

RESEARCH ASSIGNMENT

PROJECT TITLE

The prevalence of established factors associated with adherence to Highly Active Antiretroviral Therapy (HAART) in non-adhering patients at the ARV clinic of Madzikane KaZulu Memorial Hospital

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Declaration

I, Dr. **OO Anizoba**, hereby declare that this dissertation is my own idea and the result of my own original research; that it has not been submitted for any degree or examination at any other University, and that all the sources I have used or quoted, have been indicated and acknowledged with complete references.

Dr OO ANIZOBA

ABSTRACT

The prevalence of established factors associated with adherence to Highly Active Antiretroviral Therapy (HAART) in non-adhering patients at the ARV clinic of Madzikane KaZulu Memorial Hospital

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Background

Adherence to HAART is key to any successful HAART programme. In Madzikane KaZulu Memorial Hospital ARV Clinic, there is an increasing number of patients on HAART and an increasing number of patients still awaiting HAART initiation. With the paucity of healthcare personnel in this rural district hospital, suboptimal patient's preparation for HAART often occurs, and the HAART defaulter rate is on the increase. This is may be attributed to an interplay of factors affecting HAART adherence.

Aim and Objectives

The aim of this research was to determine the prevalence of established factors associated with adherence to Highly Active Antiretroviral Therapy (HAART) in non-adhering patients at the Madzikane KaZulu Memorial Hospital (MKMH) ARV clinic.

The objectives were:

- To conduct an audit on all case files of patients on HAART over the study period.
- To explore the behavioural aspects of poor HAART adherence in a focused group discussion.
- To describe the factors associated with good HAART adherence

Methods

Study design: A cross-sectional descriptive study which focused on determining the prevalence of established factors(patient-related, therapy-related and facility-related factors) affecting HAART adherence at the ARV clinic was carried out among identified HAART non-adhering patients. Patients that were not adhering with HAART between the period of January 2009 and December 2010 were selected for the study. These patients were 19 years or more and had been on HAART for at least two months. The study was carried out between November and December 2010. The result of the focused group discussion was utilized to refine the development of the questionnaire.

Setting: The study was conducted at the Madzikane KaZulu Memorial Hospital ARV clinic. This is a modern 269 bed district hospital in the Mount Frere, Alfred Nzo district, Eastern Cape Province of South Africa. This is a predominantly rural region.

Results:

Data for analysis was provided by 215 patients that fulfilled the inclusion criteria. The prevalence rate of the factors affecting HAART adherence at the hospitals ARV clinic was 24%. A total of 60% of the patients were females. Majority of the patients (86.1%) had treatment supporters, and more than half of the patients (57.2%) were unemployed and not on disability grant. A total of 62.8% of the patients prefer to take their ARV at a clinic near them, and the majority of these patients (96.3%) want to start taking their ARV in a nearby clinic within 6months. The female gender, unemployment not on disability grant, longer period on HAART, Regimen 1A ARV(stavudine or tenofovir plus lamivudine and efavirenz according to the National ART guideline 2004 and its modified version of April 2010) single marital status and probably poorly selected unprepared treatment supporters, are associated with poor HAART adherence at this ARV clinic.

Conclusion

The study revealed that the prevalence rate of the factors affecting HAART adherence at the Madzikane KaZulu Hospital ARV clinic was 24% amongst HAART non-adhering patients. These patients had the prevalence rate of patient-related factors (12.4%) more than double of the prevalence rates of therapy related factors (5.8%), and facility related factors (5.7%). Topmost amongst the associated factors for not adhering to HAART were: not belonging to a support group, the pills making the patient feel unwell, and the ARV clinic being too far from where the patients live. Efforts should be targeted at enrolling the patients in support groups, encouraging the use of HAART regimens that have good tolerability profiles, and establishing the down referral.

List of abbreviations

ARV: Antiretroviral

HAART: Highly active antiretroviral therapy

ART: Antiretroviral therapy

HIV: Human immunodeficiency virus

PHC: Primary health care.

INTRODUCTION

The problem inspiring the research question stems from the context of an increasing defaulter rate, increasing number of clients on HAART and increasing number awaiting initiation on HAART, same number of staff at the ARV clinic and the down referral system which is yet to commence. The researcher was personally motivated and committed to do this research because of the need to improve adherence and potentially decreasing the defaulter rate, the work load on the ARV clinic staff and by contributing towards kick-starting the down referral system which is long overdue. The down referral is a systematic process of routinely transferring patients who have been on HAART at a higher level health facility to a lower level health facility for continuity of care. The motivation for doing the study was based on the long queue of patients at the ARV clinic every working day, which leaves the ARV clinic staff that is few in number with an enormous job of attending to these patients. There is also an ever-increasing call to attend to these patients holistically at every clinic visit, which is not always practically possible given the constraints in available staff.

Quality of patients care is likely to be compromised. Previous studies on this topic were carried out in Khayelitsha, a township in Cape Town, and Soweto which is a big residential area near Johannesburg. These areas have widespread poverty, unemployment and HIV/AIDS similar to that of Mount Frere where the researcher conducted the study. However these areas have some influence from the big cities near them in terms of social amenities, job opportunities and level of development in general, which are way too different from what is obtainable in the Mount Frere community, a deeply rural community in the Alfred Nzo District of the Eastern Cape Province. All these set a stage for differences in adherence to HAART by patients in Mount Frere when compared to patients in Khayelitsha and Soweto.

The researcher hoped that the study will impact positively on adherence improvement (and overtly improving the ARV clinic performance), engaging other stakeholders in the HIV/AIDS management at the Clinic and Community and providing inputs towards kick-starting the down referral system. Literature review revealed that there are broadly three factors affecting HAART adherence (Therapy Regimen Related Factors, Patient Related Factors and Facility Related Factors).¹⁻⁶ Adherence is however measured with many tools though none of them is perfect. Adherence is highly unpredictable when considering clients' biophysical profile and a well focused multidisciplinary individualized strategy is paramount in solving adherence related issues. Near perfect Adherence ultimately is of fundamental importance for any successful HAART programme.¹ The long term HAART goals include suppression of viraemia and reduction of risk of resistance emergence, restoration and preservation of immune function, reduction of HIV-related morbidity and mortality, and lifestyle adjustment.⁷

LITERATURE REVIEW

The UNAIDS report of 2009 reveals that sub-Saharan Africa accounts for 71% of all new HIV infections in 2008, and a total of 5.7 million South Africans are infected.⁸ However with the need to scale up comprehensive treatment interventions by the government in partnership with various stakeholders, this HIV/AIDS scourge in the country is receiving much long overdue attention presently than was the case some years back. Increasing access to HAART has been shown to alter the trend of morbidity and mortality attributable to HIV/AIDS over time in any given place.⁹⁻¹¹

More and more studies on adherence issues in Highly Active Antiretroviral Therapy (HAART) programmes keep coming up thereby underscoring the importance of adherence. Adherence has been shown to be a cornerstone for any successful antiretroviral therapy, with low adherence being one of the

leading causes of therapeutic failure.⁴ Adherence has been defined in practical terms as the extent to which a person's behaviour in taking medications, following dietary specifications and/or executing lifestyle changes correspond to agreed recommendations from a health care provider.¹² Adherence has also been defined in terms of clinic attendance, deficits in the number of pills given and the number consumed. These can be measured by using tools like physicians' assessment, self-report questionnaires, pharmacy records, pill counts, antiretroviral clinic attendance register and electronic drug monitors. However, these tools used in adherence measurement have biases inherent in them.¹³ These biases include: subjectivity and inaccuracy in physician's assessment, accuracy affected by poor patients recall; mistimed doses; inability to determine who took the pills in patients self-report, pill count and pharmacy refill records, in addition to the expensive device used in electronic drug monitoring which does not indicate who consumed the pills or whether the pill was consumed or not.¹³

The qualitative aspect of adherence like treatment timing, food restrictions, correct dosage intake cannot be objectively measured by all these tools thereby leaving us with no gold standard tool designed to measure adherence.¹⁴ Studies have also shown that patient self-reported adherence is known to be overly optimistic^{15,16} because of recall bias or desire to please the provider and prevent criticism, or both.⁶ A good number of factors have been shown to influence adherence. These include therapy regimen related factors, patients related factors and facility related factors.¹ Wagner reported better adherence in patients living alone,⁵ which contrasts to the pattern of adherence more likely to be obtained in resource poor settings like the research study location. With the increasing prevalence of weakened family ties/structures and child headed families in sub-Saharan Africa especially in Southern Africa, the social climate will keep playing a significant role in determining adherence patterns of patients on HAART.

A cross sectional study to evaluate factors associated with adherence to antiretroviral therapy by Brazilian HIV-infected patients showed that the most frequently cited reason for non-adherence was 'being away from home'.¹⁷ This has also been reported in studies conducted in Soweto South Africa and in the United States.^{18,19} Antiretroviral therapy dosing interval, food restrictions, therapy side effects, life style modification, stigmatization, lack of social support and poor patient-provider relationship are amongst other obstacles to HAART adherence that have been reported. Studies however showed that adherence pattern of an individual cannot be predicted based on demographic profiling.^{20,21}

With the current challenges faced in developing countries whereby the need to improve on the HAART coverage and not compromising the quality of the programme,^{21,22} adherence promotion strategies need strengthening. Studies have shown that high adherence rates have been achieved in sub-Saharan Africa as evidenced in >95% adherence rate in 88% of patients in a Soweto South Africa study¹⁸ and median adherence rate of 93.5% reported in Cape Town South Africa.²⁰

The researcher hopes that this study will further identify the already established factors affecting adherence to HAART in the ARV clinic of Madzikane KaZulu Memorial Hospital, which is a district hospital in a deeply rural setting. This will invariably lend support to the fact that these factors are well established in affecting HAART adherence in various settings. Furthermore, the researcher aims to provide information on the adherence pattern to HAART in a rural setting in South Africa taking cognizance of the impact of the social environment on HAART adherence in this setting that will be different from reports obtained in semi-urban and urban settings in South Africa.

