

**A DESCRIPTIVE STUDY TO EVALUATE THE EFFECT OF GUIDELINES USED BY
COUNSELLORS TO IMPROVE ADHERENCE TO ANTIRETROVIRAL THERAPY IN THE
PRIVATE SECTOR**

Marais, Melanie (M Cur)

School of Nursing, University of the Western Cape

Nikodem, Cheryl, (DCur), Ass. Professor

School of Nursing, University of the Western Cape

Correspondence address:

Prof. Dr. C. Nikodem

School of Nursing, University of the Western Cape

Private Bag x17, Bellville, 7535, South Africa

Email. cnikodem@uwc.ac.za

Abstract

Introduction: To achieve a virological outcome to antiretroviral therapy, a high adherence level is required.

Objective: To implement and evaluate guidelines that will be used by treatment support counsellors in an attempt to increase client adherence to antiretroviral treatment.

Methods: A quasi - experimental comparative study was used to assess whether a structured treatment support guidelines can improve client adherence to antiretroviral therapy. The treatment outcome of two groups was compared: one group received the adherence guidelines and the other group was a historical group where no adherence guidelines were applied. The main outcome measure was whether adherence guidelines improved adherence to ART.

Participants: Forty clients were exposed to the adherence guidelines and 34 were not.

Setting: Clients that subscribe to Aids for Aids.

Intervention: A structured guideline used by counsellors with regular contact.

Results: Specific guidelines used by counsellors to improve adherence to antiretroviral therapy has shown that significantly more clients in the intervention group had their CD4 blood tests done after six months and adhered to regularly claim their medications. In addition were there more clients in the intervention group who had viral loads of less than 400 copies / ml after six months.

Conclusion: Specific counselling using effective guidelines improve adherence to antiretroviral treatment.

Key Words: Adherence guidelines, antiretroviral therapy, counselling.

Introduction

The UNAIDS (2002:153) raised a general concern about extensive provision of antiretroviral therapy (ART) in all societies. A further concern is whether health systems have the capacity to ensure adherence to multifaceted ART regimens. There is

a general consensus among researchers that an adherence level of 90 – 95% is required to achieve an acceptable virological outcome for most clients (Bartlett & Galant, 2002) Aids for Aids (Afa) points out that if adherence levels to ART's are below 80% an 80% reduction in the effect of ART could be

expected (AfA, 2005). AfA is a HIV / AIDS disease management company offering access to antiretroviral therapy (ART), prevention of opportunistic infections, treatment and blood results monitoring, treatment support through adherence coordinators and expert clinical support and advice to healthcare providers. They monitor treatment adherence through claims history, CD4 and viral load (VL) results as well as telephonic contact with the client.

Rational

AfA (2005) currently provides their employees as well as clients with information booklets pertaining to clinical guidelines in the management of human immune deficiency syndrome (HIV). These guidelines mainly concentrate on managing or treating the HIV-infected individual and not on the importance of adherence to ART. It appears from some client records that optimal viral suppression is not achieved, despite availability of these clinical guidelines. Failure to adherence of prescribed therapy is one of the main causes why optimal viral suppression may not be obtained. Clients are often advised by their healthcare providers to change their current therapy or to include other drugs. These changes of medication usually occur without investigation of their adherence to their current therapy regimen. A problem was identified at AfA whereby some doctors requested a change in treatment within less than a year after their patients started antiretroviral therapy. The requests were normally based on treatment failure. From the medication claim history, it was clear that the desired treatment outcome was not achieved due to poor adherence to therapy. The concern is that there are limited affordable drugs on the market and the danger of poor adherence and continuous changing of regimens is that it may result in an

increase of mutations and viral resistance. Another problem that was identified was the fact that treatment support counsellors did not have a clearly formulated adherence guideline that could assist them to maintain a structured and consistent conversation with patients around the issue of adherence to ART.

