RESEARCH ASSIGNMENT

PROJECT TITLE

Adherence of HIV/AIDS patients to antiretroviral therapy in a district hospital in Nankudu, Namibia.

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PROJECT TITLE

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Declaration

I, the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

Signature: .....……..... **Date: ..…….....”**

Print Name: .....

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ABSTRACT

Title

Adherence of HIV/AIDS patients to antiretroviral therapy in a district hospital in Nankudu, Namibia.

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Background:

Non-adherence to highly active antiretroviral therapy (HAART**)** is a strong predictor of progression to AIDS and death. It remains the most important potentially alterable factor that determines treatment outcome.

AIM:

The main purpose of this study is to determine the current frequency of adherence to HAART in a major HIV/AIDS treatment center in Nankudu District and to identify the local factors contributing to non-adherence.

OBJECTIVES:

To assess and measure the adherence to antiretroviral therapy.

To assess and describe the defaulter rate

To assess and describe the interruption rate

To describe the local barriers to sub-optimal adherence in the sample patients

Methods:

The study was a descriptive survey of the below mentioned three methods used to assess adherence to HAART and the determination of local barriers to adherence. The three methods used to measure HAART adherence were: pill counts, pharmacy refill data and self-report. The participants CD4 counts and viral loads were also evaluated. It included a randomly selected sample of 225 adult patients

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receiving HAART treatment in the Communication for Disease Control (CDC)-HIV clinic of Nankudu district hospital of Namibia.

Results:

A total of 90% of the patients had an adherence >95% comparable to those reported in most sub-Saharan Africa**.** The major local barriers to adherence included: distance from clinic (100%), lack of food (100%), lack of money (100%), poverty (100%), occupational factors-migration (100%), travel (81%), ran out of medicine (69%), too busy (69%), medication side effects (56%), felt better (56%) and too sick (50%). The major reasons given by the treatment defaulters were similar to those given by the treatment interrupters except for stigma (100%), compared to 19% for the treatment interrupter.

Conclusion:

The level of HAART adherence in the Communication Diseases Control (CDC)- HIV Clinic, of Nankudu District Hospital in Namibia is comparable to those reported in most sub-Saharan Africa, which is the recommended 95%. The pattern of non-adherence is characterized by treatment defaulters and interrupters. The study revealed that there were more treatment interrupters than defaulters. Financial constraints, travel, running out of ARV medicine, food insecurity, poverty, distance from the clinic, were the major reasons given by the treatment interrupters, while occupational factors, lack of transport, stigma, and long distance of the health facility were the major reasons given by the treatment defaulters.

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BACKGROUND AND MOTIVATION

Appropriate use of antiretroviral treatment (ART) has improved the health of many human immunodeficiency virus (HIV) positive individuals who otherwise may have died. Notably, the efficacy of any treatment depends on sustained high levels of adherence to ART. [1,2,3,4,5] ART regimens are often complicated and can include varying dosing schedules, dietary requirements, and adverse effects.[6]

Different levels of adherence have been reported in several countries in sub-Saharan Africa and North America.[5] In sub-Saharan Africa, concerns about adherence problems have been an important consideration in expanding access to antiretroviral therapy (ART).[5] Reports have proved that adherence to ART is better in sub-Saharan Africa than in North America.[7,5,8]

Although reported barriers to adherence are consistent across multiple settings and countries, studies had shown adherence levels and the profile of factors that influence it differ by settings[9-11]

Namibia is one of the Southern African countries that has one of the highest prevalence rates of HIV/AIDS infection which peaked at 22% in 2002 sentinel survey,[12] but now has decreased to 18.8% in the 2010 sentinel survey.[13] The Kavango region in which the Center for Disease Control (CDC) HIV Clinic of Nankudu hospital is situated had a similar prevalence of 18.8% in the 2010 sentinel survey.[13]

Despite adequate knowledge of HIV/AIDS and ongoing counseling sessions given to patients on ART receiving treatment at the CDC clinic of the Nankudu Hospital, adherence problems still persist.[14] This has necessitated the formal assessment of HAART in this area. To improve antiretroviral adherence, we conducted a cross- sectional survey of the social, cultural, personal, structural and economic determinants of treatment adherence.

LITERATURE REVIEW

The advent of highly active antiretroviral therapy (HAART) regimens have brought about a highly significant reduction in HIV related morbidity and mortality in recent years.[15] Unlike treatment for most chronic conditions, ART requires very high levels of adherence for an indefinite period to achieve the desired results.[16]

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Evidence shows that poor adherence to antiretroviral treatment regimens has serious consequences for HIV infected patients, including treatment failure, viral replication, the development of clinical complications and shortened survival.[17-19]

This review focuses on the discussion and comparison of various measures of treatment adherence, and a description of barriers to and predictors of treatment adherence, and a commentary on strategies to improve treatment adherence. [20]

Currently HAART adherence can be measured by researchers using the following methods: data obtained from patients, providers, pill bottles, pharmacy records, electronic devices, biochemical assays, or combinations of these sources. To date, there is no established "gold standard" for measuring adherence [20]

The abovementioned mentioned approaches have distinctive benefits and drawbacks. But, only the patient self report, pill bottles count, pharmacy records and electronic devices will be discussed below.

Estimates of treatment adherence from patients' self reports are less complex to obtain than other methods. It is subject to recall and/or social desirability bias. All forms of self-report inevitably overestimate adherence compared with other treatment adherence measures.[19,21]

Treatment adherence can also be measured by having the pharmacist or a designee count the number of pills remaining in one bottle. Unfortunately, pill counts are time consuming and determining the date when the patient commenced the current prescription(s) can be difficult, especially when patients combine all their medications in one bottle. Although pill count is less subjective than self reporting, inaccuracies occur when patients remove pills from their bottles without taking them ("pill dumping'') to appear more adherent when counts occur. Unannounced pill counts have been adopted to limit this behaviour. Patients may also forget their pill bottles, separate pills into weekly organizers, or use different formulations of the same medication that may appear to be different medications[22]

The pharmacy based method examine the rate of refilling medications over a period of more than 2 months.[23]This method is based on a straightforward premise that when a patient does not receive timely refills of a drug from the pharmacy, he or she is either not taking medications between refills or is missing doses such that a given prescription takes longer than it should. The strengths of this approach are that it is not susceptible to reporting bias or tampering and offers population based information. [23]

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Electronic monitors offer a more objective measure of treatment adherence than do self reports. However, the cost of these devices limits their use in non-research settings, and the caps can malfunction or get lost. Decanting (removing >1 dose at a time) or loosening the caps to make it easier to remove pills has been shown to be a common problem in studies using electronic monitors. [24]

Generally, the factors that influence adherence to antiretroviral therapy (HAART) fall into three categories namely: patient-related (psychosocial and educational) factors, patient- provider factors (interaction with physicians and other health workers and access to medications) and clinical factors (pill burden, dosing frequency and adverse effects of medications).[25,26] Physical and psychological distress amidst financial constraints and stigmatization as well as conflicting messages from health care providers and religious authorities may form significant barriers to sustained HAART adherence and medical care. Furthermore, medication side effects, behavioral factors (forgetting doses, stopping medications when symptoms disappear) confidentiality, occupational factors, illiteracy, long distances to HIV/AIDS care centers may contribute to major barriers to HAART adherence.