However the issue still remains on how these high adherence rates can be sustained over time in order to achieve the long term HAART goals. In a study conducted in Senegal, over 95% of patients on HAART had >80% adherence after one month on therapy but 18 months later only 80% remained above that level.²³ This invariably implies that adherence should be a continuous process and any contact with the patient will be an avenue to address adherence issues. Some of the methods which help in improving adherence include; provision of adherence promoting devices(pill boxes, alarms/beepers, diaries),^{20,24,25}

reinforcing the roles of treatment supporters for each patient on HAART which also includes the proposed DOT (directly observed therapy) HAART model,^{26,27} simplifying therapy regimen,²⁸ enrolling patients on HAART in treatment support groups, and prompt treatment of side effects of HAART. All these methods will not yield the needed results if the patient lacks the understanding of the HAART objectives and goals. Therefore continuous patient education and motivation on the treatment goals of HAART is necessary in achieving and sustaining high adherence level.⁷ Adherence issues should as much as possible be individualized and appropriate adherence-enhancing intervention undertaken for each patient as varying reasons for poor adherence to HAART differ from one patient to another.⁷

The researcher hopes that this study will impact positively in promoting the adherence enhancing structures already in place at the ARV clinic which include; treatment supporter for each patient on HAART,²⁹ completion of at least 3 sessions of Pre-ART assessment prior to initiation of HAART and use of support groups amongst others. In addition, soliciting partnership between the non governmental organizations/ community based organizations/ faith based organizations and the ARV clinic and fostering the mentorship from the regional training centre of the Walter Sisulu University with the ARV clinic, will surely go a long way in impacting positively on adherence levels in the clinic. These bodies will also provide logistics in terms of capacity building, human resources provision/training and continuous development, and provision of other material resources that are crucial in the HAART programme. The sustainability of optimum adherence especially in sub-Saharan Africa, calls for further qualitative research into the behavioural reasons for non adherence to HAART.¹³ More attention, therefore, should be focused on adherence studies as it forms the cornerstone of any successful therapy. Research towards developing a convenient tool to monitor adherence by clinicians in ARV programmes is very crucial.³⁰ HAART effectiveness can be improved by putting on greater efforts to design and evaluate interventions aimed at enhancing adherence. This has necessitated a study on the prevalence of established factors affecting HAART adherence at the Madzikane KaZulu Memorial Hospital's ARV clinic.

AIM

The aim of this research was to determine the prevalence of established factors affecting adherence to Highly Active Antiretroviral Therapy (HAART) in non-adhering patients at the Madzikane KaZulu Memorial Hospital (MKMH) ARV clinic.

The objectives were:

- To conduct an audit on all case files of patients on HAART over the study period.
- To explore the behavioural aspects of poor HAART adherence in a focused group discussion.
- To describe the factors associated with good HAART adherence

METHODS

A cross-sectional descriptive study which focused on determining the prevalence of established factors affecting HAART adherence at the ARV clinic was carried out among identified HAART non adhering patients. HAART non adhering patients are those that either had unbalanced pill counts for two or more months or missed ARV clinic appointment days for ARV refill for two or more months, or both. HAART non adhering patients between the period of January 2009 and December 2010 were selected for the study. The inclusion criteria are; adult patients who are 19 years and above, who have been on HAART for at least 2 months within January 2009 and December 2010. Exclusion criteria are; patients with cognitive impairment and transfer-out patients to other facilities. Approval for the study was obtained from the Ethics Committee of University of Stellenbosch with reference number N10/02/034, and the Eastern Cape Department of Health. The study was carried out between November 2010 and December 2010.

Setting

Madzikane KaZulu Memorial Hospital is a newly built rural district hospital in the Mount Frere community of the Eastern Cape Province. The hospital was built under the national hospitals revitalization project with modern state of the art facilities. The ARV clinic in the hospital caters for more than one thousand patients, with approximately ten healthcare workers(2 doctors, 3 nurses, 1 pharmacist, 1 social worker, 3 vlay councilors) and four feeder clinics(PHC clinics that prepare patients for HAART and refer them to the hospitals' ARV clinic for HAART initiation and management). These feeder clinics are; Mtwana clinic, Mpoza clinic, Tshungwana clinic and Gate way clinic.

Study Population/Sampling Procedure

The Stellenbosch University centre for Statistical Consultation assisted in calculating the sample size for the study, which was 263 within a confidence interval of 95% with a precision of 6%. Eligible patients were randomly selected from the ARV Clinic attendance records and pharmacy records. A simple random sample was taken. The research ethics committees of both the Stellenbosch University and Eastern Cape Department of Health approved this study. Permission was obtained from the Chief Executive Officer of the Madzikane KaZulu Memorial Hospital as well as from the hospital's ARV clinic co-ordinator.

Pilot Study/Data Collection Method

A semi-structured interviewer administered questionnaire was the main tool utilized in this study. The three paged questionnaire was designed to cover demographic variables, patient related factors, therapy related factors, facility related factors, of adherence, and down referral data.

An audit was conducted on the case files of the patients attending the ARV clinic, and defaulters that fulfilled the inclusion criteria identified. A total of 217 patients had unbalanced pill counts for two months or more, while 68 patients missed ARV clinic attendance for two months or more. A total of 32 patients had unbalanced pill count and missed ARV clinic attendance for two months or more. A pilot survey was carried out with five randomly selected HAART defaulters and colleagues at work. Their feedback revealed that the semi-structured questionnaire was unambiguous, with simple questions and response options.

A focus group discussion was also conducted with seven identified HAART non adhering patients, with the help of an interpreter. The discussion was analysed afterwards and three themes developed. These were; reminders versus preventers of HAART consumption, life style adjustment issues, and down referral issues. These themes were covered in the three paged semi-structured questionnaire. The result of the focused group discussion was utilized in further refining the semi-structured questionnaire.

Two lay counselors, one from the ARV clinic and the other a volunteer, were trained on the administration of the questionnaire. A total of 280 questionnaires were administered to identified HAART non adhering patients at the ARV clinic on their clinic appointment days. The questions were translated to Isixhosa to the patients by the trained lay counselors whenever the need arose. Participation in the study was strictly on voluntary basis. Informed consent was obtained from all participants and all had the information leaflet verbally explained to them in their local language Isixhosa when needed.

Data Analysis

Of the 280 questionnaires administered to the patients, 215 qualified for analysis. The remaining 65 questionnaires were not valid for analysis due to the following reasons:

1. 47 questionnaires were incomplete.
2. 14 patients had been on HAART for less than 2 months.
3. 4 patients were below 19 years of age.

Microsoft office Excel spread sheet 2007 version was used to capture the data. The components of the data were each analysed separately and the results arranged in figures.

Ethical Considerations

The following ethical considerations have been considered in this research:

Informed consent was obtained from all the participants prior to taking part in the study. Confidentiality was strictly maintained throughout the study period. Where relevant and necessary, interviewers and participants were addressed to maintain confidentiality. The interviewers provided clear explanation of the aim/objectives, procedure of the research and requirements from the participants, to the participants especially in the local language Isixhosa .

Data collection strictly observed anonymity and therefore there was no disclosure of the participants' identity in the data collection and analysis. The questionnaire did not carry items that require the identity of the participants. There was no cost borne by the participants during the course of the study

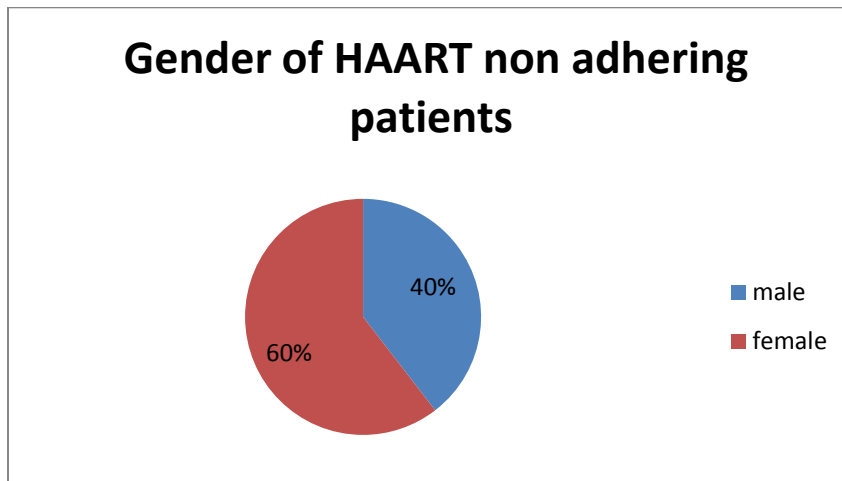
The participants' HIV status was not disclosed in any way. The interviewers were recruited from the staff of the ARV clinic and a feeder clinic in order to promote and maintain confidentiality of information. Participation in the study did not jeopardize the participants' financial (nil impact on grants), physical or social conditions (nil promotion of stigmatization). The administration of the questionnaire was done in a private comfortable room within the ARV clinic.

