)	0.00	166 (73.45)	4 (1.77)	0.02	160 (78.82)	15 (7.39)	0.02
My friends or family help me remember to take my medication									
Yes	336	27		188	8		148	19	

	(78.50)	(6.31)		(83.19)	(3.54)		(73.27)	(9.41)	
No	60 (14.02)	5 (1.17)	1.00	28 (12.39)	2 (0.88)	0.63	32 (15.84)	3 (1.49)	0.77
Trust in antiretroviral therapy									
I believe I will take all or most of my medication									
Yes	391 (91.57)	32 (7.49)		213 (95.09)	10 (4.46)		178 (87.68)	22 (10.84)	
No	4 (0.94)	0 (0.0)	1.00	1 (0.45)	0 (0.0)	1.00	3 (1.48)	0 (0.0)	1.00
HIV medications have a positive effect									
Yes	387 (90.85)	31 (7.28)		210 (93.33)	10 (4.44)		177 (88.06)	21 (10.45)	
No	7 (1.64)	1 (0.23)	0.47	5 (2.22)	0 (0.0)	1.00	2 (1.00)	1 (0.50)	0.30
HIV medications will not work if I don’t take my treatment exactly as instructed									
Strongly agree	360 (84.11)	22 (5.14)		194 (85.84)	5 (2.21)		166 (82.18)	17 (8.42)	
Agree	32 (7.48)	7 (1.64)		20 (8.85)	4 (1.77)		12 (5.94)	3 (1.49)	
Neutral	3 (0.70)	2 (0.47)		0 (0.0)	1 (0.44)		3 (1.49)	1 (0.50)	
Disagree	2 (0.47)	0 (0.0)		2 (0.88)	0 (0.0)		0 (0.0)	0 (0.0)	
Strongly disagree	0 (0.0)	0 (0.0)	0.00	0 (0.0)	0 (0.0)	0.00	0 (0.0)	0 (0.0)	0.15

Emotional limitations and psychological functioning in the past month									
I felt unable to control the important things in my life									
Yes	217 (50.82)	20 (4.68)		104 (46.43)	4 (1.79)		113 (55.67)	16 (7.88)	
No	178 (41.69)	12 (2.81)	0.41	110 (49.11)	6 (2.68)	0.75	68 (33.50)	6 (2.96)	0.34
I felt nervous and stressed									
Yes	251 (58.78)	24 (5.62)		135 (60.27)	7 (3.13)		116 (57.14)	17 (8.37)	
No	144 (33.72)	8 (1.87)	0.19	79 (35.27)	3 (1.34)	0.75	65 (32.02)	5 (2.46)	0.22
I felt that things were going my way									
Yes	206 (48.24)	18 (4.22)		119 (53.13)	5 (2.23)		87 (42.86)	13 (6.40)	
No	189 (44.26)	14 (3.28)	0.66	95 (42.41)	5 (2.23)	0.76	94 (46.31)	9 (4.43)	0.33
I felt confident in my ability to handle my personal problems									
Yes	277 (64.72)	19 (4.44)		150 (66.67)	7 (3.11)		127 (62.56)	12 (5.91)	
No	119 (27.80)	13 (3.04)	0.21	65 (28.89)	3 (1.33)	1.00	54 (26.60)	10 (4.93)	0.14
I found that I could not cope with all the things that I had to do									
Yes	229 (53.38)	24 (5.59)		112 (49.56)	7 (3.10)		117 (57.64)	17 (8.37)	
No	168 (39.16)	8 (1.86)	0.06	104 (46.02)	3 (1.33)	0.34	64 (31.53)	5 (2.46)	0.24
I was able to control irritations in my life									
Yes	284 (66.20)	24 (5.59)		158 (69.91)	8 (3.54)		126 (62.07)	16 (7.88)	

No	113 (26.34)	8 (1.86)	0.68	58 (25.66)	2 (0.88)	1.00	55 (27.09)	6 (2.96)	0.76
I felt that I was on top of things									
Yes	191 (44.63)	19 (4.44)		100 (44.44)	6 (2.67)		91 (44.83)	13 (6.40)	
No	205 (47.90)	13 (3.04)	0.23	115 (51.11)	4 (1.78)	0.52	90 (44.33)	9 (4.43)	0.44
I was angered because of things that happened that were outside of my control									
Yes	260 (60.61)	25 (5.83)		134 (59.29)	8 (3.54)		126 (62.07)	17 (8.37)	
No	137 (31.93)	7 (1.63)	0.15	82 (36.28)	2 (0.88)	0.33	55 (27.09)	5 (2.46)	0.46
I felt problems were piling up so high that I could not overcome them									
Yes	229 (53.50)	22 (5.14)		114 (50.67)	6 (2.67)		115 (56.65)	16 (7.88)	
No	167 (39.02)	10 (2.34)	0.23	101 (44.89)	4 (1.78)	0.75	66 (32.51)	6 (2.96)	0.40
I was upset because of something that happened unexpectedly									
Yes	232 (57.43)	21 (5.20)		118 (54.13)	5 (2.29)		114 (61.29)	16 (8.60)	
No	141 (34.90)	10 (2.48)	0.54	90 (41.28)	5 (2.29)	0.75	51 (27.42)	5 (2.69)	0.50

