THESIS

Title: Measuring Adherence levels to antiretroviral treatment (ART) and assessing certain

factors affecting adherence in a state primary health care clinic, Mitchells Plain

Community Health Centre, South Africa.

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This thesis is presented in partial fulfillment of the requirements for the MMed (Family

Medicine) degree at the University of Stellenbosch.

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DECLARATION

I, undersigned, hereby declare that the work contained in this assignment is my own

original work and that I have not previously in its entity or in part submitted it at any

University for a degree.

Signature.....

Date.....

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Summary

Objective. Measuring adherence levels and assessing the impact on adherence to ART (antiretroviral treatment) of the factors: disclosure to partner, partner support, other support and length of time between diagnosis and ART commencement, in a state-run ART clinic at Mitchells Plain Community Health centre.

Design. A retrospective case control study was conducted and the information was obtained by means of a file audit.

Methods. Every 5th file was selected for the study and 199 participants were chosen based on the inclusion and exclusion criteria. Adherence for each patient was measured using a formula documented in a published study. For the comparison group 82 cases (non-adherent patients) were matched for age and gender with 82 adherent controls.

Results. The mean adherence for the initial group of 199 participants was 80.1%. Disclosure to a partner and partner support were not found to significantly affect adherence. The time between HIV diagnosis and ART commencement was also not found to make a statistically significant difference to adherence. There appeared to be an association, though not statistically significant, between other support (not from the partner) and >95% adherence (p= 0.0579).

Conclusion. It can be concluded that adherence is probably influenced by a wide variety of factors. More qualitative studies or larger samples are recommended to better assess the impact of partner support and acceptance of HIV on adherence. Approaches to partner disclosure prior to commencing ART should be reviewed. The mean adherence level of 80.1% is an indication that more work is urgently needed to improve adherence levels in state-run clinics in South Africa.

Introduction

The total number of South Africans infected with HIV in 2008 is estimated to be about 5.6 million by the Actuarial Society of South Africa (ASSA) 2003, the most respected of the mathematical models of the HIV epidemic. South Africa has the largest public ART programme in the world, with at least 340 000 people accessing ART by the end of 2007 according to Aspen Pharmacare as quoted in Business Day. Even though there is a marked shortfall in terms of the goals set by the HIV & AIDS and STI Strategic Plan for South Africa (2007 – 2011), treatment has become increasingly accessible especially in certain provinces like the Western Cape and Gauteng.

With increasing accessibility to treatment, there has been an expectation of poor adherence amongst impoverished people from developing countries. This has been a concern, as adherence to therapy has been shown to predict viral responses, immunological outcome and treatment prognosis. ⁴

Gross (2001) has measured adherence in individuals with newly initiated ART after 4 months and has discovered that adherence was greater in participants with undetectable viral loads, who took a median of 93% of doses. The participants with a detectable viral load took a median of 70% of doses. Moore (2006) has further determined that CD4 count increases are directly related to adherence: a CD4 cell increase of less than 25 cells/microlitre at 6 months in patients with viral load suppression at 3 to 9 months after initiating ART was inversely associated with good adherence. A CD4 count less than 200 cells/microlitre at ART commencement as well as CD4 count increases below 25 cells/microlitre were associated with a higher rate of AIDS progression or death. Bangsberg's study has shown that there is a "strong relationship" between the level of adherence to ART and the risk of progression to AIDS in a cohort of urban poor adult participants with a high risk of non-adherence.

At least 2 independent studies have produced results showing that adherence levels of participants using ART in resource-limited settings are much higher than expected: Laurent, et al in Senegal⁸ and Orrell, et al in South Africa.⁹ Mean adherence rates were 87.9% and 87.2% respectively.

In Laurent's study, participants were expected to pay only a small portion of the cost of ART – 90% of the patients paid US\$34 (government-sponsored). This, together with the fact that individual psychosocial requirements were assessed before inclusion in the study, indicates the possibility of a selection bias. In Orrell's study, participants were not expected to pay for their ART, but the selection of participants for the trial was done at a time when ART was not yet freely available in the public sector in South Africa. This, too, is cited in Orrell's article as a possible selection bias as those selected were highly motivated to use ART.

Orrell and Laurent's research opinion would seem to be in disagreement with that of Kagee¹⁰ and Gill.¹¹ Kagee has cited patient non-adherence to treatment regimens for chronic disorders in South Africa as a widespread problem. The reasons suggested for

poor adherence include the socioeconomic status of patients, psychological factors as well as the inadequately funded primary health care system. The psychological factors include social support. His research also highlights a paucity of studies in adherence to treatment regimens in the South African primary health care context. Gill maintains that adherence will prove to be a challenge in Africa, as it has in the developed world and that the ART programmes with good external funding and comprehensive adherence support mechanisms (like MSF) were most successful in terms of adherence and low default rates.

