CLIENT FACTORS DETERMINING ARV ADHERENCE IN NATALSPRUIT HOSPITAL AND IMPILISWENI CHC IN GAUTENG PROVINCE IN 2006

Lubwama John KIGOZI

A RESEARCH REPORT SUBMITTED TO THE FACULTY OF HEALTH SCIENCES, UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG IN PARTIAL FULMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF PUBLIC HEALTH

JOHANNESBURG, 2008

DECLARATION

I declare that this research report is my own unaided work. It is submitted in partial fulfillment of the requirements for the degree of Master of Public Health at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in this or any other university.

……..

20th day of APRIL, 2008

In memory of my late mother

Angela Nashakhoma KIGOZI

1956-2004

ABSTRACT

Introduction: South Africa has embarked on a massive roll out of ARVs to more than 1.4 million people living with HIV/AIDS. Provision of ARVs to people living with HIV/AIDS encounters many challenges associated with adherence. Properly taken ARVs have been shown to reduce viral loads to undetectable levels and increase the CD4 count. This in turn leads to a drop in opportunistic infections and better health outcomes but the requirements for adherence are high. Several patient-related factors have been reported to affect adherence rates. Non-adherence on the other hand has been reported to lead to the development of drug resistant strains of HIV. It recognised that the resistance to ARVs can quickly lead to build up of highly resistant strains in the blood due to one week of missed medication.

Aims and objectives: This study set out to identify factors which affect adherence to HAART among adults on HAART in two health facilities in Gauteng province in 2006.The main objectives were to assess the patient adherence using viral load response and self-report data. Secondly, the study was to determine factors that facilitate adherence and finally barriers to adherence at the two sites.

Materials and methods: A cross sectional study was done at the two ARV facilities in Gauteng from July to November 2006. Two physiological methods -CD4 counts and plasma viral load, and one subjective-3 day recall self- report methods were used to asses adherence. Exit interviews and record reviews were done to collect data. Virologic outcome was the preferred surrogate marker for adherence. Univariate and bivariate analyses were done to determine measures of association. Measures of association (Chi square) at a 95% significance level for factors affecting adherence were then determined and results obtained.

Results: The mean age was 36.9 years (range 18-70 years) and 73.5% were women. Self-report data (n=343) indicated 98.4% in the higher adherence category (taken 100% of their doses). Viral load data (n=343) showed that 88.8% were in the adherence lower category (<400 RNA copies). Viral load outcome ("adherence") was significantly associated with the length on treatment ($p<0.05$) and patients who had been on treatment for 12-24 months had lower viral load than those who had been treatment for a shorter time (<12 months) or longer (>24months). However, gender ($p=1.000$), age ($p=0.223$), level of education ($p=0.697$) and access to social grants ($p=0.057$) were not associated with "adherence". Socio-economic status was significantly associated with viral load outcome ($p<0.01$) as well as cost ($n=185$; $p<0.05$). Individuals who incurred the highest costs (>R25) were the least likely to adhere followed by those facing average costs (R15-25) compared to the reference group (< R15).

Conclusion: Adherence rates of 88.8% suggest that respondents from both facilities can optimally adhere to their medication when they have been on ARVs for longer than a year. These are minimum adherence rates. There were factors that still hinder adherence at both the individual patient level. There is still a need for more targeted interventions especially towards men who were noted to have a relatively low uptake of HAART within the two sites.

ACKNOWLEDGEMENTS

My sincere thanks to:

The Eternal Almighty God for granting me the gift of life and giving me the opportunity to expand my mind through learning and researching knowledge.

My father Mr. Disan Kigozi, for showing me love, understanding and granting me the means and support to my education and financial assistance during the tenure of my studies.

The South African Medical Research Council (MRC) and the Wits University Post Graduate financial aid office for the financial assistance in carrying out the research.

My supervisor, Jane Goudge for her valuable ideas, guidance and support. The facility managers and staff at the Natalspruit Hospital and Empilisweni Community Health Centre for assistance with accessing the facility during data collection.

Dr. Rugola and Mr. Eustacius Musenge for assisting with data cleaning and technical statistical data management and analysis support at all hours that I needed them.

The staff at Center for Health Policy who participated in the study in one way or another and were helpful in terms of advise and assistance with data collection and data entry including Harry Nyatela the leader of the field interviewers.

Mr. Godfrey Mulaudzi and Mrs. Dudu Mlambo, a wonderful driver and friend respectively at the Center for Health Policy for offering to transport to the data collection sites and coordinating the research project in timely fashion.

Last but not least the Kigozi family; Gladys Nanteza Kigozi, Esther Nalumansi Kigozi and Flavia Nantege Kigozi for the prayers, understanding and moral support during the long hours I had to work on this report.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS

ART	Antiretroviral therapy
ASSA	Actuarial Society of South Africa
ARV	Antiretroviral drugs
b.i.d	Twice daily , { from Latin bis in die}
CHC	Community Health Centre
CCM	Chronic Care Model
DoH	Department of Health of the Republic South Africa
HAART	Highly Active Antiretroviral Therapy
HIV/AIDS	Human Immune Deficiency Virus/Acquired Immune Deficiency Syndrome
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NNRTI	Non Nucleoside Reverse Transcriptase Inhibitor
PLWHA	People Living With HIVAIDS
q.d	each day, {from Latin, quaque die}
SAHIVS	Southern African HIV Clinicians Society
SES	Socio-economic Status
TAC	Treatment Action Campaign
VCT	Voluntary Counseling and Testing
WHO	World Health Organisation
UNAIDS	United Nations AIDS organisation, a Joint United Nations programme for HIV/AIDS.

Part of this report and the work therein was presented at the HIV symposium at the MRC Conference centre, Cape Town on 28th March, 2008 as an oral presentation

Part of this report has been accepted as a poster presentation at the forthcoming PHASA 2008 conference at the Southern Sun Cape Sun hotel on the 3rd -4th June, 2008 in Cape Town

CHAPTER ONE: BACKGROUND

1.1 INTRODUCTION

In 1996 HAART was launched as one of the latest therapies on the frontier to combat HIV/AIDS. Nine years later the government of South Africa launched a roll out programme in the public health sector health facilities to more than one million people in need of treatment. This also initiated challenges associated with non-adherence.

Adherence is now recognised as key to effective antiretroviral therapy if viral loads are to be brought down to manageable levels and resistance avoided. Benefits which accrue from such therapy therefore need to be maximized in resource constrained environments. This study therefore set out to explore and document the factors that are associated with adherence at two public sector health facilities. Ethical permission was sought from the Wits University and permission sought and obtained from the provincial and facility managers to carry out the study. Requirements for anonymity and confidentiality were strictly adhered to throughout the study. The study population was mainly males and female patients registered at the two health care facilities on HAART for longer than 3 months.

The study was based on an evidence based health care model for management of the chronically sick(CCM).This study thus focuses on one of the elements of the CCM ,mainly the patient side factors and how they influence adherence outcomes. The main factors that were investigated include the following: Socio-demographic variables, health literacy (health knowledge), medication adherence support, HIV status disclosure and their association to viral load outcomes.

A cross sectional study was done utilizing exit interviews to collect data for the study. There were 355 interviews of which 343 were eligible for data analysis. More than 70% were females and the population had a mean age of 36.9 years. Only 1% reported being on medical aid whilst half were receiving a social support grant. More than 99% reported not missing their medication but on the other hand the viral load outcome indicted that only 88% had lowered viral load. Adherence rates suggest that if optimally supported, patients' adherence well in comparison to those elsewhere. The results further indicated that there were factors that still hinder adherence at the individual patient level in addition to the wider health system level.

1.2 THE HIV/AIDS TIME LINE

According to the 2006 report on the global AIDS epidemic of the UNAIDS, it has marked more than 25 years since the first AIDS cases were reported.

From the same report a summary timeline of the development of key events is outlined below:

In **1981** the first cases of unusual immune deficiency are identified among gay me in the USA and a new deadly disease noticed (UNAIDS, 2006).

In **1982**, the Acquired immune deficiency Syndrome (AIDS) was identified for the first time. AIDS is defined for the first time. The human immunodeficiency virus (HIV) was identified for the first time.

1983- A heterosexual epidemic is revealed in Africa. The first AIDS cases were reported in South Africa in 1983. At that time the numbers were small, affecting mostly white gay men, haemophiliacs and some intravenous drug users

1985-The first HIV antibody test becomes available. While there was little focus on HIV/AIDS in South Africa in general, the AIDS Advisory Group was appointed at that time.

1989-The WHO launches the Global programme on AIDS. The first therapy for AIDS; AZT is approved for use in the USA.

1990-The first antenatal surveys to test for HIV rates in pregnant women were carried out in South Africa. 0.8% of women were found to be HIV positive. It was estimated that there were between 74 000 and 120 000 people in South Africa living with HIV. Since this time, antenatal surveys have been carried out annually.

1991-1993- HIV prevalence in young pregnant women in Uganda and in young men in Thailand begins to decrease, the first major down turns in the epidemic in developing countries. In South Africa the first governmental response to AIDS came when President Nelson Mandela addressed the newly formed National AIDS Convention of South Africa (NACOSA). Although there was little action from the government in the following few years, the purpose of NACOSA was to begin developing a national strategy to cope with AIDS.

1994-Scientists develop the first treatment regimen to reduce mother to child transmission of HIV.

1996- Highly Active Antiretroviral Treatment is launched.

1997- Brazil becomes the first developing country to provide antiretroviral therapy through its public health system. By 1998 the prevalence rate in South Africa had climbed to 22.8%. The pressure group the Treatment Action Campaign (TAC) was launched under the leadership of Zackie Achmat. The TAC has played a major role in advocating for the rights of people living with HIV/AIDS and in demanding a national treatment plan for those who are infected.

2001-The UN General Assembly special session on HIV/AIDS , the Global fund to fight AIDS, Tuberculosis and malaria is launched.

2003-WHO and UNAIDS launch the '3X5' initiative with the goal of reaching 3 million people in the developing world with antiretroviral treatment by 2005. In August of 2003 the Health Department

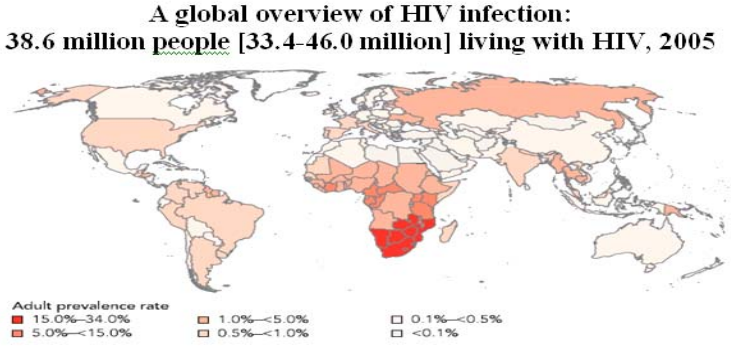
was directed to develop a detailed plan for the roll out of antiretroviral (ARV) drugs to those who were living with HIV/Aids.

2003-After much delay the government finally committed to providing free treatment to 53,000 patients by March in South Africa. The program began in Gauteng province, where five major hospitals began treatment. It is estimated that there are currently 110 000 patients in the public sector and 80 000 in the private sector who are currently receiving treatment at 192 facilities around the country.

1.3 OVERVIEW OF THE GLOBAL AIDS EPIDEMIC

To date around 38.6 million people have been infected with HIV (Fig1-1). The vast majority of the 38.6 million people living with HIV in 2005 were unaware of their status (UNAIDS, 2006).In that period deaths attributable to AIDS have risen from almost none in 1980 to more than 25 million men and women, orphaning millions of children, exacerbating poverty and hunger and in some countries even reversing human development altogether. From the UNAIDS report of 2006, the global HIV incidence rate (the annual number of new HIV infections in a population of previously uninfected persons) is believed to have peaked in the late 1990s and to have stabilised subsequently. The numbers of people living with HIV have continued to rise, due to population growth and more recently, the life prolonging effects of antiretroviral therapy.

Figure 1-1: Global HIV infection in 2005.



Source: global report on the HIV/AIDS epidemic, UNAIDS.2006

An estimated 38 million people world wide were living with HIV in 2005(Fig 1-2). An estimated 4.1 million became newly infected with HIV and further 2.8 million lost their lives to AIDS.

Globally, there were an estimated 17.3 million women living with HIV in 2005 – three quarters (or 13.2 million) were living in sub-Saharan Africa. Around 59% of all adults living with HIV in sub-Saharan Africa were women (UNAIDS, 2006).

Figure 1-2: Statistics and features of the HIV/AIDS epidemic

Regional HIV and AIDS statistics and features, 2004 and 2006

	Adults and children living with HIV	Adults and children newly infected with HIV	Adult (15–49) prevalence (%)	Adult and child deaths due to AIDS
Sub-Saharan Africa				
2006	24.7 million [21.8–27.7 million]	2.8 million [2.4–3.2 million]	5.9% [5.2%–6.7%]	2.1 million [1.8–2.4 million]
2004	23.6 million [20.9–26.4 million]	2.6 million [2.2–2.9 million]	6.0% [5.3%–6.8%]	1.9 million [1.7–2.3 million]
Middle East and North Africa				
2006	460 000 [270 000–760 000]	68 000 [41 000–220 000]	0.2% [0.1%–0.3%]	36 000 [20 000–60 000]
2004	400 000 [230 000–650 000]	59 000 [34 000–170 000]	0.2% [0.1%–0.3%]	33 000 [18 000–55 000]
South and South-East Asia				
2006	7.8 million [5.2–12.0 million]	860 000 [550 000–2.3 million]	0.6% [0.4%–1.0%]	590 000 [390 000–850 000]
2004	7.2 million [4.8–11.2 million]	770 000 [480 000–2.1 million]	0.6% [0.4%–1.0%]	510 000 [330 000–740 000]
East Asia				
2006	750 000 [460 000–1.2 million]	100 000 [56 000–300 000]	0.1% [<0.2%]	43 000 [26 000–64 000]
2004	620 000 [380 000–1.0 million]	90 000 [50 000–270 000]	0.1% [<0.2%]	33 000 [20 000–49 000]
Oceania				
2006	81 000 [50 000–170 000]	7100 [3400–54 000]	0.4% [0.2%–0.9%]	4000 [2300–6600]
2004	72 000 [44 000–150 000]	8000 [3900–61 000]	0.3% [0.2%–0.8%]	2900 [1600–4600]
Latin America				
2006	1.7 million [1.3–2.5 million]	140 000 [100 000–410 000]	0.5% [0.4%–1.2%]	65 000 [51 000–84 000]
2004	1.5 million [1.2–2.2 million]	130 000 [100 000–320 000]	0.5% [0.4%–0.7%]	53 000 [41 000–69 000]
Caribbean				
2006	250 000 [190 000–320 000]	27 000 [20 000–41 000]	1.2% [0.9%–1.7%]	19 000 [14 000–25 000]
2004	240 000 [180 000–300 000]	25 000 [19 000–35 000]	1.1% [0.9%–1.5%]	21 000 [15 000–28 000]
Eastern Europe and Central Asia				
2006	1.7 million [1.2–2.6 million]	270 000 [170 000–820 000]	0.9% [0.6%–1.4%]	84 000 [58 000–120 000]
2004	1.4 million [950 000–2.1 million]	160 000 [110 000–470 000]	0.7% [0.5%–1.1%]	48 000 [34 000–66 000]
Western and Central Europe				
2006	740 000 [580 000–970 000]	22 000 [18 000–33 000]	0.3% [0.2%–0.4%]	12 000 [<15,000]
2004	700 000 [550 000–920 000]	22 000 [18 000–33 000]	0.3% [0.2%–0.4%]	12 000 [<15 000]
North America				
2006	1.4 million [880 000–2.2 million]	43 000 [34 000–65 000]	0.8% [0.6%–1.1%]	18 000 [11 000–26 000]
2004	1.2 million [710 000–1.9 million]	43 000 [34 000–65 000]	0.7% [0.4%–1.0%]	18 000 [11 000–26 000]
TOTAL				
2006	39.5 million [34.1–47.1 million]	4.3 million [3.6–6.6 million]	1.0% [0.9%–1.2%]	2.9 million [2.5–3.5 million]
2004	36.9 million [31.9–43.8 million]	3.9 million [3.3–5.8 million]	1.0% [0.8%–1.2%]	2.7 million [2.3–3.2 million]

Source: global report on the HIV/AIDS epidemic, UNAIDS.2006

1.4 HIV/AIDS IN AFRICA

Sub-Saharan Africa is the region of the world that is most affected by HIV/AIDS (Fig1-2). An estimated 25.8 million people in the region were living with HIV and approximately 3.2 million new infections occurred in 2005. The rates of infection are not uniform throughout Africa. West Africa is generally less affected with increasing rates of infection in South Africa (Fig 1-3).

Figure 1-3: Adults (aged 15-49 years) HIV/AIDS prevalence in sub-Saharan Africa

Country	Median HIV prevalence (%) among women attending antenatal clinics 2003–2004*	Population-based survey prevalence (%) (year)	2003 HIV prevalence (%) reported in 2004 Report on the global AIDS epidemic	Adjusted 2003 HIV prevalence (%) in current report	2005 HIV prevalence (%) in current report	Trend in prevalence
Botswana	38.5	25.2 (2004)	38.0	24.0	24.1	Stable
Burkina Faso	2.5	1.8 (2003)	4.2	2.1	2.0	Decline in urban areas
Burundi	4.8	3.6 (2002)	6.0	3.3	3.3	Decline in capital city
Cameroon	7.3†	5.5 (2004)	7.0	5.5	5.4	Stable
Ethiopia	8.5	1.6 (2005)	4.4	(1.0–3.5)	(0.9–3.5)	Decline in urban areas
Ghana	3.1	2.2 (2003)	3.1	2.3	2.3	Stable
Guinea	4.2	1.5 (2005)	2.8	1.6	1.5	Stable
Lesotho	28.4	23.5 (2004)	29.3	23.7	23.2	Stable
Rwanda	4.6	3.0 (2005)	5.1	3.8	3.1	Decline in urban areas
Senegal	1.9	0.7 (2005)	0.8	0.9	0.9	Stable
Sierra Leone	3.0	1.5 (2005)	–	1.6	1.6	Stable
South Africa	29.5	16.2 (2005)	20.9	18.6	18.8	Increasing
United Republic of Tanzania	7.0	7.0 (2004)	9.0	6.6	6.5	Stable
Uganda	6.2‡	7.1 (2004–5)	4.1	6.8	6.7	Stable

*WHO Africa (2005). HIV/AIDS epidemiological surveillance report for the WHO African region, 2005 Update. Harare.
†Estimate based on country report for 2002 (2003). Ministry of Public Health Cameroon. National HIV sentinel surveillance report 2002.
‡Estimate based on country report 2002 (2003). Ministry of Health Uganda. STD/HIV/AIDS surveillance report. STD/AIDS control programme. Kampala.

Source: global report on the HIV/AIDS epidemic, UNAIDS 2006

In 2005, the region was home to 2 million children under 15 years of age living with HIV. Almost 90% of the total numbers of children living with HIV are in sub-Saharan Africa and fewer than one in ten of those children are being reached by basic support services.