Defaulting or interruption of treatment is one of the most important problems in the management of HIV/AIDS. Low adherence can result in cross-resistance to other antiretroviral medications[27] which potentially interfere with future therapeutic option for those being treated and those who subsequently become infected with resistance virus.[28] Ninety- five percent adherence to antiretroviral medication regimen is often needed to achieve optimal rates of viral suppression in people living with HIV/AIDS. Even so, there is often undetectable viral load in approximately 80% of patients. [29] Adherence level of 95% implies that a patient taking a twice daily regiment cannot miss more than 3 doses per month. This can be more difficult than it might seem particularly if the need to refill prescriptions every month, to have medications available when working and traveling, and to avoid side effects of medication are considered.[30]

AIM:

The main purpose of this study is to determine the current frequency of adherence to HAART in a major HIV/AIDS treatment center in Nankudu District and to identify the local factors contributing to non-adherence.

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OBJECTIVES:

To assess and measure the adherence to antiretroviral therapy.

To describe the local barriers to sub-optimal adherence in the sample patients

To assess and describe the defaulter rate

To assess and describe the interruption rate

METHODS

Study design: Descriptive cross-sectional survey

Setting

A descriptive cross-sectional survey was conducted over six months to assess and measure adherence rate and to identify those local factors that impede on optimal HAART adherence among patients attending the Center for Disease Control (CDC) HIV outpatient clinic of Nankudu hospital in Namibia. Nankudu District Hospital in Kavango region of Namibia, with a 120 bed capacity, serves as a referral hospital for four community health centers and 10 primary health care clinics. Its CDC-HIV clinic provides HAART services free of charge**.** When there are no complications, patients attend the clinic on a monthly basis for HAART refill and every six months for CD4 count test plus other essential laboratory tests monitoring as well as viral load test six months after HAART initiation and when necessary.

Sample selection

CDC-HIV clinic had in its computerized database about 1500 registered patients on HAART programme by the first quarter of 2010. Based on the 1500 registered patients on HAART, a calculated 240 sample size was obtained. Included in the sample were male and female (18-60 years old) outpatients diagnosed to be having HIV/AIDS (using both laboratory and clinic data) that were attending HIV/AIDS clinic between January 2006 and March 2010, and refilling their prescriptions in the pharmacy section of Nankudu District Hospital. All the patients had been on HAART and were regular at the clinic for not less than 6 months prior to the study and had consented to participate in the study. The study participants, who met the inclusion criteria, were randomly selected as they came to refill their prescriptions during the

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Mon- Fri clinic days. Fifteen of the study participants who did not complete the study, due to relocation to a different region of the country were not included in the computed adherence data. Participants excluded in the study sample, were those with a history of serious cardiovascular illness, diabetes and/or cancer (excluding non-melanoma skin cancer) within the previous 2 years. The exclusion of people with chronic disorders was because the severity and stress of their medical conditions; in addition, to associated negative emotional factors might compromise their ability to give voluntary informed consent

Ethical considerations

The Research question which has never been carried out in the region/districts, will identify barriers to optimal HAART adherence and make recommendations which will help the relevant health authority to draft policy that will overcome the identified obstacles to HAART adherence in HIV patients on treatment at the Center for Disease Control (CDC) HIV clinic of Nankudu District Hospital of Namibia.

The planned design and methods were well thought-through; and the planned sample sizes and the statistical analysis plan were in accordance with the directives received from the statistical services of the University of Stellenbosch.

The study population included: both female and male gender; those on treatment with antiretroviral medications for HIV infection; as well as, participants that speak English or the local language Kwangali. The randomly selected study population was not vulnerable in any way: being participants whose ages make them competent to consent. Patients were excluded if they have a history of serious cardiovascular illness, diabetes and/or cancer (excluding non-melanoma skin cancer) within the previous 2 years. The exclusion of people with chronic disorders was because the severity and stress of their medical conditions; in addition, to associated negative emotional factors might have compromise their ability to give independent informed consent. However, pregnant women have been included as study participants, since there were no risks to the foetus and the mother but rather for the health benefit and best interest of the mother and the foetus.

No imaginable risks and discomfort were anticipated for the study patients. However, any participant who might have experienced discomfort , was anxious or afraid at any point of the study would have been withdrawn from the study and would have been referred to a counselor, to enable him/her to return to normal emotional state and routine health care.

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The research was submitted to the Health research ethics committee, University of Stellenbosch and the hospital management of my facility for independent ethical review and officially approved.

Participant autonomy was respected by: adequate informed consent, confidentiality, truth telling and good communication. Confidentiality was achieved by ensuring the collection and storage of data had code numbers as a patient identification, but the key that linked the code number to the patient was kept by a third party that was not directly involved in the research.

Privacy was protected by conducting the interviews in a separate office room in the hospital where the conversation could not be overheard. Participation was entirely voluntary and participants were free to withdraw without explanations and without compromise of their routine health care

Instruments

The standard structured questionnaire {validated Adult AIDS Clinical Trial Group Adherence Instrument (ACTG)} [31] was modified and used for the collection of socio-demographic and information on adherence. The questionnaire contained open –ended and/or closed questions. The questionnaire was piloted on 20 study participants and the resultant data were not included in the final computed data reported.

Treatment variables were obtained from the medical records. Clinical variables such as patients HIV status , CD4 counts , viral load results were also obtained from patients' medical records. Patient counseling was done for each patient every month when they came to refill their prescriptions using standard procedure.

Operational definitions:

- **Adherence**: With respect to HIV/AIDS care specifically, medication adherence has been defined as the ability of the people living with HIV/AIDS(PLWHA) to be involved in choosing, starting, managing and maintaining a given therapeutic combination regimen to control viral (HIV) replication and improve immune function [32]
- **Optimal adherence:** This is the level of adherence needed to maximally suppress viral replication in patients receiving HAART estimated to be at least >- 95%.[29]
- T**reatment interrupter**: HAART patients that miss their treatment for more than 2 weeks and less than 8 weeks but were adherent to the medications when they had the medications.[33]

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- **Treatment defaulter**: HAART patients that miss two consecutive clinic visits or had interrupted treatment for eight consecutive weeks.[33]
- **Virologic failure**: This is defined in the Namibian national antiretroviral (ART) guideline as a viral load(VL)>1000copies/ml 24 weeks after starting HAART or viral rebound to> 1000copies/ml on two consecutive measurements after a period of viral suppression.[33]

Outcome measures

Adherence to HAART medication was assessed at the end of each month for 6 months using pill counting, patient self-reporting and pharmacy refill medication records.CD4 count test was done at the final (6^{th}) month of the study to confirm or rule out any immunological failure. Viral load test was done when there was immunological failure and/or clinical failure.

In the first method, pharmacy medication records for patients were matched by the pharmacist against the not-yet-used medicines brought to the pharmacy by the patients as a routine for refill of prescriptions by patients and the number of doses that ought to have been taken that were missed were recorded.