Objective

The objective of this study was to determine the effectiveness of newly formulated adherence guidelines in antiretroviral treatment support to clients registered on the AfA disease management programme.

Statement

The authors postulated that clear adherence guidelines used by treatment support counsellors may enhance adherence to therapy and better adherence to therapy will result in less frequent change in treatment and enhance virology outcomes.

Methods

A quasi-experimental, descriptive study design was used to evaluate the effectiveness of the proposed adherence guideline. Thus there was no randomisation but a comparison group was used. The design for this study made use of an intervention and comparison group and the purpose of the design is quantitative-descriptive.

Participants

Two groups were selected for the purposes of this study. One group was identified as the intervention group (IG) and they were counselled by AfA counsellors who used structured adherence guidelines and were contacted at regular intervals. The control group (CG) were a historical group

where no structured adherence guidelines were used and where there were no control over the total number of contacts. The study population included all men and women over the age of 21 years who registered on the AfA program for the first time, had no previous experience of ART and qualified for Highly active antiretroviral treatment (HAART). The participants of the IG were selected from the overall population who registered on the AfA program from 01 October 2004 until 30 November 2004. The participants in the CG were selected from the overall population who registered on the AfA program from 01 February 2004 until 31 March 2004. All patients who qualified for the study had to either have a CD4 cell count of 250 cells / μ L and less or had to qualify for ART based on an Aids defining illness.

The records of medical scheme members, males and females over the age of 21 who were registered on the AfA programme were evaluated. Those who had previous exposure to ongoing ART and those who did not clinically qualify for therapy were excluded from the study. After applying the inclusion and exclusion criteria, the number of subjects in the intervention group (IG) was 40 and the number of subjects in the comparative group (CG) 34.

Inclusion criteria

The inclusion criteria included the following:

- Men and women over the age of 21 years;
- Registered on the AfA program;
- Started HAART for the first time within the period (months) as mentioned in the study population section;
- Had to be members of a medical scheme administered by Medscheme to enable the

researcher immediate access to their claims history.

Exclusion criteria

The exclusion criteria included the following:

- All clients under the age of 21 years;
- All medical schemes not administered by Medscheme at the time of the study period;
- All corporate clients of AfA;
- All medical schemes administered by external parties;
- All international clients of AfA;
- All the clients who received post exposure prophylaxis (PEP) at the time;
- All clients with a CD4 cell count over 250 cells / μ L who had no Aids defining illness;
- All clients with a history of previous ART use.

Setting: The study was conducted at AfA, a Medscheme Integrated Company. Members of medical schemes that are contracted with AfA may join the AfA programme when their HIV positive status is confirmed.

Intervention

Those in the IG were exposed to counsellors who used specific formulated guidelines and were contacted monthly for a period of six months. The CG consisted of client records which met the inclusion and exclusion criteria prior to the newly implemented guidelines.

Research Instrument

The research instrument (adherence guidelines) was administered to all subjects in the intervention group. The research instrument was a newly formulated adherence guideline that was applied at every contact with the subjects. This tool was formulated based on adherence literature as well as

inputs from AfA. The research instrument consisted of questions, advice to subjects and explanations to the treatment support counsellors to enable them to understand the context in which the questions were asked. Factors like self reporting (tolerability of ART, missed dosages), AfA adherence assessment, claims history, use of other medicines, problems experienced / adherence barriers, HIV status disclosure, reminders of follow up blood tests, emphasizing adherence to HAART, healthy lifestyle and intervention based on the interaction were included in the research instrument. The guidelines were administered in English and completed by 40 subjects. The content, face and construct validity of the instrument was evaluated.

Data Analysis

Data were analysed with Excel software and transferred from the excel spreadsheet using the SAS statistical package (SAS institute Inc., Cary, NC, USA). The data was cleaned and entered twice to ensure correctness. The first part of the data analysis gave descriptive statistics for each group separately. Tests of homogeneity of variance were applied to continuous variables. If the variables were homogenous, the ANOVA test was applied. If variables were heterogeneous, the Kruskal - Wallis Test was applied. The Chi - square test was used for proportion and the Fisher's exact test used when numbers were less than five. The results are expressed as means (standard deviation) or proportions.