An estimated 12 million children under the age of 17 (just under 10% of children) living in sub-Saharan Africa have lost one or both parents to AIDS. In 2005, an estimated 2.7 million people in the region became newly infected with HIV and 2 million adults and children died of AIDS. Around 72% (4.7 million) of all people in need of antiretroviral therapy live in sub-Saharan Africa. In 2005 around one in six people in need of treatment in the region were receiving it.

There are varying statistics with respect to HIV/AIDS prevalence that were reported in the UNAIDS (2005) report. In East Africa HIV prevalence was reported to either have decreased or remained stable from the past years. There were 1.3 million people living with HIV in Kenya in 2005. Interestingly, the UNAIDS report indicates that the national HIV prevalence fell from 10% in the late 90s to stabilise around 6% in 2005. This was attributed to rising condom use, women delaying sexual debut and people reducing the number of sexual partners based on the various surveys that UNAIDS quoted. Uganda has seen a steep decline from more than 35% in the mid 80s to late 90s to stabilise around 6.7% with more than 1 million people living with the virus in 2005.In Tanzania a prevalence of 6.5% in adults was noted in 2005 with about 1.4 million people. The epidemic although appearing to have stabilised, is noted to have increased markedly in the older people reaching 13% among women aged 30-34%. In Somalia, although national HIV prevalence is low (0.9% of adults), knowledge of HIV transmission is poor and condom use uncommon – one study showed that 17 out of 20 men and 19 out of 20 women aged 15-24 years old had never used a condom.

West Africa has generally been less affected by HIV/AIDS compared to the rest of sub-Saharan Africa based on the prevalence rates. At 7.1% Côte d'Ivoire has the highest national HIV prevalence in West Africa. Available data show that the epidemic appears to have stayed relatively stable for almost a decade and significant declines in HIV prevalence are being seen in pregnant women. Nigeria has the third-largest number of people living with HIV in the world at 2.9 million. Infection levels vary across this large country – from 1.3% in the south west to 4.9% in northern and central areas. Sex work is a driving factor in Ghana's epidemic, where adult HIV prevalence is estimated at 2.3%. Infection levels have been rising among antenatal attendees and reached just under 4% in 2005. In the Democratic Republic of the Congo an estimated 1 million people were living with HIV in 2005. Adult HIV prevalence was estimated at 3.2%, but HIV prevalence as high as 7% was found in pregnant women in Lubumbashi.

1.4.1 SOUTHERN AFRICA

In Southern Africa, HIV prevalence levels are exceptionally high (except for Angola at 3.7%). Southern Africa has nine of the ten highest HIV/Aids prevalence rates in the world and more than 3, 3-million orphans due to the virus. This combination is straining government budgets for health care and social services, food security, education, communities and extended families (Mail and Guardian, 13th December, 2006). However, in Zimbabwe, where 1.7 million people are living with HIV, data have shown a decline in HIV prevalence which is currently estimated at 20.1%, down from 22.1% in 2003. This decline has two possible causes; studies have shown both a substantial increase in condom use since

the early 1990's and that more young people have been delaying their sexual debut and reducing the number of casual sexual partners; however, a significant factor in the decline is attributed to high-mortality rates.

There were no signs of a decline in other parts of southern Africa, at the end of 2005.Botswana's national HIV prevalence stood at 24.1%, Namibia's was at 19.6% and Swaziland's at 33.4%. In Swaziland, HIV prevalence among pregnant women attending antenatal clinics rose from 4% in 1992 to 43% in 2004.

South Africa's epidemic is now one of the worst in the world with an estimated 5.5 million people (18.8% of adults) living with HIV in 2005. Almost one in three pregnant women attending public antenatal clinics were living with HIV in 2004 and trends show a gradual increase in HIV prevalence. Around 600,000 are sick with AIDS i.e. 11% of those infected by HIV. There has been significant scale-up on the treatment front – around 190,000 people were receiving therapy by the end of 2005 – however this still only represents less than 20% of those in need.

According to ASSA (2003) projections and estimates, the prevalence of HIV/AIDS in the country and most provinces is reaching a plateau with KwaZulu-Natal having the highest (40% antenatal prevalence), the Western Cape the lowest (estimated antenatal plateau of 15.5%). The Northern Cape(19.9%) and Limpopo(19.6%) were slightly higher than the Western Cape while the other provinces were are expected to either level off or peak at an antenatal prevalence of between 30-35% among which was Gauteng Province (35.8%).

Some key indicators from the ASSA (2003) projections include the impact and death indicators of the HIV/AIDS epidemic across South Africa. The impact of the epidemic has been felt all over the country with the greatest impact in KwaZulu-Natal and the least affected being the Western Cape. Some key findings from the report include the following: Kwa Zulu-Natal accounted for 28.7% of all infections, while Gauteng accounts for 26.2%. The Western Cape was providing HAART to about 8%, Gauteng to about 5% while the Eastern Cape was reaching only about 3%. Kwa Zulu-Natal accounted for nearly a third of all orphans with Gauteng the next highest at 18%. With a population of 7.54 million people in 1996, Gauteng's population had risen to an estimated 9.68 million people in 2006 according to ASSA (2003) estimates. The total number of HIV positive people by 1997 was estimated to be 279,208 infected people and currently is estimated to be more than 1.4 million people. For South Africa as a whole, the total cumulative AIDS deaths for South Africa were estimated at 6,074 in 1996 compared to 2006 (estimated at 437,762).The total AIDS orphans were estimated at 4,465 of the total number of 63,264 in 1996 while in 2006 they were estimated at 203,287 of the total orphan population of 277,109 with a rise of 59,000 orphans from the previous year.

The AIDS epidemic, which is estimated to have resulted in the death of more than 688,000(SAHR,2000) people in South Africa by mid 2002, has caused profound negative social, economic and individual effects and has placed a particularly heavy toll on existing health care systems, particularly those already facing severe resource constraints. Businesses, and consequently South Africa's economy, incur huge financial losses each year to HIV/AIDS. A study commissioned by AIC Insurance last year showed that South Africa lost about R12-billion a year because of workplace absenteeism, of which between R1,8-billion and R2,2-billion could be attributed to HIV/Aids, with close to one in five South Africans between the ages of 20 and 64 are infected with HIV-a large part of South Africa's workforce (*The Mail and Guardian,13th December,2006*).

1.4 STATEMENT OF THE PROBLEM

South Africa's commitment to roll out anti-retroviral therapy (ART) to over 1.4 million people in South Africa by 2008 has initiated challenges associated with non-adherence and related interventions to promote lifelong adherence (Hanson et al, 2003).Anti-retroviral (ARV) provision to people living with HIV/AIDS (PLWHA) encounters challenges associated with adherence. Adherence is key to the effectiveness of ARVs in bringing the viral loads of PLWHA to manageable levels (Carpenter et al, 1997). Poor adherence leads to the development of resistant strains of the virus leaving drug naïve patients with few effective treatment options given the length of time it takes to develop and test a single drug and have it approved for human use.

This massive roll out programme will have several negative impacts on the health system itself especially the service providers, health facilities and service provision within the health system that is stretched to the outmost limits. Although effective provision of ARVs will reduce the numbers of critical ill AIDS patients in hospitals, the use of the health services for chronic out-patient care will increase. This may impact on the health care seeker especially regarding access and referral to the nearest facilities. With an ever increasing demand for more from the health sector, it is therefore important to ensure that patients on HAART adhere to the anti-retroviral therapy in order to maximise the benefits that accrue thereof in such a resource constrained environment.

There is very little published information in South Africa about factors associated with non-adherence let alone those that facilitate adherence to HIV medication in the public health sector from a patient's perspective. There is therefore need to gain a better understanding of these factors that facilitate adherence and barriers to adherence in order to design better implementation strategies and ensure that resistance is prevented or minimised in the long term.

1.5 RATIONALE FOR THE STUDY

In the literature, adherence to antiretroviral therapy (ART) still dominates debates as one of the challenges facing continued treatment of HIV positive patients and health service delivery (Chesney, 2000; Fogarty et al, 2002; Simoni, 2003, Orrell et al, 2003). Properly taken ARVs have been shown to reduce viral loads, but the requirements for adherence are high, with most studies suggesting that it has to be higher than 90% to avoid the risk of resistance (Singh et al, 1999; WHO, 2005). There are many factors that have been reported to negatively affect adherence leading to non adherence. These factors were broadly categorised in a review by Chesney as those related to the patients themselves, medication and the system of care. (Chesney,2000).Among the problems noted in the various studies concerned with non-adherence by patients have been: failure to fill prescriptions at the clinic due to travel away from home, go to appointments and take medication outside the home which can be attributed to the fear of disclosing one's status ,forgetfulness or being too busy, changes in daily routine of the patient, the side effects of the medication, depression or illness and lack of interest or taking drug holidays(Chesney,2000;Golin et al; 2002; WHO, 2005).

This research investigated the barriers associated with adherence on the public health HAART pilot programme. It is hoped that the results of this research will inform operational research and programme managers enhance better patient management in order to lead to better adherence and enhanced quality of care. The results will further be disseminated to policy makers in order to inform and contribute to the decision-making process about chronic care of PLWHA in Gauteng Province.

CHAPTER TWO: LITERATURE REVIEW

2.1 THE CHRONIC CARE MODEL (CCM)

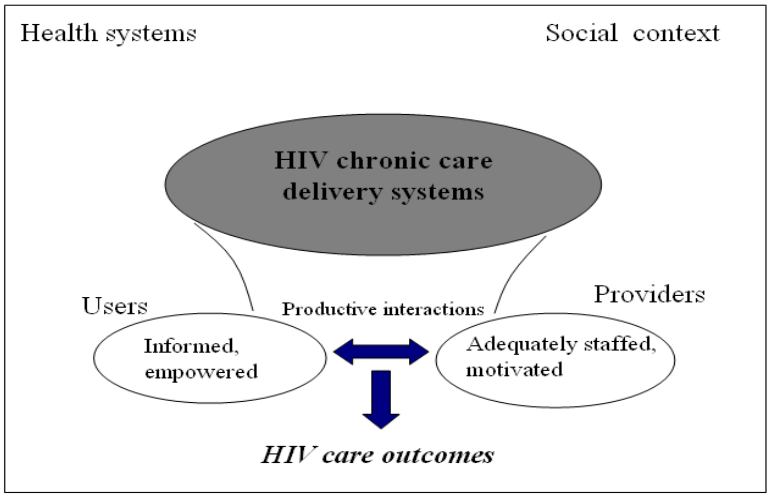
The current study will draw on an evidence based model framework, the Chronic Care Model (CCM), designed to guide quality improvement in health care activities first described and developed by (Wagner et al,2001). He suggests that in order to ensure improvement in the provision of chronic care, there needs to be a focus on several crucial components. These are broadly divided into first, the provider oriented components and secondly the patient oriented interventions all interacting to ensure productive interactions between the patient and provider that will eventually lead to effective and beneficial chronic disease management (in this case HAART).

The health care system is depicted as a part of a larger community with the ARV clinic as part of the health care organisation (Fig 2-1) .The framework provides a guide linking the health care system with the patients on HAART. Interactions are further described as productive between the providers and the patient with the ultimate goal of ensuring that patients are informed, activated and able to cope with challenges of living with and treating the chronic illness (Wagner et al, 2001: page 68).

The CCM model stresses interventions that encourage people to acquire self management skills that are essential to chronic care. This in effort to improve health care delivery systems traditionally designed for acute illness, towards chronic illness. A common set of challenges is presented by chronic illnesses to the sufferers and their families-dealing with symptoms, disability, emotional impacts, complex medication regimens, difficult lifestyles adjustments and obtaining helpful medical care. Persons in contact with the heal care system should be empowered to ensure that they are informed, confident and have the skills necessary to manage their condition and thus ensure that they can productively take part in their health care (Wagner et al, 2001: page 64).

This forms a shift in focus from the traditional health care system that sought to treat illnesses as they presented within the health care system to meeting the needs of the chronically ill since they are more likely to be part of the health care setting for a long time. As Wagner, 2003 summarises; "The CCM shifts focus from the historical didactic education of the patient to a more pragmatic form of encouragement and support for the more effective self-management. It also emphasises the patients' crucial role in maintaining health and function, the importance of setting goals, establishing action plans, identifying barriers, and solving problems to overcome barriers."

Figure 2-1: The CCM: A performance framework



Source: adapted from Schneider et al, 2007

2.2 DEFINING ADHERENCE

The definitions of adherence are many and have changed to suit the particular context within which they are applied. Some examples include the following:

Adherence is defined by most dictionaries as "to stick, to remain loyal, or to have fidelity". Since adherence to complex medical regimens requires an active interaction between patients, disease, treatment, medical care and outcome it was felt that terminology that implies a more active role for the patient was preferable, rather than the phrase "compliance" (Garcia et al, 2003).

Adherence, "the extent to which a person's behaviour-taking medication, following a diet, and/or executing lifestyle changes-corresponds to with agreed recommendations from a health provider" (WHO, 2002: page 1), is a crucial element for the implementation of the HIV treatment scale-up initiative.

Therefore to achieve the aims of this study, the definition of adherence will refer to "the ability of the person living with HIV/AIDS to be involved in choosing, starting, managing and maintaining a given therapeutic combination medication regimen to control viral (HIV) replication and improve immune function" as defined by Simoni et al, 2003.

2.3 THE CHALLENGE OF MEDICATION ADHERENCE

One of the key challenges to better adherence has been both the number of drugs that patients have to take as well as their toxicity. Advances in research about HAART have introduced multi drug pills that contain two or three drugs in one but with lower toxicity when compared to the previous mono-therapies (Kalichman and Malow, 2004). These are commonly known as Highly Active Antiretroviral

Therapy which has brought longer and healthier lives to PLWHA . This has resulted in lowered patient loads in hospital beds, PLWHA leading more productive lives and a marked reduction in annual HIV related deaths.

Studies have shown that for HAART regimens to be effective, strict adherence to prescribed dosing schedules is necessary. This is to reach and maintain therapeutic levels of these drugs and prevent the development of drug resistant viral strains in the body .However excellent adherence doesn't always result in complete viral load suppression while non adherence increases the risk of death due to treatment failure(Chesney, 2003 and 2004).

In a review of theorising contextual relationships in adherence, (Goudge et al 2004) and (Gill et al2005) mention that missing more than 5-10% is linked to incomplete suppression of viral replication, declining CD4 cell counts, clinical progression to AIDS or death and the development of and spread of antiretroviral drug resistance to HIV. It has been established that adherence to most chronic diseases varies between 33-80% with a mean of 67% of doses taken or prescribed (Paterson et al, 1999:2000) in Goudge et al,(2004). When it comes to HIV/AIDS the margin between success and failure is narrow. In order to maximise the benefits of HAART maximum adherence is required. The unique characteristics of the HIV require near perfect adherence with >95% defined as the acceptable level required to achieve complete viral suppression (Fogarty et al,2002). The resistant strains of HIV due to non-adherence can be transmitted to uninfected patients leaving people who have recently acquired the virus infection and previously drug naïve patients without effective options for treatment (Wainberg & Friedland, 1998). Liechty & Bangsberg (2003) further state that resistant strains of the virus accumulate most rapidly when patients have high levels of adherence but with incomplete viral suppression.

2.4 MEASURING ADHERENCE

Forgaty et al(2002) in a review of published and abstract reports of patient adherence to HIV medication regimens reported that methods used to asses adherence fell into three categories:

i. Subjective measures of adherence based on self report or others' report of adherence, including medical chart review.

ii. Objective measures of adherence (pill counts, pharmacy refill records, use of mechanical or electronic monitors of pill or drug use) and

iii. Physiological methods or indicators (undetectable viral load, CD4 count, plasma assay or lab reports).

The review further noted that most of the studies used multiple methods of assessments, with the most frequent being subjective (87.7% of the studies). These used interviews and questionnaires and surveys administered by self or others.

The most reliable subjective method for measuring adherence is the self-reporting (Family Health Planning, 2001), where a patient is asked how many doses s/he missed in the last day or two days or two weeks. The format of the questions varies from study to study. Non-adherence rates are higher in studies where a longer recall time is used. With a longer recall period the chance of inaccuracy increases. Answers are influenced by patients' desire to provide a socially acceptable answer, particularly when the interviewer is a health worker whose role has been to exhort the patient to adhere. Other inaccuracies may result from imprecise or inconsistent questioning, or patient forgetfulness. The three day recall period has the advantage of being moderately shorter compared to similar measures like the seven day or one month recall methods that have been used in other studies. This means that the patient can easily recall with accuracy the exact amount of tablets taken or missed. This method was further enhanced by asking the patients the number of tablets that they had missed the previous day and two days to ensure that the results were reliable. The underside to this method is the fact that the patient may desire to provide a socially acceptable answer especially where healthcare workers are concerned. Paterson et al(1999;2000) suggest that less than a 7-day recall period may not be adequate to determine longer term adherence. They proposed that additional questions be used to determine adherence over weekends compared with weekdays due to behaviour differing over those two periods. Two studies report that the self-report method fails to detect 20-35% of non-adherent individuals (Morisky 1986, Arnsten et al 2001). Despite these failings a significant association has been shown between self-reported levels of adherence and viral load (Bangsberg et al ,2001; Nieuwkerk et al, 2001; Weidle et al ,1999;Hecht, 1998).

Pharmacy records can be a convenient measure of adherence assessment in situations in which a patient has a single source of antiretroviral medication. However, it may therefore not be absolutely reliable because it requires patients to always use the same pharmacy and that they don't share the pills prescribed. Sharing or otherwise would lead to overestimating adherence (Paterson et al, 2002).

A patient's viral load can be used as an indicator of possible poor adherence yet there can be instances where a fully adherent patient's viral load is not as low as expected hence as a result poor adherence cannot be assumed (Mocroft, 2003). Biological parameters like the Mean corpuscular volume (MCV),Uric acid levels and hyperbilirubinemia include some of the biological markers that are reported to have been used as crude markers of adherence (Paterson et al ,2002).However there are varying reports of the association between these biological markers and the virologic outcome due to the dose response relationship variations. These would be inadequate if used to measure adherence.

Monitoring of plasma concentrations of drug levels has been indicated as another means of assessing adherence. These methods however remain to be standardised especially procedures for sample collection, cross validation of analytic procedures and interpretation of assay results (Paterson et al, 2002). "White coat compliance effect" or "the toothbrush effect" a situation where increased adherence occurs immediately before a clinic visit limits the usefulness of this method to assess adherence.

Physicians and other health care providers routinely make predictions of the adherence of their patients to antiretroviral therapy, especially prior to initiating treatment and when assessing reasons for poor adherence outcome (Paterson et al ,1999;2000). Assessments of adherence by health providers are often inaccurate and are often no better than chance (Bangsberg et al 2001). Providers don't have time to collect detailed adherence assessments - which pills are being taken less, why, and what times – missing an opportunity to help the patient work out a solution. Providers have expectations of patients to adhere, an expectation that makes it more difficult for a patient to be open about non-adherence (Bangsberg et al 2002).

In the absence of methods that measure adherence perfectly, data triangulation procedures must be applied to measure the outcome of interest. Triangulation can be achieved through using multiple data sources, different researchers and multiple perspectives to interpret a single issue, program or problem (Carel et al, 1995). Thus for the purpose of this study self-reported adherence from patient exit interviews will be triangulated with a record review of the patients' viral load records in order to establish adherence levels.