Patients self -reporting method was carried out as previously described by Weiser S, Wolfe W, Bangsberg D, Thior I, Gilbert P, and Makhema J. Kebaabetswe P, Dickenson D, Mompati K, Essex M, Marlink R. [26] After normal consultation, the consented patients were taken to a designated private room within the clinic where the interviews were conducted. In this method, patients were interviewed with a standard questionnaire, about their adherence over the previous day, previous week and previous months successively in an attempt to minimize recall bias. The principal researcher and other research assistants interviewed the participants in the local language of Rukwangali with the help of a trained assistant fluent in the local language. The questionnaire was a modified version of the validated Adult AIDS Clinical Trials Group[31]

In the pharmacy medication refill HAART patient records, the rate of HAART refill medications was determined every month for each patient through out the studied period. Each participant follow –up date for refill prescriptions was checked each month throughout the study period. In each of the methods, the average adherence was determined and the data compared with those reported from studies conducted in other parts **of** sub-Saharan Africa. [34-39]

Access to medicines was evaluated by examining pharmacy records of antiretroviral drugs and other medicines (antibiotics, and multivitamins/haematinics) often prescribed by the attending physicians for

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the patients. The average stock-out duration (SOD) for the medicines was evaluated as the average number of days in the 6 months study period, each medication was out -of –stock. In order to introduce availability of the medicines for each patient, stock out duration for patients in the treatment center SODpt and at home (SODph) were introduced as the average number of days per patient the required medicines could not be dispensed to each patient in the treatment center (SODpt) because of stock-out (SODpt) or available for use at home (SODph). Patients who ran out of their medicines at home were interviewed with the questionnaire on the reasons why the medicines were not available for use at home. The reasons for any stock- out of medicines in the treatment center were obtained from the pharmacy records.

RESULTS

Of the 240 patients recruited for the study, with written informed consent, 15 (6.25%) of them did not complete the study due to relocation to other regions of the country for employment and social reasons and were consequently excluded. Therefore, 225 (93.75%) study participants completed the study.

Section 1

Demographic and Treatment Data

The demographic data are summarized in Table 1. The majority (65%) of the study participants were females, consistent with the prevalent statistics of more female enrolment in HAART treatment in the health facility. About 51% males and 18% females were married, 24% females and 3% males were widowed, 21% males and 44% female were single. While the same percentage of 15% of males and of females were cohabiting. Christianity was their major religion. While as many as 25% of them had no dependants, some (11%) study participants had between 5 and 12 dependants. The majority of the study participants had primary education-67% males and 59% females respectively, while the rest of the study participants educational achievements were as stated- 33% males and 38% females had secondary education, 3% had no formal education and none of them (0.0%) had tertiary education. About 41% males and 65% females were peasant farmers, while 88% were unemployed. Only 6% (3% males and 3% females) of the study participants were engaged in retail trading and none (0.0%) stated being a civil servant or self- employed. The majority of the study participants - 55% males and 85% females drank alcohol before HAART initiation as compared to- 10% males and 1% females that still drink alcohol after HAART initiation. About 14% of the males and 5% of the females had a history of smoking before HAART initiation, as compared to 6% males and 0% females that still smokes after HAART initiation.

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Table 1. Demographic data of the study participants

Characteristics	Male (%)	Female (%)
Ages(y) Range 18- 30 30-49 ->50 Total Grand total(226)	 36 (46) 23 (30) 19 (24) 78 (100)	 85 (58) 46 (31) 16 (11) 147 (100)
Religion		
Christianity Traditional/no religion	70 (90) 8 (10)	145 (99) 2 (1)
Marital status		
Single Married Widowed Separated Divorced Cohabiting	16 (21) 40 (51) 2 (3) 5 (6) 3 (4) 12 (15)	44 (30) 27 (18) 35 (24) 12 (8) 7 (5) 22 (15)
No. of dependants(adults &children		
0 1-2 3-4 5-10 >10	6 (8) 13 (17) 14 (18) 2 (3) 1 (1)	23 (17) 20 (14) 13 (9) 10 (7) 0 (0.0)
Level of education		
No formal education Primary Secondary Tertiary	0 (0.0) 52 (67) 26 (33) 0 (0.0)	5 (3) 86 (59) 56 (38) 0 (0.0)
Occupation		
Peasant farmer Retail trader Self employed Civil servant Un-employed	32 (41) 2 (3) 0 (0.0) 0 (0.0) 44 (56)	95 (65) 5 (3) 0 (0.0) 0 (0.0) 47 (32)
Substance habits:		
Prior alcohol Prior smoking Current alcohol Current smoking	43 (55) 11 (14) 8 (10) 5 (6)	125 (85) 8 (5) 2 (1) 0 (0.0)

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Section 2
Clinical variables

The clinical variables are summarized in tables 2- 4. The CD4 counts for 65% of the patients included in this study were higher than 200 cell/microlitre. The study participants with counts below 50cells/microlitre were on the minority (11%). At the end of the six(6) months study period, 59% of the 78 males and 63% of the 147 females study participants had a much higher immunologic response with a CD count of >350cells/microlitres respectively, while as few as 1% male and 3% females(4%) had an immunologic failure with a CD4count of <100cells/microlitres respectively. The 4% of the study participants who had immunologic failure, had their viral loads(VL) tested; a concordance virologic failures of 3% and 1% (total 4%)were detected with the results of >1000-10000copies/ml and >10000copies/ml respectively.(VL <1000copies/ml is undetectable according to the current Namibian ART national guideline).[33] Out of this 4% of the virologic failures, 3% are the treatment defaulters while 1% belong to the treatment interrupters.

Table 2. Gender distribution and baseline CD4count among study participants.

Variable	Male (%)	Female (%)
CD4 count (baseline)		
<50	20 (26)	4 (3)
100-200	40 (51)	15 (10)
>200	18 (23)	128 (87)
Total	78 (100)	147 (100)

Table 3. Gender Distribution and Immunological(CD4count) response evaluation among study participants on HAART

Variable	Male (%)	Female (%)
CD4 count		
<100	1 (1)	4 (3)
200-350	31 (40)	51 (35)
>350	46 (59)	92 (63)

Table 4. Gender distribution and Viral Load response evaluation among study participants on HAART

Variable	Male (%)	Female (%)
Viral Load		
<1000copies/ml	77 (99)	143 (97)
>1000-10000copies/ml	1 (1)	3 (2)
>10000copies/ml	0 (0.0)	1 (1)

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Section 3

Treatment variables

At the time of recruitment for the study, all the patients were on first line HAART regimen. However, 4% of the study participants were switched to second line HAART regimen of Tenovofir+ Zidovudine+ Lamivudine+Lopinavir due to poor response to the first line medications (virologic failure) at the end of the 4th month of the six months study period, while the rest of the study participants-99% males and 97% females continued with their first line therapy throughout the study period. The percentage proportions of the study participants that used the 6 different first line antiretroviral medication combinations in the study were roughly as stated:- 45% females and 52% males -Zidovudine/Lamivudine/Nevirapine, 19% females and 19% males -Zidovudine/Lamivudine/Efavirenz, 18% females and 7 males-Tenovofir/Lamivudine/Nevirapine, 6% females and 8% males -Tenovofir/Lamivudine/Efavirenz), 8% females and 8% males-Stavudine/Lamivudine/Nevirapine and 4% females and 6% males -Stavudine/Lamivudine/Efavirenz. All the study participants received routine multivitamins while 79% of the study participants with a CD4 count of < 350cells/microlitre received routine cotrimoxazole prophylaxis.(patients with a CD4 count of<350 shall be placed on Cotrimoxazole prophylaxis- Namibian national ART guideline.[33]).