Ethical Approval

The proposal of the study was submitted to the Senate Higher Degrees at the University of the Western Cape for ethical approval. Written consent was obtained from AfA to perform the study. Client confidentiality remained intact by keeping the

collected data under an identification code (patient key number) and no form of identification of clients were added on to the thesis / published.

Results

All subjects were HIV – infected males and females over the age of 21 years who qualified for ART and registered on the AfA disease management programme. Forty subjects were exposed to the adherence guidelines and contacted on a monthly basis for six months. Their baseline variables and outcome variables were compared to the 34 subjects (CG) that was not exposed to adherence guidelines. The two cohorts were similar with respect to age, gender, CD4 count, viral load and province. Baseline CD4 counts was available on all the subjects. Nearly all subjects 70 / 74 (94.5%) had a baseline CD4 of ≤ 250 cells / μl which met the ARV treatment inclusion criteria. Only four subjects had a baseline CD4 cell count of more than 250 cells / μl , two in the IG (334 & 386 cells / μl) and two in the CG (256 & 267 cells / μl). The mean cells / μl were the same between the two groups 121.05 (93.5) cells / μl IG and 121.47 (83.5) cells / μl CG, $p = 0.983$. Some subjects had cell counts of as little as 3 cells / μl and the ranges were IG (3.00 - 386 cells / μl) and CG (5.00 - 267 cells / μl) (Table 1).

All subjects in the IG had baseline viral loads done and the mean viral load for the IG was 156500.8 (177491.2) copies / ml. One subject in the CG did not had a baseline viral load. The mean viral load in the CG was slightly higher 204 125.9 (244 467.1) but the difference was not significant, $p = 0.412$. Only 8 / 73 (10.9%) subjects had baseline viral loads of less than 100 000 copies / ml. It is recommended that viral load measures should rather be reported in Log_{10} because viral loads values may vary by up to three times, such as from

5000 – 15 000 and the variation appear to be large but this variation is within the margin of error of the test (AFA, 2005:9). The mean of the Log₁₀ readings of the baseline viral load was similar IG 4.83 (626)

with a range of 3.72 - 5.80 and CG 4.90 (747) with a range of 2.63 to 5.87 and a p value of 0.671