It would be of value to ascertain adherence levels in a state-resourced clinic with no or minimal external funding where ART is more accessible and available free of charge. In the ART "roll out" environment patients with substance abuse disorders and other problems (like unreliability: missing appointments) also need to be managed. They are often referred for further help for their substance abuse disorder and they initially show promise and are commenced on ART. Anecdotally, many of these patients, once their physical condition has improved, will have problems again. In a research environment like with the studies of Orrell and Laurent mentioned above, it is easier to exclude potential "problem patients".

The study setting for this article's research will fit the above criteria: an ART clinic situated at Mitchells Plain Community Health Centre, which is in an area which originated after forced removals by the Apartheid regime in the 1970's. The clinic also serves a large part of Nyanga, as well as Phillipi, which are impoverished townships. The majority of patients attending the clinic are from poor socioeconomic backgrounds. The clinic is state-run with minimal external funding and access to treatment is generally not difficult. Most patients live within 7km of the clinic and use public transport, which is available throughout the day.

The literature describes various ways of measuring adherence and there seems to be consensus about the level of adherence needed. Possible methods of measuring adherence include self-reported adherence, questionnaires, pill counts (pharmacy refill data) and electronic monitoring devices applied to pill bottles and drug levels. 12, 13, 14, 15

Grossberg has shown that pill count data correlated with viral load decrease (2004) and has later (2007) stated that this will be used in an increasing number of clinical and research settings. ^{16, 17} San Lio agrees that the pill count method appears to be a good tool to use in resource-constrained settings and has found this effective in Mozambique, a sub-Saharan setting. ¹⁸ Recent research by Bisson, et al has also lauded using pharmacy refill data for possibly predicting future virological failure. ¹⁹ Some studies have cast doubt about the accuracy of pill counts and self-reporting and have called for more effective ways to measure adherence. ^{11, 20} Unfortunately many of these methods are costly and not very practical in resource-limited areas.

Low-Beer, et al, in a letter to the editor in 2000, explains that patients with adherence levels over 95% are far more likely to have undetectable viral loads.²¹ The success rate drops sharply with decreasing levels of adherence. Gross also concurs with the level of

95%.²² Many subsequent studies have used the 95% level to determine adherence versus non-adherence.

It is known that numerous factors affect adherence to ART. 4 main categories of barriers and aids to adherence have been described in the literature ²³: patient characteristics, the healthcare provider – patient relationship, the healthcare system and issues related to the medication regimen.

This study is focused on the patient factors: disclosure to partner, social support (partner and other than partner) and length of time from HIV diagnosis to ART commencement.

Rowe, Godin and Gonzalez's studies show a relationship between lack of perceived social support and non-adherence to ART. ^{24, 25, 26} A study conducted by Power in California shows that perceived satisfaction with support from a partner is associated with better adherence to ART, whereas satisfaction with support from family and friends could not be significantly linked to adherence. ²⁷ Rowe (in the South African context) has linked disclosure of HIV status, not necessarily to the partner though, with improved adherence to TB preventive therapy in HIV positive patients. ²⁴ Defega in Ethiopia has seen an association between disclosure to a partner and improved adherence. In Defega's setting, only one third of patients on ART had disclosed to their partners. ²⁸ Living alone, not surprisingly, has been linked with poor adherence. ²⁵

As part of the preparation for patients accessing ART, healthcare workers strongly encourage and motivate patients to disclose to their partners. Therefore it cannot be assumed that disclosure is linked to partner intimacy.

This study will therefore seek to examine the rate of disclosure in this setting and whether disclosure and partner support impact on adherence.

The work by Morgenstern, et al has shown that although 98% of patients have admitted to at least one emotional response to an HIV diagnosis, fewer than 25% actually believed that this would interfere with their adherence to ART. Only about 50% of patients felt ready to commence treatment at the time of their HIV diagnosis.

Kübler-Ross speaks of the following phases in the mourning process: denial and isolation; anger; bargaining; depression; acceptance and finally hope.³⁰ It will not be feasible in this study to assess each individual emotion and the effect on adherence to ART but length of time from HIV diagnosis till commencement of ART can be studied. It is postulated that there is a relationship between time and acceptance/ hope: the old English idiom "time heals all wounds".

There is currently a lack of research concerning the effect of length of time from HIV diagnosis to commencing ART on adherence. This study aims to address this issue.

Aims and Objectives

Aims

- 1) To determine the mean adherence to anti-retroviral treatment (ART) of a sample of adult patients attending a state-funded ART clinic in Mitchells Plain using pill count data over a 48 week period.
- 2) To explore the contribution of certain patient factors to non-adherence to ART: disclosure to partner, support from partner, support from someone other than partner, length of time from HIV diagnosis to ART commencement.