2.5 HAART REGIMENS IN SOUTH AFRICA

The benefits and aims of antiretrovirals are summarized in the UNAIDS(2005) summary report that includes the ones listed below:

1. To cause a sustained suppression of HIV multiplication and hence the reduction in the amount of virus in the body. In this case the patients viral load should remain undetectable (<400 copies/ml), and remain so when on HAART.
2. To restore the body's ability to fight infections (immunity), improve the quality of life and prolong life(i.e. decrease HIV-related morbidity and mortality).The aim is to raise the patients CD4 count and remain above the baseline count. This should result in fewer HIV-related illnesses.
3. ARVs can also be used to prevent transmission after exposure to HIV. This is referred to as post exposure prophylaxis (PEP).
4. ARVs are used in the prevention of mother to child HIV transmission (PMTCT).

In case of HAART, all drugs consist of a dual nucleoside component and a third potent non-nucleoside drug to complement it (WHO,2002). There are two recommended regimens in adults for use in the South African public sector. These consist of a combination of NNRTIs and NRTIs with PIs(SAHIVS,2002; DoH,2003)

The first regimen1(a) consist of a combination of Stavudine(d4T)/ Lamivudine (3TC) and Efavirenz(EFV).For drug naïve adult patients commencing treatment,d4T (40mg) is taken every 12 hours with 3TC(150mg) every 12 hours and EFV (600mg) at night (SAHIVS,2002; DoH,2005).

Alternatively, in case of pregnant women or those who are unable to guarantee reliable contraception while on therapy the regimen 1(b) is recommended. Regimen (1b) consists of d4T/3TC and Nevirapine (NVP). d4T (40mg) is taken every 12 hours with 3TC(150mg) every 12 hours and NVP (200mg) daily for two weeks followed by 200mg every 12 hours(SAHIVS,2002; DoH,2003). Patients who continue to fail virologically despite demonstrated adherence may be changed to regimen 2. Regimen 2 consists of Zidovudine (AZT)/Didanosine (ddl) and, Lopinavir and ritonavir (LPV/r). AZT (300mg) is taken every 12 hours with ddl(400mg) once a day –taken alone, dissolved in water on an empty stomach and LPV/r (400/100mg) every 12 hours (SAHIVS,2002; DoH,2005).

The Table (1-1)below shows the recommended regimens in the South African public health sector as described above.

Table 1-1: Recommended ARV regimens in South Africa

Regimen and dosage	DRUG			
	NRTI		NNRTI	PI
1a Dose	**d4T** 1x40mg b.i.d	**3TC** 1x150mg b.i.d	**EFV** 1x600mg qd	
1b Dose	**d4T** 1x40mg b.i.d	**3TC** 1x150mg b.i.d	**NVP** 1x200mg b.i.d	
2 Dose	**AZT** 1x300mg b.i.d	**Ddl** 1x400mg qd		**LPV/r** 1x400mg b.i.d

2.6 PLASMA VIRAL LOAD AND TREATMENT RESPONSE

With HIV infection, there is usually a rapid increase in plasma viral load. In untreated infection, replications usually produce billion of new viral copies daily. Plasma HIV/RNA (viral load) testing quantifies the HIV viral burden in the plasma. In resource rich areas of the world with access to viral load monitoring, the viral load is a standard tool for used for monitoring treatment response in patients taking HAART. In certain situations the viral load maybe a factor into decisions to initiate or change HAART (U.S Department of Health and Human services, 2006).Viral load assays include the HIV/RNA

polymerase chain reaction, the branched chain DNA and the nucleic acid sequence-based amplification. The lowest level of detection differs for each test. Ultra sensitive assays measure viral loads up to 50-80 copies/mL whereas older assays usually have a cut off at <400 copies/mL. A viral load below the level of detection ("undetectable") indicates inability of the assay to detect HIV in the plasma but does not indicate absence or clearance of the virus from the body. Suppressing RNA to an undetectable level is an important goal of HAART. Viral load is usually checked at regular intervals depending on the patient's clinical situation (Palella et al, 2003).

Recent studies of the pathogenesis of HIV have increased our understanding of HIV infection. Initially thought to be slowly evolving, HIV infection is now understood to be a dynamic process. Very high levels of HIV are found within weeks of primary infection (Ho and Alam, 1989). Embretson and colleagues(1993) further report that even during the clinically silent period of infection, massive amounts of HIV are usually present in the lymph tissue thus indicating that there is no virologic latency.

HAART is a strategy of ARV treatment that has a reasonable chance of suppressing HIV replication completely; suppression is defined as a decrease in HIV RNA plasma levels to below the detection limit. Currently, HAART usually involves two NRTIs plus either an NNRTI or protease inhibitor, however, double protease inhibitor therapy is also widely used (Henry et al, 1997). It is recommended that treatment response should be assessed within first 2 to 4 weeks of treatment. Treatment response, as defined by viral load, is usually evident within 2 to 4 weeks and is greatest by 4 to 12 weeks. However, if the initial viral load is quite high, 12 to 24 weeks may be needed to achieve a maximum decrease.

2.7 DETERMINANTS OF ADHERENCE

There are several factors which can influence adherence. These have been measured using various techniques and methods. The Barriers to Adherence Checklist (BAC) has been developed to assess common environmental, physical and social barriers to adherence (Catz, 2000). Holzemer (1997) developed a scale to asses the extent of engagement of the patient and the provider, but none focuses on the way the patient interacts with the health care provider from the perspective of the Chronic Care Model. Under the CCM is where the patient related factors determining adherence are investigated.

In a review by Fogarty et al (2002), they conclude that the possible factors can be grouped as: those relating to treatment regimen, social and psychological factors, institutional resources and personal attributes. From the same study by Fogarty(2002), issues that relate to treatment regimen like scheduling and cognitive demands and regimen side effects were found to impact on adherence. Other studies found institutional resources like access to medication and health services, and personal attributes like age, gender and social economic status to be associated with adherence (Orrell et al, 2003).

Psychological factors, including the patients' perception of the provider's degree of caring can influence the ability to comply with the drug regimen. Few studies have examined continuous counselling as a form of support for patients that are affected by HIV/AIDS. In a prospective randomised two arm study by Tuldra & colleagues in 2000, 116 patients on ARVs were administered a psycho-educative intervention to implement adherence. He observed highly consistent adherence levels in the experimental group (94%), compared to 69% in the control arm. This was suggestive that counselling could help reduce the correlates of poor adherence like poor effort to take medication and self capacity to follow regimens. Given the patients reports of depression and fear and anxiety it will be important to examine the role played by the quality of counselling in enhancing adherence in patients on ARV and to define and monitor certain variables related to adherence in order to enhance compliance to ARVs.

2.8 STUDY AIM AND OBJECTIVES

2.8.1 RESEARCH AIM

To identify factors which affect or limit adherence to HAART among adults on HAART in two sites in Gauteng province in 2006.

2.8.2 RESEARCH QUESTIONS

1. What is estimated rate of adherence to HAART?
2. What are the facilitators of adherence to ARVs among patients on HAART?
3. What constitute barriers to adherence in patients on HAART?

2.8.3 STUDY OBJECTIVES

1. To quantify patient adherence to ARVs using viral load response in two selected public ARV roll out sites-Natalspruit hospital in the East Rand area (region F) and Empilisweni community health care centre in the region G (the former Vaal triangle) both in Gauteng province in 2006.
2. To determine factors that sustain good adherence in patients attending Natalspruit hospital and Empilisweni Community Health centre in 2006.
3. To determine the barriers to patient adherence to the Gauteng HAART programme in 2006.
4. To determine the relationship between the factors identified and adherence.
5. Recommend possible interventions to improve adherence.

2.9 DEFINITION OF TERMS

Adherence-Adherence to a drug regimen is most commonly represented as the proportion of doses prescribed actually taken by the patient. Therefore for the purposes of this study adherence will be defined as that proportion of patient on ARVs taking >95% of the doses prescribed by the health care giver or having a viral load outcome of <400 RNA copies/ml..

CHAPTER THREE: TOOLS AND METHODS

3.1 STUDY DESIGN

The study was a cross-sectional study. Exit interview questionnaires were administered to patients attending the two public ARV roll out sites in Gauteng province. The study also involved the review of patient records to assess adherence to ARVs using viral load data and CD4 counts obtained from these. The study was carried out from August to November 2006.

3.2 STUDY POPULATION

The study area covered two selected public ARV sites in the Johannesburg Metro area of Gauteng province, South Africa in 2006.One was a hospital, Natalspruit, located in the Ekhuruleni Metropole and another was a Community Health Centre, Empilisweni, located in Sedibeng region of Gauteng province. The study population included all the patients that had been registered at the ARV sites in Gauteng province for longer than four months prior to the start of the study in August, 2006.

3.3 SAMPLING

The study employed a random sampling method. Two pilot ARV roll out sites were randomly selected from 28 sites in Gauteng using simple random sampling from the larger study. Interviewees were selected randomly during the "HIV/AIDS clinic days"-when they were scheduled to attend for medication at the site. Exit interviews were administered over a 6 week period at each site. All patients over 18 years of age who attended the clinic during the 6 week period on designated HIV days were eligible for the study. Clinical records of all patients interviewed where then reviewed. The weakness of this method was that it only included registered patients still attending the HAART programme. This has the effect of underestimating barriers affecting adherence in the public health sector in Gauteng since the ones who would most likely give a true picture of non-adherence were no longer in the health care system. Further work is still being done by the Centre for Health Policy on following up on those who have dropped out in another study.

The sample size was calculated based on Dobson's paper (1994). Assuming a 95% level of confidence and a 75% response rate, a minimum of 128 interviewees was calculated. A total study sample (n=355) was randomly selected from the study population-the two public ARV sites in Johannesburg, Gauteng province.

3.4 MEASUREMENT TOOLS

This study utilised two research methods: exit interview questionnaires and pharmacy record review. Questionnaires were administered to determine the self reported adherence using client exit interviews to those attending the two sites. Record reviews were done to eventually determine viral load and CD4 count adherence from the pharmacy records.

3.4.1 EXIT QUESTIONNAIRES

A patient exit interview questionnaire administered to collect self-report adherence data from the patients attending the ARV sites. A total of 355 questionnaires were administered at Natalspruit Hospital (n=191) and Empilisweni CHC (n=164). 12 of them were declared invalid and therefore not considered part of the study after cross checking for quality.

The exit interview dealt with 5 main themes namely:

1. Socio-demographic characteristics of the client
2. Knowledge of HIV/AIDS and ARVs(Health literacy)
3. Patient-health provider communication
4. Adherence to medication

A brief summary of the various variables within the five sections is given below.

(The full questionnaire is in Annex E)

3.4.1.1 Socio-demographic background

The questionnaire dealt mainly with demographic characteristics of the client in order to build up a profile. The client/patient was asked questions that dealt with:

- gender,
- highest level of education
- The type of work they do as well as whether or not they are engaged in any earning activity i.e economic or money generating activity.
- Whether they were recipient of a disability grant from the provincial government
- Costs involved in the process of seeking treatment like transport to and from the site, accommodation and cost of medication.

3.4.1.2 Knowledge of HIV/AIDS and ARVs

In this section the questionnaire dealt with:

- Whether the client knew what ARVs do

- They were further asked to either agree or disagree with several statements in this section e.g. Whether ARVs cure HIV/AIDS. These statements were structured according to a 4 point Lickert scale.

3.4.1.3 Patient-provider communication

This section dealt with structured questions about the experiences of the client at the facility where the exit interview was talking place and their interactions with the health care provider.
This section sought to obtain information about whether:

- The clients were able to talk in private with the health care provider
- How many hours they spent at the health care facility.
- The health care worker was too busy to listen to their problems
- It was a problem that the health care worker did not speak their language
- They were provided with feedback on whether the drugs were working or not
- The health care workers were helpful or not

3.4.1.4 Adherence to HAART

This section of the questionnaire sought to obtain information about the how the clients/patients were coping with taking ARVs on a regular basis. The information was needed to gain a better understanding of the real challenges that people taking ARVs faced in order to gain an insight into the barriers to them achieving 100% adherence and to help in the determination of self report adherence. Examples questions in this section dealt with the number of tablets taken in a day and the number missed within various periods. These involved 24 hour recall, 3 day recall and one month recall periods. These were later collated and used to calculate adherence after combining the information with the pharmacy record review. Further information was sought about the reasons for missed doses and appointments to collect the tablets at the health care facility.

3.4.2 RECORD REVIEW

Laboratory records were retrieved from patient files at the two ARV sites. The CD4 count and viral load was determined from the pharmacy records of the ARV sites where the clients were accessing treatment. The data concerning adherence and the physiological markers was collected using specially designed data capture sheets. (See annex F).

3.5 PILOT STUDY

A pilot study was carried out in a similar setting to the intended study sites. In the pilot study, respondents who are were on ARV medication from another site (Helen Joseph hospital) were recruited and the questionnaires administered .The pilot study was done to investigate the following:

1) Test the validity of the questionnaire to measure or assess the outcomes of interest especially barriers to attendance and adherence.
2) Test the understanding of the language in the questionnaires by the interviewers. The questionnaire proved to be easily understood since the field researchers were proficient in English and IsiZulu (used mostly in Natalspruit) as well as Sotho (used mostly in Empilisweni clinic) for translation and back translation purposes
3) The pilot study was used to determine the logistical requirements for the rest of the study that commenced much later in August 2006.During this time the requirements in terms of cost of transport, time taken to and from the sites and budgetary estimates for stationery and computer facilities were determined from the estimates offered by the field researchers.
4) The limitations of the questionnaire were analysed and changes made to the questionnaire during and immediately after this initial period and thereafter modifications were incorporated in the questionnaire.

3.6 LIMITATIONS AND VALIDITY OF THE STUDY

Given that the study was based on questionnaires to measure the barriers to adherence there are several limitations that are bound to arise inherent in questionnaires, some of which are highlighted below:

i. The study was not able to interview patients who had dropped out of the ARV programme due to the poor health information systems at either site that could not trace them. Patients who had dropped out of the HAART programme would have ideally provided the best views regarding the barriers to adherence.
ii. 85 patients' viral loads and 38 patients CD4 counts had not been measured.

To further strengthen the study in terms of validity, several steps were undertaken as outline below: These dealt mainly with recall problems and creating a rapport with the respondents among others.

a) Due to recall problems (given the longer recall period of three days) and reluctance of respondents to honest about missed doses, the questionnaire may not have been able to

properly measure adherence hence the use of patients' record review of the viral loads to ensure that there clear picture of adherence is obtained through triangulation of results.

b) Given the likelihood of patients' reluctance to be truthful about missed doses, experienced interviewers (all of whom were PLWHA) conducted the interviews. They were able to put respondents at ease, establish a rapport in order to encourage respondents to be truthful about adherence.

c) Additionally the interviewers were proficient in Zulu, Sotho and English as well as a fourth language in case the respondent preferred it. Employing same language-speakers to interview respondents was meant elicit the likelihood of more honest responses.

d) Structured questionnaires were used to improve the consistency of the questions during the interviews.

3.7 EXCLUSION CRITERIA & DATA MANAGEMENT

There was exclusion at the collection and analysis of data. HAART clients who had been on treatment less than 4months were excluded from the study. A database was created using Epiinfo® to capture all information. The data was captured using Epiinfo® *version 2002* and stored in Microsoft® Database format. Data cleaning and processing and analysis was done using computer software; Epiinfo® *version 2002* and Intercooled *Stata 9*®.

3.7.1 ANALYSIS OF DATA

Triangulation of information from the different sources was done to determine adherence and the major themes explored from patients' perspective. Quantitative and semi-qualitative methods were utilized in analysis of data. Descriptive statistics were further used to bolster the qualitative methods.

Three measures were used to assess adherence. One subjective (3 day recall self report) and two physiological methods (CD4 counts and plasma viral load) methods were used to asses adherence.Each adherence measure was collapsed into two categories for analysis - high adherence and low adherence. Individuals who reported taking 100% of their medication were categorised as highly adherent, while individuals who took less than 100% of their prescribed doses of ARVs were categorised as having low adherence. The physiological/clinical outcomes were further used as a surrogate measure for adherence (Chesney, 2003). High physiologic "adherence" was categorised as those individuals who had a higher T-lymphocytic CD4 count (>=200) and low plasma viral load (<400 RNA/ml) while lower "adherence" included individuals with a low CD4 cell count (<200) and a high viral load (>=400 RNA/ml). Drug regimes were classified as either first line (1a and 1b) or second line of treatment according to the National Department of health, South Africa (2005) guidelines.

Proportions were compared using the two tailed Chi-square and Fisher's exact tests of association. All hypotheses tested were two tailed at a 95% confidence interval (α=0.05). Univariate analyses were performed using the Kaplan-Meier survival estimates for each of the exposure variables reported. To estimate the independent effects of selected risk factors on "adherence" as measured by the plasma viral load, simple linear logistic regression was used with maximum estimation of the regression co-efficient and their confidence intervals. Only crude odds ratios were reported.

3.8 EETHICAL CONSIDERATIONS

1) Permission was sought and obtained, before start of the study, from the facility level managers and provincial department heads to carry out research at the selected sites and to further access the records of the clients to obtain data and information regarding viral loads of the duration of the study period.
2) Before the commencement of the research study, ethical clearance was sought and obtained from the University of Witwatersrand, Johannesburg to carry out research on human subjects. The study was thus found to be of no harm to human subjects by either being risky, invasive or embarrassing.
3) Emphasis was put on informing the respondent of the aims and objectives of the study before being asked to give their informed written consent to be interviewed. Written informed consent was thereafter sought and obtained before exit interviews could be conducted with the clients at the selected ARV sites.
4) Attention was paid to anonymity and confidentiality by ensuring that the interviews are anonymous with no names or other identifiers used except for codes to help in analysis of results. Permission was sought from the patient to examine their medical record to extract the viral load and CD4 counts. Patients gave interviewers their file number to facilitate this. If a respondent was unable or unwilling to provide written consent, verbal consent was sought and they were asked to mark with symbols on the information sheet.
5) The client was informed of his/her right and choice to either participate or to opt out of the study at anytime even when the study has commenced and written consent obtained. Six prospective interviews refused to be interviewed but offered their files for record review.

CHAPTER FOUR: RESULTS

4.1 CHARACTERISTICS OF RESPONDENTS

Table 4-1 shows a summary of the socio-demographic, economic and clinical characteristics of the participants. From a total of 355 interviews only 96.6% were declared valid with the rest either information or informed consent.