Table 1 Biographical and baseline data

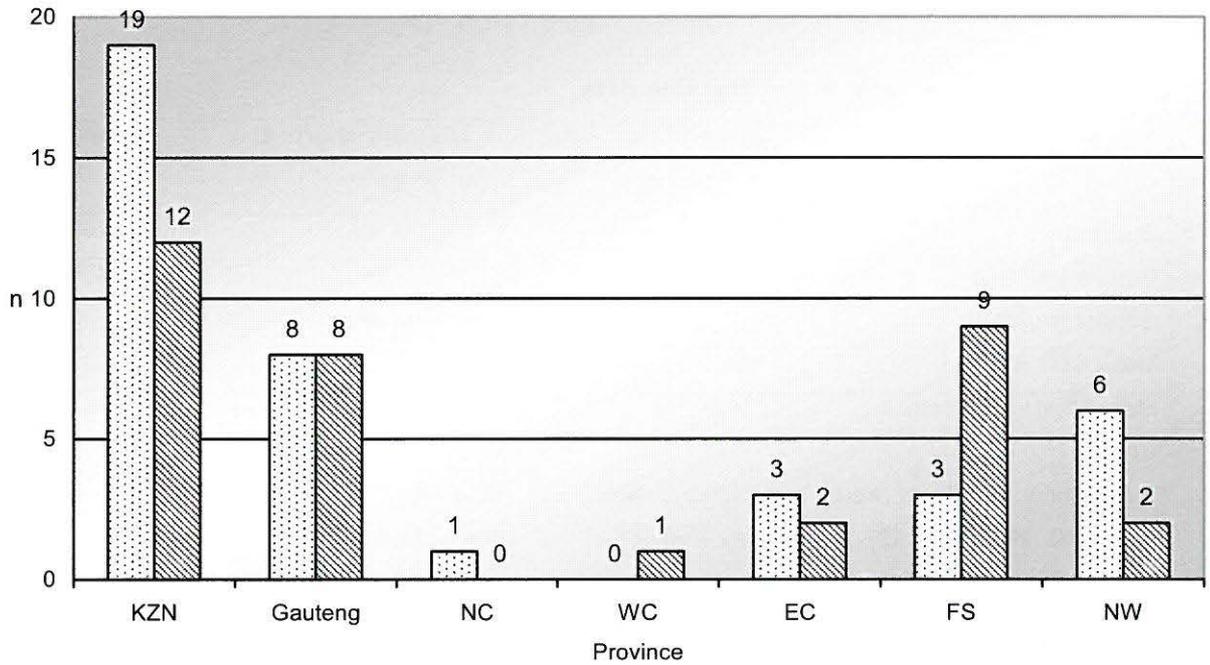
Baseline variables	Intervention group N 40	Control group N 34	P value
Age groups	25 - 56	26 – 48	0.164
Gender (female)	31 / 40 (77.5%)	24 / 34 (70.6%)	0.497
Gender (male)	9 / 40 (22.5%)	10 / 34 (29.4%)	
Mean CD4 (cells/μl)	121.05 (n 40)	121.47 (n 34)	0.983
Mean Viral load (copies/ml)	156500.8 (n 40)	204 125.9 (n 33)	0.412.

The majority of clients were from Kwazulu-Natal (KZN), (IG 19 vs CG 12). The same number of clients came from Gauteng, 8 in each group. Twelve clients were from the Free State (IG 3 vs CG 9) and eight were from the North West Province (IG 6 vs CG 2). The least subjects came from the Eastern Cape (IG 3 vs CG 2), Northern Cape (IG1 vs CG 0) and the Western Cape Province (IG 0 vs CG 1).

It is important to note that no statistical differences were found in the baseline data between the intervention and the comparative groups. Thus the comparative group were comparable with the intervention group.

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Figure 1 Geographical distribution



Results

The counsellors were able to contact the clients significantly more over the six month trial period (IG 164 vs CG 35). The average calls per patient in the Intervention group were 4.7 vs. 1 in the Comparative group. Significantly more clients in the intervention group returned for follow up CD4 blood counts (IG 37 vs CP 13). The mean CD4 count has improved in both groups.

More clients had a viral load of less than 400 copies / ml after six months of treatment in the intervention group, but there were no statistical difference noted between the two groups (IG 28 /37 vs 7 / 13). Significantly more subjects in the intervention group claim their ART more regularly (IG 32/40 vs CG 15/34). Fewer subjects in the intervention group

changed treatment over the six month follow up time period (IG 4/40 vs CG 6/34). Side - effects such as a rash were the most common reason for changing therapy. As expected were there more

side effects, more hospital visits and more hospital admissions in the intervention group. The reason for this is that the counsellors encourage clients to immediately seek medical advice when during the telephonic conversation it was detected that the client needs to see a medical practitioner. No deaths were recorded in the intervention group and two deaths were recorded in the comparison group (Table 2).