Section 4
Adherence to antiretroviral therapy

The result of the assessment of adherence to HAART is summarized in Table 5
A total of 90% of the study participants were adherent by self -report, based on the definitions of adherence which is, completing -> 95% of the prescribed doses each month. In addition, 7% of the study participants interrupted treatment, based on the definitions of treatment interruption which is, missed treatment for more than 2 weeks and less than 8 weeks but were adherent to the medications when they had the medications. In addition, 3% of the study participants defaulted in their treatment as defined which is, missed two consecutive clinic visits or had interrupted treatment for eight consecutive weeks. However, according to the pharmacist assessment of adherence of the study participants; 80% were adherent based on the definition of adherence as stated above, 12% defaulted in their treatment based on the definition of treatment defaulter as stated above, 7% interrupted their treatment based on the definition of treatment interruption as stated above. Although the estimates of treatment interruption by patient self-report and pharmacist assessment were the same (7%); however, there were disagreement about which proportion of study participants were able to adhere to treatment and which proportion of study participants defaulted in treatment. We latter found that, out of the 12% of the study participants said to

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have defaulted in their treatment by the pharmacist assessment, only 3% truly defaulted in their treatment, which is in agreement with the defaulter rate of 3% by patient self -report. This 3% that defaulted treatment were seasonal farm workers that usually temporarily migrate to harvest grapes in different farms in another distant regions of the country for a period of 3 to 5months. The reason for their defaulting is as result of their inability to refill their medications due to multiple factors (summarized in Table 6b) ranging from: fear of the consequences of the disclosure (stigma-discrimination and/or loss of employment) to the farm owners of their reason for the hospital visit, long distance to the nearest health facility, lack of easy availability of transport and lack of money for the transport if the transport is found. The remaining 9% said to have defaulted treatment by the pharmacist assessment did not default treatment. We found out that 7% of them traveled and therefore missed their appointment with the pharmacist, but collected their refill medications at a nearby health facility. The remaining 2% choose to have their refill medications at the private health facilities for convenience and availability of funding. At last, these findings brought about the concordance in adherence and defaulter rates assessment by patient self- report and the pharmacist assessment.

Table 5. Patients and Pharmacy reports on adherence

Findings	Numbers (%)
Patient self-report of adherence(n=225)	
Adherent*	203 (90)
Treatment defaulter!	6 ((3)
Treatment interrupter+	16 (7)
Pharmacist assessment of adherence(n=225)	
Adherent*	181 (80)
Treatment defaulter!	28 (12)
Treatment interrupter+	16 (7)

* Defined as completing->95% of prescribed doses
! missed two consecutive clinic visits or had interrupted treatment for eight consecutive weeks.
+ missed their treatment for more than 2 weeks and less than 8 weeks but were adherent to the medications when they had the medications.

Section 5

Principal local barriers to HAART Adherence

In assessing the local barriers to treatment adherence, both open-ended and structured questions were posed. The results of the local barriers to treatment adherence are summarized in Table 6a and 6b**.** The

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commonest reasons given for interrupting treatment were lack of food (100%), lack of money (100%) and poverty (100%). Other reasons included: travel (81%), too busy (69%), ran out of medicine (69%), distance from the clinic (100%), side effects (56%), and felt better (56%) and too sick (50%). The commonest reasons given for defaulting treatment included: travel and migration (100%), stigma (100%), distance from the health facility (100%), ran out of medicine (100%), and lack of transport (100%) Others included: lack of finances (33%) and too busy (67%).

Table 6a: Local barriers to interrupting treatment.{treatment interrupters+(n=16)}

Findings	Number(%)
Lack of food	**16 (100)**
Ran out of medicine	**11 (69)**
Travel	**13 (81)**
Side effects	**9 (56)**
Too busy	**11 (69)**
Distance from clinic	**16 (100)**
Too sick	**8 (50)**
Misunderstood doctor	**5 (31)**
Stigma	**3 (19)**
Alcohol	**1 (6)**
Felt better	**9 (56)**
Stresses at home/work	**1 (6)**
Too many pills	**1 (6)**
Poverty	**16 (100)**
Lack of money	**16 (100)**

+ missed their treatment for more than 2 weeks and less than 8 weeks but were adherent to the medications when they had the medications.

Table 6b: Local barriers to defaulting treatment { treatment defaulters!(n=6)}

Findings	Numbers (%)
Finances	2 (33)
Ran out of medicine	6 (100)
Travel and migration	6 (100)
Too busy	4 (67)
Distance from hospital	6 (100)
Stigma	6 (100)
Lack of transport	6 (100)

! missed two consecutive clinic visits or had interrupted treatment for eight consecutive weeks.

Section 6

Access to medicines

In the CDC-HIV clinic, patients receive ARVs free of charge. The average stock out duration for each of the antiretroviral medications, multivitamins and or haematinics/ Cotrimoxazole often prescribed for the

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patients during the 6 months period was zero. Similarly, the mean number of days the medications could not be dispensed in the clinic was zero. However, 69% of the treatment interrupters ran out of their medicines at home while 100% of treatment defaulters ran out of their medicine, when they migrated for their seasonal harvesting of grapes in other distant regions of the country. Lack of money for transport (100%) and too busy (69%) were the reasons given by the treatment interrupters, while lack of money (33%), unavailability of transport (100%), and too busy (67%) were among the reasons given by the treatment defaulters.

DISCUSSION

The data suggest that HAART adherence rates among the patients studied are comparable with HAART adherence rates in most sub-Saharan Africa.[34-37] . However, in contrast to this survey findings, some studies in few sub-Saharan Africa reported a lower adherence rates among their study participants.[38,39] This result is consistent with reports that, although reported barriers to adherence are consistent across multiple settings and countries, the adherence levels and the profile of factors that influence it differ by settings.[9-11]

Measuring the adherence by patient self-report, pill counting, and pharmacy refill medications and validated by CD4 count and viral load testing, showed that 90% of the patients were adherent with 95% of prescribed doses. Patients in this study had to overcome great odds (they lacked funds for transport, food insecurity, not easily availability of transport etc.) to adhere to treatment by often using carts driven by cows for transport to the clinic, often had to travel great distances by trekking on their feet at the danger of wild animals, to the CDC-HIV clinic to receive HAART medications, borrow money for transport and take medications without eating food. The results suggested by this study may be attributed mostly to the existence of excellent provider-client interaction in the CDC-HIV clinic.[14] Evidence suggest that good counseling at an HIV clinic is important in improving adherence.[40] Randomized controlled trials in Europe and the United States have also confirmed that dedicating time to individualized counseling and education increases patients' sense of self-worth and efficacy.[41-43]

For many patients, optimal adherence to antiretroviral therapy is often difficult to achieve for reasons ranging from patient factor to patient-health professionals relationship and clinical factors.[44,25,26] Most of the factors identified in our study for treatment interruption and defaulting (financial constraints, medication adverse effects and occupational factor) have been reported in previous studies carried out.[45,28,46]