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Appendix 2: Ethics Approval

Date: 28/03/2008

PROTOCOL NO.	**44/2008**
PROTOCOL TITLE	An Evaluation of determinants of adherence to antiretroviral therapy in AIDS patients in Gert Sibande District, Mpumalanga Province
INVESTIGATOR	**Name:** Dr LM Zungu **Cell:** 0824953953 **Work:** 0123542489 or 0123186502 **Email:** muzi.zungu@up.ac.za
DEPARTMENT	School of Health Systems and Public Health
STUDY DEGREE	MMed (Com Health)
SUPERVISOR	Prof J Matjila
CONTACT DEATAILS	**Phone:** 012-3541770 **E-Mail:** john.matjila@up.ac.za
MEETING DATE	26/03/2008

This **Protocol** has been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 26/03/2008 and found to be acceptable.

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*Prof V.O.L. Karusseit MBChB; MFGP (SA); M.Med (Chir); FCS (SA): Surgeon
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*Snr Sr J. Phatoli (female) BCur (Et.Al) Senior Nursing-Sister
*Dr L Schoeman (female) Bpharm, BA Hons (Psy), PhD
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DR R SOMMERS; MBChB; M.Med (Int); MPhar.Med.
SECRETARIAT of the Faculty of Health Sciences Research Ethics Committee - University of Pretoria

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Appendix 3: Information Leaflet and Informed Consent

TITLE OF STUDY: An Evaluation of determinants of adherence to antiretroviral therapy in AIDS patients in Gert Sibande District, Mpumalanga province

Dear Participant

1) INTRODUCTION

We invite you to participate in a research study. This information leaflet will help you to decide if you want to participate. Before you agree to take part you should fully understand what is involved. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask the investigator / interviewer.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this study is to determine the factors that influence adherence (ability to take your medicines as instructed by the health worker, including number of tablets to take, when you take them and how you take them) to antiretroviral therapy at Bethal and Embuleni hospitals (urban and rural hospitals respectively) of the Gert Sibande District in Mpumalanga province

You as a patient are a very important source of information on the factors that influence your ability to take your medicines according to the instructions of the health workers at this clinic.

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

This study involves asking you questions about your health, social life and personal life, should you choose to give consent to be a study participant. The study doctor will extract information from your hospital records to use in the study, if you give consent for the records to be used in the study.

We will ask you some questions about the medication you take, the people who help you take your medication if any and we will ask you if you can give us permission to look at your hospital record. In your hospital record we will look if according to your health care providers you are taking your medicines well and if your CD4 count or Viral load is improving.

Should you choose to take part in the research study you will be asked questions that may upset you, as they are of a sensitive nature. If you experience any discomfort or you are not feeling well during the interview or after the interview because of the questions asked, the study assistant or study doctor will provide counselling to you or refer you to a trained counsellor in the clinic

4) RISK AND DISCOMFORT INVOLVED

There are no risks in participating in the study as there are no procedures to be performed on you. If the information that is going to be asked of you is upsetting, the study assistant or study doctor will provide counselling to you or refer you to a trained counsellor in the clinic

5) POSSIBLE BENEFITS OF THIS STUDY

Although you will not benefit directly from the study, the information that will be gained from your participation will enable the health providers to render better service to you and others in your area in future.

6) WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your participation in this study is entirely voluntary. You can refuse to participate or stop at any time during the study without giving any reason. Your withdrawal will not affect you or your treatment in any way.

7) HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received written approval from the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria and the Mpumalanga Provincial Department of Health. Copies of the approval letters are available if you wish to have one.

8) INFORMATION AND CONTACT PERSON

The contact person for the study is **Dr LM Zungu**. If you have any questions about the study please contact him at tel.: 012 354 2489 or 012 354 1770.

9) COMPENSATION

Your participation is voluntary. No will be given for your participation.

10) CONFIDENTIALITY

All information that you give will be kept strictly confidential. Once we have analyzed the information no one will be able to identify you. Research reports and articles in scientific journals will not include any information that may identify you.

CONSENT TO PARTICIPATE IN THIS STUDY

I confirm that the person asking my consent to take part in this study has told me about nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I am participating willingly. I have had time to ask questions and have no objection to participate in the study. I understand that there is no penalty should I wish to discontinue with the study and my withdrawal will not affect any treatment / access to services in any way.

I have received a signed copy of this informed consent agreement.

Participant's name ……..... (Please print)

Participant's signature: .....…… Date.....