Objectives

- 1) To calculate the mean adherence of the selected participants.
- 2) To define adherence and non-adherence in the context of this study.
- 3) To select a comparison sample from the initial group non-adherent participants matched for gender and age with adherent controls.
- 4) To define and quantify each of the patient factors to be studied.
- 5) To assess the presence or absence of an association between the patient factors and adherence to ART in the comparison sample.
- 6) To make recommendations on implications of this study and on possible future research.

Study Methods

Study Design

A retrospective case-control study was conducted. The data was obtained by means of a file audit.

Selection of initial sample

Every 5th folder in the ARV clinic, filed according to the folder number, was selected for participation in the study. A total of 307 folders were screened in order to obtain 200 participants who complied with the inclusion and exclusion criteria (see below). Numerical study numbers were supplied to each participant. Due to insufficient information for one participant, only 199 folders were included in the initial sample.

Inclusion criteria

- 1. HIV positive adults over 18 years.
- 2. ART first commenced at Mitchells Plain CHC.
- 3. Started on ART at least 48 weeks prior to the date on which the files were selected for the audit.

Exclusion criteria

- 1. Treatment experienced at time of first commencing treatment at Mitchells Plain CHC except in cases of prevention of mother to child transmission short ART treatment courses
- 2. Folder lost.
- 3. Treatment stopped due to an adverse event.
- 4. Death before 48 weeks of treatment completed.
- 5. Transfer to another facility prior to 48 weeks being completed.

Measuring adherence

Pill counts over the individual participant's previous 48-week period were used. Fortunately this is accurately recorded in the folder at each visit. Adherence was recorded as a percentage using the formula documented by the Orrell group⁸: (sum of tablets dispensed – sum of tablets returned)/ (total tablets prescribed over the 48 week study period).

Some participants received 3 months supply of medication and did not return at exactly 48 weeks. On the occasion where the pill count was not recorded at the 48 weeks visit, the pill count was calculated at 44, 52 or 56 weeks, depending on the availability of data. The adherence percentage in a number of participants exceeded 100%, i.e. the participant returned fewer pills than was expected. These participants were given an adherence percentage of 100%, which was consistent with what has been done by the Orrell group in their study⁸ (personal communication with the author).

Defining the adherent and non-adherent groups

The adherent and non-adherent groups were defined: the non-adherent group <95% adherence; =>95% in the adherent group. All patients who commenced treatment more

than 48 weeks prior to the file audit but who did not continue treatment due to non-adherence or were lost to follow up were given a score of 0% adherence.

Mean adherence level

The level of adherence in the clinic, based on the results of the 199 participants, was calculated as a mean percentage.

The comparison sample

A comparison group was selected from the initial group. The cases were defined as those participants included in the study with <95% adherence. Each case was matched for age and gender with one control from the adherent group. All non-adherent participants who could be matched with adherent controls in the group (82 of 94 participants) were selected.

Matching did not take into account socioeconomic status as the majority of the patients from the clinic were from a poor socioeconomic background. Employment status was also not included as very few participants had permanent jobs; most worked as casual labourers and most patients who were not employed were accessing disability grants so had some limited income. In a study by Orrell⁹ et al, socioeconomic status (which included the educational level) and HIV stage had no impact on adherence.

Disclosure and Social support

Firstly, the cases were grouped according to those with a serious partner at the commencement of ART as defined by a partner for at least 6 months and those without. This information was obtained easily from the patient information sheet and clinical notes.

Secondly, information regarding disclosure to the partner at time of the commencement of ART was easily gathered from the patient notes.

Thirdly, the support from the partner was assessed. If the partner had been asked to be the treatment supporter or if the partner had attended the clinic with the patient for the patient (and not for reasons of his/ her own health alone) at least once before the 48-week period, then it is likely that the partner is supportive. Information on whether there was support from someone other than the partner (e.g. a family member or friend) could be accessed from the notes.

Length of time from HIV diagnosis to ART commencement

The dates of HIV diagnosis and ART commencement are recorded in the folder and easily retrieved. The length of time from HIV diagnosis to commencement of ART was measured in weeks as a continuous variable. In a few instances, the exact day of the month of HIV diagnosis was not recorded in the folder. The date of the 15th of that month was then used.

Statistical analysis

The statistical analysis was done by the Centre for Statistical Consultation, University of Stellenbosch. Standard summary statistics (e.g. frequency tables, means) were used to summarize the data.

ANOVA and cross tabulation (using the Chi-square test) were used to compare variables.

Extrapolation of data

Extrapolation may only be made to groups very similar to the one under investigation. Further extrapolation beyond the data, as well as to other groups, is dangerous, as case-control studies cannot establish the 3 criteria of contributory cause: strength of association, consistency of association and biological plausibility.

Ethical considerations

Ethical approval was obtained from the Stellenbosch University's Faculty for Health Sciences Committee for Human Research in 2006 prior to the commencement of the study.