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We also found that the two groups of non-adherent patients {treatment interrupters (7%) and the treatment defaulters(3%)} were overall 10%. The commonest reasons for both interrupting and defaulting treatment were due to varying degrees of poverty (lack of money, lack of food and inability to afford medication) for varying periods of time the overall socio-economic situations (as defined: lack of money, poverty and lack of food) and inability to afford medications for varying period of time

Although the patients studied received free antiretroviral medications, the positive effect of free treatment is often offset by indirect transportation costs in areas in which the patients live far away from health facilities. This is consistent with findings in other studies on patients that received free antiretroviral medication.[47]

The decentralization of HAART services and task shifting to the primary health care centers and clinics will alleviate the patients' problems of lack of transport, lack of money for transport, depleted medication stock, too busy, long distance to the clinic, as well as alleviate the problems of capacity at the CDC-HIV clinic and various other major HAART clinic centers. This is consistent with the findings of studies done in most major HAART clinics centers in South Africa.[48-50]

There is now considerable evidence across Africa of the feasibility of integrated district-based approaches that achieve universal access while maintaining quality and outcome.[51-53]However, a rapid transfer of large numbers of patients can overwhelm minimally staffed health centers and clinics, if appropriate steps are not taken. In addition, to the increased workload, clinic staff may not feel confident enough to carry out their new responsibility, particularly if training and supervision mechanisms are not adequately provided. Furthermore, providing HAART at the primary health care clinic level increases the number of entry points to care while the greater proximity of services encourages retention in care.[49]

Overall, the virologic failure was present in only 4% of the study participants, a much lower proportion than the average rate in South Africa, which ranges between 10% and 16%. [55] Not surprisingly, the proportion of patients with virology failure were present only among both groups of HAART non-adherent (treatment interrupters and defaulters) resulting to adherence levels of less than 95%, with its associated consequences of the susceptibility to virologic failure.

Short-term and long-term adverse reactions (can be early and transient or evident with more prolonged use) have been identified with all of the available antiretroviral agents. [32] The occurrence of side effects

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was a common regimen factor affecting adherence in our study, similar to previous findings elsewhere.[51,56 ,46, 28]

HIV stigma was more in the treatment defaulters than the treatment interrupters. A total of 100% of treatment defaulters believed that stigma impeded their ability to take treatment in contrast to 19% of treatment interrupters. Other factors that were predictive of non-adherence were 'being too sick' (50%) and were 'hospitalized' in a traditional healing home as well as 'felt better' (56%).

The strength of our study was to corroborate patient self -report of adherence with CD4 cell count and viral load responses. The weaknesses of our study were not ascertaining why stigma was more in the treatment defaulters than the interrupters. In addition, we did not ascertain the degree of the repercussions of stigma on the study participants as well as not determining if the following factors-, educational status, marital status, number of dependants, psychological distress, adverse life events, religion and types of occupation affected their HAART adherence. These weaknesses will serve as a stimulus for future research in this setting.

Our limitations-financial constraints and logistical barriers impacted negatively on the sample size. Consequently, the patients in our study may not be a true representative of the broader population of HIV – positive individual. Another limitation of this study is that we were unable to carry out HIV viral load test on all study participants because the National guideline stated only those patients with clinically and/or immunological evidence of failure should have their viral load tested, Consequently, the study may have underestimated the percentage of patients with virologic failure.

CONCLUSION

The performance of the CDC-HIV clinic in Nankudu district hospital in relation to HAART adherence was good. It is comparable to the levels previously reported in most sub-Saharan Africa. Financial constraints, long distances to the clinic medication side effects, confidentiality, occupational factors/migration and stigmatization were the major factors accounting for non-adherence. The pattern of adherence among the studied population, characterized by treatment defaulters and interrupters rather than day to day adherence, reflects the presence of socio-economic effects, medication adverse effects and structural barriers.

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RECOMMENDATIONS

Programs (decentralization of HAART services to the primary health clinic and health centers) that will take medicines near the door step of the poor patients are recommended. Moreover, medication related factors can be remedied by the selection and procurement of ARVs with a better frequency of administration and side-effects profile. Furthermore, three – six monthly supply of medications will remedy the situation of those patients that encounter great difficulty in refilling their medications. Equally important, improving their socio-economic situations and minimizing identified structural barriers will enhance optimal HAART adherence These recommended strategies, if implemented, should improve adherence and, consequently, treatment outcomes for patients receiving therapy in the CDC-HIV clinic and other major HAART clinic centers in the country.

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REFERENCES

1.Deeks SG, Smith M, Holodniy M, Kahn JO. HIV-1 Protease Inhibitors. A review for clinicians. *JAMA.* 1997 Jan 8;**277(2):**145-53.

2.Saag MS, Schooley RT. Antiretroviral Chemotherapy. *Curr Clin Top Infect Dis.* 1998;**18:**154-79.

3. Altice FL, Mostashari F, Friedland GH. *J.* Trust and the acceptance of and adherence to antiretroviral therapy. *J. Acquir Immune Defic Syndr.* 2001Sep 1;**28(1)**:47-58.

4.Mannheimer SB, Matts J, Telzak E, Chesney M, Child C, Wu AW, et al. Quality of life in HIV-infected individuals receiving antiretroviral therapy is related to adherence. *AIDS Care*. 2005;**17(1)**:10-22.

5.Mills EJ, Nachega JB, Buchan I, Orbinski J, Attaran A, Singh S, et al. Adherence to Antiretroviral Therapy in Sub-Saharan Africa and North America: A Meta-analysis. *JAMA*. 2006;**296(6):**679-690.

6.Ferguson TF, Stewart KE, Funkhouser E, Tolson J, Westfall AO, Sagg MS. Patient-perceived barriers to antiretroviral adherence: associations with race. *AIDS Care*. 2002 Oct;**14(5)**:607-617.

7. Kaiser HJ. African HIV/AIDS patients show better adherence to antiretroviral drug regimens than US counterparts: In Kaiser Daily HIV/AIDS Report. Available from:URL://www.kaisernetwork.org/dailyreports/hiv. 2003 Sept 3.(Accessed March 15,2009)

8.Ware NC, Idoko J, Kaaya S, Biraro IA, Wyatt MA, Agbaji O, et al. Explaining Adherence Success in Sub-Saharan Africa: An Ethnographic Study. *PloS Med*. 2009 Jan 27; **6(1):**e11

9.Wagner GJ, Kanouse DE, Koegel P, Sullivan G. Adherence to HIV antiretroviral among persons with serious mental illness. *AIDS Patient Care STDS*. 2003 Apr;**17(4)**:179-186.

10 Howard AA, Arnsten JH, Loy, , Vlahov D, Rich JD, Schuman P, et al. A prospective study of adherence and viral load in a large multi-center cohort of HIV infected women. *AIDS.* 2002 Nov 8; **16(16):**2175-2182.

Stellenbosch University https://scholar.sun.ac.za

11.Mcnabb J, Ross JW, Abriola K, Turley C, Nightingale CH, Nicolau DP. Adherence to highly active antiretroviral therapy predicts virologic outcome at an inner-city human immunodeficiency virus clinic. *Clin Infect Dis.* 2001 Sep 1; **33(5):700**-5.

12. Namibia Ministry of Health and Social Services (NMOHSS): Report of the 2002 National HIV Sentinel Survey

13. Namibia Ministry of Health and Social Services (NMOHSS) : Report of the 2010 National HIV Sentinel Survey.

14.Nankudu District Hospital-CDC HIV Clinic: Annual report 2008.