Table 4-1 : Sample characteristics

Characteristics of respondents		Total (%)
Facility(n=343)	Empilisweni	159(46.4%)
	Natalspruit	184(53.6%)
Gender(n=328)	Males	87(26.5%)
	Females	241(73.5%)
Age(n=340)	Mean	36.9 years
	Range	18-70 years
Level of education(n=343)	Formal education	333 (97.1%)
	No formal education	10 (2.9%)
Earned money in the past week? (n=343)	No	277(80.8%)
	Yes	66(19.2%)
Do you currently receive a disability grant? (n=343)	No	187(54.5%)
	Yes	156(45.5%)
At present, do you have medical aid? (n=343)	No	339(98.8%)
	Yes	4(1.1%)
Do you have electricity in your household? (n=342)	No	47(13.7%)
	Yes	295(86.3%)
Tell me if your household has any of the following appliances that are working? Fridge(n=343)	No	97(28.3%)
	Yes	246(71.7%)
Radio (n=343)	No	90(26.2%)
	Yes	253(73.8%)
Cellphone (n=343)	No	98(28.6%)

Characteristics of respondents				Total (%)
Television (n=343)	Yes			245(71.4%)
	No			94(27.4%)
Does any member of your household own any of the following? Bicycle (n=342)	Yes			249(72.6%)
	No			300(87.7%)
	Yes			42(12.3%)
Donkey/horse (n=342)	No			341(99.7%)
	Yes		1 (0.3%)	
Sheep or cattle (n=342)	No			341(99.7%)
	Yes			1(0.3%))
Clinical profile		**Mean**	**S.D**	**Range**
Months on ARV therapy (n=340)		14	7.1	1-47
CD4 count (cells/ml) (n=343)		208	166	1-1014
Detected viral load (copies/ml) (n=343)		3,457.6	28,846.58	1- 460,000

There were similar proportions of respondents from both facilities (1:1). In terms of gender (n=349), there were more females than males (a ratio of 5:2). The ages (n=340) of the respondents ranged from the youngest (18 years) to the oldest (70 years) old with a mean of 36 years and ten months. The majority (97.1%) had attained some form of formal education and only about 19.7% were working compared to those who were not. The ratio of respondents with access to disability grants (n=343) to those without was almost the same (1:1).Less than 2% of the respondents had access to medical aid with the overwhelming majority without medical cover.

The clinical profile of the respondents suggests that the majority had spent on average one year and a month on ARVs. Most had an average T-lymphocyte CD4 count (n=343) of 206 cells per ml with a standard deviation of 164.31 and a mean viral load (n=343) of 4,186 RNA copies/ml of blood with a standard deviation of 32,437.1.

4.2 MEASURES AND PROXIES OF ADHERENCE

This section deals presents data for missing results in the various adherence assessment measures respectively. This is followed by a comparison of the various measures and finally a comparison of the respondents' length on treatment with immunological and viral load outcome measures respectively.

Virologic "adherence" was the main outcome used as a surrogate marker for adherence. As previously mentioned,CD4 counts were discounted due to the design of the study and the correlation of CD4 counts with the length on treatment.

4.2.1 MISSING DATA

Table 4-2: Missing self-report data

Prescribed doses taken in last 3days (%)	Frequency (n)	Overall percentage distribution	Valid adherence rate (%)
Lower adherence (<100%)	2	0.6	0.6
Higher adherence (=100%)	339	98.8	99.4
Missing data	**2**	**0.6**	
Total	**343**	**100**	**100**

Table 4-2 shows a summary of the univariate analysis of missing data done using Stata®. The results (in Table 4-2) show that there was no missing data when self-report as an adherence measure was considered. The valid adherence rate was 0.6% and 99.4% respectively for respondents in the low and high adherence categories.

Table 4-3: Viral load: Missing data

Virologic outcome (RNA copies/ml)	Frequency (n)	Percentage (%)	Valid Viral load distribution (%)
Lower viral load(<400)	230	67.1	88.8
Higher viral load (>=400)	29	8.4	11.2
Missing viral load data	84	24.5	
Total	**343**	**100**	**100**

Results in Table 4-3 show that missing data accounted for 24% of the total viral load distribution. The valid viral load distribution for the respondents was 88% and 11% for the higher and lower viral load categories respectively.

Table 4-4: CD4 count categories: missing data

CD4 count category	Frequency (n)	Percentage (%)	Valid CD4 distribution (%)
Lower CD4 count(<200)	151	44.0	49.5
Higher CD4 count (>=200)	155	45.2	50.5
Missing CD4 counts data	37	10.8	
Total	**343**	**100**	**100**

In the CD4 count categories, the results (in Table 4-4) indicate that missing data accounted for 11% of the CD4 count distribution. The valid CD4 count distribution excluding the missing data was 49.5% and 50.5% for the respondents with a lower CD4 count and those with higher CD4 count respectively.

4.2.2 COMPARING ADHERENCE MEASURES

Table 4-5 :Self-report adherence by Plasma viral load categories

Self reported adherence Adherence categories (n=261;p= 1.000)	Virologic outcome (RNA copies/ml)		
	Higher viral load (>=400)	Lower viral load (<400)	Total
Lower adherence (<95%)	-	2(0.9%)	2(100%)
Higher adherence (>95%)	29(11.1%)	230(88.8%)	260(100%)
Total	**29(11.1%)**	**232(88.9%)**	**261(100%)**

Analysis of adherence data was done as previously mentioned in the methods section using bivariate analysis with viral load as the outcome variable. The results for the viral load outcomes are then summarised in tables in this chapter.

Of the total respondents (n=261), as shown in Table 4-5, 11% had a higher viral load compared to 89% with lower viral load. The results further show that of the respondents who reported higher adherence (n=260), there was a substantial number (29/262) whose viral load was actually high (11%) indicating that

they had over estimated their adherence. The virologic outcome seemed to be a better indicator of whether an individual was taking their medication as prescribed compared to the self-report adherence.

Table 4-6 :Self-report adherence by CD4 count categories(n=309)

Self reported adherence Adherence categories (χ^2 = 1.973 ;p= 0.498)	Immunological outcome(CD4 count)		
	Lower CD4 count(<200)	Higher CD4 count (>=200)	Total
Lower adherence (<100%)	-	2(100%)	2(100%)
Higher adherence (=100%)	153(49.8%)	154(50.2%)	307(100%)
Total	**153(49.5%)**	**156(50.5%)**	**309(100%)**

Regarding CD4 count as an outcome measure of adherence, the respondents who reported higher adherence were more evenly distributed with almost half in the lower CD4 count and higher CD4 count categories respectively as shown in the Table 4-6.The two who reported lower adherence had a CD4 >200.

4.2.3 MONTHS ON TREATMENT AND DRUG REGIMENS *

Table 4-7: Months on treatment by plasma viral load (n=263)

Months on treatment	Plasma viral load categories (RNA copies/mL)		
	High (>=400)	Low(<400)	Total
< 12 months	14(14.3%)	84(85.7 %)	98(100%)
12-24 months	11(7.4%)	137(92.6%)	148(100%)
> 24 months	5(29.4%)	12(70.6%)	17(100%)
Total plasma viral load	**30(11.4%)**	**233(88.6%)**	**263(100%)**

There was a significant association between the months on treatment and the virologic outcome ($p<0.05$).A comparison of the months on treatment of the respondents with their viral load (in Table 4-7) shows that if a patient has been on treatment for longer than a year he/she is more likely to have a lower viral load – suggesting that the patients that have been on treatment longer are more adherent.

* previously explained in Table 1-1

Table 4-8: Months on treatment by immunological outcome (n=310)

Months on treatment ($\chi^2 = 35.3; p<0.01$)	Immunological outcome		
	Lower CD4 count (<200)	Higher CD4 count (>=200)	Total
< 12 months	91(68.9%)	41(31.1%)	**132(100%)**
12-24 months	56(34.7%)	105(65.2%)	**161(100%)**
> 24 months	6(35.3%)	11(64.7%)	**17(100%)**
Total	**153(49.4%)**	**157(50.6%)**	**310(100%)**

The number of months on treatment were significantly associated with the immunological outcome ($p<0.01$) as shown in Table 4-8. These were noted to be statistically significant especially between respondents who had been on treatment less than 12 months and those on treatment for longer periods (between 12 to 24months or more).Respondents CD4 counts while seemingly low in the first 12 months tended to rise after a year on treatment and stayed that way as long as respondents were on treatment.

As has been reported earlier, there is no generally accepted gold standard for measuring adherence but some studies have reported the use of a combination of measures in order to interpret the complex issue that is adherence (Fogarty, 2000). Some cohort studies have demonstrated a strong association between HAART and successful virologic outcomes (Deeks et al, 1999) while others showed an association between adherence and immunologic outcomes (Paterson et al,1999; 2000). The results above have demonstrated that self-report as a measure of adherence is highly unlikely to estimate the true adherence effectively given the tendency of the respondents to over estimate their adherence. The other option was to use clinical outcomes (CD4 and plasma viral load) of the laboratory results. In this case, the CD4 count was found to be depending on the length of treatment and therefore decreasing its reliability in cases where patients have been on treatment for less than a year.

Therefore due to self-report as a method of determining adherence tending to overestimate adherence, the clinical criteria used for adherence estimation-viral load was instead used as a surrogate adherence marker in the analysis of factors affecting adherence in this study.

4.3 FACTORS AFFECTING ADHERENCE

This sub-section reports the factors hypothesised to affect adherence or its surrogate, in this case viral load including the following: Socio-demographic variables, adherence support, patients' knowledge of HIV/AIDS and ARVs and the quality of the patient-health provider relationship. These are compared

with the plasma viral load categories-classified as lower (<400 HIV RNA copies/ml) and higher viral loads (> 400 HIV/RNA copies/ml) respectively.

4.3.1 SOCIO-ECONOMIC AND DEMOGRAPHIC FACTORS

Among the socio-demographic indicators investigated include the facility, gender, age groups, education levels, medical insurance, access to disability grants and costs associated with access to treatment as well as estimated wealth based on assets in the household. Results for individuals whose plasma viral load was available were analysed to determine how they affected plasma viral load as an adherence outcome.

Considering that facility from which the patients were interviewed from-Empilisweni CHC and Natalspruit hospital, the results indicate that there were no statistically significant differences between the two facilities (χ^2 =0.2096;p=0.697). On doing further modelling using logistic regression analysis, it was noted however that individuals at Natalspruit were 1.8 times more likely to have a lower viral load compared to those from Empilisweni [OR=1.8 95% CI=1.15-2.81] although the differences were not statistically significant. There was no significant association (p=0.600) between gender (n=179) and the virologic outcome.

The respondents' ages were determined from the difference between their dates of birth and the dates of the interviews took place. These continuous variables were then categorised into three groups-18-28 years, 29-39 and those with greater than 40 years and compared to the viral load (χ^2 =3.063;p=0.223). Logistic regression with plasma viral load categories indicated that a greater proportion of the 29-39 age (p=0.973) group had a lower viral load and appeared to have better "adherence"[OR= 1.02; 95% CI=0.32- 3.3].The greater than 40 years age group had a higher viral load (p=0.568) [OR= 0.71; 95% CI=0.21- 2.3] using the 18-28 years age group as the reference. Of the total (n=254) respondents, women (75.6%; p=0.587) at a ratio of 3:1 were seen to be more likely to adhere to HAART compared to men (24.4%;p=0.647) when their virologic adherence rates were compared [OR= 1.27; 95% CI= 0.53-3.06] but this result was also not statistically significant.

The highest education level attained by the respondents was compared to the virologic outcome categories: low virologic "adherence" (>400 RNA copies/ml) and high virologic "adherence" (<400 RNA copies/ml. These categories were grouped into individuals with no formal schooling, primary schooling, secondary schooling and those with tertiary schooling. Regarding individuals with no formal education, there were none in the lower "adherence" group with 100% (7/7) in the higher adherence group. 8.8% (5/57) with a primary level education were in the lower "adherence" category compared to 91.2% (52/57) in the higher "adherence" group. Similarly only 12.6% (25/198) with secondary level education were in the lower "adherence" group compared to 87.4% (173/198) in the higher "adherence"

category. However there were none with tertiary level education who had lower "adherence" with both individuals (100%) belonging to the higher "adherence" category. Although a majority,88.6%(234/264), of the respondents belonged to the higher "adherence" category when education is considered, the level of education was not found to be significantly associated with the way the individuals adhered when their plasma viral load.($\chi 2$ =1.85 p= 0.672).Similarly there were no significant differences when between the two virologic "adherence" categories when medical insurance (χ^2 = 0.3890 p=1.000) and access to social grants (χ^2 =3.66; p=0.057) were considered.

The costs associated with treatment were grouped into three categories: low cost (<R15), average cost (R15-25) and highest cost (>R25) and compared with respective plasma viral loads. Cost (n=185) was found to be significantly associated with the viral load outcome (χ^2 = 0.3890 p<0.05). Using logistic regression results indicate that individuals who faced the highest cost (> R25) in accessing treatment were however the least likely to adhere [p=0.078; OR=0.29 95%CI=0.076-1.14] when compared to those who faced average costs of between R15-25[p=0.090; OR=0.33 95%CI=0.095-1.18] or the reference group (<R15).

Lastly socio-economic status was measured by proxy using a composite asset index which was created using principal component analysis of several ranked household items that indicate a level of wealth like TVs, telephones cell phones and types of housing among others and then scored to create five quintiles indicating the level of poverty. These ranged from 1(the poorest) to 5(least poor). These were: Q1=poorest, Q2=poorer, Q3=less poorer, Q4=less poor, Q5=least poor. Socio-economic status was thereafter compared to virologic outcomes. Those in the poorest and the least poor quintile have poorer virologic outcomes, although the sample size is very small in the least poor quintile. The results generally indicated that there is an association between poverty and the viral load outcome or the surrogate "adherence". (χ^2=21.73;p<0.01).

Further comparisons within the group were done. All the quintiles within the wealth category were then compared as summarised in Table 4-9.

Table 4-9 : Asset quintile by viral load category

Wealth category χ^2=21.73	**Plasma viral load categories(RNA copies/ml)**		
	High(>=400)	**Low(<400)**	**OR (95% C.I)**
Quintile 1(p<0.05) n=64	17(26.6%)	47(73.4%)	1
Quintile 2 (p<0.05)n=79	5(6.3%)	74(93.7%)	5.4(1.85- 15.57)
Quintile 3 (p<0.05)n=66	2(3.0%)	64(97.0%)	11.6(2.55- 52.54)
Quintile 4 (p<0.05)n=48	4(8.3%)	44(91.7%)	4.0 (1.2-12.74)

Wealth category χ^2=21.73	Plasma viral load categories(RNA copies/ml)		
	High(>=400)	Low(<400)	OR (95% C.I)
Quintile 5 (p=0.909) n=7	2(28.6%)	5(71.4%)	0.90(0.16-5.11)

Most notable is that respondents in quintile 3 were ten times more likely to adhere compared to the poorest [OR=11.6 95% C.I(2.55- 52.54)] while those in the quintile 2 were five times more likely to adhere when compared to the poorest[OR=5.4 95%CI(1.85-15.57)].The respondents in quintile 5 [OR=0.90 95% CI(0.16-5.11)] were however more or less adherent compared to poorest with no significant difference between the two groups. The results (Table 4-9) indicate that there statistically significant differences in "adherence" between the respondents in the five quintiles when compared against the reference group (Quintile 1). Further work needs to be done to assess whether these results are, in part, due to starting treatment later in the progression of the disease amongst the poorest quintile.

Table 4-10 : Months on treatment by asset quintile(n=345)

Months on treatment	Asset quintile					
[χ^2=**16.058 ,p<0.05**]	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5	Total
< 12 months	30(47.6%)	28(35.4%)	23(34.8%)	24(36.4%)	44(62.0%)	149(43.2%)
12-24 months	29(46.0%)	46(58.2%)	39(59.1%)	37(56.1%)	24(33.8%)	175(50.7%)
> 24 months	4(6.4%)	5(6.3%)	4(6.1%)	5(7.6%)	3(4.2%)	21(6.1%)
Total	63(100%)	79(100%)	66(100%)	66(100%)	71(100%)	345(100%)

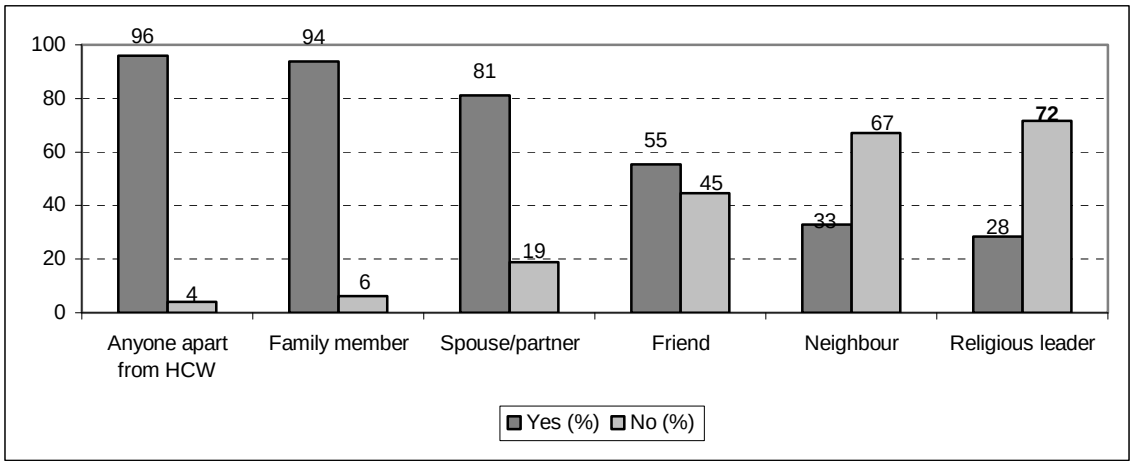
A comparison of the months by the various asset quintiles (Table 4-10) indicates that there was a significant association between the months on treatment and the asset quintiles. Most of the respondents in the quintile 1 (48%) who were the poorest had been on treatment for less then 12months compared to the rest in quintile 2(58%), quintile 3(59%) and quintile 4 (56%) and quintile 5(51%) who had all been on treatment for about more than a year respectively. Their poor "adherence" (quintile 1) could probably be explained by the fact that respondents had not been on treatment long enough or had taken longer to access treatment compared to the other wealth groups.

4.3.2 DISCLOSURE AND SUPPORT

This section presents the results regarding disclosure status and social and medication support that the respondents reported from the exit interviews, and the extent to which factors are associated with virologic outcomes and by association "adherence".

4.3.2.1 Disclosure status

Figure 4-1: Disclosure status of respondents



The results as shown in Fig4-1 suggest that the respondents had high disclosure rates to someone other than the health care worker at the health facility with over 95% of the respondents stating that they had disclosed to someone else. The three people that the respondents were most likely to disclose to were a family member 94% (230/245), spouse/partner 81 %(199/245) and friend 55% (134/242) respectively. The respondents were least likely to disclose to a neighbour 33% (114/346) or religious leader 28% (98/346) compared to the rest. Only 4% said they would not disclose to anyone else at all.

4.3.2.2 Disclosure status by viral load category

This section highlights the comparison of disclosure and virologic outcome and reasons that respondents gave for non-disclosure are shown. Results (in Table 4-11) indicate further that disclosure did not significantly affect respondents' virologic outcomes. Given the importance of disclosure, reasons for non-disclosure were analysed and are presented below (Table 4-11). Results (in Table 4-12) indicate the major reasons for lack of disclosure by the respondents.