Approval was also obtained from the Metro District Health Services organization in 2006 prior to the commencement of the study.

As the study was a retrospective file audit, informed consent was not required from participants whose folders were used. Care was taken to protect the confidentiality of personal information of each client. No folder left the clinic at any time. The principal investigator collected all the data and kept a study file. The study file did not contain any names of patients and study numbers provided could not be linked to specific patients.

Folders of patients who had been lost to follow up were kept aside and handed to a clinic staff member for further intervention as per clinic protocol.

Results

1. Adherence levels

A total of 199 folders were included in the initial sample. The mean adherence of the 199 participants was 80.1% with 105 (52.8%) participants greater than or equal to 95% adherent and 94 (47.2%) participants being <95% adherent. (See Fig. 1 for a breakdown of the number of participants in each percentage adherence category.)

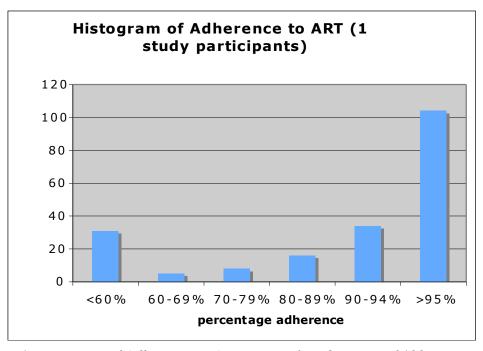


Fig. 1. Histogram of Adherence to ART in initial study group of 199 participants

2. Age and Gender

The mean age of the initial sample was 35.3 years with 69.3% female participants and 30.7% male. A histogram (Fig. 2) shows the majority of the participants were between 25 and 50 years old.

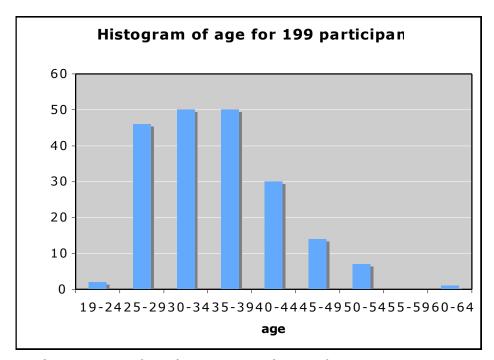


Fig. 2. Histogram of age frequencies in the initial group. Median = 35.0, mean = 35.3, $standard\ deviation = 7.1$, minimum = 21, maximum = 64

The comparison group had 164 participants consisting of 82 non-adherent cases matched for age and gender with 82 adherent controls. 29.3% of participants were male with 70.7% female. The comparison group (see Fig. 3) has a similar age and gender profile to the initial group.

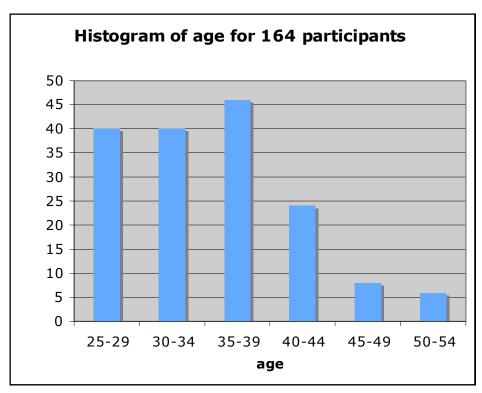


Fig. 3 Histogram of age frequencies in the comparison group

3. Partner: presence, disclosure, support

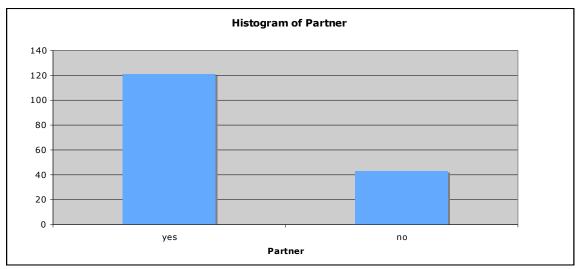


Fig. 4. Histogram of the presence of a partner in the comparison group. In the comparison group (82 cases and 82 controls), 121 (74%) had a partner as defined above (Fig.3).

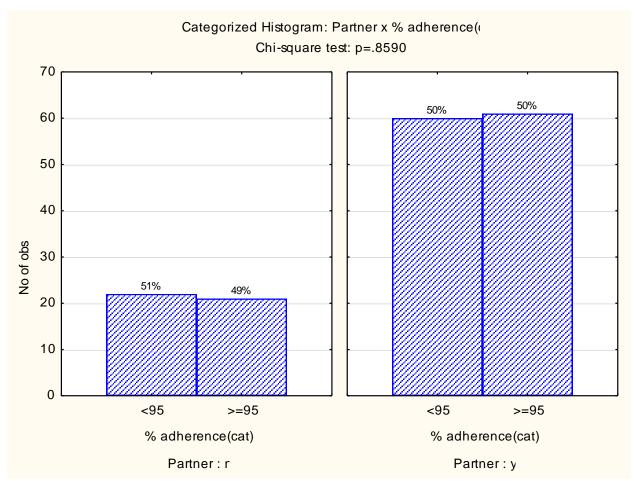


Fig. 5. Categorized Histogram of adherence categories (cat) <95% adherent, >=95% adherent in the group without a partner (Partner: n) versus the group with a partner (Partner: y).