15.Hogg RS, Heath KV, Yip B, Craib KJ, O'Shaughnessy MV, Schechter MT, et al. Improved survival among HIV infected individuals following initiation of antiretroviral therapy. *JAMA* 1998 Feb 11;**279:**450-4.

16. Chesney MA. The elusive gold standard: future perspectives for HIV adherence assessment and intervention *J Acquir Immune Defic Syndr*.2006 Dec1;**43.Suppl 1**:S149-55.

17. Miller LG, Hays RD. Adherence to combination antiretroviral therapy : synthesis of the literature of the literature and clinical implications. *AIDS Read* 2000; **10:**177-85.

18. Gifford AL, Bormann JE, Shively MJ, Wright BC, Richman DD, Bozzette SA. Predictors of self-reported adherence and plasma HIV concentrations in patients on multidrug antiretroviral regimens. *J Acquir Immune Deficiency Syndr* 2000;**23**:386-95.

19. Arnsten JH, Dermas PA, Farzadegan H, Grant RW, Gourevitch MN, Chang CJ, et al. Antiretroviral therapy adherence and viral suppression in HIV infected drug users: comparison of self report and electronic monitoring. *Clin Infect Dis* 2001;**33**:1417-23.

20. Turner BJ. Adherence to antiretroviral therapy by Human Immunodeficiency Virus-infected patients. *J. Infect Dis* 2002 May 15;**185 (Suppl 2):**S143-51.

Stellenbosch University https://scholar.sun.ac.za

21. Melbourne KM, Geletko SM, Brown SL, Willey- Lessne C, Chase S, Fisher A. Medication adherence in patients with HIV infection: a comparison of two measurement methods. *AIDS Read* 1999;**9(5)**:329-38

22.Dixon WM, Stradling P, Wootton IDP. Outpatient P.A.S therapy. *Lancent* 1997;**2**:871-2.

23 Steiner JF, Prochazka AV. The assessment of refill compliance using pharmacy records: methods, validity ,and applications. *J Clin Epidemiol* 1997;**50**:105-16

24. Wendel CS, Mohler MJ, Kroesen K, Ampel NM, Gifford AL, Coons SJ. Barriers to the use of electronic adherence monitoring in an HIV clinic. *Ann Pharmacother* 2001;**35**:1010-5.

25.Esch LD. Issues in human immunodeficiency virus (HIV) pharmacotherapy practice: The emerging role of pharmacotherapy specialists in enhancing antiretroviral success. *J. Informed. Pharmacother*. 2001; **4:306**-316.

26.Weiser S, Wolfe W, Bangsberg D, Thior I, Gilbert P, Makhema J, et al. Barriers to antiretroviral adherence for patients living with HIV infection and AIDS in Botswana. *J. Acquir Immune Defic Syndr*. 2003 Nov 1; **34(3):281**-8.

27. Leake H, Horne R. Optimizing adherence to combination therapy. *J. HIV ther*. 1998; **3:67**-71.

28 Nwauche CA, Erhabor O, Ejele OA, Akani CI. Adherence to antiretroviral therapy among HIV-infected subjects in a resource limited setting in the Niger Delta of Nigeria. *Afr.J. Health Sci*. 2006; **13(3-4):**13-7.

29. Paterson DL, Swindells S, Mohr J, Brester M, Vergis EN, Squier C, et al. Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. *Ann Intern Med* 2000 Jul 4;**133(1)**:21-30.

30. Hardy WD. New strategies: Optimizing antiretroviral therapy for treatment experienced patients. *IMedOptions.* LLC, USA. 2003. p. 1-24.

Stellenbosch University https://scholar.sun.ac.za

31.Chesney MA,Ickovics JR, Chambers DB, et al. Self-reported adherence to antiretroviral medications among participants in HIV clinical trials: The AACTG adherence instruments. Patient Care Committee and Adherence Working Group of the Outcomes Committee of the Adult AIDS Trials Group (AACTG). *AIDS CARE* 2000 Jun; **12(3):255**-266.

32.Ammassari A, Trotta MP, Murri R. Correlates and predictors of adherence to highly active antiretroviral therapy: overview of published literature. *J Acquir Immune Defic Syndr.* 2002; **31** (Suppl 3): S123-127.

33. Namibia Ministry of Health and Social Services. National Guidelines for Antiretroviral Therapy. Windhoek, Namibia: Directorate of special programmes; 2010.

34. Mohammed MD, Sarki R. Adherence to antiretroviral drugs in North Central zone of Nigeria. *East and Central African Journal of Pharmaceutical Sciences*. 2004; **7(3):**52-55.

35. Orrel C, Bangsberg DR, Badri M, Wood R. Adherence is not a barrier to successful antiretroviral therapy in South Africa. *AIDS* 2003 Jun 13;**17(9):**1369-75.

36. Nachega JB, Stein DM, Lehman DA, et al. Adherence to antiretroviral therapy in HIV infected adults in Soweto, South Africa. *AIDS Res Hum Retroviruses*. 2004;**20(10)**:1053-1056.

37.Diabate S, Alary M, Koffi CK. Determinants of adherence to highly active antiretroviral therapy among HIV- infected patients in Cote d' Ivoire. *AIDS.* 2007 Aug 20:**21(13)**:1799-803.

38.Chabikuli NO, Datonye DO, Nachega J, Ansong D. Adherence to antiretroviral therapy, virologic failure and workload at the Rustenburg Provincial hospital, South Africa. *SA Fam Pract*. 2010; **52(4):**350-355.

39.Erah PO, Arute JE. Adherence of HIV/AIDS patients to antiretroviral therapy in a tertiary health facility in Benin City. *Afr. J. Pharm Pharmacol*. 2008 Sept 28; **2(7):**p145-52.

Stellenbosch University https://scholar.sun.ac.za

40.Mugusi FMS, Bakari M, Heldemann B, et al. Enhancing adherence to antiretroviral therapy at the HIV clinic in resource constrained countries: The Tanzanian experience. *Trop. Med. Int. Health*. 2009; **14(10):**1226-32.

41.Goujard C, Bernard N, Sohier N, Peyramond D, Lancon F, Chwalow J, et al. Impact of a patient education program on adherence to HIV medication: A randomized clinical trial. J Acquir Immune Defic Syndr. 2003**; 34(2):**191-4.

42. Smith SR, Rublein JC, Marcus C, Brock TP, Chesney MA. A medication self- management program to improve adherence to HIV therapy regimens: *Patient Educ Couns.* 2003 Jun;**50(2):**187-99.

43. Pradier C, Bentz L, Spire B, Spire B, Tourette-Turgis C, Morin M, et al. Efficacy of an educational and counseling intervention on adherence to highly active antiretroviral therapy: French prospective controlled study. *HIV Clin Trials*. 2003 Mar-April; **4(2):**121-3.

44.Tseng AL. Compliance issues in the treatment of HIV infection. *Am.J.Health-Syst.Pharm.* 1998 Sep 1; **55(17):**1817-24.