There was no coercion and participation was strictly voluntary. Participants maintain the right to withdraw when and if they so wished. Withdrawal by any participant from the study did not in any way impact on any aspect of their current management received at the ARV clinic. Thus care received at the ARV clinic by the participants was not affected in any way.

RESULTS

Gender of HAART non adhering patients

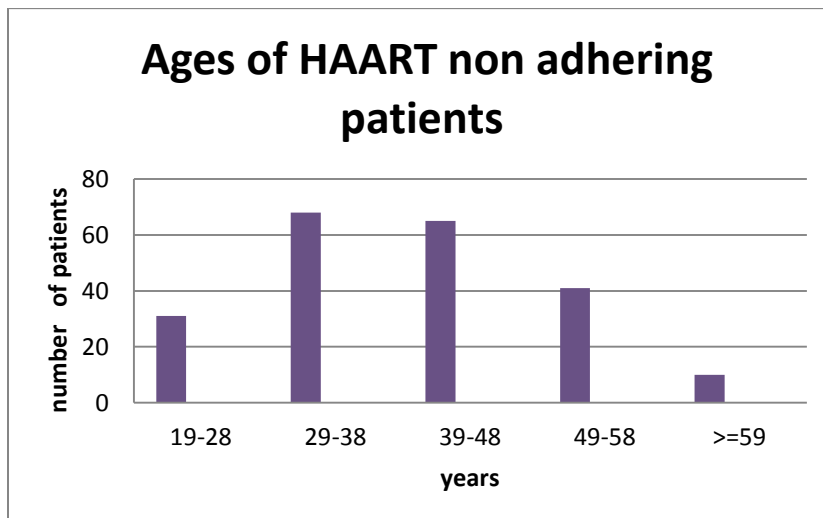
Figure 1: gender (n=215)



There were 130 (60%) female patients and 85(40%) male patients of the 215 patients that participated in the study. (Figure 1)

Ages of HAART non adhering patients

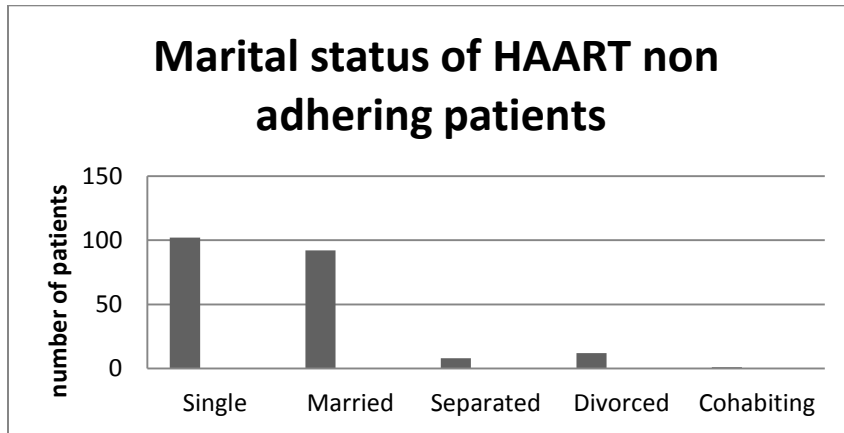
Figure 2: age (n=215)



31(14.4%) patients were between the ages of 19-28years, while 68(31.6%) patients were between 29-38years. 65(30.2%) patients were aged between 39-48years and 41(19.1%) patients were between 49-58years. 10(4.7%) patients were 59years and above. The mean age of the patients was 40.4years. (Figure 2)

Marital Status of HAART non adhering patients

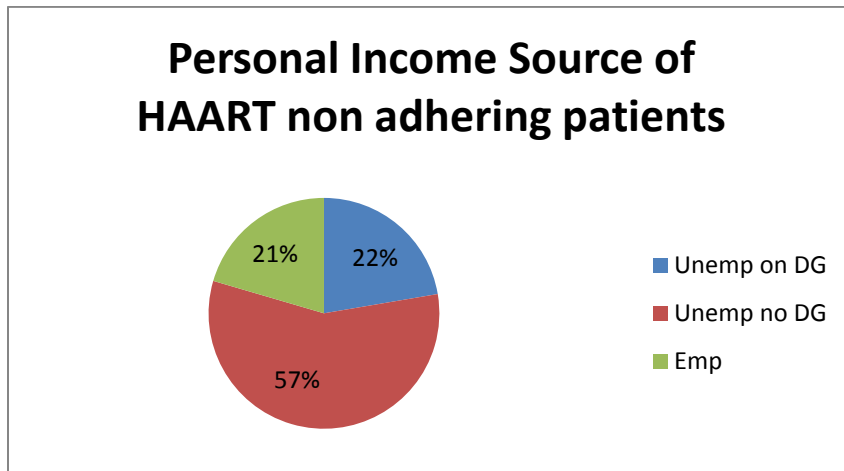
Figure 3: marital status (n=215)



Of the 215 patients that participated in the study, 102 (47.4%) were single, 92 (42.8%) were married, 8 (3.7%) were separated from their marriage, 12 (5.6%) were divorced and 1(0.5%) was cohabiting. (Figure 3).

Personal Income Source of HAART non adherent patients

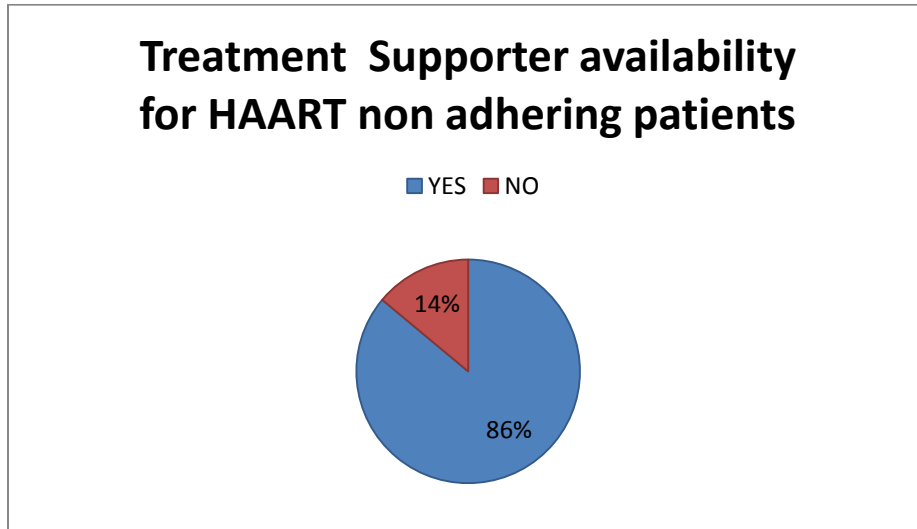
Figure 4: income source (n=215)



A total of 48 (22.3%) patients were unemployed on disability grant, 123 (57.2%) patients were unemployed and not on disability grant, which is more than half of the total number of participant patients, while 44 (20.5%) patients were employed. (Figure 4).

Treatment Supporter availability for HAART non adhering patients

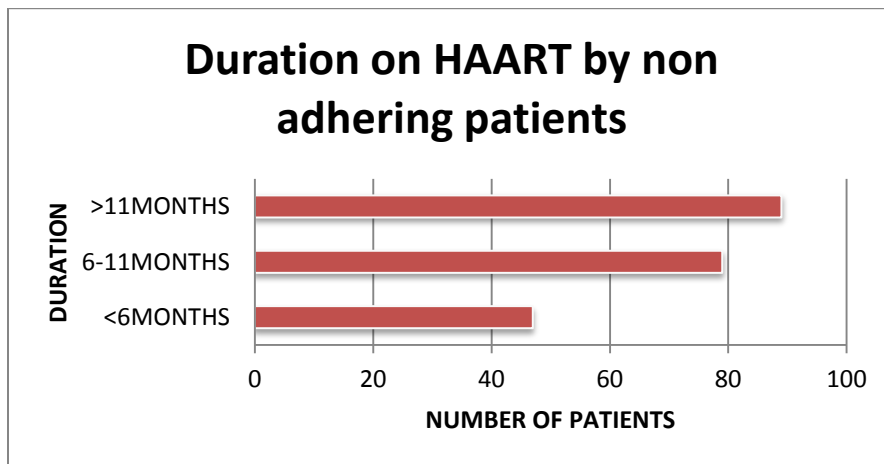
Figure 5: treatment supporter (n=215)



More than three-quarters of the patients that participated in the study had treatment supporters. A total of 185 (86.1%) patients had treatment supporters while 30 (13.9%) patients did not have. (Figure 5)

Duration on HAART by non adhering patients

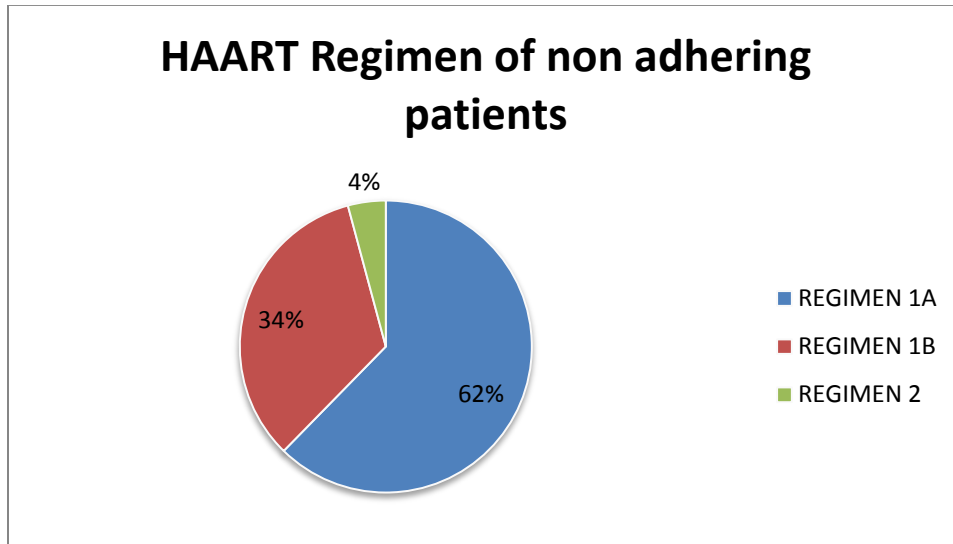
Figure 6: duration on HAART by non adhering patients (n=215)