There was no difference in adherence between those with a partner and the group without a partner (Fig. 5).

Most participants had disclosed to their partner: 107 out of 121 (88.4%) participants (Fig. 6).

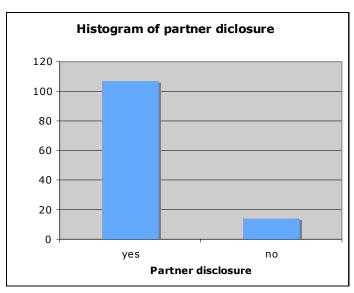


Fig. 6. Histogram of partner disclosure in the 121 participants with a partner.

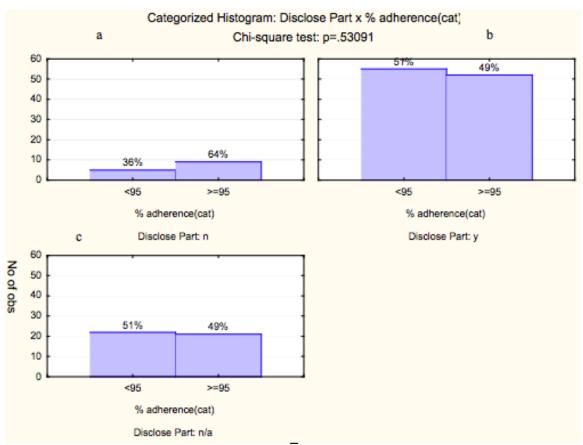


Fig. 7. Categorized Histogram of adherence categories in the groups: no disclosure to the partner (a), disclosure to the partner (b), no partner/disclosure not applicable (c).

There was no significant difference in adherence between those who had disclosed versus those who had not (Fig. 7).

Of those participants who had not disclosed to their partners, it might appear as if more were adherent, but this is not a statistically significant finding as the numbers are very small.

A fair number of participants who had disclosed had support from their partners: 67/107 = 63% (Fig. 8).

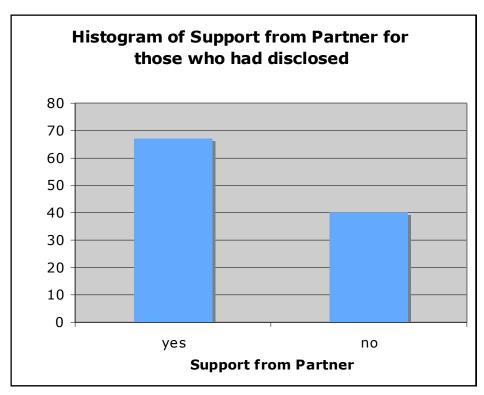


Fig. 8. Histogram of the presence of support from the partner in the group with partner disclosure.

There was no significant difference in adherence between the group with support from their partners and the group without partner support, but it may seem like a trend that more participants with partner support (57%) were non-adherent versus fewer without partner support (43%). (Fig. 9)

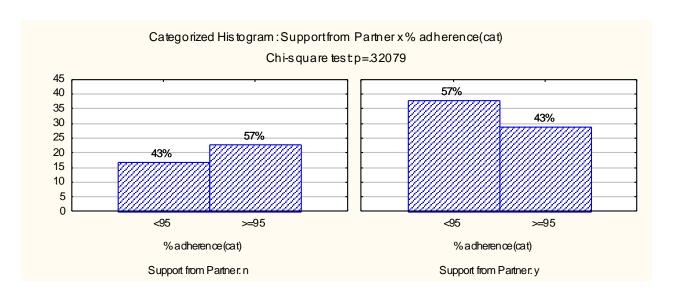


Fig. 9. Categorized Histogram of adherence categories in the groups: participants without partner support (support from partner: n), participants with partner support (support from partner: y)

4. Other Support

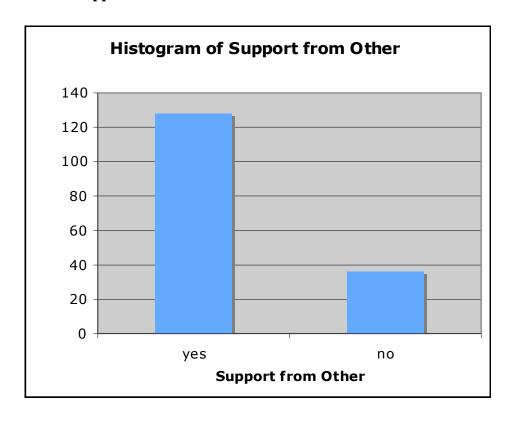


Fig. 10. Histogram of the presence of support from sources other than the partner.