45.Ekong E, Akinlade O, Uwah A, Grant-isibor I. Study of determinants of non-adherence to antiretroviral drug therapy in a resource-limited setting. Proceeding of the 9^{th} *European AIDS conference (EACS)*: Ist EACS resistance &pharmacology workshop. Warsaw, Poland. 2003 Oct 25-29; AbstractF5/474. . Available from:URL://www.natap.org/2003/EACS (Accessed May 5, 2011)

46. Mukhtar M, Adeleke S, Gwarzo D, Ladan ZF. Preliminary investigation of adherence to antiretroviral therapy among children in Aminu Kano teaching hospital, Nigeria. *Afr.J.AIDS Res*. 2006; **5(2):**141-144.

47.Mills EJ, Nachega JB, Bangsberg DR, Singh S, Rachlis B, Wu P,et al. Adherence to HAART: a systematic review of developed and developing nation patient reported barriers and facilitators. *Plos Med.* 2006 Nov; **3(11):**e438.

48.Bedelu M, Ford N, Hilderbrand K, Reuter H.. Implementing antiretroviral therapy in rural communities: The Lusikisiki model of decentralized HIV/AIDS care. *J Infect Distance*. 2007 Dec 1; **196:Suppl 3:**464-8.

Stellenbosch University https://scholar.sun.ac.za

49. Janse Van Rensburg-Bonthuyzen E, Engelbrecth M, Steyn F, et al. Resources and infrastructure for the delivery of antiretroviral therapy at primary health care facilities in the Free State Province. South Africa. *SAHARA J.* 2008Sep; **5(3):**106-12.

50.Wouters E, Heunis C, Van Rensburg D, et al. Patient satisfaction with antiretroviral services at primary health-care facilities in the free state, South Africa: A two year study using four waves of cross-sectional data. *BMC Health Serv Res.* 2008 Oct 9;8:210.

51.Ojikutu B, Makadzange AT, Gaolathe T. Scaling up ART treatment capacity: lessons learned from South Africa, Zimbabwe and Botswana. *Curr HIV/AIDS Rep*. 2008 May; **5(2):**94-8.

52.Decroo T. Panunzi I, Dores C, et al. Lessons learned during down referral of antiretroviral treatment in Tete, Mozambique. *J Int AIDS Soc*. 2009 May 6; **12:**6.

53.Medina LA, Kigozi JAJ, Muchabaiwa L, et al. Cost effectiveness analysis of routine laboratory or clinically driven strategies for monitoring antiretroviral therapy in Uganda and Zimbabwe (DART Trial). The *5th IAS Conference on HIV Pathogenesis, Treatment and Prevention*, Cape Town, South Africa. 2009 Jul 19-22. Available from:URL://www.gatorserverl.com/capetown/content/slidekit.ppt (Accessed May 2, 2011)

55.Schneider H, Naidoo N, Ngoma, Williams E, Pursell R et al. Performance and capacity of second-generation comprehensive care management and treatment(CCMT) sites in Gauteng Province. In: CHP Monographs. Johannesburg: Center for Health Policy; 2008.

56.Ammassari A, Murri R, Pezzotti P, et al. Self reported symptoms and medication side effects influence adherence to highly active antiretroviral therapy in persons with HIV infection. *J.Acquir Immune Defic.Syndr*. 2001 Dec 15; **28(5):**445-9.

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ANNEXURE

ANNEXURE 1 (Information letter)

PARTICIPANT INFORMATION LEAFLET

TITLE OF THE RESEARCH PROJECT: Adherence of HIV/AIDS patients to antiretroviral therapy in a district hospital in Nankudu, Namibia

REFERENCE NUMBER:NO9/10/286

PRINCIPAL INVESTIGATOR: Dr Okebie C.O

ADDRESS: P/BAG 2099,Rundu, Kavango Region, Namibia

CONTACT NUMBER:00264813009523

E-MAIL : mmerifechris@yahoo.com

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

This study has been approved by the **Committee for Human Research at Stellenbosch University as well as by the Namibia Ministry of Health and Social Welfare services** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South

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African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

Detailed information of the Research:

The study will be conducted at the Center for Disease Control (CDC) HIV clinic of the Nankudu Hospital of Namibia. Its aim is to determine the current frequency of adherence to ART in a major HIV/AIDS treatment center in Nankudu District and to identify the local factors contributing to non-adherence.

The method will involve face to face interviewing of each of the 240 consenting participants (that will be recruited over a six (6) month period) with a self report questionnaire(response form) during clinic attendance. In addition, to the questionnaire, other important participants information will be gotten from the pharmacy medication records and the participants computer data base.

A total of 240 participants (members) will be selected in a random (chance) manner, that is, any participant has an equal chance of being selected to participate in the study..
The chosen random sample will be a representative of the entire patients on the antiretroviral tablets.

It is the responsibility of this health facility to promote health and prevent disease as well as to treat illness when it occurs. We want to find out about the factors that may affect people's willingness not to take antiretroviral tablets as advised. Since we cannot select all on antiretroviral tablets to help us to achieve this, therefore, you have been selected in this regard. You can help us to achieve this by filling the self report questionnaire (response form) given.

The information you give will help us to care better for you, and other present and future patients from within and outside the community that attend the hospital.

You will not be exposed to any risk or harm during and after the research.

You will be accordingly informed at any point of the study any new important information that may arise as the research is going on and the informed consent(permission) form will be changed, where necessary to include this information..

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The information given will be handled in strict confidence and only by authorized members of the research staff. No participant will be identified or mentioned in particular in any reports or publications. Study monitors may need to inspect the research records, if need be. Research report will be made available to the hospital authority and the state policy makers for appropriate action

You will not be paid for taking part in the study, neither, will you be involved in any cost, if you take part.

The contact details of the committee for Human research: Division for research Development and Support at University of Stellenbosch, Cape town-South Africa(+27219389207) for any further queries.

My contact details are stated above and my cell phone number is 0813009523 if you have any further question or encounter any problems.

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ANNEXURE 2 (Questionnaire)

Modified Adult AIDS Clinical Trials Group Questionnaire(A-H)

A. What is your age? (Tick one box)

☐ 1. 18-30

☐ 2. 30-49

☐ 3. _>50

B. **What is your sex? (Tick one box)**

☐ 1. Male

☐ 2. Female

What is your religion? (Tick one box)

☐ 1 Christianity

☐ 2. Islam

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☐ 3 Traditional

☐ 4 No religion

D. These last questions ask about your background.

1. What is the highest level of education you have completed? (check one)

- 0 Primary School
- 1 Secondary School
- 2 2 years of college / Technical school training
- 3 University (BA or BS)
- 4 Master's degree

2.What is your occupation? (Tick one box)

☐ 1. Business Executive

☐ 2. Civil Servant

☐ 3. Trader

☐ 4. Self-employed

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☐ 5. Peasant farmer

☐ 6. Unemployed

3. What is your marital status? (Tick one box)

☐ 1. Married

☐ 2. Cohabiting

☐ 3. Widowed

☐ 4. Separated

☐ 5 Divorced

☐ 6. Single

4. Do you have any dependants (Adult and Children)? • 1 Yes • 2 No
If Yes, how many live with you? • •

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E. People have various health habits. The following questions ask about your alcohol and smoking habits, past and current

Ei. Please check "Yes" or "No" for each question.
a. • 1 Yes • 2 No **Have you ever drank alcohol?**

b. • 1 Yes • 2 No **Have you ever been involved in smoking (cigarettes, marijuana, cocaine, etc)**

Eii. Are you currently taking Alcohol? • 1 Yes • 2 No

Eiii. Are you currently smoking? • 1 Yes • 2 No

F. When was the last time you missed any of your medications? Check one box

• 5 Within the past 4 days
• 4 Within the past **week**
• 3 2-4 **weeks** ago
• 0 **Never** skip medications or
not applicable

G. People may miss (interrupt) taking their medications for various reasons. Here is a list of possible reasons why
you may miss taking your medications.