A total of 47(21.9%) patients had taken HAART for less than 6 months, 79(36.7%) patients had been on HAART between 6-11 months. 81(41.4%) patients had taken HAART for more than 11 months.(Figure 6)

HAART regimen of non adhering patients

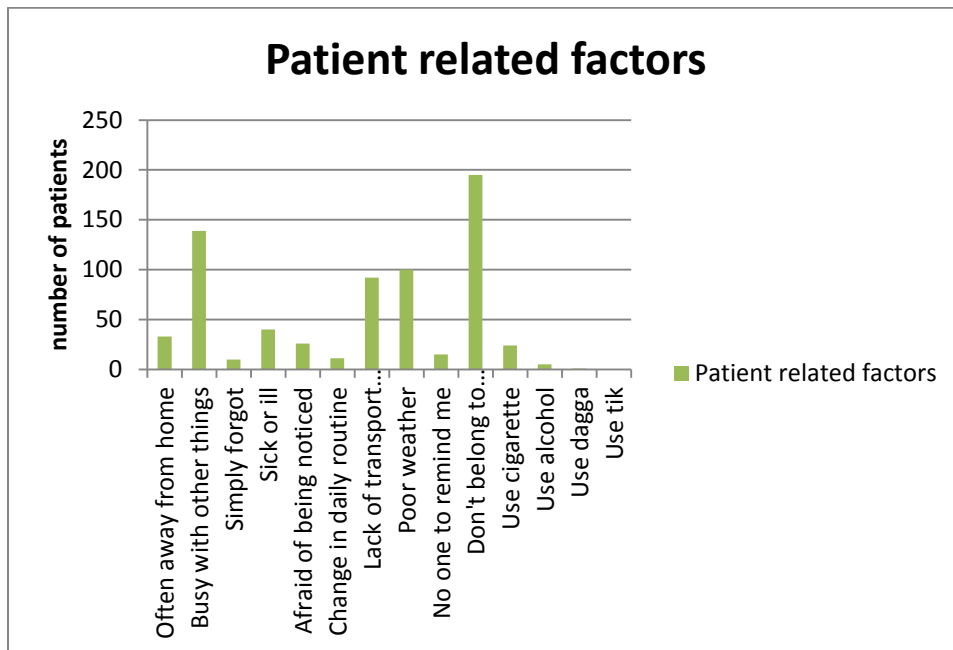
Figure 7: HAART regimen of non adhering patients (n=215)



More than half of the patients, 134 (62.3%) patients, are presently on regimen 1A, 72 (33.5%) patients are presently on regimen 1B while 9 (4.2%) patients are on regimen 2.(Figure 7)

Patient related Factors

Figure 8: patient related factors (n=215)

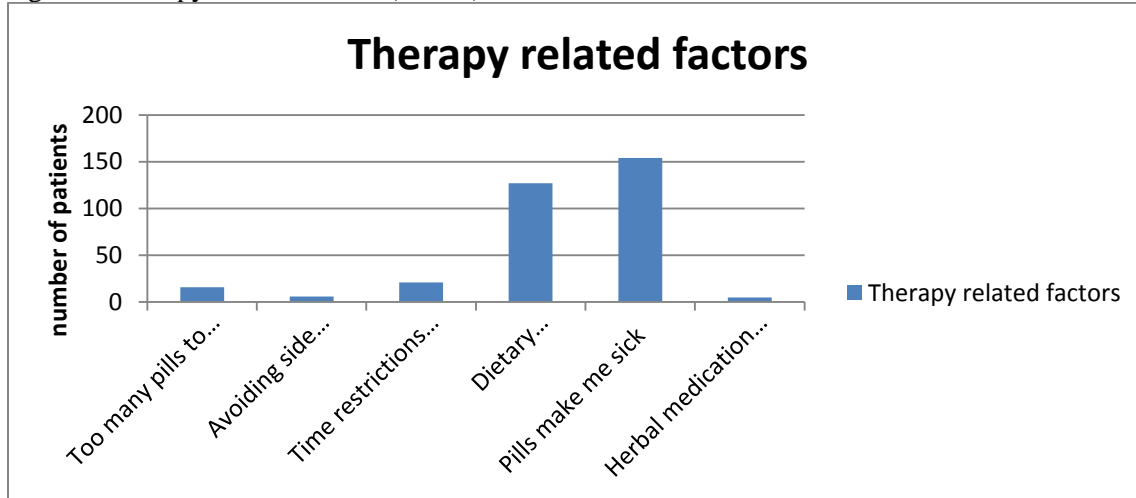


There were fourteen items on this component. The highest number of patients, 195 (90.7%) patients, reported 'not to belong to a support group' as part of their reasons for their defaulting HAART. 139

(64.7%) patients and 100 (46.5%) patients reported that ‘they were busy with other things’ and ‘the weather did not allow them to come to the ARV clinic’ respectively as part of their reasons for defaulting HAART. However, only 1(0.5%) patient reported that ‘he uses substances like dagga’, while no patient reported to ‘use substances like Methamphetamine (‘tik’). (Figure 8)

Therapy related Factors

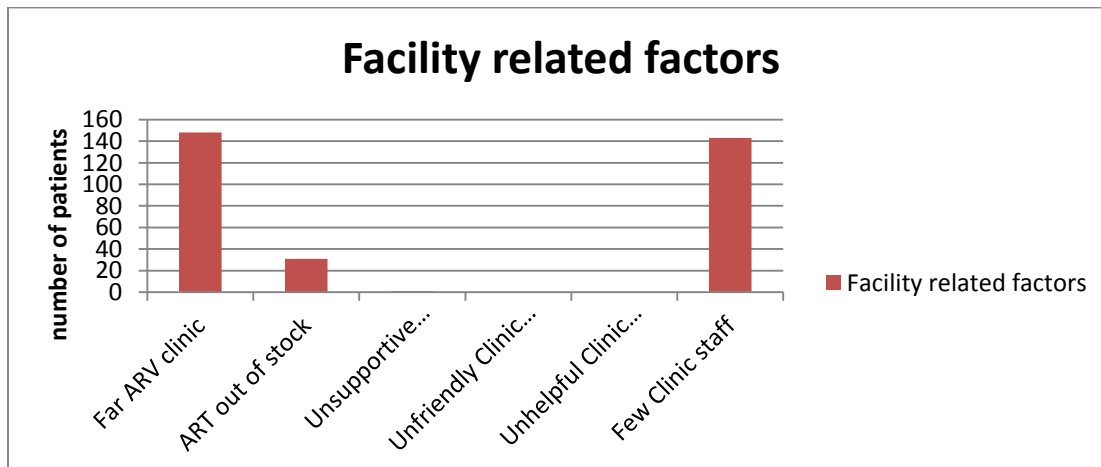
Figure 9: therapy related factors (n=215)



There were six items in this component. The highest number of patients, 154 (71.6%) patients, reported that ‘the pills make them sick’, while the lowest number of patients, 5 (2.3%) patients, reported that they ‘take herbal medications also’. (Figure 9)

Facility related Factors

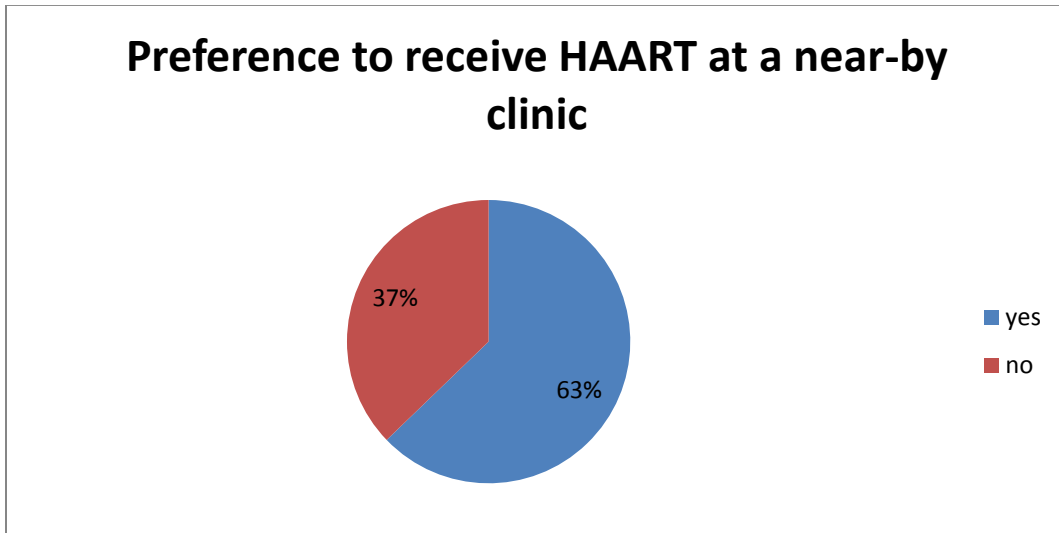
Figure 10: facility related factors (n=215)



