

Providing Immediate CD4 Count Results at HIV Testing Improves ART Initiation

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Running head

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Abstract

Background

In South Africa, CD4 count results are typically available within a week of testing. However, 35-55% of newly diagnosed HIV positive patients do not return for their CD4 results and therefore do not access further care¹². We evaluated the impact of a CD4 count result and patient written information provided immediately after diagnosis on retention in care.

Methods

HIV infected subjects were randomized to three arms; receipt of a CD4 result at time of HIV diagnosis, receipt of written information and standard of care (CD4 collection after one week) or standard of care alone. The outcome of interest was enrolment for further care within 1 month for pre-ART care or within 3 months for ART initiation. Secondary outcome was time taken from diagnosis to each stage of care pathway. Independent predictors of retention were assessed with multivariate analysis.

Results

344 patients recruited, of which 64.5% were females with a median age of 30 years [IQR 27-35]. Subjects were similar in age, gender, CD4 count, education and employment status.

Providing CD4 results at HIV diagnosis increases the likelihood of reporting for ART initiation (RR=2.1; 95%CI=1.39-3.17) compared with standard of care. Written information only reduced the time to presentation for pre-ART care whilst increasing age was associated with retention. There was 49% attrition in the standard of care arms.

Conclusion

Receipt of a CD4 count at the time of HIV testing increases ART initiation rates. Point-of-care diagnostics can be used to improve retention but losses to pre-ART care remain high.

Keywords

point-of-care diagnostics; CD4 monitoring; retention in care; pre-ART loss to care; loss to initiation; point-of-care CD4

Introduction

In South Africa, it is estimated that there are just under 6 million people living with HIV/AIDS.¹ In the last five years, the South African government has established the largest antiretroviral therapy (ART) program in the world² with almost a million adults on treatment by the end of 2009.³

The official plan of the South African government is to provide an appropriate package of care to 80% of people living with HIV and their families by the end of 2011.⁴ This requires a comprehensive service underpinned by early HIV diagnosis, with enrolment and retention in care and access to ART for those who qualify as soon as possible. However, meeting these targets presents significant challenges, chief amongst which is the continued loss to follow up from pre-ART care^{5,6,7} and poor retention in care prior to ART initiation.^{8,9,10} This often results in patients presenting late to clinical services with low CD4 counts and subsequent high mortality rates within the first year.¹¹ Distance from health centre, a history of TB treatment, male gender, referral by third parties, psychosocial factors such as stigma, denial of HIV status, and undocumented mortality have all been identified as factors that explain loss to care after diagnosis or during treatment.⁵⁻¹⁰

Furthermore, analyses of the steps patients have to go through in order to eventually receive treatment have shown attrition at every stage.^{5,6} In one study, out of 7005 newly diagnosed HIV positive patients, only 43.5% presented for CD4 testing; despite half being eligible for ART, only a third (31.3%) started ART.⁶

In South Africa, CD4 testing is done through centralized laboratories with results usually available to the patient within one week. Currently, in inner city Johannesburg, newly diagnosed HIV infected patients are asked to return to the HIV counseling and testing site one week after their HIV test to collect their CD4 result. At this visit the patients' eligibility for treatment is assessed and where appropriate, referrals are made to local treatment centers to implement treatment. On average, 1300 people are seen every month for HIV testing at the site of this study, with 30% testing positive. Only 55-65% of patients tested, return to collect their CD4 results.¹² Various strategies have been employed to minimize the impact of such loss including active patient follow up with telephone calls and/or written instructions, with varying degrees of success.^{6,8,13}

Policy makers have proposed reducing the number of steps in the process as well as reducing the time lag between diagnosis and treatment. The provision of a CD4 result immediately after HIV diagnosis^{6,7,14} could meet those requirements and would allow for patients to be tested, receive their CD4 on the same day if HIV infected with subsequent enrolment in appropriate care.

This study evaluated the impact of providing a CD4 count result at HIV diagnosis or written information on enrolment into pre-ART or ART care in a large urban primary health care clinic in Johannesburg.

Methods

A randomized three-arm study was conducted at an urban primary healthcare clinic (Esselen clinic) in the inner city of Johannesburg from August to December 2009. Services available at the clinic include HIV counseling and testing, antenatal services, TB treatment and monitoring, pre-ART care, child health surveillance, STI and family planning. The clinic serves a catchment area that is densely populated and industrialized. Unemployment, alcohol abuse, sex work, poverty and gender violence are common, with a significant proportion of the community not from South Africa.

The inclusion criteria were adults over the age of 18 who had already received pre-test counseling and were awaiting HIV testing. Patients were excluded if they were pregnant as their options for further care was based on higher CD4 count cut-offs. Patients who had WHO stage IV clinical disease at presentation were also excluded as they were required to start empirical ART regardless of CD4 count.

The model of care in operation for study subjects started with pre-test counseling, followed by HIV testing using rapid antibody based tests; Advanced Quality One Step Test (Intec products Inc) for first test and confirmatory test with First Response HIV Rapid Card Test 1&2 (Premier Medical Corporation Ltd). A venous blood sample was subsequently drawn for a CD4 count analysis when HIV infection was confirmed. Post test counseling followed, with the patient being interviewed by the research fieldworker thereafter.