Table 4-11: Disclosure status by plasma viral load categories

Disclosure status		Plasma viral load (RNA copies/ml)		
		High (>=400)	Low (<400)	Total
Apart from health workers have you told anyone about your HIV status (χ^2 =1.273;p=0.259)	No	-	10(100%)	10(100%)
	Yes	27(11.3%)	211(88.7%)	238(100%)
Spouse/partner if you have one (χ^2 =0.938;p=1.000)	No	4(10.8%)	33(89.2%)	37(100%)
	Yes	17(11.5%)	131(88.5%)	148(100%)
Family member (χ^2 =0.42;p=1.000)	No	1(6.3%)	15(93.7%)	16(100%)
	Yes	28(11.4%)	218(88.5%)	246(100%)
Friend (χ^2 =0.29;p=0.692)	No	14(12.4%)	99(87.6%)	113(100%)
	Yes	15(10.3%)	131(89.7%)	146(100%)
Neighbour (χ^2 =0.13;p=0.836)	No	20(11.7%)	151(88.3%)	171(100%)
	Yes	9(10.2%)	79(89.8%)	88(100%)
Religious leader (χ^2 =1.09;p=0.387)	No	23(12.5%)	161(87.5%)	184(100%)
	Yes	6(8.0%)	69(92.0%)	75(100%)

Table 4-12: Reasons for non-disclosure

Do you keep your status secret for any of the following reasons: (n=337)	No (%)	Yes (%)
fear of rejection by family	281(83.4%)	56(16.6%)
fear of rejection by friends	189(56.1%)	148(43.9%)
fear of violence	164(48.7%)	173(51.3%)
I do not trust people	89(26.4%)	248(73.6%)
I will not get help from others if they know my status	89(26.4%)	248(73.6%)
fear that I will be stigmatised	97(28.8%)	240(71.2%)
fear that people will gossip about me	93(27.6%)	244(72.4%)
fear that my HIV status will be known by the community	88(26.1%)	249(73.9%)

Do you keep your status secret for any of the following reasons: (n=337)	No (%)	Yes (%)
fear that my partner will know and ask me to explain	249(73.9%)	88(26.1%)

The most important reasons for lack of disclosure were mainly due to the following:

a. The fear that their HIV status would be known by the community (73.9%).
b. The fear that they would not get help from any other person who may know their status (73.6%).
c. Lack of trust of other people (73.6%).
d. Fear of violence (51.3 %).

This is mainly seen when gender differences were investigated (n=220). When respondents were asked whether their HIV status had been disclosed to others without their consent, there were statistically significant differences between the genders (χ^2 =10.74;p<0.05). Men were 3.2 times more likely to have had their HIV status disclosed to other people without their knowledge compared to women in this study [OR=3.2 95% C.I(1.5- 6.8)]. There were no major differences between the genders when fear of not getting help (χ^2 =0.63;p=0.43), lack of trust(χ^2 =0.63;p=0.43) and fear of violence(χ^2 =1.38;p=0.24) were analysed further. This would probably explain the fear that most of the respondents had that their HIV status would be known by the community when gender differences are considered especially in men. This could possibly explain their low access rates to HAART compared to women. There is a clear split between disclosure rates in the family and public contexts as seen by low rates of family people that were not disclosed compared to those in the community level (table 4-11).The pattern is further reflected in the reasons for non disclosure. In that respondents' rates of disclosure were very high to members of the family but low to those of the public. This was further reflected by fewer proportions of members who did not disclose to their families as compared to those who disclosed to the public e.g only 16% feared that rejection by family (in the family context) compared to 74% who feared that the community knowing their HIV status. Results showing the extent of support that the respondents received from the support groups at the health facilities are shown below (Table 4-13).

4.3.2.3 Support group services

Table 4-13: Support group services by plasma viral load categories

Services offered at support groups (n=32)		Plasma viral load (RNA copies/ml)		
		High (>=400)	Low(<400)	Total
Advice and information on staying healthy e.g .nutrition, exercise & prevention (χ^2 =0.342;p=1.000)	No	-	3(100%)	3(100%)
	Yes	3(10.3%)	26(89.7%)	29(100%)
ARV information:CD4 counts, ARVs, viral load (χ^2 =0.342;p=1.000)	No	-	3(100%)	3(100%)
	Yes	3(10.3%)	26(89.7%)	29(100%)
Treatment buddies (χ^2 =0.927;p=1.000)	No	-	7 (100%)	7 (100%)
	Yes	3(12.0%)	22(88.0%)	25 (100%)
Help with collecting medicines from the clinic (χ^2 =0.007;p=0.935)	No	1(10.0%)	9(90.0%)	10 (100%)
	Yes	2(9.1%	20(90.9%)	22 (100%)
Home visits (χ^2 =1.734;p=0.188)	No	-	11(100%)	11 (100%)
	Yes	3(14.3%)	18(85.7%)	21 (100%)
Food (χ^2 =2.265;p=0.132)	No	-	13 (100%)	13 (100%)
	Yes	3(15.8%)	16(84.2%)	19 (100%)
Income generating activities (χ^2 =0.521;p=0.589)	No	1(5.9%)	16(94.1%)	17 (100%)
	Yes	2(13.3%)	13(86.7%)	15 (100%)
Individual counselling and emotional support (χ^2 =0.764;p=1.000)	No	-	6 (100%)	6 (100%)
	Yes	3(11.5%)	23(88.5%)	26 (100%)

The services that were offered at the support groups were generally not found to affect virologic outcomes, in part because of the small numbers of individuals attending support groups. Based on the respondents' responses (either yes or no), medication support is reported below (Table 4-14). Patients were asked whether they were visited, sent an sms/called by telephone, given food to take with their medication, provided transport money or emotional support in order to determine the form medication support took.

Table 4-14: Medication adherence support

Do you receive any of the following help or support from your friends or family to help you take your tablets regularly?	Patient's Response	
	No	Yes
they visit you (n=343)	155(45.2%)	188(54.8%)
they send an sms or call you by phone(n=349)	169(48.4%)	180(51.6%)
they give you food to take with your pills(n=349)	84(24.1%)	265(75.9%)
they provide transport money(n=349)	71(20.3%)	278(79.7%)
they provide emotional support(n=349)	33(9.5%)	316(90.5%)

A large majority received emotional support(90%),transport money(80%) and food to take with their pills(76%) and to a lesser extent were visited (55%) or sent and sms/called by phone (52%) to take their medication as a reminder. It seems that patient's were much more likely to receive support from family or friends than attend a support group. On the other hand there was a significant association between disclosure and emotional adherence support (χ^2=6.7453;p<0.05) suggesting that the respondents received emotional support as the most common form of adherence support after disclosing to a family member. Support from family (χ^2=0.4197; p=0.517) and friends (χ^2 =0.2867; p=0.592) respectively was however not significantly associated with plasma viral load suggesting other reasons responsible for adherence in this instance.

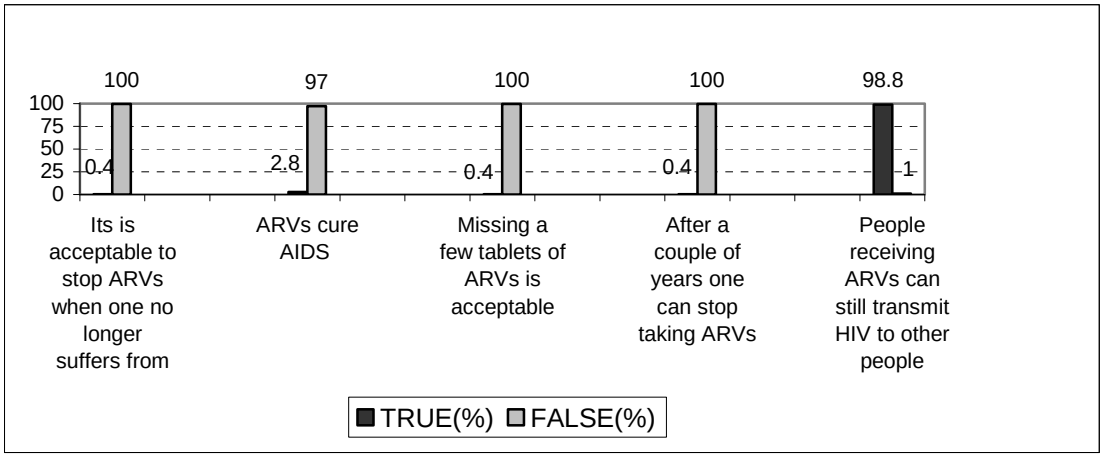
4.3.4 KNOWLEDGE OF HIV/AIDS AND ARVs

Knowledge of HIV/AIDS (health literacy) was used as a proxy for the cognitive demands the patient had to be aware of regarding HIV/AIDS management using ARVs. The objective was to determine whether the patient had enough information to help them cope with the ARV regimens and what was expected of them when on ARV treatment. Their responses were categorised as either correct or incorrect and further investigated.

A majority of the respondents (Fig 4-2) answered correctly when asked questions like for example "its acceptable to stop ARVs when one no longer suffers from opportunistic infections"99.1%(340/343); "After a couple of years one can stop taking ARVs" 99.4%(339/341),"ARVs cure AIDS" 97.2%(317/326) or "people receiving ARVs can transmit HIV to other people through unprotected sex"(98.8%) which were to be answered as either true or false responses.

4.3.4.1 Patient health literacy responses

Figure 4-2: Patient knowledge of HIV/AIDS and ARVs



4.3.4.2 Health literacy

Table 4-15: Health literacy by viral load categories (n=240)

Knowledge question	Response	Plasma viral load (RNA copies/ml)		
		High (>=400)	Low (<400)	Total
Can you tell me about what ARVs do? (χ^2 =0.507;p=0.702)(n=244)	Incorrect	1(6.2%)	15(93.8%)	16(100%)
	Correct	29(12.2%)	209(87.8%)	238(100%)
Its is acceptable to stop ARVs when one no longer suffers from opportunistic infections (χ^2 =0.128;p=1.000) (n=262)	False	30(11.5%)	231(88.5%)	261(100%)
	True	-	1(100%)	1(100%)
ARVs cure AIDS (χ^2 =0.917;p=1.000) (n=248)	False	28(11.6%)	213(88.4%)	241(100%)
	True	-	7(100%)	7(100%)
Missing a few tablets of ARVs is acceptable (χ^2=0.129;p=1.000) (n=242)	False	30(12.5%)	233(87.5%)	240(100%)
	True	-	1(100%)	1(100%)
After a couple of years one can stop taking ARVs (χ^2 =0.1321;p=1.000) (n=258)	False	30(11.7%)	227(88.3%)	257(100%)
	True	-	1(100%)	1(100%)

Knowledge question	Response	Plasma viral load (RNA copies/ml)		
		High (>=400)	Low (<400)	Total
People receiving ARVs can still transmit HIV to other people through unprotected sex (χ^2 =1.642;p=0.272) (n=258)	False	1(33.3%)	2(66.7%)	3(100%)
	True	28(11.0%)	227(89.0%)	255(100%)

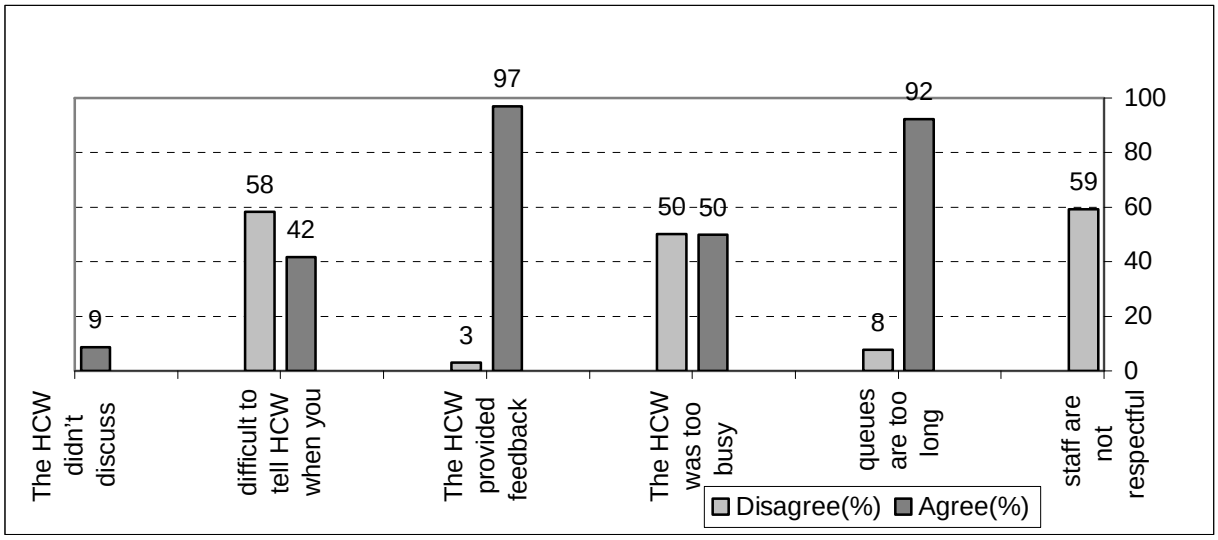
There were no significant differences between the two individuals who gave a "true" or "false" response across the two "adherence" categories when asked the knowledge questions (Table 4-15).

4.3.5 PATIENT-HEALTH PROVIDER COMMUNICATION

The patient- health provider communication was investigated by examined by asking the respondents several questions. They were asked to choose between one of five responses to weighted statements on a Lickert scale. These were categorised into whether the respondent agreed or disagreed with the statement, or was neutral, or found the question not relevant to them. Responses that found the statement not relevant, that were neutral or missing were excluded from analysis.

4.3.5.1 Assessment of patient-provider communication

Figure 4-3: Patient provider communication



Patient-health provider communication (n=240) was generally uniform with most of the respondents agreeing to the questions that were asked. A majority agreed that the health care worker (HCW) gave them feedback on HAART (97%), that the HCW discussed the treatment fully with them (91%) and that they found it difficult to tell the HCW whenever they missed taking their tablets (58%).An equal proportion indicated that the HCW was too busy to listen to their problems and only 8% agreed that the queues at the facility were long to see a nurse or doctor.

A comparison of the questions asked was made across the "adherence" categories to determine any associations across the "adherence" groups (Table 4-16). The results as shown in the table below seem to suggest that the quality of care in terms of patient–provider communication may have not affected the way the patients took their medication as measured by their viral loads in a significant way.

4.3.5.2 Patient-provider communication by plasma viral load categories

Table 4-16: Patient-provider communication by plasma viral load

Patient-health provider communication question		Plasma viral load (RNA copies/ml)	
		High(>=400)	Low(<400)
The health worker didn't discuss treatment fully with you, including how it works and side effects (χ^2=0.11;p=1.000)	Disagree	27(11.4%)	209(88.6%)
	Agree	2(9.1%)	20(90.9%)
You find it difficult to tell HCW when you have missed taking your tablets (χ^2 = 0.33;p= 0.567)	Disagree	12(9.8%)	111(90.2%)
	Agree	11(12.2%)	79(87.8%)
The health worker provided feedback on whether drugs were working or not (χ^2 =0.91;p=1.000)	Disagree	0 (0%)	7(100%)
	Agree	29(11.5%)	223(88.5%)
The health worker was too busy to listen to your problems (χ2 = 0.28;p=0.669)	Disagree	23(12.2%)	165(87.8%)
	Agree	7(9.9%)	64(90.1%)
The queues to be seen by a doctor/nurse are too long at this facility (χ^2 = 0.25;p=0.713)	Disagree	3(14.3%)	18(85.7%)
	Agree	26(10.7%)	216(89.3%)
Some staff don't treat patients with sufficient respect(χ^2 =0.02;p=0.891)	Disagree	18(11.6%)	137(88.4%)
	Agree	12(11.3%)	94(88.7%)

4.4 REASONS FOR NON ADHERENCE

This section presents the patient related reported barriers to "adherence". Asked whether there has ever been a month when the respondents could not come to the clinic for the monthly visit (n=259), the majority 87% replied in the negative but the rest agreed (12%). These responses were however not significantly associated with the viral load (p=0.681). Asked about the frequency of missing, all of them said they had missed at least one appointment (n=37) excluding those who couldn't remember. Patients then gave reasons why they missed facility appointments and missed dosages.

The results (Fig 4-4) suggest that the three most commonly cited reasons for missing facility appointments were the following:

a. Sickness (19.6%). This would probably have been due to respondents suffering from the adverse effects of the drugs a common reason given during the piloting of the questionnaire to a focus group.
b. Being out of town(19.6%) and
c. Having no transport money (17.9%) but other reasons (19.6%) accounted for a large percentage of the barriers to accessing treatment at the facilities.

The respondents were least likely to miss appointments either because they were working or simply forgot.

4.4.1 REASONS FOR MISSING FACILITY APPOINTMENTS

Figure 4-4: Reasons for missing Facility appointments

4.4.2 DAYS MISSED DOSES AND REASONS

The respondents were further asked to determine the longest time they had missed their medication which were further analysed by drug regimens and asset quintiles as shown in Tables 4-17 and 4-18 respectively.

Table 4-17: Longest days missed tablets

If you didn't miss any tablets in the last three days, when was the last time you missed?	Frequency	%
Week	6	1.7
2 weeks	8	2.3
3 months	5	1.5
more than 3 months ago	22	6.4
never missed	302	88.1
Total	343	100

A majority (88%) of the respondents reported never having missed a day in taking their medication while of those who missed, most reported missing taking their medication more than 3 months ago (6.4%).Table 4-18 shows the longest days missed by drug regimens.

Table 4-18: Longest days missed by drug regimen†(n=327)

Longest time missed any tablets (days) [$\chi 2 = 16.891; p < 0.05$]	Drug regimen			
	Regimen 1a	Regimen 1b	Regimen 2	Total
Never missed	270(92.5%)	25(96.2%)	5(55.6%)	300(91.5%)
1-10 days	15(5.1%)	1(3.8%)	3(33.3%)	19(5.8%)
> 10 days	7(2.4%)	-	1(11.1%)	8(2.5%)
Total	292 (100%)	26(100%)	9(100%)	327(100%)

The respondents responses regarding drug regimens (n=327) indicated that 89% (292/327) were on regimen 1a, 8% (26/327) on regimen 1b with the rest (9/327) on regimen 2.

† Regimens previously explained in Table 1-1

Categorising those who had missed into three categories as shown in Table 4-18 showed that respondents on drug regimen two or regimen 1a were more likely to miss and this was highly significant($p<0.05$). These were also more likely to miss for between 1-10 days as compared to the rest of the days.

Table 4-19: Longest days missed by asset quintile

Longest time missed tablets (days) [$\chi^2=16.891;p<0.05$]	**Asset quintile**					
	1	**2**	**3**	**4**	**5**	**Total**
Never missed	57(96.6%)	71(94.7%)	51(82.3%)	59(95.2%)	63(91.3%)	301(%)
1-10 days	1(1.7%)	2(2.7%)	9(14.5%)	1(1.6%)	6(8.7%)	19(%)
> 10 days	1(1.7%)	2(2.7%)	2(3.2%)	2(3.2%)	-	7(%)
Total	59(100%)	75(100%)	62(100%)	62(100%)	69(100%)	327(100%)

The Table 4-19 above shows a comparison of the longest time respondents missed their tablets and the asset quintile categories. The results indicate that the poorer groups(quintile1,2 and 3) were more likely to miss their tablets compared to the less poorer groups (quintile 4 and 5) with a significant association to the number of days missed($p<0.05$).