	YES	**NO**
1. Were away from home(travel)?		
2. Too busy with other things?		
3. Had too many pills to take?		
4. Wanted to avoid side effects?		
5. Stigma a barrier?		
Reason that stigma is a barrier:		
5i Isolation		
5ii loss of employment		
5iii Discrimination		
5iv Divorce		
5v. Others-		
6. Distant from clinic?		

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7. Felt sick or ill?

8. Lack of food?

9. Misunderstood Doctor?

10. Ran out of ARV medicine at home?
Why:
10i

10ii

10iii

10iv

11. Stop when asymptomatic(felt better)?

12. Stresses at home/work?

13. Poverty?

14.Lack of money?

18 Alcohol ?

19 Other reasons:-

H. **People may miss dosages of ARV medicine for more than two months(treatment defaulters) for various reasons. Here is a list of possible reasons why that may happen.**

	Yes	No
1. Lack of finance?		
2. Too busy?		
If yes, state reasons:		
2i		
2ii		
3. Travel/migration?		
4. Distance from hospital?		
5. Lack of transport?		
6. Ran out of medicine?		

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If yes, state reasons:

6I

6ii

7. Stigma?

If yes, state reasons:

7i Loss of employment

7ii Discrimination

7iii Divorce

7ivOther reasons-

8. Too sick?

9. Felt better?

10.Other reasons:

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ANNEXURE 3 (Consent forms)

CONSENT (permission) FORMS

Declaration by participant

By signing below, I ……..……. agree to take part in a research study entitled : Adherence of HIV/AIDS patients to antiretroviral therapy in a district hospital in Nankudu, Namibia

I declare that:

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

Signed at (*place*) .....…..…….. on (*date*) ……...…….. 2010.

....

Signature of participant **Signature of witness**

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Declaration by investigator

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter. (*If a interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) .....…..…….. on (*date*) ……...…….. 2009.

....

Signature of investigator **Signature of witness**

Declaration by interpreter

I *(name)* ……..…… declare that:

- I assisted the investigator (*name*) ……. to explain the information in this document to (*name of participant*) ……..…….. using the local language medium of Kwangali.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) .....…..…….. on (*date*) ……...…….. 2009.

....

Signature of interpreter Signature of Witness

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ANNEXURE 4 (Raw data depicting the results of the questionnaires)

Table 1. Demographic data of the study participants

Characteristics	Male (%)	Female (%)
Ages(y) Range 18- 30 30-49 ->50 Total	 36 (46) 23 (30) 19 (24) 78 (100)	 85 (58) 46 (31) 16 (11) 147 (100)
Religion		
Christianity Traditional/no religion	70 (90) 8 (10)	145 (99) 2 (1)
Marital status		
Single Married Widowed Separated Divorced Cohabiting	16 (21) 40 (51) 2 (3) 5 (6) 3 (4) 12 (15)	44 (30) 27 (18) 35 (24) 12 (8) 7 (5) 22 (15)
No. of dependants(adults &children		
0 1-2 3-4 5-10 >10	6 (8) 13 (17) 14 (18) 2 (3) 1 (1)	23 (17) 20 (14) 13 (9) 10 (7) 0 (0.0)
Level of education		
No formal education Primary Secondary Tertiary	0 (0.0) 52 (67) 26 (33) 0 (0.0)	5 (3) 86 (59) 56 (38) 0 (0.0)

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Occupation		
Peasant farmer	32 (41)	95 (65)
Retail trader	2 (3)	5 (3)
Self employed	0 (0.0)	0 (0.0)
Civil servant	0 (0.0)	0 (0.0)
Un-employed	44 (56)	47 (32)
Substance habits:		
Prior alcohol	43 (55)	125 (85)
Prior smoking	11 (14)	8 (5)
Current alcohol	8 (10)	2 (1)
Current smoking	5 (6)	0 (0.0)

Table 2. Gender distribution and baseline CD4 count among study participants.

Variable	Male (%)	Female (%)
CD4 count (baseline)		
<50	20 (26)	4 (3)
100-200	40 (51)	15 (10)
>200	18 (23)	128 (87)
Total	78 (100)	147 (100)

Table 3. Gender Distribution and Immunological (CD4count) response evaluation among study participants on HAART

Variable	Male (%)	Female (%)
CD4 count		
<100	1 (1)	4 (3)
200-350	31 (40)	51 (35)
>350	46 (59)	92 (63)

Table 4. Gender distribution and Viral Load response evaluation among study participants on HAART

Variable	Male (%)	Female (%)
Viral Load		
<1000copies/ml	77 (99)	143 (97)
>1000-10000copies/ml	1 (1)	3 (2)
>10000copies/ml	0 (0.0)	1 (1)

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Table 5. Patients and Pharmacy reports on adherence

Findings	Numbers (%)
Patient self-report of adherence(n=225)	
Adherent*	203 (90)
Treatment defaulter!	6 ((3)
Treatment interrupter+	16 (7)
Pharmacist assessment of adherence(n=225)	
Adherent*	181 (80)
Treatment defaulter!	28 (12)
Treatment interrupter+	16 (7)

Table 6a: Local barriers to interrupting treatment.{treatment interrupters+(n=16)}

Findings	**Number(%)**
Lack of food	**16 (100)**
Ran out of medicine	**11 (69)**
Travel	**13 (81)**
Side effects	**9 (56)**
Too busy	**11 (69)**
Distance from clinic	**16 (100)**
Too sick	**8 (50)**
Misunderstood doctor	**5 (31)**
Stigma	**3 (19)**
Alcohol	**1 (6)**
Felt better	**9 (56)**
Stresses at home/work	**1 (6)**
Too many pills	**1 (6)**
Poverty	**16 (100)**
Lack of money	**16 (100)**

+ missed their treatment for more than 2 weeks and less than 8 weeks but were adherent to the medications when they had the medications.

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Table 6b: Local barriers to defaulting treatment { treatment defaulters!(n=6)}

Findings	Numbers (%)
Finances	2 (33)
Ran out of medicine	6 (100)
Travel and migration	6 (100)
Too busy	4 (67)
Distance from hospital	6 (100)
Stigma	6 (100)
Lack of transport	6 (100)

! miss two consecutive clinic visits or had interrupted treatment for eight consecutive weeks.

ANNEXURE 5 (Questionnaire summary)

The modified AIDS Clinical Trials Group questionnaire (AACTG) used in this survey is a self- reported questionnaire instrument to ascertain adherence information to antiretroviral medications among the study participants. This adherence instrument asked study participants about their ARV adherence over the previous day, previous week and previous months. It also asked closed and open ended questions; in addition to questions on the background of the study participants, in order to identify local barriers to ARV adherence.