There were six items in this component. The highest number of patients, 148 (68.8%) reported that ‘the ARV clinic is too far from where they leave’, while no patient (0%) reported that ‘the ARV clinic staff are not supportive’ or ‘the ARV clinic staff are unhelpful’. (Figure 10)

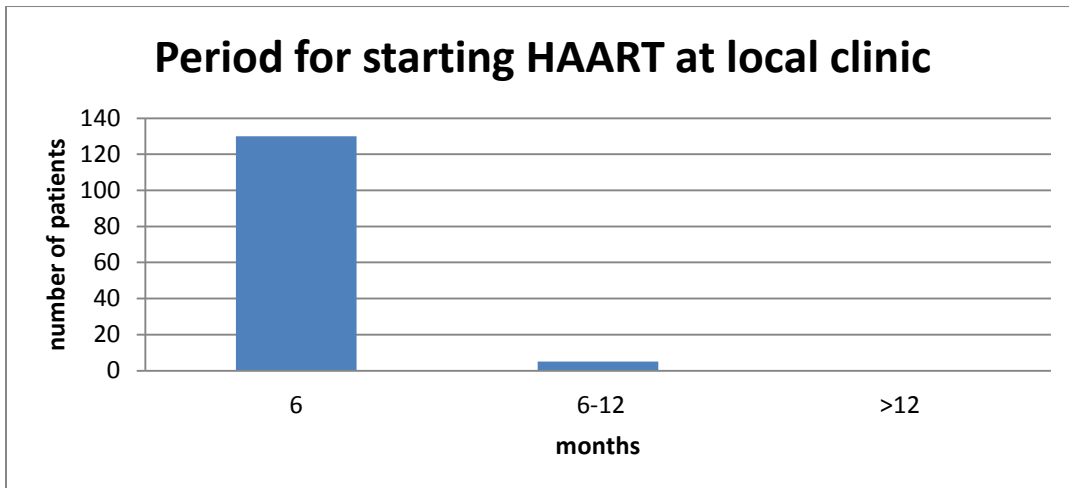
Down referral

Figure 11: preference to receive HAART at a near-by clinic (n=215)



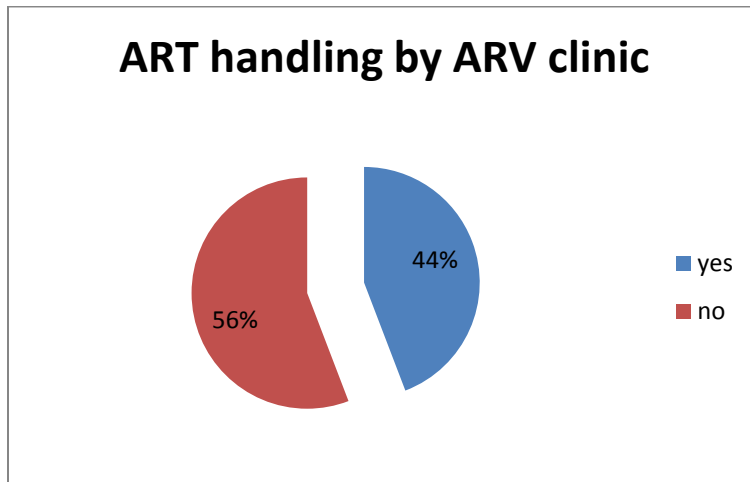
More than half of the patients, 135 (62.8%) patients, prefer to receive their HAART at a clinic near them, while 80 (37.2%) patients did not. (Figure 11)

Figure 12: period for starting HAART at local clinic (n=135)



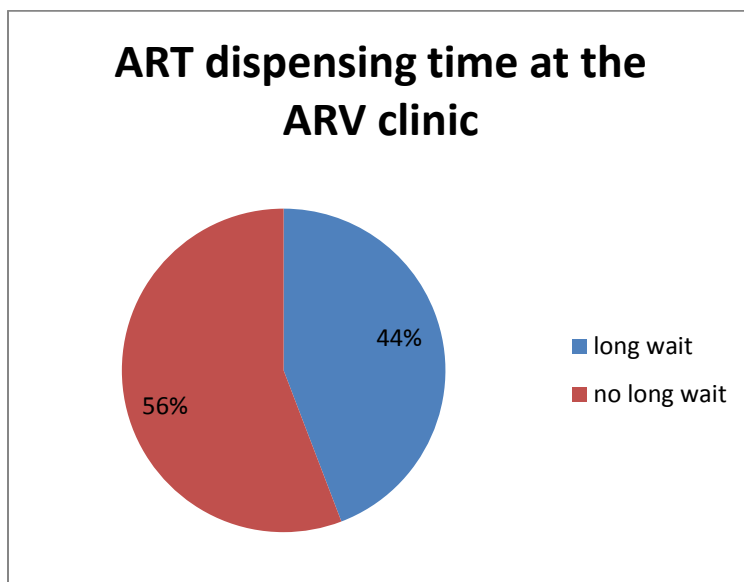
Almost all the patients, 130 (96.3%) patients that prefer to take their HAART at a clinic near them want this to start within 6 months. 5 (3.7%) patients want to start between 6 and 12 months, while no patient want to start after 12 months. (Figure 12)

Figure 13: ART handling by ARV clinic (n=215)



More than half of the patients, 137 (63.3%) patients, think that the ARV clinic has enough workers to handle the ART roll out, while 78 (36.3%) patients did not think so. (Figure 13)

Figure 14: ART dispensing time at the ARV clinic (n=215)



More than half of the patients, 120 (55.8%) patients, did not have to wait too long to receive the medications at the ARV clinic, while 95 (44.2%) patients did. (Figure 14)

DISCUSSION

The aim of the study was to determine the prevalence of established factors affecting HAART adherence at the ARV clinic. The study revealed that patient-related factors, therapy-related factors, and facility-related factors all affect HAART adherence at the clinic though at varying rates. The prevalence rate for these factors was 24%. The patient-related factors had a prevalence rate of 12.4% while therapy-related and facility-related factors had prevalence rates of 5.8% and 5.7% respectively. This clearly shows that patient-related factors affect HAART adherence most at the ARV clinic, and thereby overtly attaching more importance to the patient undergoing HAART.

In terms of patient-related factors, the majority of the patients (90.7%) cited that they did not belong to a support group and more than half (64.7%) cited that they were busy with other things, as the reasons for not taking HAART. The reasons for these responses are due to poor social support structures prevalent in the rural districts of the province, as well as preoccupation with social/financial issues like job hunting, family funerals and other family engagements. 'Too busy' was one of the common reasons for suboptimal adherence as reported by Chesney M et al.³¹ Lack of or paucity of social support has also been shown to be associated with lower HAART adherence.³²

More than two thirds of the patients (71.6%) reported 'difficulty with dietary restrictions on taking pill' as their main therapy related reason for defaulting HAART. This is in keeping with the main reason cited in the study by Nachega JB et al¹⁸ for HAART default. Another main reason in this section was 'pills making the patients sick'. The HAART regimens presently available in the public sector health system are old generation ARVs which in most instances are not without side effects that could be persistent and discomforting. The tolerability profile of these ARV's is very equivocal. Recent ARV's with improved tolerability profiles are still not yet available in the public sector health system due to logistic reasons.

The majority of the patients (68.8%) cited that 'the ARV clinic was too far from where they live' and 'there are few staff at the ARV clinic to attend to patients' as the main facility related reason for defaulting HAART. These are in line with the rural nature of the Mount Frere community with poor social amenities and paucity of health care workers in rural under-resourced district health care facilities all over the country. Some of the reasons for defaulting HAART were under reported by the patients. These include; use of substances like cigarette, alcohol, dagga and herbal medications. These habits are known to be prevalent in the Mount Frère community. One can attribute these finding to denial on the part of the patients due to measurement bias inherent in the interviewer administered questionnaire. Utilizing staff from the ARV clinic may have contributed to some bias experienced in this study especially the aspect that dealt with the facility-related factors and down referral issues.

Though there are conflicting reports on the predictors of good or poor adherence to HAART, this study revealed that female gender, unemployment without disability grant, longer duration on HAART, Regimen 1A ARV's, single marital status, mean age 40.4 years and probably poorly selected unprepared treatment supporters, as associations of poor HAART adherence at the ARV clinic. Godin G et al² reported 'female sex' as one of the demographic variables associated with low HAART adherence, which is in keeping with this study. The corollary was also the case in the same study using the Generalized Estimated Equation (GEE) method where Godin G et al² cited that the male gender was one of the predictors of HAART adherence.

A greater percentage of patients (62.8%) prefer to receive their ART at a nearby clinic. This obviously would help in saving the cost incurred on transportation to and from the ARV clinic given that poverty is rife in this region of the country. Likewise most of the patients also reported that the 'ARV clinic was too far from where they live'. There is a national trend towards empowering the primary healthcare (PHC) clinics for ART rollout in order to increase access to HAART. This will mean bringing the services to the

communities in line with the principles of primary healthcare. Starting these services within six months was overwhelmingly reported by the patients that want to be receiving their HAART at a clinic near them. However, the question still remains on whether there is adequate capacity to start and sustain this ART rollout at the PHC clinics, bearing in mind that one of the local challenges to ART rollout is under-developed healthcare infrastructure.³³ On the other hand, it is very necessary to have more health facilities that would deal with manageable patient numbers, instead of having a few large referral health facilities which may have difficulty in tracking their patients.²² This would ensure continuity of care.