The five most frequently cited reasons for missing to take medication (n=310) were:

i. Forgetfulness or didn't have the medication with me (16.7%),
ii. Don't believe the medication will work or don't care or irresponsible (13.7%),
iii. Alcohol abuse (9.6%),
iv. Very sick or side effects (9.0%) and
v. Other reasons or don't know (34.6%) .

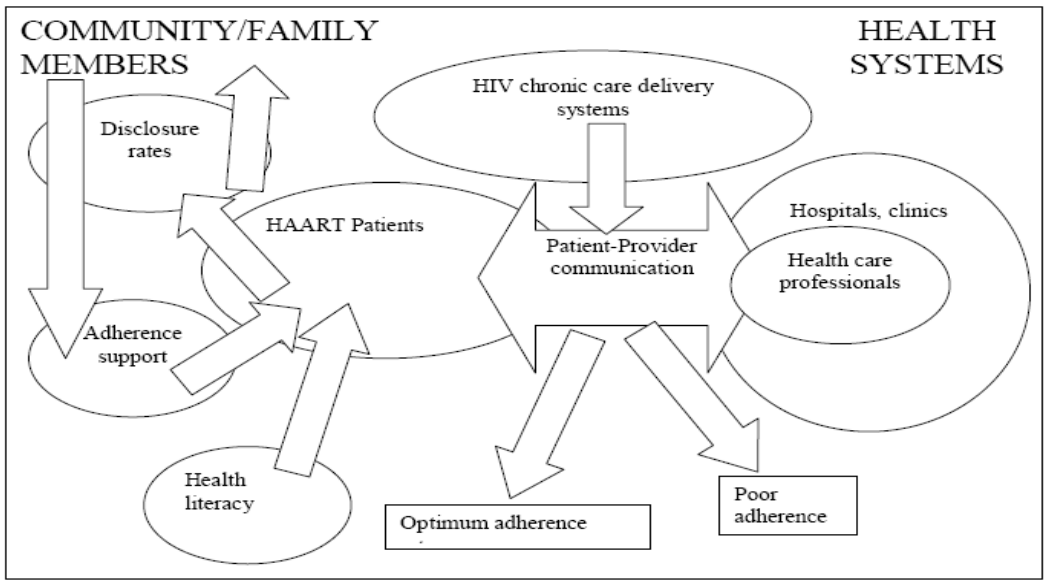
Stress or depression (1.8%) and having the wrong information (5.1%) were the reasons least likely to be cited for missing taking the medication.

CHAPTER FIVE: DISCUSSION

5.1 CCM MODEL: PRODUCTIVE INTERACTIONS

This report adopts the CCM‡ framework (developed by Wagner and colleagues) to assess adherence to HAART and whether it can be used as a possible intervention towards the chronic illness disease management in the health care system. Wagner (2001) views the health care team as part of the health system which form part of the much larger community (fig 2-1). In his study, Wagner argues that chronic illnesses care is characterised by a series of continuous relationships through time with the health care team, individualisation of care according to patients' needs and values, based on evidence and cooperation among clinicians in order to optimise patient health outcomes. The health care team helps the patients set goals and solve problems, reviews data on course of management, applies clinical and behavioural interventions to prevent complications and ensure continuous follow up. The patients on the other hand are more involved if they are empowered and acquire skills to confidently take part in their health care management thus leading to the so called "productive" interactions.

Figure 5-1: An Operational framework for chronic health care



This study draws from the CCM framework to determine challenges that HAART patients face in a health care system largely designed to cater for acute illnesses with regards to adherence to antiretrovirals in order to provide evidence base to operationalise the model.

‡ previously discussed in chapter 2.1 on page 9

Five selected patient side themes were explored in this research which form part of the elements within the CCM framework as indicated in fig 5-1. These included adherence support, health literacy and disclosure rates that constitute the elements of an informed and activated patient to engage with confidence in the chronic health care system. Either of two possible outcomes can result depending on how the interactions with the health system part occur as shown above (fig5-1).

5.2 ADHERENCE MEASURES

This report describes the results of a study that determined factors that affect ARV medication adherence at two public sites in Gauteng province in South Africa. For purposes of this study, adherence was assessed using one subjective method (the self report) and two physiologic indicators (CD counts and plasma viral load). The main surrogate marker for adherence was plasma viral load due to limitations of the self-report method.

In other studies using the self report method- Ammassari (2001), Murri et al , (2000), Haubrich et al (1999) have reported that poor adherence is linked to viral suppression. In this study the proxy adherence rate was determined by measuring the estimated virologic outcome. The proxy adherence rate was 89% which was consistent with similar studies (Bangsberg et al, 2000; Chesney, 2000 and Liu et al, 2001). Although these findings are consistent with the adherence rates for chronic diseases (Paterson et al, 2000), they are way below the acceptable range (greater than 95% adherence) for achieving complete viral suppression in HAART as suggested by Chesney (2003). Other studies done in the developed countries state that the percentage of patients who can be classified as adherent to ARV therapy ranges from 50-90%, with the average around 75%. These studies involved the administration of questionnaires to patients at HIV clinics or AIDS service organizations with some using record reviews (WHO, 2005). In the developing world evidence from Uganda, South Africa and Botswana, as well as other African countries indicates that adherence levels range from 60-80% (WHO, 2005). On the other hand 12% of the respondents had sub-optimal 'adherence' rates. This result was way below the internationally acceptable levels of adherence (Singh et al, 1999; Fogarty, 2002;Paterson et al, 1999;2000; Goudge, 2004).

This therefore calls for strategies that are aimed at patients on HAART in the public health care sector especially in the light of the few available treatment options. These may include regular monitoring and evaluation of comprehensive HAART programmatic interventions which are important components of HAART programmes. The cross sectional nature of this study highlights the need for a more robust method to assess adherence rates for example a longitudinal or intervention (RCT) study which would be able to investigate the causal nature of non-adherence and produce stronger evidence .

5.3 PATIENT FACTORS AFFECTING ADHERENCE

The facility, gender, age groups, educational levels and access to social grants were not found to be significantly associated with the plasma viral load outcome. However these findings are consistent with earlier studies done elsewhere (Fogarty et al,2002; Chesney, 2000) that socio-economic factors are not associated with successful adherence outcomes. The more important aspect in the gender category was that women who accessed HAART services far outnumbered men by a ratio of 3:1 and were more likely to adhere compared to the men 20% of the time. This was often attributed to the larger numbers of women who were more familiar with the health care system compared to the men as they interact with it when accessing other services-antenatal and family planning services (Muula et al, 2007). Muula (2007) further suggested that the women's familiarity with the health care system was more likely to work in their favour by facilitating access to the HAART services as they had greater interaction through family planning and maternity services. On the other hand men were thought to be slower in uptake of HAART services due to the stigma which was as a result of the belief that they would be thought of as having acquired the infection outside the marriage. This fact is borne out by the fact that women are generally perceived to be infected by their own spouses as reported in another Southern African country (Moon et al, 2002).This study however found that the main reason was more to do with stigma in its various forms. This would be attributed to the reason that men feared their HIV status would be disclosed to someone else without their consent.

The SES however was strongly associated with "adherence" especially when categorised into four categories or quintiles based on the analysis of their household assets. There was a general trend in the SES categories indicating that the least poor were more likely to have a poorer virologic outcome compared to those not as poor indicating a possible poorer adherence rate as well. This could be attributed the high costs of accessing treatment suggesting possible significant financial barriers to accessing treatment at the health facilities.

Younger individuals were more likely than the older individuals (>40years) to adhere. It was however noted that the younger age groups in the 29-39 range were the most likely to adhere followed by the 18-28 age group. It would be interesting to determine how and what motivates individuals of particular age group to adhere and others not to adhere.

ADHERENCE SUPPORT

Adherence support is facilitated when there exists communication between the patient and the treatment supporter (in most cases a close member of the family or spouse). This can only occur with disclosure being the first step in the support process. In this study most of the respondents had disclosed to at least someone other than the healthcare worker. The majority were more likely to have disclosed to a family member. The disclosure status was however not found to be significantly different across the two

"adherence" groups (Table 4-11). The respondents were further asked their reasons for non-disclosure and several reasons were given that were consistent with the view that disclosure carries with it some risks. The main reasons advanced for non disclosure were mainly either fear that the respondents HIV status would be known by the community, fear that they would not get help from any other person who may know their status, lack of trust or fear of violence among mostly the women. These reasons are consistent with other studies done about disclosure and its risks (Orumazu, 2000; Klitzman, 2004). The responses to disclosure question generally indicate that there is a big problem of stigma in the community at large and it would be therefore be important to have programmes in place by the provincial and municipal governments that encourage the disclosure of HIV positive persons and their acceptance by their families and community at large. This however contrasts with disclosure to family members which were quite high perhaps indicating that the stigma existed more outside the family set up especially in the community.

Adherence to HAART medication was also associated with the support group services offered at the facilities where the respondents accessed their medication but the results were not statistically significant. Support group services offered included: advice and information on staying healthy, ARV related health literacy, individual counselling and emotional support from treatment buddies. Medication adherence support generally took the form of visitation, reminders to take medication by calling respondents or sms, or providing emotional support. Some received food to take long with their pills or transport money to access their pills at the health facility most likely from their family members.

KNOWLEDGE OF HIV/AIDS & ARVS

Knowledge of HIV/AIDS (health literacy) was measured by asking respondents about various treatment related questions about adherence. On one hand, from the results in this study, numbers of years of schooling were not significantly associated with the virologic outcome. On the other hand, respondents generally gave the correct responses to the knowledge questions indicating that they had adequate knowledge regarding HIV/AIDS, ARVs and adherence related issues regardless of the level of education. This indicates the generally thorough treatment preparation that's done before the patients are accepted onto the HAART programme(*Dr. Lintso Morena, personal communication,25th September,2007)*)This was consistent with studies by Kalichman et al(1999) and Kalichman & Rompa(2000) who demonstrated that health literacy in addition to years of education were independent predictors of treatment adherence. They also suggested that people of lower education and lower literacy were 3-4 times more likely to default on medication over a 2 day recall period. They further suggested that low health literacy is important in adherence to HAART and must be considered, in addition to level of education, as a reasonable marker for potential non-adherence. Even in people with more than 12 years of education the risk of non-adherence should be determined before commencing treatment as well. Miller et al, 2003

further suggested that due to knowledge deficits after treatment initiation clinicians, should still assess patients' understanding of medication dosing soon after regimen initiation or change.

PATIENT-HEALTH PROVIDER COMMUNICATION

On one hand, the respondents generally rated well the relationship between them and their health care providers with most rating it as either good or excellent when asked. As can be seen from this study most respondents generally agreed that the health care providers' feedback on whether the drugs were working or and health care workers discussed the treatment fully with them especially how ARVs work and their side effect which are a crucial aspect for HAART preparation and ongoing treatment. On the other hand some of the respondents had missed some doses but did not indicate that to the interviewers pointing to a level of dishonesty in the respondents. This was mainly due to the fact that their clinical data indicated otherwise especially from the pill counts This may possibly explain that respondents were generally rating the way the health providers were communicating with them but not the other way round or they viewed this type of communication as a one way issue to help explain the high levels of agreement among the respondents.

Studies have established that doctor-patient communication is regarded as an essential part of successful medical care. This is because it's the main method by which information can be exchanged between the two parties. Aspects of the doctor-patient communication may result in desirable patient outcomes like influencing patients' behaviour and well being e.g. satisfaction with care, adherence to treatment, recall and understanding of medical information, coping with disease and better quality of life or state of health (Ong et al, 1995). Research has shown that better patient-health care provider relationships result in better adherence rates. It has been suggested that patients with chronic illnesses almost always want as much information as possible while the physician on the other hand seems to underestimate the patients' desire for information. This could be due to lack of agreement between the way the patients and the physicians perceive the disease. Physicians who see their relationships as a partnership have a more satisfied patient compared to physicians who have a more authoritarian relationship (Anderson & Zimmerman, 1993). As further confirmed by Bakker et al(2000) patients who are more engaged with their health care providers will report greater adherence to medication regimen and provider advice while those who miss at least one appointment point to significantly less engagement.

5.4 REASONS FOR NON-ADHERENCE

These mainly refer to reasons that hinder (barriers to) medication adherence that were investigated at two levels. On one hand, there was the assumption that there were barriers to accessing ARVs from the health facility by the respondents and on the other missing doses of the medication due to different reasons related to the patient's lifestyle. This was based on the framework suggested by van

Servellen & colleagues in 2004 that there are individual and system level factors associated with treatment non-adherence in HIV infected men and women.

At the individual level most respondents said that they missed medication due to forgetting or didn't believe that the medication will work, alcohol abuse, side effects or stress and depression. Consistent with similar studies forgetfulness emerged as the most common reason cited by the respondents for missing to take their medication (Chesney et al, 2000; Weiser et al, 2003). It can be argued that forgetfulness was indeed a reason that could be related to alcohol abuse, stress or lack of belief that the medication will work. This could help explain why most individuals reported forgetfulness as a reason for not taking their medication. The side effects of the medication itself are expected and more to do with the regimen demands that arise depending on the line of treatment one is on as reported by Harry Nyatela (Centre for Health Policy,November;2006 *personal communication*) as a result of subsequent qualitative interviews with a subset of patients .

This study has also shown the high costs of accessing treatment as a barrier to adherence. In this case it could be explained by the mostly unaffordable monthly cost implications for accessing HAART at the health care centres by both sexes.

Other individual barriers to adherence include stigma as observed from the low rates of disclosure. The main reasons that pointed to stigma were mainly either fear of not getting help from other people who may know the patients' HIV status, fear of their HIV status being known by the community of fear of gossip. Other indicators of stigma were lack of trust of people by the patients. These reasons indicate that the respondents generally viewed stigma as coming from community as opposed to the family set up. This is evidenced by the low numbers of respondents who feared members of their own family knowing about their HIV status compared to the ones fearing community members.

Regarding missing clinic appointments most respondents cited sickness, being out of town, having no transport money and mixing up dates as common reasons for not going to the health facility. Sickness was the most common reason that was cited for missing facility appointments in this study. It can be deduced that the major reason the respondents would be sick due to either the onset of opportunistic infections or adverse effects but more likely the latter. Side effects have been well documented ranging from nausea, vomiting, diarrhoea, abdominal pains, headaches, skin rashes, fatigues and dizziness (Pakendorf, 2005).

Finally, this study also confirmed another reason that has been cited by other studies as responsible for non adherence. This is the poor access to the health care system by men when compared to the women. In the case of men, they were fewer on HAART due to poorer uptake of voluntary counselling and testing services that served as the entry point into the HAART and health care system.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

The proxy adherence rate of 89% that was determined using the surrogate adherence marker for adherence in this study compares favourably with several similar studies. However this rate is generally low for good clinical outcomes when compared to the recommended level of >95% adherence from other studies. This however should be considered as the minimum adherence rate. Adherence generally is a complex issue and therefore involves more than one approach to address the barriers as well as the key facilitators. Moreover determining adherence is limited by the methodological difficulties of adherence assessment that still exist. Since there is no agreed upon gold standard for adherence assessment.

Factors that favour adherence include medication adherence support. This form of support included provision of food, transport and emotional support from close family members.

The barriers which were identified were the following: lack of transport money to the health care facilities for the monthly medication trips, extended absence from the home or town where the patient lives, sickness associated with side effects and opportunistic infections, forgetting to take the medication as prescribed, stress and lack of self-belief that the medication will work and stigma from the community and people to whom the patient has not disclosed.

RECOMMENDATIONS

These recommendations are based on the bottlenecks to adherence noted in the study and should be considered as the minimal interventions necessary to improve adherence. The interventions can be effected at the individual, health facility and health system level as outlined below.

At the individual level, couples embarking on HAART that are in a relationship should be advised or encouraged to disclose to one another in order to reduce the fear and stigma surrounding stigma as well as increase adherence support for the long term.

Increase support for health literacy and empowerment of both men and women regardless of the education levels of the patients. This should be done before they embark on HAART programmes as well as being on an ongoing basis in order to asses the risk of non adherence given the increasing risk of resistance to antiretrovirals.

Similarly efforts should be made to involve more patients in the decision making process regarding treatment regimens and dealing with the toxicity thereof to help increase belief in the self efficacy of the medications. Additionally in order to deal with the lack of belief that the medicines don't work or self-efficacy it would be important to develop practical guidelines to implement adherence

management strategies. For example ensuring continuous adherence counselling of the patients, health education and assessment of patient knowledge levels thereafter, using practical devices to remind patients to take their medication on time (these though should be easily affordable or subsidised for patients in the public health sector). Adherence counselling should emphasise and teach stress coping interventions especially to discourage alcohol abuse among both men and women so that related incidences of forgetting to take medication are decreased.

Efforts should be made to particularly target men who were found to be accessing ARVs at an unusually low rate compared to women in this study. Men should therefore be targeted specifically to encourage increased health seeking behaviour so that they would increasingly access the VCT and HAART programmes in the health care facilities as well. This can be done through mass mobilisation programmes on community radio stations to encourage men to interact more with the health care system starting with going for voluntary counselling and testing, disclosing to their partners (those on HAART), training as "treatment buddies" and volunteering as peer counsellors or adherence counsellors to fellow men within the health care facilities. Studies targeting men to evaluate their level of access to VCT should be done and reasons why very few of the men access such services addressed within the study. Other studies can be done to identify the factors that facilitate the high uptake of women onto HAART programmes in order to sustain the current trend.

Regarding health care providers and their relationship with the patients, more understanding of the patient should be encouraged especially by building a rapport with the patient in order to remove the feeling that the health care workers are judgemental of their patients especially when non adherent. Finally increased support for training and further research about adherence and antiretroviral medication to address the side effects and regimen complexity should be done if challenges to adherence are to be addressed. This will then help understand the problem of patients skipping medications because patients are either travelling out of town or skipping medication due to side effects.

Introduce and ensure that simple methods to measure adherence are monitored and evaluated periodically to keep track of the trends in adherence within the population being served by the public health sector HAART programmes. Pharmacy refill records, doctors' assessments as well as standardised one month recall should be used in addition to the usual clinical criteria of physiological markers like CD4 counts and plasma viral loads. More needs to be done to enhance and strengthen the treatment buddy programme in terms of research and helping set up of more programmes especially in Impilisweni where the author found them to be under utilised. This could be done hand in hand with the introduction of peer support groups at the health care centre to help the patients deal with the reality of HAART and gain coping strategies and emotional support from each other while on treatment. This should ultimately lead

to improved levels of adherence in the long term as the patients become more activated and empowered to deal with long term HAART.

At the health system level, the National Department Of Health, SA should consider enacting inclusive policies that give lifelong social grant support for people who are on HAART especially those in public sector. Both patients with a CD4 count of above and below 200 should be eligible or better still eligibility should not depend on CD count as a measure since one stays sick even if their CD4 count is high. Perhaps applying equitable scales to determine the poorest of the poor may help in this regard. This money then helps to reduce drug treatment holidays as patients skip medications on certain days due to various reasons since they are too poor to afford food which is essential for proper adherence. The government should ensure/consider increasing social support and welfare for PLWHA on HAART by increasing access to disability grant services to cater for transport and problems associated with lack of food and telecommunication (money for sms ,cell phone airtime and telephone calling cards).