Investigator's name .....…….. (Please print)

Investigator's signature .....…… Date….....

Witness's Name .....……..... (Please print)

Witness's signature .....…….. Date….....

Appendix 4: Questionnaire Mpumalanga

Participant number

Please tick or fill the box next to question

1. When did you start ART (drugs): date (dd/mm/cccc?)

2. Period since enrollment in months

3. a) Age

b) Sex Female
Male

c) Education

i) Primary school

ii) High school

iii) Technical school

iv) Tertiary education

d) i. Employed Yes
No

ii. Working outside the home Yes
No

iii. Type of Job

Laborer

Semi-skilled

Professional

Other

iv) In which industry, specify

e) Having any children Yes
No

f) Number of children Alive
Passed On

g) Family size (no. of people in house)

h) Number of people contributing to household income

i) Residence Bethal
Embuleni

4. Social support

a. I feel satisfied with the overall acceptance I get from my friends and my family.

0 1 2 3 4 5

b. I feel satisfied with the overall encouragement I get from my friends and my family.

0 1 2 3 4 5

c. I feel satisfied with the overall support I get from my friends and my family.

0 1 2 3 4 5

d. My friends or family help me remember to take my medication.

Yes

No

5. Trust in antiretroviral therapy

a. I believe I will take all or most of my medication

Yes

No

b. HIV medications have a positive effect.

Yes

No

c. HIV medications will not work if I don't take my treatment exactly as instructed.

Strongly agree

Agree

Neutral

Disagree

Strongly disagree

6. Emotional limitations and psychological functioning in the past month:

a. I felt unable to control the important things in my life
Yes

No

b. I felt nervous and “stressed.”
Yes

No

c. I felt confident in my ability to handle my personal problems
Yes

No

d. I felt that things were going my way
Yes

No

e. I found that I could not cope with all the things that I had to do
Yes

No

f. I was able to control irritations in my life.
Yes

No

g. I felt that I was on top of things.
Yes

No

h. I was angered because of things that happened that were outside of my control
Yes

No

i. I felt problems were piling up so high that I could not overcome them

Yes

No

j. I was upset because of something that happened unexpectedly.
Yes

No

7.

a	Please point the tablets you take from the ones shown on the side attachment (research assistant to cross corresponding box below)							
	A = Lamiv-udine	B = Efaviren z	C = NV P	D = AZ T	E = stavudin e	F = Lopinavir / Ritonavir	G = Ritonavi r	Do not kno w
b.	how many tablets do you drink of in							
	A = LAMIV - UDIN E	B = Efaviren z	C = NV P	D = AZ T	E = stavudin e	F = Lopinavir / Ritonavir	G = Ritonavi r	Do not kno w
Morning								
Afternoo n								
At night								

8. Any special instructions regarding food/liquid restrictions

9. The number of pills and doses taken for each medication:

(i) Yesterday pills and doses

(ii) The day before yesterday pills and doses

(iii) Last Saturday pills and doses

(iv)Past-week adherence: 0 1 2 3 4 5

v) Past–month adherence: 0 1 2 3 4 5

10. Have you missed medication in the past month?

Yes

No

11. Reasons for missing an HIV medication dose: tick all that apply

a. I was away from home.

b. I was busy with other things.

c. I simply forgot.

d. I had too many pills to take.

e. I wanted to avoid side effects

f. I did not want others to notice me taking medication.

g. I had a change in daily routine.

h. I thought the drug was toxic/harmful.

i. I felt sleepy/slept through dose time.

j. I felt sick or ill.

k. I felt depressed/overwhelmed.

l. I found difficult to take pills at specified times.

m. Other specify

12. Race
    - o Black
    - o Coloured
    - o Indian
    - o White
    - o Other
13. Marital status
    a. Never married
    b. Married
    c. Separated
    d. Divorced
14. Ever experienced side effects
    a. Yes
    b. No
15. Declaration to spouse

a. Yes

b. No

16. How much in total do you pay to come to hospital for the return trip?

R

17. Do you ever forget to take your medication?

a. Yes
b. No

18. When you feel better, do you stop taking your medication?
a. Yes
b. No
19. Sometimes when you feel worse do you stop taking your medication?
a. Yes
b. No

Participant Records hospital record review

Participant number

1.

	Dates of laboratory results from the latest, then 3 months before latest and lastly 6 months before latest		
HIV RNA			
CD4ct			

2. Antiretroviral Therapy regimen: cross the correct box

1a: d4T / 3TC / efavirenz

1b: d4T / 3TC / NVP

2: AZT / ddI / lopinavir / ritonavir

3. Is patient taking the correct regimen (drugs and doses?)

Yes

No

4. is the a record of missed doses

Yes

No

5. Reports of any therapy interruptions >2days duration in last 3 months

Yes

No

6. Adequate spacing (intervals)

Yes

No

7. reasons given for missed doses?

Yes

No

8. list reasons given for missed doses if available