Most participants (78%) had social support from other sources – family, friends, work colleagues, employers, members from churches and other social organizations they belonged to (Fig. 10).

Comparing the adherence of the group with support from other to the group without support from other, the difference is not statistically significant (p= 0.0579), but there appears to be a trend.

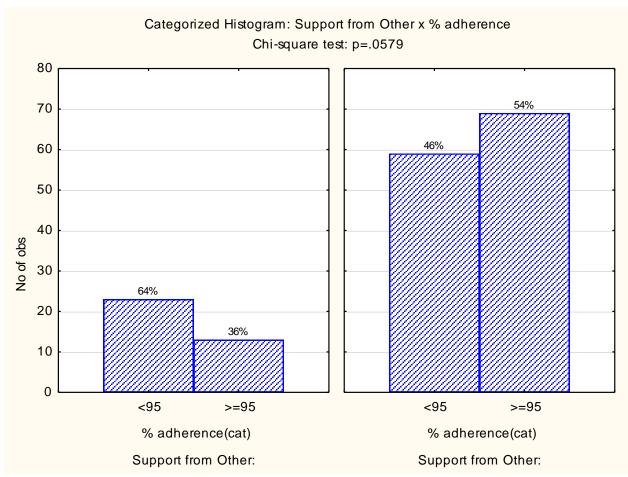


Fig. 11. Categorized Histogram of adherence categories in the groups: no support from sources other than the partner (support from other: n) and support from sources other than the partner (support from other: y).

5. Time between HIV diagnosis and ART commencement

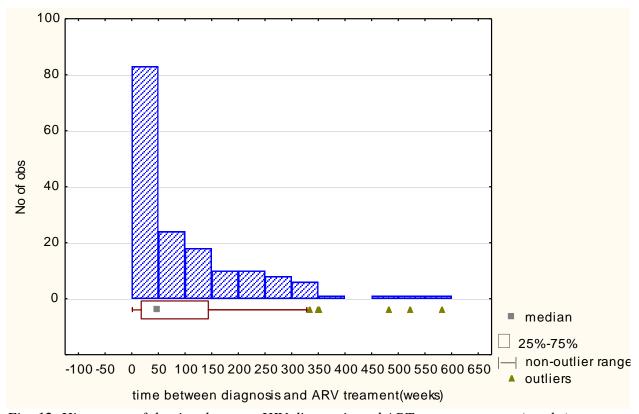


Fig. 12. Histogram of the time between HIV diagnosis and ART commencement (weeks) The mean time between diagnosis and treatment was 97.7 weeks and the median was 47 weeks. About half the patients were commenced on ART within one year of discovering their HIV diagnosis.

Fig. 13. Table depicting descriptive statistics for the adherent and non-adherent groups: the mean time in weeks between HIV diagnosis and ART commencement (HIV diag & ART com), the standard deviation, the standard error and the lower and upper limits of the 95% confidence interval.

Effect	Number	Time in weeks between HIV diag & ART com Mean	Time in weeks between HIV diag & ART com Std. Dev.	Time in weeks between HIV diag & ART com Std Err.	Lower limit 95% confidence interval	Upper limit confidence interval
Total	164	97.12	109.79	8.57	80.19	114.04
adherence <95%	82	91.45	111.64	12.33	66.92	115.98
adherence >=95%	82	102.78	108.30	11.96	78.99	126.58

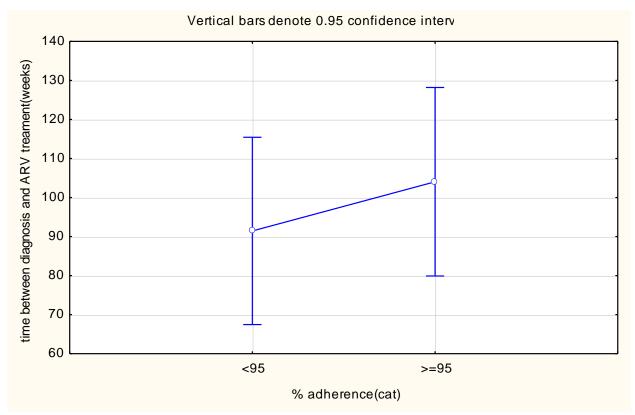


Fig. 14. Graph of Least Squares (LS) Means of the time between HIV diagnosis and ART commencement (in weeks) with the confidence intervals depicted comparing the adherent and non-adherent groups.