Finally increased support for training and further research about adherence and antiretroviral medication to address the side effects and regimen complexity should be done if challenges to adherence are to be addressed. This will then help understand the problem of patients skipping medications because patients are either travelling out of town or skipping medication due to side effects.

REFERENCES

ASSA.2005.HIV/AIDS statitistics. Available on the internet at www.assa.org.za downloaded on the 15th January,2005

Anderson L. A. & Zimmerman M. A. 1993.Patient and physician perceptions of their relationship and patient satisfaction: a study of chronic disease management. *Patient Educ. Counseling* 20 and 27.

Arnsten, J.H. Demas, P.A. Farzadegan, H. Grant, R.W. Gourcvitch, M.N. Ching, G. Buond, D. Eckholdt, H. Howard, AA Schoenbaum, E.E.2001. Anti-retroviral therapy adherence and viral suppression in HIV-infected drug users: comparison of self-report and electronic monitoring. *Clinical infectious Diseases*: 33:1717-1723

Ammassari A et al.2001. Self-reported symptoms and medication side-effects influence adherence to highly active antiretroviral therapy in persons with HIV infection. *Journal of Acquired Immune Deficiency Syndromes*: 28:**5**:445-449.

Bakken ,Holzeimer WL, Brown A.et al.2000.Relationships between perception of engagement with health care provider and Demographic characteristics, health status, and adherence to therapeutic regimen in persons with HIV/AIDS.*AIDS Patient care and STDs*.14:**4**:189-197.

Bangsberg D.R., Hecht F.M., Charlebois E.D., et al. 2000.Adherence to protease inhibitors, HIV-1 viral load, and development of drug resistance in an indigent population. *AIDS*.14:357-66.

Bangsberg DR, Hecht FM, Charlebois ED, Chesney M, Moss A. 2001.Comparing objective measures of adherence to HIV antiretroviral therapy: electronic medication monitors and unannounced pill counts. *AIDS Behav*.5: 275–281.

Carel M, Cleland J, Ingham R.1995. Extra marital sex: implications of survey results for STD/HIV transmission. In: AIDS prevention and impact in developing world. Demographic and social science perspectives. *Health Transit Rev*. **4**(Suppl): 153-173.

Carpenter CCJ, Fischl MA, Hammer SM et al. 1997.Anti retroviral therapy for HIV infection in 1997: updated recommendations of the international AIDS society-USA panel.*JAMA*.277: 1962-1969:

Catz, SL., Kelly, JA. Bogart, LM. Benotsch, EG, McAuliffe TL.2000.Correlates and barriers to medication adherence among persons prescribed new treatments for HIV disease. *Health Psychology*. 19:**2**:124-133:

Chesney, M. A.2000. Factors Affecting Adherence to Antiretroviral Therapy. *J Clinical Infectious Diseases*. 20:171-176.

Chesney, M A. 2003. Review: Adherence to HAART Regimens. *AIDS Patient CARE and STDs*. 17:4:169-177.

Chesney, M 2004. Adherence to HAART Regimens. In Medication adherence in HIV/AIDS. Ed. Laurence J. Mary Ann Liebert, Inc publishers.page 18-26.

Dobson, A.J 1984.Calculating sample size. *Trans. Menzies Foundation*.7:75-79.

Deeks SG Hecht FM, Swanson M, et al. 1999. HIV/RNA and CD4 cell count response to protease inhibitor therapy in an urban AIDS clinic: response to both initial and salvage therapy.*AIDS*.13:**6**:F35-F43.

Department of Health 1998. National HIV sero-prevalence survey of women attending public antenatal clinics in South Africa. Pretoria; 1999.

Department of Health, Government of South Africa.2003. Pretoria. Accessed on the Internet on URL http://www.doh.gov.za accessed on the 26th May 2005.

Doherty T and Colvin M.2004.Chapter 14:HIV/AIDS In South Africa Health review 2003/04. Health Systems Trust. Durban. pp 191-212.

Embretson J, Zupancic M, Ribas JL, et al. Massive covert infection of helper T lymphocytes and macrophages by HIV during the incubation period of AIDS. Nature 1993; 362(6418):359-62

Family health international (FHI). 2001.Evaluating programs for HIV/AIDS prevention and care in developing countries. A handbook for program managers and decision makers. Arlington, Virginia. ISBN 1-931547-0107.

Fogarty, L. et al. 2002.Patient adherence to HIV medication regimens: a review of published and abstract papers. *Patient Education and Counselling*. 46 :93-108.

Garcia R, Schooley RT, Badaro R.2003.An adherence trilogy is essential for long term HAART success. *The Brazilian journal of infectious diseases*. 7:**5**:307-314.

Golin C, Isasi F, Bontempi JB, Eng E.2002. Secret pills: HIV patients' experience taking ant-retro viral therapy in North Carolina. *AIDS Education & Prevention*. 14:**4**: 318-329.

Goudge J,Ngoma B and Schneider H.2004.Adherence to anti-retroviral drugs: Theorising contextual relationships, A review of the adherence and related literature with annotated bibliography. Centre for Health Policy, University of the Witwatersrand. Johannesburg.

Gill CJ, Davidson HH, Simon JL et al. 2005.No room for complacency about adherence to antiretroviral therapy in sub-Saharan Africa..*AIDS*.19:**12**:1243-1249.

Haubrich HR, Little SJ Currier JS, et al.1999. The value of patient self-reported adherence to antiretroviral therapy in predicting virologic and immunologic response. *AIDS*: 13:1099-1107

Hecht FM, Colfax G, Swanson M, Chesney M.1998. Adherence and effectiveness of protease inhibitors in clinical practice [abstract 15]. In: Program and abstracts of the 5th Conference on Retroviruses and Opportunistic Infections (Chicago). Alexandria, VA: Foundation for Retrovirology and Human Health.

Henry K, Stiffman, M. and Feldman, J.1997.Antiretroviral therapy for HIV infection; Heartening success mixed with continuing challenges. *Post graduate medicine*: 102:4

Ho DD, Moudgil T, Alam M.1989.Quantitation of human immuno-deficiency virus type 1 in the blood of infected persons. *N Engl J Med*;321(24):1621-5

Holzemer WL, Corless IB, Nokes KM, Turner JG, Brown MA, Powerll-Cope GM, Inouye J, Henry SB. et al. 1999.Predictors of self-reported adherence in persons living with HIV disease. *AIDS Patient Care and STDS*. 13:**3**:185-197.

Kalichman KC, Bineetha R and Catz S.1999.Adherence to combination ant retroviral therapies in HIV patients with low literacy. *JGM*.:14:267-273.

Kalichman SC and Rompa R.2000.Functional health literacy is associated with health status and health related knowledge in people living with HIV/AIDS.*JAIDS*; 25:337-344.

Kalichman, S and Malow, M.2004.Adherence to Antiretroviral Therapies. In Medication adherence in HIV/AIDS. Ed. Laurence J. Mary Ann Liebert, Inc publishers. page 11-17.

Klitzman RL et al.2004. Intricacies and inter-relationships between disclosure and HAART: a qualitative study. *AIDS Care*, 16:**5**:628-640.

Liechty C, Bangsberg DR.2003.Doubts about DOT: HIV Antiretroviral Therapy for Resource-poor Countries. *AIDS*.XX: XXX-X (in press).

Liu H, et al. 2001. A comparison of multiple measures of adherence to HIV protease inhibitors. Annals of Internal Medicine.134:968 - 997.

Miller LG,Honghu Liu,Hays RD,et al. 2003.Knowledge of regimen dosing and Adherence: A longitudinal study. *Clinical Infectious Diseases*: 36:514-8.

Moon MW, Khumalo-Sakutukwa GN, Heiman JE, Mbizvo MT, PadianNS.2002.Vaginal microbicides for HIV/STI prevention in Zimbabwe:What key informants say. *J Transcult Nurs*.::13:19-23.

Mocroft A, Lederberger B, Katlama C, et al. 2003.Decline in AIDS and the death rates in the EuroSIDA study: an observational study.*Lancet*.362: 22-29:

Morisky, D. E. Green, L.W. Levine, D. M. 1986. Concurrent and predictive validity of a self-reported measure of medication adherence. *Medical Care:* 24: 67-74.

Muula AS,Ngulube TJ,Siziya S et al.2007.Gender distribution of adult patients on HAART in Southern Africa: a systematic review. *BMC Public Health*. 7:**63**.XXX-XXX.doi:10.1186/1471-2458/7/63

Nieuwkerk P, Sprangers MA, Burger DM, Hoetelmans RM, Hugen PW, et al.2001.Limited patient adherence to highly active antiretroviral therapy for HIV-1 infection in an observational cohort study. *Arch Intern Med* 161: 1962–1968.

Ong LML ,De Haes JCJM,et al. 1995.Doctor-Patient communication: A review of the literature.*Soc Sci Med*.40:**7**:903-908.

Orrell C, Bangsberg DR, Badri M, Wood R. 2003. Adherence is not a barrier to successful antiretroviral therapy in South Africa. *AIDS*.17:9.

Orumazu JA.2000. Disclosure decision model: determining how and when individuals will self-disclose. *Personality and Social Psychology Review*.4:174 -185.

Murri R, Ammassari, Gallicano K, et al. 2000.Patient reported non-adherence with HAART is related to protease inhibitor level. *J Acquir Immune Defic Syndr*; 24:23-8.

Palella FJ, Deloria-Knoll M, Chmiel JS, et al.(2003) Survival benefit of initiating antiretroviral therapy in HIV-infected persons in different CD4+ cell strata. *Ann Intern Med.*138(8):620-6.

Paterson D, Swindles S, Mohr J, et al.1999.How much adherence is enough? A prospective study of adherence to protease inhibitor therapy using MEMS caps. In conference proceedings. Retrovirus Opportunistic Infect 1999.Jan 31-Feb4; 6th:8. Abstract no.92.Chicago IL.USA

Paterson DL, Swindels S, Mohr J, et al.2000.Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. *Ann Intern Med.*133:21-30

Paterson L, Potoski B and Capitano B .2002. Measurement of adherence to antiretroviral mediactions.JAIDS.31:S103-S106.

Pakendorf MA.2005. Adherence to antiretroviral treatment in a South African setting. MSc (Med) thesis submitted for the award of Master of Science (Medicine) to the University of the Witwatersrand.

SAHR (South African Health Review).2000.Health Systems Trust. Durban. Downloaded from the internet at: **http://www.hst.org.za/generic/29** on January 23rd,2007.

SAHIVS.2005. Clinical guidelines for antiretroviral therapy in adults.Eds. Millera,S. Available on the web portal at http://www.tac.org.za/ downloaded on the 22nd March,2007.

Schneider H et al. 2007.Can the public sector rise to the challenge of ART? Evidence from second generation sites in Gauteng Province. Third South African AIDS Conference, Durban, abstract 474, 2007.

Simoni JM, Frick PA, Pantalone AB, Turner BJ.2003. Anti-retroviral adherence interventions: A review of current literature and ongoing studies. *Topics in HIV medicine.* **11** :6.

Singh N ,Squier, C. Sivek, C, Wagener, M et al.1999. Determinants of compliance with antiretroviral therapy in patients with human immunodeficiency virus: prospective assessment with implications for enhancing compliance. *AIDS Care,* 8:3:261-269.

Tuldra, A. Fumaz, C.R. Ferrer, M.J. Bayers, R. Arno, A. Balague, M. Bonjoch, A. Jou. A. Negredo, E. Paredes, R. Ruiz, L. Romeu, J. Sirera, G. Tural C. Burger, D. Clotet, B. 2000. *J Acquir Immune Defic Syndr.* 25:**3**: 221-228.

U.S. Department of Health and Human Services.October,2006. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.Available online at http://www.aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=7. Accessed July 3, 2007.

Wagner E, Austin BH, Davies C ET al.2001. Improving chronic illness care: Translating evidence into action. Health Affairs. 20:6.

Wainberg, MA and Friedland, G. 1998.public health implications of antiretroviral therapy and HIV drug resistance. *JAMA*:279:1977-83

Weidle, PJ. Ganea, CE. Irwin, LS. et, al. 1999. Adherence to Antiretroviral in an Inner-City population. *JAIDS*. 22:**5**: 498.

Weiser S, Wolfe W, Bangsberg D, et al. 2003. Barriers to effective adherence for patients living with HIV and AIDS Botswana. *J Acquir Immuno Defic Syndr*; 34:281-288.

WHO.2002.Scaling up antiretroviral therapy in resource-limited settings, Guidelines for a public health approach. Available on the web at the following address http://www.who.int/en/ accessed on 23rd May, 2007.

WHO, Department of HIV/AIDS.2005.Adherence and HIV/AIDS, World Health Organization, Geneva, Switzerland. 2005.WHO, Department of HIV/AIDS. Adherence and HIV/AIDS, World Health Organization, Geneva, Switzerland.

UNAIDS 2005.HIV/AIDS Sudan Fact sheet C. Antiretroviral therapy (ART) for advanced AIDS available on the internet address: http://www.unaids.org/en/HIV_data/epi2006/default.asp . Accessed on the 10th October, 2007.

UNAIDS.2006. AIDS epidemic update.December:2006. http://www.unaids.org/epi2005/doc/EPIupdate2005_pdf_en/Epi05_05_en.pdf, p. 17 Accessed on the 30th October, 2007

Van Servellen G,Chang B,Garcia L and Lombardi E. 2004. Individual and System level factors associated with treatment adherence in Human Immuno Deficeincy virus infected Men and women. In Medication adherence in HIV/AIDS. Ed. Laurence J. Mary Ann Liebert, Inc publishers page 119-132.

APPENDIX

A. ETHICAL CLEARANCE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Kigozi

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M051105**
PROJECT	Patient" Factors Determining Adherence to HAART in Two Sites in Johannesburg Gauteng Province in 2005
INVESTIGATORS	Dr JL Kigozi
DEPARTMENT	School of Public Health
DATE CONSIDERED	05.11.25
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 06.02.08 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr J Goudge
RECEIVED: J. L. KIGOZI (MPH)

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

B. CHANGE OF RESEARCH TITLE

.

Amended letter

Postgraduate Office, Faculty of Health Sciences
Wits Medical School, 7 York Road, PARKTOWN, 2193, Johannesburg • Tel: (011) 717 2075 • Fax: (011) 717 2119 • e-mail: alison.mclean@wits.ac.za

Ref: 0507497N
MPH

Dr J L Kigozi
Room 218
West Campus Village
PO WITS
2050

12 October 2006

Dear Dr Kigozi

APPROVAL OF CHANGE OF TITLE

This letter confirms that the Chairman of the Postgraduate Committee has approved your application for a change in the title of your MPH research report, as follows:

Previous title:

"Patient" factors determining adherence to HAART in two sites in Johannesburg, Gauteng Province in 2006

New title:

Client factors determining ARV adherence in Natalspruit Hospital and at Impilisweni CHC in Gauteng Province in 2006

Yours sincerely

Mrs A McLean
Postgraduate Office

cc Supervisor
HOD

C. PROVINCIAL APPROVAL

PROVINCIAL RESEARCH COMMITTEE.

Enquiries: Dr ML Likibi
Tel: 011 355 3310
Fax: 011 355 3264
MupataL@gpg.gov.za

TO WHOM IT MAY CONCERN

Re: Authorisation for research projects to be conducted in health facilities in Gauteng province by Wits MPH students

This serves to inform you that the Gauteng Department of Health (GDOH), through the research and epidemiology unit of the ITM Directorate has developed a relationship with the Wits School of Public Health, which provides SPH an opportunity to link its service, research and teaching functions, while addressing priority health needs of the GDOH.

In this regard, a group of MPH students at the Wits SPH have developed their MPH research projects in line with the health priorities of GDOH. We believe these projects are relevant to GDOH as they will provide useful tool that will assist us to monitor and evaluate our health services and programmes.

These students (listed in the table below), through the Wits SPH, have requested the GDOH for authorisation to conduct their research projects in our health facilities.

Ethics clearance certificate has been granted by the wits ethics committee and are hereby attached.

The facility managers will be timely approached for permission to access their respective facilities.

We have no objection to recommend that the studies be conducted in this Province.

Thank you,

Yours sincerely,

Dr ML Likibi
Research and Epidemiology unit

D. FACILITY APPROVAL

OFFICE OF THE CHIEF DIRECTOR
Department of Health
Lefapha la Maphelo
Departement van Gesondheid
Umnyango wezeMpilo

MEMORANDUM

TO: Dr M Kawonga, MPH Research Coordinator

CC: Mr Modise Makhudu, Director Ekurhuleni District
Mr Thulani Madonsela, Acting CEO Natalspruit Hospital
Dr Moji, Fare East Rand Hospital

FROM: Dr Frew Benson, Chief Director Health Region

DATE: 25 April 2006

SUBJECT: **WITS UNIVERSITY SCHOOL OF PUBLIC HEALTH MPH PROJECTS**

I acknowledge receipt of your letter dated 22 March 2006 regarding the above mentioned matter.

Please be informed that the Chief Executive Officers of the identified institutions and the Director of the District will be informed of the research project.

The students should proceed and contract the institutions.

Yours faithfully

_____

Dr Frew Benson
CD: Ekurhuleni – Sedibeng Health Region

E. ARV ADHERENCE QUESTIONNAIRE

CONSENT			
INTERVIEWER INTRODUCES HIM/HERSELF, AND THE STUDY, AND THEN…. **I would like to ask you questions to ensure that the information I have provided so far is clear, and give you the opportunity ask any question(s) you have.**			
NO	QUESTION	RESPONSE	CODES
1.	**Do you understand the purpose of the study, and what will be required of you if you agree to take part?**		Yes=1 No=0
2.	**If no, what further questions what further questions do you wish?**		
3.	**Do you understand that any time you may withdraw from this study without giving a reason?**		
4.	**Do you understand that this study is in no way linked to the organizations that provide care, and withdrawing or participating will not affect the care that you receive?**		
5.	**Do you agree to take part in this study?**		
Written consent I agree to participate in this study, having understood and answered yes to all of the above questions. **Initials of respondent:** ……..			
Verbal consent As the respondent is illiterate, or is happy to provide verbal but not written consent, I, the field worker, confirm that the respondent gave verbal consent to be interviewed. **Signature of interviewer**: …….			