Healthcare workers were thought to be enough to handle the ART rollout at the PHC clinics near the patients by more than half (63.3%) of them. This may be far from what is obtainable at these clinics which are still grossly under staffed (usually three nurses at each clinic). Approximately an equal number of patients reported to either wait too long or not, to receive their medications at the ARV clinic. Several factors however affect the turn around time for services rendered at the ARV clinic. These are topics for further research especially in the Quality Improvement (QI) audit.

Limitation of the Study

This cross-sectional descriptive study had the usual limitations of the survey methodology. These include inability to provide causal/temporal relationships, and the presence of bias (recall, translation, interviewer). Patients who were on HAART for <2months were excluded. Due to limited resources and time, not all the patients that met the inclusion criteria were included in this study.

Recommendation

More importance should be placed on patient preparation for HAART, and continuous review of patients on HAART, especially as their duration on HAART increases, is required. This is due to the fact that patient related factors were found to be most prevalent in the study. Efforts should also be made towards ensuring that patients to be enrolled on the ART programme are attached to functional support groups. Introduction of ARV's with high tolerability profiles in the public health care sector will aid in decreasing the non adherence rate on HAART due to related side effects. Prompt identification and treatment of side effects is therefore important in this regard.

There is a compelling need to start the down referral of patients already on HAART at the ARV clinic. However, this should be done cautiously so that the benefits would be sustained. This should go hand in hand with recruiting more PHC clinic staff and equipping them as well. Finally, the treatment supporter selection criteria need to be reviewed. Emphasis should be on the treatment supporters understanding their roles and committing towards fulfilling them thereby making them relevant to the ART programme. Routine assessment of their impact towards enhancing patients' adherence to HAART should be done.

Conclusion

The study revealed that the prevalence rate of the factors affecting HAART adherence at the Madzikane KaZulu Hospital ARV clinic was 24% amongst HAART non-adhering patients. These patients had the prevalence rate of patient-related factors (12.4%) more than double of the prevalence rates of therapy related factors (5.8%), and facility related factors (5.7%). Topmost amongst the associated factors for not adhering to HAART were: not belonging to a support group, the pills making the patient feel unwell, and the ARV clinic being too far from where the patients live. Efforts should be targeted at enrolling the patients in support groups, encouraging the use of HAART regimens that have good tolerability profiles, and establishing the down referral.

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Annexure 1

Summarized Curriculum Vitae

Personal Details

Name: Ogochukwu Obed

Surname: Anizoba

Address: Madzikane KaZulu Memorial Hospital
Private Bag X9002, Mount Frere. 5090

E-mail: ogozanizoba@yahoo.com

Cell phone: 0764891853

Qualifications

MBBS(Nig)-----2003

Dip. HIV man(SA)---2008

Work Experience

Senior medical officer,
Madzikane Kazulu Memorial hospital
May 2006---June 2007.

Principal medical officer

Madzikane Kazulu Memorial hospital
July 2007---February 2009.

Clinical Associate Educator
Walter Sisulu University
Madzikane Kazulu Memorial hospital
March 2009 till date.

Membership of Professional Bodies

1. Member South African Medical Association.....Membership number 82901.
2. Member Southern African HIV Clinicians Society....Membership number 15104.

Postgraduate Programme

Masters in Family Medicine (Final year)
University of Stellenbosch

References

1. Dr N.G Bekoka
Clinical Manager, Sebokeng Provincial Hospital
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2. Dr W.B Yogolelo
Senior Family Physician
Kimberley Provincial Hospital Kimberley. +27728987413

Annexure 2 (For participants completing the questionnaires)

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM TITLE OF THE RESEARCH PROJECT:

“THE PREVALENCE OF ESTABLISHED FACTORS AFFECTING ADHERENCE TO HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART) AT THE ARV CLINIC OF MADZIKANE KAZULU MEMORIAL HOSPITAL”.

ETHICS REFERENCE NUMBER: N10/02/034

PRINCIPAL INVESTIGATOR: DR O.O ANIZOBA

ADDRESS: MADZIKANE KAZULU MEMORIAL HOSPITAL MOUNT FRERE EASTERN CAPE PROVINCE.

CONTACT NUMBER: 0764891853

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 entails and how you could be involved. Also your participation is ENTIRELY VOLUNTARY and you are free to decline to participate. If you say no,

this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the COMMITTEE FOR HUMAN RESEARCH AT STELLENBOSCH UNIVERSITY and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

WHAT IS THE RESEARCH STUDY ALL ABOUT?

The study will be conducted in Madzikane KaZulu Memorial Hospital ARV Clinic and a total of 263 patients will be recruited for the study. The study aims to find out the rate at which known factors affect the patients adherence to HAART in order to make plans on how to tackle these factors thereby improving HAART adherence amongst patients in the ARV Clinic and when the down referral system starts. I am embarking on this study because of the concern of the increasing defaulter rate in the ARV Clinic and the need to improve adherence at the ARV Clinic presently and in the down referral site later on. The study involves getting approval from the Hospital Management and the ARV Clinic, recruiting and training interviewers and research assistants, reviewing the ART register and ART Pharmacy records to identify patients that defaulted HAART within the period of January 2009 and December 2010, pilot testing of the questionnaire and its modification subsequently, data collection by interviewer administered questionnaire in English and Isixhosa as appropriate to the identified consenting patients in a private room within the ARV Clinic, analyzing the data collected and writing up the study findings.

WHY HAVE YOU BEEN INVITED TO PARTICIPATE?

You have been invited to participate in this study because this study hopes to find out why you are experiencing difficulty taking your medicine/ARVs. This also means that information regarding the reason(s) for defaulting HAART will be collected with an interviewer administered questionnaire. This questionnaire will be made clear to you and all information obtained will be treated with utmost confidence and therefore your identity will not be required in completing the questionnaire. With this information we hope to improve the system so that patients on ARV medication can be helped better. The completion of this questionnaire will take between 20 and 30 minutes.

WHAT WILL YOUR RESPONSIBILITY BE?

You will be responsible for completing the questionnaire that will be administered by an interviewer, to the best of your honesty and ability.

WILL YOU BENEFIT FROM TAKING PART IN THIS RESEARCH?

There are no personal benefits for taking part in the research but patients at the ARV Clinic presently and future patients at the Clinic will benefit from the findings of the research.

ARE THERE RISKS INVOLVED IN YOUR TAKING PART IN THIS RESEARCH?

There are no known risks involved by participating in this research. However issues of concern to the patients may include stigmatization, discontinuation of grants and possible financial costs to be incurred. These issues will in no way be affected by taking part in the study.

WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS?

The information obtained will be treated as confidential and protected. When it will be used to write up the thesis and published, the identity of the participants will remain anonymous. The Principal Investigator and the Research Assistants/Interviewer (who all will be recruited from the ARV Clinic Staff) will have access to the information.

WILL YOU BE PAID TO TAKE PART IN THIS STUDY AND ARE THERE ANY COSTS INVOLVED?

No you will not be paid to take part in this study and there are no costs involved as you will be administered the questionnaire when you will be at the Clinic for your regular monthly Clinic appointment though priority will be given to you for the ARV Clinic services on the day you come.

IS THERE ANYTHING ELSE THAT YOU SHOULD KNOW OR DO?

You can contact Dr O.O Anizoba at tel 0764891853 if you have any further queries or encounter any problems. In addition you can contact the Committee for Human Research at 021-9389207 if you have any concerns or complaints that have not been adequately addressed by your study doctor. You will receive a copy of this information and consent form for your own records.

Declaration by Participant

By signing below, I.....agree to take part in a research study entitled THE PREVALENCE OF ESTABLISHED FACTORS AFFECTING HAART ADHERENCE AT MADZIKANE KAZULU MEMORIAL HOSPITAL ARV CLINIC.

I declare that:

- 1. I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- 2. I have had a chance to ask questions and all my questions have been adequately answered.
- 3. I understand that taking part in this study is *VOLUNTARY* and I have not been pressurized to take part.
- 4. I may choose to leave the study at any time and will not be penalized or prejudiced on any way.
- 5. 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

Declaration by investigator/assistant

I(name).....declare that:

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

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

.....
Signature of investigator/assistant

.....
Signature of witness

Declaration by interpreter

I(name).....declare that:

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

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

.....
Signature of interpreter

.....
Signature of witness.

Annexure 3 (For Focus Group Discussion Participants)

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

“THE PREVALENCE OF ESTABLISHED FACTORS AFFECTING ADHERENCE TO HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART) AT THE ARV CLINIC OF MADZIKANE KAZULU MEMORIAL HOSPITAL”.

ETHICS REFERENCE NUMBER: N10/02/034

PRINCIPAL INVESTIGATOR: DR O.O ANIZOBA

ADDRESS: MADZIKANE KAZULU MEMORIAL HOSPITAL MOUNT FRERE EASTERN CAPE PROVINCE.

CONTACT NUMBER: 0764891853

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 entails and how you could be involved. Also your participation is ENTIRELY VOLUNTARY and you are free to decline to participate. If you say no,

this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the COMMITTEE FOR HUMAN RESEARCH AT STELLENBOSCH UNIVERSITY and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

WHAT IS THE RESEARCH STUDY ALL ABOUT?