Current effect: F(1, 161) = 0.53, p = 0.47, Mann-Whitney U p = 0.25

There was no statistically significant difference for the factor length of time between HIV diagnosis and ART commencement between the groups with adherent and non-adherent participants.

Discussion

Adherence to ART has been introduced as an important factor impacting on clinical outcomes and treatment prognosis for HIV infected people.

There has been a great fear that the adherence to ART in developing countries would be suboptimal resulting in dire public health consequences. Results from 2 research sites in the developing world have shown mean adherence to be around 87%. ^{8,9} Mitchells Plain CHC is different from the 2 sites quoted above because it is a state-run treatment facility with minimal outside support. It is not a research facility so patients are not selected to participate in clinical trials.

A possible limitation in this study is that deceased patients were excluded. It is likely that some of the deaths were at least in part as a result of poor adherence to ART. Excluding these patients might have influenced the study. It is also possible that some of the patients who were lost to follow up and allocated a 0% adherence level had actually died and that their deaths were not reported to us. The death notification form could have been completed at the secondary hospital or alternatively at the local Tuberculosis clinic.

The mean adherence was found to be 80.1% with 52.8% of participants having >95% adherence. This is slightly less than that found in the studies at the 2 research sites quoted above. It is a cause for concern as 80.1% might already be inflated due to stringent psychosocial criteria, which patients are expected to meet prior to commencing ART, e.g. the progress needed to be seen in the management of conditions like Depression and Alcohol use disorders prior to ART commencement. Since this study was done at the time of the novelty of ART in the state sector in South Africa, it would be interesting to see if there is a significant difference in adherence in a few years and whether there have been interventions with measurable effects.

The gender bias and age profile is as expected, with just under 1/3 participants being male. The HIV prevalence in the age group 15-24 years was 16.9% in women and 4.4% in men in 2005 in South Africa.³¹ Women are offered testing at the time of pregnancy and this is an entry point for many into the health care system so it is not surprising that more than 2/3 of the participants were female.

A major limitation in this study has been the uncertainty of the validity of pill count data usage. There has been an ongoing debate about this issue. Pill counts are not always accurate, but other tools are not always available or practical. In this study adherence was calculated to be over 100% for a few participants, a possible sign that patients were "pill dumping", a method used by some patients to fool health care workers into thinking that they had been taking their pills regularly. There might also be other reasons for an inaccurate pill count: accidental pill dropping, patient forgetting pills and omitting to inform health care workers, etc. This poses real challenges for measuring adherence in resource-poor settings. This limitation impacts on the entire study as the calculation of adherence of each participant is important to all aspects of the study.

There is no significant difference in adherence between those who had disclosed to their partners and those who had not. This is in conflict with a study by Defega in Ethiopia where disclosure was found to impact positively on adherence.

A possible explanation for the differences in the results is that only a third of patients in Defega's study had disclosed to their partner. The two groups (disclosure versus no disclosure to the partner) in Defega's study are of a more similar size compared to the groups in this study where so few participants have not disclosed. It should therefore be easier to see if there is a significant difference between the two groups in Defega's study. Also, because of the level of encouragement of disclosure in the South African clinics, it is fair to assume that many patients who would not have had the courage or the willingness to disclose to their partners, have been educated and supported so that they are much more likely to do so.

Prior to the commencement of ART at clinics in South Africa, most patients are strongly encouraged to disclose to their partners or a treatment supporter. Therefore the disclosure rate of 88.4% at Mitchells Plain CHC at the time of commencing ART is actually lower than expected. There are occasions e.g. with pregnant women or very ill patients where the risk of waiting for disclosure does not justify delaying the commencement of ART. Occasionally the partner might be living in another province and the patient prefers to disclose when they are face-to-face rather than telephonically. In these cases, the patient has agreed to disclose to the partner by a given time and has assured the health care worker that the partner will not be placed in unnecessary risk, but whether this actually happens in reality is not known.

There is also no significant difference between the groups with partner support and those with no partner support. This is in conflict with the study by Power²⁷, conducted in California, USA, where perceived support from a partner was shown to impact positively on adherence. The differences in settings as well as the methods of measuring partner support could provide an explanation for the contrasting results.

The approach to measuring partner support may be a limitation in this study. Support is a subjective phenomenon and therefore a more qualitative study might be more effective in measuring this as compared to objective criteria. The question about partner support specifically was not directly posed to all patients and therefore not recorded in the notes. The objective criteria used were: The partner must have accompanied the patient to the clinic for the patient's benefit or the partner should be a nominated treatment supporter. A case could be made that for working spouses it was more difficult to take time off to attend the clinic. In such a case the patient might ask a relative to accompany him/ her to the clinic. In such cases, the patient may give the name of the relative as the treatment supporter. In practice, patients often give more than one name as treatment supporter which includes the relative as well as the partner if he/ she is felt to be supportive. This is a possible limitation to bear in mind when interpreting the results and could account for the discrepancy between the study by Power and this study.