INTERVIEW DETAILS				
NO	**QUESTION**	**RESPONSE**	**CODES**	**SKIP**
6.	**Clinic patient number** (8 digits + 2 letters)			
7.	**Facility name**		Carltonville = 1 Zola = 2 Empilisweni = 3 Natalspruit = 4	
8.	**Date of interview**	D D M M Y Y Y Y		
9.	**Name of interviewer**		*Interviewer names* =1 =2 =3 =4	
Signature of researcher that has checked questionnaire				

10.	**Questionnaire number** ONLY TO BE COMPLETED ONCE QUESTIONNAIRE HAS BEEN CHECKED, AND IS COMPLETE				

SECTION 1: SOCIO-DEMOGRAPHIC BACKGROUND					
I would like to ask you a few questions about yourself. We are asking these questions of everybody participating in this study. Feel free to stop me if you have any questions.					
No.	QUESTIONS	RESPONSES		CODES	SKIP
11.	GENDER			Male =01; Female= 02	
12.	**What is your date of birth?** WRITE AGE IF DATE NOT KNOWN	D D M M Y Y Y Y			
13.	**What is the highest educational level that you have COMPLETED?**		No formal education =0 Grade 1/SubA=1 Grade 2/Sub B=2 Grade 3/Standard 1 =3 Grade 4/Standard 2/ABET L1 =4 Grade 5/Standard 3=5 Grade 6/Standard 4/ABET L2=6 Grade 7/Standard 5 =7 Grade 8/Standard 6/ABET L3 = 8 Grade 9/Standard 7 = 9 Grade 10/Standard 8/ABET L4 = 10 Grade 11/Standard 9 = 11 Grade 12/Standard 10/ABET L5 = 12 Diploma = 13 Degree = 14 Other: Specify--------=99	
14.	**Have you done any activity to earn money in the past two weeks?**				**IF NO, >Q17**

15.	IF YES: **Can you describe the type of work you have been doing, including how often you do this work?** PLEASE WRITE EXPLANATION			
16.	IF WORKING**: How would you best describe the work that you do?**		Full time =1 Self-employed = 2 Casual or part-time work = 3	
17.	**Do you currently receive a disability grant?**		Yes=1 No=0	**IF YES >Q19**
18.	IF NO: **Have you applied for one?**		Yes=1 No=0	

I'd like to now ask you about your costs coming here today				
	ITEM	COST PER VISIT	**Codes**	
19.	**How much did it cost you to travel to and from the hospital/clinic (the return trip)?**	**R**	Don't know = -1 PUT ZERO IF SPENT NO MONEY ON ITEM	
20.	**Subsistence (food) during visit?**	**R**		
21.	**Medication received at hospital/clinic?**	**R**		
22.	**Consultation at hospital/clinic?**	**R**		
23.	**Accommodation (if needed to stay over) during visit?**	**R**		
24.	**Are there any other COSTS that I have not mentioned?**		Yes =1 No = 0	
25.	IF YES: **What else did you spend money on, and how much?**			
26.	**At present, do you have a medical aid?**		Yes =1 No=0	
27.	DID THE PERSON SAY THEY HAVE BEEN WORKING IN THE PAST TWO WEEKS? CHECK Q15		Yes =1 No = 0	**IF NO, > Q31**
28.	IF YES, **Did you miss work by coming here?**		Yes =1 No = 0	**IF NO, > Q31**
29.	IF YES: **Did you loose salary or income by coming here?**		Yes =1 No = 0	**IF NO, > Q31**
30.	IF YES, **How much income do you lose per visit?**		R_____per visit	

31.	**What is the main source of drinking water for members of your household?** READ OUT EACH OPTION Other: Specify……		Rain water /tank = 1 Borehole/well = 2 Water carrier/tanker = 3 Public tap = 4 Piped water (tap) in site, yard = 5 Piped water (tap) in dwelling = 6 Bottled water = 7 Other = 99	
32.	**What kind of toilet facility does your household have?** READ OUT EACH OPTION Other: Specify…….		Flush toilet (own)=5 Flush toilet (shared) = 4 Bucket latrine = 3 Pit latrine=2 No facility/bush or veld = 1 Other=99	

33.	**What type of home do you live in?** READ OUT EACH OPTION Other: Specify…….		Shack / informal dwelling in back yard=1 Shack / informal dwelling =2 Hostel =3 House/flat/Room in back yard=4 Room/flatlet not in back yard but on shared property=5 Flat in a block of flats = 6 Formal house = 7 Other = 99	
34.	**What is the main material of your house's floor?** READ OUT EACH OPTION Other: Specify…….		Earth / sand / dung = 1 Bare wood planks = 2 Cement = 3 Vinyl or plastic = 4 Carpet/ tiles/ polished wood = 5 Other = 99	
35.	**What is the main material of your house's wall?** READ OUT EACH OPTION Other: Specify…….		Plastic / cardboard = 1 Mud = 2 Mud and cement = 3 Corrugated iron / zinc = 4 Bare brick / cement blocks = 5 Plaster / finished = 7 Other = 99	
36.	**Do you have electricity in your household?**		Yes=1 No = 0	

Can you tell me if you household has any of the following appliances, that are working?					
37.	**Television**		Yes=1 No = 0		
38.	**Telephone (land line)**				
39.	**Fridge**				
40.	**Personal computer**				
41.	**Washing machine**				
42.	**Radio**				
43.	**Cell-phone**				
44.	**What does your household use <u>mainly</u> for cooking?** READ OUT EACH OPTION If other, specify……		Electricity =6 Gas = 5 Paraffin = 4 Wood = 3	Coal = 2 Animal dung=1 Other = 99	
45.	**What does your household use <u>mainly</u> for heating?** READ OUT EACH OPTION If other, specify……		Electricity =6 Gas = 5 Paraffin = 4 Wood = 3	Coal = 2 Animal dung=1 Nothing=7 Other = 99	
46.	**What does your household use <u>mainly</u> for lighting?** READ OUT EACH OPTION If other, specify……		Electricity =6 Gas = 5 Paraffin = 4 Wood = 3	Coal = 2 Animal dung=1 Other = 99	
Does any member of your household own any of the following?					
47.	**A bicycle**		Yes=1 No = 0		
48.	**A motorbike**				
49.	**A car**				
50.	**A donkey or horse**				
51.	**Sheep or cattle**				
52.	**Would you say that the people at home often, sometimes, seldom or never go hungry?**		Often = 1 Sometimes = 2	Seldom = 3 Never = 4	
53.	**Do you receive food supplement/food parcel from any source?**			Yes = 1, No =0	

SECTION 2: KNOWLEDGE OF HIV/AIDS AND ARVs				
I would now like to ask you some questions about AIDS and ARVS				
NO	QUESTION	RESPONSE	CODES	SKIP
54.	**Can you tell me about ARVs, what do they do?** WRITE RESPONSE		Correct response=1 Incorrect response =0 Don't know = -1	

I am going to read you some statements. I would like you to tell me, for each one, whether you think the statement is True or False, or you don't know			
55.	**People receiving ARVs can still transmit HIV to other people through unprotected sex.**		True = 1 False = 0 Don't know = -1
56.	**It is acceptable to stop ARVs after gaining weight**		
57.	**It is acceptable to stop ARVs when one no longer suffers from opportunistic infections**		
58.	**ARVs cure HIV/AIDS.**		
59.	**After a couple of years one can stop taking ARVs.**		
60.	**Missing a few tablets of ARVs is acceptable.**		
61.	**Unprotected sex is safe when one is taking ARVs**		

SECTION 3: CONTINUITY OF CARE

I will like to obtain some information from you about when you were diagnosed with HIV or AIDS and where and how you have received treatment and care.

NO	QUESTION	RESPONSE	CODES	SKIP
62.	**When did you first test positive for HIV?**	D D M M Y Y Y Y	Don't know = -1	
At which health care facility (clinic or hospital) did you FIRST test HIV positive?				
63.	Name of clinic or hospital:…….			
64.	FILL IN IF YOU KNOW Town / City:……..			
65.	Province:	Gauteng = 1 Mpumalanga = 2 Limpopo = 3 North West = 4 Free state = 5 E. Cape = 6 W. Cape = 7 N. Cape = 8 KZN=9		
Where did you FIRST seek treatment after you were FIRST diagnosed with AIDS?				
66.	Name of clinic or hospital:…….			
67.	Town / City:……..			
68.	Province:	Gauteng = 1 Mpumalanga = 2 Limpopo = 3 North West = 4 Free state = 5 E. Cape = 6 W. Cape = 7 N. Cape = 8 KZN=9		
69.	**When did you FIRST begin taking ARVs?**	D D M M Y Y Y Y	Don't know = -1	
70.	**Have you received ARVs from a clinic / service other than this one?**	Yes = 1; No = 0		**IF NO, >Q74**
Can you tell me the name of the clinic / hospital, which town/city AND province?				

71.	Facility name:……					
72.	Town / city: …….					
73.	Province		Gauteng = 1 Mpumalanga = 2 Limpopo = 3	North West = 4 Free state = 5 E. Cape = 6	W. Cape = 7 N. Cape = 8 KZN=9	

SECTION 4: ADHERENCE				
I would like to ask you some questions about how you are coping with taking the ARVs regularly. We want to understand better the real life challenges that people on ARVs face in taking their pills.				
NO	QUESTION	RESPONSE	CODES	SKIP
74.	**Can you tell me the name of each of your drugs?** (WITHOUT LOOKING AT THE CONTAINER)		Yes = 1 No = 0	**IF YES >Q76**
75.	IF NO**: Can you point to the pictures of each of your drugs?** OR PERSON READS THE NAMES FROM THE CONTAINERS WRITE IN ALL DRUG NAMES BELOW FIRST AND THEN GO BACK ASK QUESTIONS ABOUT EACH ONE?		Yes = 1 No = 0	
76.	**DRUG 1**: WRITE DRUG NAME GIVEN, CHECK SPELLING ON LIST			
77.	**How many times a day to do you take …….** (drug)**?**			
78.	**How many tablets of ……** (drug) **do you take in one day?**			
79.	**DRUG 2**: WRITE NAME GIVEN, CHECK SPELLING ON LIST			
80.	**How many times a day to do you take ……** (drug)**?**			
81.	**How many tablets of …….** (drug) **do you take in one day?**			
82.	**DRUG 3**; WRITE NAME GIVEN, CHECK SPELLING ON LIST			
83.	**How many times a day to do you take …..** (drug)**?**			
84.	**How many tablets of …..** (drug) **do you take in one day?**			
85.	**DRUG 4:** WRITE NAME GIVEN, CHECK SPELLING ON LIST			
86.	**How many times a day to do you take ……** (drug)**?**			
87.	**How many tablets of ….** (drug) **do you take in one day?**			
People may miss taking their ARVs for various reasons. What, in your experience, are the main reasons why people miss their tablets? WRITE RESPONSES, PROMPT FOR MORE THAN ONE REASON				

88.	**Reason 1:**			
89.	**Reason 2:**			
90.	**Reason 3**			

For each of drugs, can you tell me how many tablets, if any, you missed YESTERDAY? WRITE IN DRUG NAMES FROM ABOVE

		NAME OF DRUG	**Number of tablets missed**	**Reason for missing**
91.	Drug 1			
92.	Drug 2			
93.	Drug 3			
94.	Drug 4			

For each drug, can you tell me how many tablets, if any, you missed THE DAY BEFORE YESTERDAY (INDICATE WHICH DAY YOU ARE REFERRING TO - MON, TUE ETC.)? WRITE IN DRUG NAMES

		NAME OF DRUG	**Number of tablets missed**	**Reason for missing**
95.	Drug 1			
96.	Drug 2			
97.	Drug 3			
98.	Drug 4			

For each drug, can you tell me how many tablets, if any, you missed 3 DAYS AGO? (INDICATE WHICH DAY YOU ARE REFERRING TO - MON, TUE ETC.)? WRITE IN DRUG NAMES

		NAME OF DRUG	**Number of tablets missed**	**Reason for missing**
99.	Drug 1			
100.	Drug 2			
101.	Drug 3			
102.	Drug 4			

103.	**If you didn't miss any tablets in the last three days, when was the last time you missed any of your medications?**		**Within the last:** Week =1 2 weeks = 2 3 months = 3	More than 3 months ago = 4 Never missed = 5
104.	IF EVER MISSED TABLETS: **What is the longest time you have ever missed your tablets?**			INDICATE DAYS OR MONTHS

105.	**Do you belong to a support group?**		Yes=1, No= 0	**If NO, >Q115**
106.	IF YES**: How often do you attend?**		Weekly = 1 Monthly = 2 Occasionally =3	
IF YES, **What services are offered at the support group?** READ OUT EACH OPTION				
107.	**Advice and information on staying healthy e.g. nutrition, exercise and prevention**		Yes=1, No= 0	
108.	**ARV information: CD4 counts, ARVs, viral load**			
109.	**Treatment buddies**			
110.	**Help with collecting medicines from the clinic**			
111.	**Home visits**			
112.	**Food**			
113.	**Income generating activities**			
114.	**Individual counselling and emotional support**			
Do you receive any of the following help or support from your friends or family to help you take your tablets regularly? READ OUT EACH OPTION				
115.	**They visit you**		Yes=1, No= 0	
116.	**They send an sms or call you by phone**			
117.	**They give you food to take your pills with**			
118.	**They provide transport money to the clinic**			
119.	**They provide emotional support**			
120.	**Is there any other type of help that you receive?** Specify:……			
121.	**Are there people interested in buying ARVs?**		Yes =1, No=0 Don't know = -1	
122.	**Do you know of people who have sold their ARVs?**			
123.	**Has there ever been a month when you couldn't come to clinic for your monthly visit?**		Yes =1 No=0	**IF NO >135**
124.	IF YES, **how many times did you miss coming in the last 6 months, since _____** (MONTH)**?**			
IF YES, **What was the reason for skipping the appointment?** READ OUT EACH OPTION				
125.	**You were working**		Yes =1 No=0 Not relevant - 2	
126.	**You were sick**			
127.	**You forgot**			
128.	**You mixed up the dates**			
129.	**You were away out of town**			
130.	**You had no transport money**			
131.	**You had nobody to look after the children**			

132.	**You were afraid that somebody would see you and judge you negatively**			
133.	**You were afraid that your partner would find out and ask me to explain**			
134.	**Is there any other reason that made you miss your visit?** Specify reason:……..			
135.	**Can you tell me in your own words what a CD4 count is?** *WRITE DOWN WORDS HERE:*			
136.	**Can you tell me what your most recent CD4 count is?**		*Write in number given,* OR, Don't know = -1	
137.	**When are you due for your next CD4 count?**		MONTH AND YEAR	
SECTION 5: QUALITY OF CARE/PATIENT PROVIDER RELATIONSHIP				
I would now like to know about your experiences when at this clinic and how the health providers interact with you.				
138.	**Are you able to talk to the health workers in private?**		Yes = 1, No = 0	**If YES >Q140**
139.	IF NO, **does it bother you?**		Yes =1, No=0	
140.	**How many hours do you spend at the clinic at each visit?**		INDICATE HOURS	
I am going to read some statements about your meeting with the health workers today. Can you tell me whether you agree or disagree with these statements? IF THE PERSON CAN'T DECIDE CHOOSE NO VIEW/DON'T KNOW				
141.	**The queues to be seen by a doctor or nurse are too long at this facility**		Agree=1 Disagree=2 Agree and disagree=3 No view/don't know=4 Not relevant= -2	
142.	**The *health worker* DID'NT discuss the treatment fully with you, including how the treatment works and side effects.**			
143.	**It is a problem that the *health worker* DOESN'T speak your language**			
144.	**You find it difficult to tell the *health worker* when you have missed taking your tablets**			

145.	**You would not tell him/her because s/he would shout at you.**			
146.	**The *health worker* was too busy to listen to your problems**			
147.	**The *health worker* provided you with feedback on whether the drugs were working or not**			
148.	**The *health worker* understood the difficulty of taking the drugs and assisted you where possible**			
149.	**Some staff DO NOT treat patients with sufficient respect.**			
150.	**When I need to obtain other care that they cannot provide in this clinic, I was given enough help to get to the right place**			
151.	**The health workers I see care about me.**			
152.	**Since enrolling at this clinic/hospital, have you ever left without being helped**		Yes=1 No=0	**IF NO >Q154**
153.	IF YES, **why did you leave without being helped?** *WRITE FULL EXPLANATION*:			

SECTION 6: SOCIAL SUPPORT AND ACCEPTANCE

I would like you to tell me about the support your receive to help you cope with your HIV status and to take your ARVs.

154.	**Apart from the health workers, have you told anyone about your HIV status?**		Yes =1 No= 0	**If NO, > Q162**
IF YES, **whom of the following have you told about your HIV status?** READ OUT EACH OPTION				
155.	**Spouse / partner, if you have one**		Yes =1 No= 0 If no spouse = -2 Yes = 1, No = 0 Don't know =-1	
156.	**Family member**			
157.	**Friend**			
158.	**Neighbour**			
159.	**Religious leader**			
160.	**No-one**			
161.	**Is there another category of person to whom you have told your status we have not already mentioned?** Other (specify)----------			
162.	**Has your HIV status been disclosed to other people without your permission?**		Yes=1 No=0	
Do you keep your status secret for any of the following reasons: READ OUT EACH OPTION				
163.	**Fear of rejection by family**		Yes =1 No= 0	
164.	**Fear of rejection by friends**			
165.	**Fear of violence**			
166.	**I do not trust people**			

167.	**I will not get help from others if they know my status**			
168.	**Fear that I will be stigmatised**			
169.	**Fear that people will gossip about me**			
170.	**Fear that HIV my status will be known by the community**			
171.	**Fear that my partner will know and ask me to explain**			
172.	**Is there any other reason?** Specify ……			
I would like to ask you how supportive your family, friends and colleagues are towards you.				
173.	**How would you describe your partner's behaviour towards you, if you have a partner – supportive or unsupportive?**		Supportive=1 Unsupportive=2 Both supportive and unsupportive=3 Not relevant=4	
174.	**How would you describe the behaviour of your family towards you?**			
175.	**How would you describe the behaviour of your friends towards you?**			
176.	**How would you describe the behaviour of the people you live with towards you?**			
177.	**How would describe the behaviour of your work colleagues towards you?**			
SECTION 7: FOLLOW-UP				
We are planning to do a more detailed study, visiting a few patients in their homes to find out more about how they are coping the HIV and the treatment. Would you be willing to be part of that study? IF YES, WRITE NAME AND TEL NO ON SEPARATE PIECE OF PAPER			Yes=1 No = 0	

THAT IS THE END OF THE INTERVIEW DO YOU HAVE ANY QUESTIONS YOU WANT TO ASK ME?.....

DO YOU WANT TO ADD ANYTHING? WRITE IN SPACE BELOW OR ON BACK OF QUESTIONNAIRE……

MANY THANKS FOR YOUR HELP – WE REALLY APPRECIATE IT!

INTEVIEWER: PLEASE COMPLETE THESE QUESTIONS IMMEDIATELY AFTER THE INTERVIEW.	

178.	INTERVIEWER: How clear was the meaning of the respondent's answers		Good = 1 Average =2 Poor = 3	
179.	INTERVIEWER: How attentive was the respondent to the questions during the interview?		Good = 1 Average =2 Poor = 3	
180.	INTERVIEWER: What was your impression about this person's willingness to talk in more detail about their illness and how they are coping with it?		Willing = 1 Doubtful = 2 Unwilling = 3	

F. RECORDS REVIEW SHEET

Patient Adherence to ARV Treatment in Four Sites in Gauteng

RESPONDENT DATA CAPTURE SHEET

Name: Hospital/ Clinic: ……..

Client file Number

Date (Day/Month/Year)

D	**D**	**M**	**M**	**Y**	**Y**

FILE RECORD

Type of Data	**Information Required**		
Start date for ART treatment			
Date stopped treatment (If applicable)			
Total visits scheduled (April 2005 and March 2006)			
Actual Number of visits made during this period			
Last viral load count	*Date of current test*	*CD4 count*	*Next scheduled test*
Last CD4 cell count	*Date of current test*	*CD4 count*	*Next scheduled test*
Screening for TB	*Dale of screening*	*Result: Neg/Pos*	*Treated for TB (Yes No)*