The study will be conducted in Madzikane KaZulu Memorial Hospital ARV Clinic and a total of 263 patients will be recruited for the study. The study aims to find out the rate at which known factors affect the patients adherence to HAART in order to make plans on how to tackle these factors thereby improving HAART adherence amongst patients in the ARV Clinic and when the down referral system starts. I am embarking on this study because of the concern of the increasing defaulter rate in the ARV Clinic and the need to improve adherence at the ARV Clinic presently and in the down referral site later on. The study involves getting approval from the Hospital Management and the ARV Clinic, recruiting and training interviewers and research assistants, reviewing the ART register and ART Pharmacy records to identify patients that defaulted HAART within the period of January 2009 and December 2010, pilot testing of the questionnaire and its modification subsequently, data collection by interviewer administered questionnaire in English and Isixhosa as appropriate to the identified consenting patients in a private room within the ARV Clinic, analyzing the data collected and writing up the study findings.

WHY HAVE YOU BEEN INVITED TO PARTICIPATE?

You have been invited to participate in this study because this study hopes to find out why you experiencing difficulty taking your medicine/ARVs. This also means that information regarding the reason(s) for defaulting HAART will be collected during focus group discussions (FGDs) with an interviewer. With this information we hope to improve the system so that patients on ARV medication can be helped better. Such focus group discussion (FGD) may last up to about 2 hours and four such FGDs may be required.

WHAT WILL YOUR RESPONSIBILITY BE?

During these focus group discussion sessions (FGD), you will be required to discuss the reasons for not taking your medication with other similarly affected patients in a focus group discussion.

WILL YOU BENEFIT FROM TAKING PART IN THIS RESEARCH?

There are no personal benefits for taking part in the research but patients at the ARV Clinic presently and future patients at the Clinic will benefit from the findings of the research.

ARE THERE RISKS INVOLVED IN YOUR TAKING PART IN THIS RESEARCH?

There are no known risks involved by participating in this research. However issues of concern to the patients may include stigmatization, discontinuation of grants and possible financial costs to be incurred. These issues will in no way be affected by taking part in the study.

WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS?

The information obtained will be treated as confidential and protected. When it will be used to write up the thesis and published, the identity of the participants will remain anonymous. The Principal Investigator and the Research Assistants/Interviewer (who all will be recruited from the ARV Clinic Staff) will have access to the information.

WILL YOU BE PAID TO TAKE PART IN THIS STUDY AND ARE THERE ANY COSTS INVOLVED?

No you will not be paid to take part in this study and there are no costs involved as the focus group discussions will be arranged to coincide with the days when you will be attending the Clinic for your regular monthly appointments and may involve 4 such sessions.

IS THERE ANYTHING ELSE THAT YOU SHOULD KNOW OR DO?

You can contact Dr O.O Anizoba at tel 0764891853 if you have any further queries or encounter any problems. In addition you can contact the Committee for Human Research at 021-9389207 if you have any concerns or complaints that have not been adequately addressed by your study doctor. You will receive a copy of this information and consent form for your own records.

Declaration by Participant

By signing below, I.....agree to take part in a research study entitled THE PREVALENCE OF ESTABLISHED FACTORS AFFECTING HAART ADHERENCE AT MADZIKANE KAZULU MEMORIAL HOSPITAL ARV CLINIC.

I declare that:

- 1. I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- 2. I have had a chance to ask questions and all my questions have been adequately answered.
- 3. I understand that taking part in this study is *VOLUNTARY* and I have not been pressurized to take part.
- 4. I may choose to leave the study at any time and will not be penalized or prejudiced on any way.
- 5. 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

Declaration by investigator/assistant

I(name).....declare that:

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

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

.....
Signature of investigator/assistant

.....
Signature of witness

Declaration by interpreter

I(name).....declare that:

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

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

.....
Signature of interpreter
Annexure 4 (Information letter)

.....
Signature of witness.

1st December 2009.

Madzikane KaZulu Memorial Hospital
Mount Frere.

Dear Participant,

I am Dr Anizoba, a third year student, in the Division of Family Medicine and Primary Care, Faculty of Health Sciences, University of Stellenbosch. I am also working as a medical officer at Madzikane kaZulu Memorial Hospital in Mount Frere.

I herewith kindly request that you assist with the completion of the questionnaire that will be administered to you by the research assistants. We are in the process of conducting research to establish the frequency of known factors that affect antiretroviral therapy adherence at the ARV clinic of the hospital. This research is conducted as part of my academic requirement in the MMed (Family Medicine) degree.

Please be assured that your participation in this study WILL NOT adversely affect your care at the ARV clinic in any way. Confidentiality will be strictly maintained throughout the study period, and there will

be no disclosure of personal information in any form whatsoever. You are also free at any time to quit participating in the research at your own discretion. Kindly feel free to get clarifications from me or the research assistants concerning any issues within the study or any queries you may still have.

Thank you for your much valued time and assistance in this regard.

Yours sincerely

Dr Anizoba

Medical Officer
Madzikane KaZulu Memorial Hospital
Mount Frere.

Annexure 5 (Permission letter)

1st December 2009.

The Chief Executive Officer,
Madzikane KaZulu Memorial Hospital
Mount Frere.

Dear Sir

Permission to conduct a research

I hereby apply for permission to conduct research at the ARV clinic of the hospital. I am presently a part-time 3rd year student in the Division of Family Medicine and Primary Care, Faculty of Health Sciences, University of Stellenbosch.

As part of the degree, I am required to conduct research which I have decided to do in the ARV clinic in order to assist in improving on the quality of service rendered there. The research title is: "*The prevalence of established factors affecting HAART adherence at the ARV clinic of Madzikane KaZulu Memorial Hospital*". This research will assist in the overall quality of care rendered to our existing pool of patient attending the ARV clinic. In particular it is hoped that the research will help decrease the HAART default

rate of patients attending the ARV clinic, and also contribute towards kick-starting the down referral system.

The required research funding has been applied for and this research will not pose any harm to the patients in the ARV clinic or the hospital at large, and confidentiality will be strictly maintained throughout the study. A copy of the research proposal is available for your perusal.

I look forward to receiving permission to proceed with this research project.

Yours Sincerely

Dr O.O Anizoba.

Medical Officer
Madzikane KaZulu Memorial Hospital
Mount Frere.
Eastern Cape

Annexure 6

QUESTIONNAIRE (interviewer-administered)

Instruction: Kindly complete this questionnaire completely and accurately by circling the items best applicable to the questions/statements. Place a tick (✓) in the box as applicable in the **demographics** section.

DEMOGRAPHICS

1. Gender
 - a. male.....
 - b. female.....
2. Age(years)
 - a. 19-28.....
 - b. 29-38.....
 - c. 39-48.....
 - d. 49-58.....
 - e. ≥59.....
3. Marital Status
 - a. Married.....

- b. Single.....
 - c. Separated.....
 - d. Divorced.....
 - e. Cohabiting.....
4. Income Source
- a. Employed.....
 - b. Unemployed on DG.....
 - c. Unemployed not on DG.....
5. Treatment Supporter
- a. Yes.....
 - b. No.....
6. Length of time on HAART(months)
- a.<6.....
 - b.6-11.....
 - c.>11.....
7. HAART Regimen presently on
- a.1A.....
 - b.1B.....
 - c.2.....
 - d. Non standard.....

Please answer the following TRUE or FALSE questions

PATIENT RELATED FACTORS

- 1. I am often away from home and cannot take my medication
... True False
- 2. I was busy with other things and could not take the medication
... True False
- 3. I simply forgot to take my medication
True False
- 4. I was sick or ill during the time that I needed to take my medication
True False
- 5. I did not want others to notice me taking medications
True False
- 6. I had a change in my daily routine
True False
- 7. I did not have money for transport to the ARV clinic
True False
- 8. The weather did not allow me to come to the ARV clinic (rainy/very cold)
True False
- 9. I have no one to remind me
True False
- 10. I do not belong to a support group

- | | |
|-------------------------------------|-------|
| True | False |
| 11. I use substances like cigarette | |
| True | False |
| 12. I use substances like alcohol | |
| True | False |
| 13. I use substances like dagga | |
| True | False |
| 14 I use substances like Tik | |
| True | False |

THERAPY RELATED FACTORS

- | | | |
|--|------|-------|
| 1. I find that I have too many pills to take | True | False |
| 2. I wanted to avoid side effects | True | False |
| 3. I found it difficult to take pills at specified times | True | False |
| 4. I have difficulty with dietary restrictions on my pills | True | False |
| 5. The pills make me sick (e.g. nausea/vomiting/rash/headache etc) | True | False |
| 6. I take herbal medications also | True | False |

FACILITY RELATED FACTORS

- | | | |
|--|------|-------|
| 1. The ARV clinic is too far from where I live | True | False |
| 2. The medications were out of stock at the ARV clinic | True | False |
| 3. The ARV clinic staff are not supportive | True | False |
| 4. The ARV clinic staff are unfriendly | True | False |
| 5. The ARV clinic staff are unhelpful | True | False |
| 6. There are few staff at the ARV clinic to attend to patients | True | False |

DOWN REFERRAL

- Do you prefer to receive your ART at a clinic near you?
YES **NO**
- If yes, when do you want to start taking your ART at a clinic near you?

WITHIN 6 MONTHS , 6-12 MONTHS , AFTER 12 MONTHS

3. Do you think that the clinic has enough workers to handle the ART roll out?
YES **NO.**
4. Do you find that you have to wait too long to receive your medication?
YES **NO.**

.....

Key: HAART-----Highly Active Antiretroviral Therapy
DG-----Disability Grant
ART-----Anti-retroviral Therapy

NB: This questionnaire was adapted from the AACTG³⁰ (Adult AIDS Clinical Trials Group) adherence instrument which is standardized, with modifications to suit the study setting.