The other explanation is the setting, i.e. developed versus developing nation and especially the impact of intimate partner violence. In a study by the Medical Research Council, led by Abrahams, a staggering 42.3% of men interviewed in Cape Town reported physical violence against a partner in the last 10 years. ³² The rate of physical violence against an intimate partner is substantially lower in the USA, with the CDC reporting a 22.1% lifetime incidence of physical assault. ³³ Perhaps the patient might not actually feel supported if the partner has assaulted her, even if he accompanies her to the clinic and is her treatment supporter.

An assumption has been made in order to confirm that the relationship is serious: that is that the person should have been in a relationship with the participant for 6 months or longer. It is likely that a relationship of a shorter duration may be serious and that possible partners have been excluded by this assumption.

With support other than from a partner, an interesting trend is noted. Other support seems to have a positive impact on adherence (p= 0.0579). This is not statistically significant and perhaps a larger sample would have resulted in a significant result. It, however, might influence the manner in which we approach support and disclosure prior to commencing ART. Usually the patient is convinced to disclose to his/her partner prior to commencing HAART. The two main reasons for this are to improve adherence and to minimize the risk of infecting the partner.

In this setting where most patients are strongly encouraged to disclose to their partner, it appears that it does not improve adherence, so the former reason is not justified. Ethical debate surrounding patient autonomy versus the risk of injury to a third party has been rife. It is clear that when undermining the autonomy of a patient, there is damage done to the patient-health care provider relationship and there are resulting negative health consequences. It seems appropriate to suggest that further studies will be required to assess the burden of waiting for disclosure to a partner. This should include a qualitative study on the effect of this on the patient—health care provider relationship. On the other hand the actual risk to the partner should be further assessed: During the time between the commencement of ART and the disclosure, the viral load will have been substantially reduced and the patient rendered less infectious. By waiting, the patient will have a higher viral load for a longer time so will be more infectious for longer.

Access to ART remains a concern and despite attempts to improve the access and encourage voluntary testing and counseling, many people are still not aware of their status and do not test. Roughly half the comparison group had their ART commenced within 1 year of testing positive for HIV. This supports anecdotal evidence that many people are only coming forward for HIV testing when they are in the later stages of HIV and when CD4 counts have dropped to below 200 cells/ microlitre. This has public health consequences, as many potentially infectious people are not aware of their HIV status.

Time between HIV diagnosis and ART commencement was an interesting factor to study, as information about this subject in the literature was scanty. There has been anecdotal experience with women who discovered their HIV status during pregnancy,

required to start ART soon thereafter and stopped treatment after the birth of their children. There are many possible factors for this especially the fact that they were commenced on ART very soon after being diagnosed with HIV and that they most likely had not accepted their status in a short time when there were many other emotional demands on them.

In this study there was no statistical difference between the adherent and non-adherent groups for length of time between HIV diagnosis and ART commencement. The intention was to assess indirectly whether acceptance of HIV contributed to adherence. A larger quantitative sample may be required to obtain a significant result. The assumption was that with time an individual is more likely to have accepted his/ her HIV status. Alternatively, a qualitative study might more directly assess patient acceptance of HIV status and may shed some light on the effect on adherence.

Conclusion

In this study disclosure and support from a partner did not influence adherence. There is an association (not statistically significant) between social support by those other than a partner and improved adherence. Length of time between HIV diagnosis and ART commencement did not have any statistically significant effect on adherence.

Adherence is probably influenced by a wide variety of factors: Each patient has a unique experience and his/ her adherence is probably influenced by not only one but by a multitude of factors. The factors studied above may not be statistically significant on their own but in combination with other factors might prove significant. In this study not all factors, which may affect adherence were addressed, e.g. language barriers between the staff and patients shown to have a significant impact on adherence in a previous study. ⁹

The debate about the method of measuring adherence still continues. It has been found to be a major limitation of this study. New methods should be researched to assess adherence in resource-poor settings, as pill count data are not very accurate.

Furthermore using quasi-measures of acceptance of HIV like length of time between diagnosis and treatment may not provide the answers to interesting and important questions asked. Attempting to answer these questions by using qualitative research might be more appropriate. Alternatively, larger sample sizes may be necessary to prove a statistical and clinical difference between the adherent and non-adherent groups.

The mean adherence level of 80.1% seems to concur with mean adherence results in other sites in developing countries despite differences noted. This is cause for concern as well as the fact that many patients are presenting late in the course of their illness for HIV testing (roughly half of the comparison group commenced ART within a year of HIV diagnosis). It is clear that in order to prevent adverse public health consequences, there is much work that needs to be done in state-run facilities and ART clinics in terms of encouraging HIV testing as well as adherence research and adherence promotion.

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