Table 2 Outcome Variables

Outcome variables	Intervention Group		Comparative Group		p value
N	40		34		
Contacts	164		35		0.000
Follow up CD4 blood test	37 / 40	(92.5%)	13 / 34	(38.2%)	0.001
Mean CD4	229.2	(n37)	263.5	(n13)	0.824
CD4 range (cells / μ l)	45 – 568	(n37)	53 – 1000	(n13)	0.824
Viral load < 400 copies / ml	28 / 37	(76%)	7 / 13	(54%)	0.152
ART claims	32 / 40	(80%)	15 / 34	(44%)	0.003
Change in treatment	4 / 40	(10%)	6 / 34	(17.6%)	0.497
Side effects	10 / 39	(25.6%)	5 / 34	(14.7%)	0.388
Mean doctor visits	5.3	(n40)	5.1	(n34)	0.455
Hospital admissions	13 / 40	(32.5%)	6 / 34	(17.6%),	0.480
Deaths	0		2		0.400

Discussion

More females enrolled on the AfA programme. Interestingly, both female groups in this study presented with a 70.5 to 77.5% females, which is more or less in line with the Khayelitsha HIV / AIDS pilot where 70% women accessed ART. The Khayelitsha HIV / AIDS pilot proved that there is a clear improvement in mortality rate compared to people not on ART. They found that the survival rate is higher among women. Men were 1.89 times more likely to die. They also had poor adherence and follow ups over a period of 18 months. Support systems and counselling services are not sufficiently supportive for men and there are more female caregivers who do not encourage men to participate in these programmes (De Pinho, 2003: 6). Studies have shown that gender has an impact on access to health care services and adherence to treatment. There was no significant difference in the gender distribution between our study.

Fear of discrimination cause people not to participate in programmes like VCT to get to know their status. Some people get tested late in the disease where they already present with AIDS defining illnesses. This could be explained why some of the subjects in the two groups had baseline CD4 cell counts below 200 cells / μ l.

It is evident in literature that adherence to ART reduces VL to undetectable levels and increases CD4 cell counts. We can therefore make the assumption that those subjects in the CG, that did not claim their treatment, were non - adherent and would therefore, not have had undetectable VL and an increase in CD4 cell counts. The high adherence level to follow up blood tests in the IG was a very important outcome that clearly proved that the designed adherence intervention made a huge impact not only to follow up blood tests but also to the clinical outcome of these tests.

Side - effects have been reported as one of the reasons why some clients decide to discontinue their treatment (Brannon & Feist, 1992:262; Andrews, 2002:19). It is possible that in some cases, the side - effects caused the subjects in the CG to either discontinue their treatment or claim their treatment irregularly. If this assumption is correct, then poor adherence could probably have been avoided if these subjects were contacted regularly. The subjects in the IG were informed about possible side - effects, how to manage side - effects and encouraged to continue treatment.

Studies have shown that patient self - reporting is not a reliable measure of adherence (Brannon & Feist, 1992:257 – 258). It is possible that some of the subjects were not completely honest with their doctors about their adherence to ART. Doctors' estimation of their client's adherence is reported to be unreliable. Friedland reported that doctors' measurement of their client's adherence is less accurate than their clients' self - reports. Studies have shown a difference of 45% in client self - reporting and doctors' reporting of their clients' adherence to treatment (Friedland, 2002:36; USA collaborative group, [sa]). According to Brannon and Feist (1992:257), although patient self – report is more accurate than that of their physicians, they may lie or be uncertain about their adherence to therapy. The claim history was therefore used in this study to assess adherence and significantly more clients in the intervention group submitted their claims.

Implications for practice

All counsellors should use specific guidelines when they contact clients. Clients should be contacted on a regular basis at least once per month to increase adherence to ARV therapy.

Conclusion

In summary, the impact of HIV / AIDS and its treatment highlighted the importance of the need to have an effective disease management programme in place. It has also brought about the emphasis for health care workers to have counselling skills in place. People living with HIV / AIDS have a need to be empowered with knowledge about their disease and its impact in order to make informed decisions about their health and their future in the midst of myths and mixed messages. Poor adherence to a treatment regimen has remained a huge a problem throughout the world and effective management is needed to improve adherence to treatment. Not only should patients be educated about their disease but also encouraged towards behaviour change that would enhance their health status. In order to reach this goal, the commitment of the patient and health care providers are required and patients encouraged involving family, friends and the community for social support.

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