Annexure 7

Questions for Focus Group Discussion

1. The ARV clinic started initiating people on HAART in 2007, what can you say about the performance of the clinic from then till now? (objective: service comparison over time)
2. Many people are now on HAART at the ARV clinic, what makes you motivated to continue taking the medication? (objective: motivation for taking HAART)
3. Think about the period from January 2009 to December 2010, how often do you think you missed taking your medications?
(objective: treatment default frequency over the study period)
4. People often have different reasons for doing things, what reasons do you have for missing your medications between January 2009 and December 2010?
(objective: reasons for treatment default over the study period)

5. There are a number of ways of addressing any issue, what do you think could assist you not to miss your medications? (objective: solutions to treatment default)
6. Finally, would you prefer taking your HAART at a clinic nearer to you? (objective: opinion on down referral)

Annexure 8

**HEALTH RESEARCH ETHICS COMMITTEES
Faculty of Health Sciences, Stellenbosch University
CHECKLIST-GENERAL**

To be completed by Applicant and checked by Ethics Admin Office

PROTOCOL TITLE:THE PREVALENCE OF ESTABLISHED FACTORS AFFECTING ADHERENCE TO HIGHLY ACTIVE ANTIRETROVIRAL THERAPY(HAART) AT MADZIKANE KAZULU MEMORIAL HOSPITALS' ARV CLINIC

PROTOCOL NUMBER		PROTOCOL VERSION		PROTOCOL DATE	June 06th 2010
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	CV (max 2 pages)	Investigator Declaration	Conflict of Interest statement signed.	Admin Office Comments
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PRINCIPAL INVESTIGATOR: Dr Anizoba O.O	Yes	Yes	Yes	
SUB-INVESTIGATORS				
1.				
2.				
3.				
4.				
5.				
6.				
OTHER STAFF				

	Applicant	Comments	Admin Office
	Y /N / NA		
Applicant Signature	Y		
Supervisor Signature	Y		
HODiv Signature	Y		
Protocol synopsis	Y		
Full protocol	Y		
Page numbers on protocol?	Y		
Budget	Y		
Informed Consent Form	Y		
Questionnaires	Y		
Other measuring tools/instruments.	Y		
Recruitment material/ Advertisement(s)	NA		
DoH or other letters of approval to conduct research	Y		
Material Transfer Agreement	NA		

A. Section B: To Be completed by Applicant

INFORMED CONSENT FOR RESEARCH CHECKLIST.

Element	Yes (PI)	Yes/No (Reviewer)
1. That consent is being sought from the participant to participate in research.	Yes	

2. The purpose of the research and where it will be conducted.	Yes	
3. The expected duration of the participant's involvement in the research.	Yes	
4. The total number of participants that will be involved at this site and/or South Africa and worldwide.	Yes	
5. A description of all the processes and procedures to which the participant will be subjected, emphasizing any experimental procedures that are innovative and have not been used in medical practice.	Yes	
6. The principal investigator's name and contact details.	Yes	
7. Explanation of participants responsibilities.	Yes	
8. Explanation of any randomization process if applicable).	Yes	
9. Circumstances that may result in the project being terminated or the participant being withdrawn.	Yes	
10. A description of foreseeable risks and discomforts.	Yes	
11. A description of benefits to the participant or others both during and after the research. If there are no expected benefits, the participant must specifically be made aware of this.	Yes	
12. Disclosure of alternative procedures and course of treatments available if applicable	NA	
13. Description of extent to which confidentiality will be maintained and protected.	Yes	
14. Statement that sponsors of the study, study monitors or auditors or REC members may need to inspect research records.	NA	
15. Statement that the Health Research Ethics Committee has approved the research.	YES	
16. Contact details of the committee.	NA	
17. Explanation of how research related injury will be managed and details of insurance if applicable.	NA	
18. Explanation as to whom to contact in the event of research related injury.	NA	
19. Participation in the study is entirely voluntary	Yes	
20. Participants are free to withdraw at any point without explanation or any negative consequences. Their routine health care will not be adversely affected.	Yes	
21. Participants must be informed of their rights to be told any new relevant information that arises during the course of the trial and the ICF should be revised, where appropriate to incorporate this information.	NA	

22. That the study will be conducted according to the International Declaration of Helsinki and other applicable international ethical codes for research on human subject.	Yes	
23. Any expense to which the participant may be liable.	No	
24. Explanation regarding payment for participation or out of pocket expenses	NA	
25. Identity of the funder , where applicable and any potential conflict of interests.	NA	
26. Where appropriate, the participant should also be requested/advised to inform his general practitioner and life insurance company or medical aid of his/her participation. <input type="checkbox"/> Not considered appropriate/necessary	NA	
27. Simple, clear language has been used (Maximum Grade 8 reading level) and all medical and technical terms have been explained.	Yes	

Section C. To be completed by Applicant

	Yes (PI)	Yes/No (Reviewer)
1. Does the study have relevance and scientific or clinical value and applicability to the proposed research population?	Yes	
2. Does the protocol include an adequate literature review?	Yes	
3. Is the selection of subjects equitable and appropriate; adequate consideration and protection of vulnerable research populations.	Yes	

Annexure 9

SYNOPSIS / SUMMARY OF RESEARCH PROPOSAL

Student: Dr OO Anizoba; **Supervisor:** Dr Michael Pather

PROJECT TITLE

The prevalence of established factors affecting Highly Active Antiretroviral Therapy(HAART) adherence at the Madzikane KaZulu Memorial Hospitals' ARV clinic.

Introduction:

The problem inspiring the research stems from the context of an increasing defaulter rate, increasing number of clients on HAART, and increasing number of clients awaiting initiation on HAART. With the same number of ARV staff over the years, and the down referral system yet to commence, the work load in the ARV clinic and treatment defaulting rate will tend towards increasing. The researcher was motivated and committed to doing this research because of the need to improve adherence, and ultimately decrease treatment defaulting rate at the ARV clinic, and also contribute towards the down referral system which is long over due.

With the increasing number of people infected with HIV everyday and the need to increase access to HAART, adherence issues will always be very crucial for any successful HAART programme. Adherence has been defined severally in terms of clinic attendance, deficit between number of pills given and number of pills consumed and obeying dietary restrictions with respect to therapy. However, there is still no single perfect tool used in measuring adherence. Therapy related factors, patients related factors and facility related factors have been widely reported to affect adherence to HAART.

Research Question;

What is the prevalence of established factors affecting adherence to HAART at the Madzikane KaZulu Memorial Hospitals' ARV clinic?

Aim

The research aim is to determine the prevalence of established factors affecting adherence to HAART at the Madzikane KaZulu Memorial Hospitals' ARV clinic.

Objectives

The objectives of the research include;

1. To conduct an audit on case files of patients on HAART over the study period.
2. To explore the behavioural aspects of poor HAART adherence in a focused group discussion.
3. To determine the predictors of good HAART adherence.

Methods

Setting of the study is in an ARV clinic in Madzikane KaZulu Memorial Hospital, a district hospital in the Mount Frere Community of the Alfred Nzo District which is predominantly rural, in the Eastern Cape Province. The hospital is a modern district hospital which was under the hospital revitalization programme. Its a 269 bed hospital, with 223 usable beds which became functional in September 2006, and is located in Mount Frere, along the N2 national road. It serves the Mount Frere community as well as part of the Mount Ayliff and Tabankulu communities. The ARV clinic has four feeder clinics, ten staff members and over one thousand clients. The ARV clinic started initiating clients on HAART since March 2007, and is affiliated to the Infectious Diseases Clinic of Umtata General Hospital.

Study design

The study is a cross sectional descriptive study. An audit of case files of patients on HAART between January 2009 and December 2010, will be done to identify the treatment defaulters. After this, a focused group discussions will be done with 12 randomly selected treatment defaulters.. The findings from the FGDs will be incorporated into the data collection tool (questionnaire).

Piloting

The questionnaire will be piloted on a randomly selected 15 treatment defaulting patients, and the researchers colleagues (for inputs/modifications) after which the final version of the questionnaire will be administered to the selected patients by trained interviewers/field workers.

Inclusion and exclusion criteria

The inclusion criteria are; adult patients who are 19 years and above, who have been on HAART for at least 2 months within January 2009 and December 2010. Exclusion criteria are; patients with cognitive impairment and transfer-out patients to other facilities.

Sample

A total of 263 patients will be used as the sample size from a sample frame of 1014 patients on HAART at the ARV clinic, with a confidence interval of 95% and precision of 6%. The anticipated benefits

include; provision of information on the adherence patterns in a deeply rural setting of Madzikane KaZulu Memorial Hospitals' ARV clinic, promoting adherence enhancing structures already at the clinic thereby decreasing treatment default rate, and contributing towards kick-starting the down referral system.

Ethical considerations (See main proposal)

Ethical considerations include; written informed consent is to be obtained from each participant prior to taking part in the research, strict maintenance of confidentiality throughout the research, non disclosure of participants HIV status/identity, interviewer administered questionnaire to be done in a private comfortable room within the ARV clinic, and participation will be strictly on voluntary basis and participants can withdraw at any time they wish to.

Time frame (See table I main proposal)

The estimated duration for the research is 5 months possibly from March to August 2010 depending on the time of approval from the research ethics committee and other logistics mentioned in the research protocol.

Budget (See table II main proposal)

The research budget was estimated to be R8000 which includes indirect cost of about R1700. The major part of the research will be from personal funds and from funds applied for from the MRC.