Randomization was performed by the operator of the CD4 flow cytometry machine based at the clinic who received blood samples for CD4 analysis. The operator had no direct contact with the patient. Samples were randomly allocated to one of three arms – receipt of CD4 result receipt (immediate), standard collection of CD4 result and receipt of written information (leaflet) and standard collection of CD4 result only (normal collection - NC).

As flow cytometry has been validated as an accurate and reliable method of CD4 analysis in previous studies,^{16,17,18} a FACSCount™ (Becton Dickinson, San Jose, CA) instrument was used to provide a CD4 count within 45 minutes. Patients were only informed of the study arm to which they had been assigned by the counselor after post-test counseling and patient interviews had been completed which allowed sufficient time for on-site CD4 counts to be ready. Receipt of an immediate CD4 result after diagnosis permitted further care staging by a professional nurse on the same day. Those patients randomized to the leaflet arm were given printed material in a Z-fold 6 page leaflet designed by facility-based clinicians and described the HIV care pathway available to patients in the area. The leaflet was given to participants by counselors after randomization occurred with a brief explanation of its use. Participants in the leaflet and standard arms were asked to return to the clinic in 7 days to collect their CD4 result and further care staging thereafter.

The further care protocol in operation at the clinic was based on a CD4 count. Although national guidelines¹⁹ recommended ART initiation to commence within 3 months of CD4 count ≤ 200 cells/ μL , a CD4 count cut off for ART eligibility of ≤ 215 cells/ μL

was being used at the clinic on the basis that by the time of initiation this is likely to drop to 200. Patients were prepared for initiation with three adherence preparation counseling sessions before referral to the ART site 0.5km away. Patients with a CD4 count >215 cells/ μL were referred for pre-ART services based at the same clinic on the same day that the CD4 count was made available to the patient. Pre-ART care for the purpose of this study is defined as the wellness program offered at the clinic and included dietary advice, health education, screening for opportunistic infections, cotrimoxazole and isoniazid preventative treatment, TB screening and six-monthly CD4 monitoring. A patient remained in pre-ART care till they were eligible for ART and this was again based primarily on CD4 count cut off of ≤ 215 cells/ μL . The clinic also considered those with lower CD4 counts (<100 cells/ μL) as requiring 'fast-track' care with referral to the initiation site within two weeks.

Outcome measures and Statistical Analysis

The proportion of enrolled patients reporting for further care was compared by intervention arm based on arrival at pre-ART care site within one month of HIV testing if CD4 >215 cells/ μL or arrival at ART initiation site within three months if CD4 ≤ 215 cells/ μL . X^2 test for measures of association and risk ratio analyses were used to compare these outcomes.

For secondary endpoints, outcomes of interest included the effect of intervention arm on time taken from HIV testing to various end points in the patient care pathway. Wilcoxon rank sum analysis was used for intervention arm comparisons. Identification of independent predictors for continued engagement in care was also assessed using

univariate analysis on baseline demographic factors to generate a multivariate logistic regression model which incorporated variables exhibiting p-value <0.2 , starting with those showing the strongest association. Likelihood ratio tests were also conducted to ensure validity of the multivariate model. Finally, we analysed patient flow during the study to determine losses at each stage of the care pathway

All study data were entered into a Microsoft ACCESS Database, and STATA (statcorp) software version 10 was employed for the statistical analyses.

Written, informed consent was obtained from all study participants. The study was approved by the Human Research Ethics Committee (Medical), University of the Witwatersrand, Johannesburg, South Africa. Approval number: M081118

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Results

Baseline Characteristics:

344 HIV infected patients were recruited into the study, of which 222 (64.5%) were female. Median age was 30 years with an IQ range of 27 to 35. Half were originally from countries other than South Africa, with 34.5% reporting having full time employment, secondary school education (48.5%) and living locally within a 10km radius (75.1%). In addition, 61.6% were first time HIV testers with 83.7% being self-referred (walk-in HIV testing as opposed to medical referral). A third (34.1%) were eligible for ART referral according to the clinic algorithm ($CD4 \leq 215$ cells/ μ L). The median baseline CD4 count for the cohort was 300 cells/ μ L (IQR=168-473) and the median CD4 count for those needing ART was 122 cells/ μ L (IQR=60-174). The intervention arms were similar in gender, age, CD4 count, education, employment status, residence in relation to clinic, country of origin, first time tester and source of referral.

Outcomes:

Primary Endpoint:

Impact of intervention arms on reporting to further care

Of the patients that received an immediate CD4, 47.6% reported for further care (pre-ART and ART) whereas of those who had standard collection of CD4 (leaflet and NC); 33.6% presented. ($p < 0.011$)

Risk ratio assessments of attendance at further care sites showed that patients in the immediate arm were 2.1x more likely to enroll for ART than patients who had standard collection of CD4 – NC or leaflet (95%CI=1.39-3.17; $p = 0.0004$). Further comparisons between the immediate CD4 group and the NC group showed that patients with an immediate CD4 were 2.6x more likely to attend for ART initiation (95%CI=1.42-4.78; $p = 0.0004$). Table 1

Secondary Endpoints:

Time taken to report to pre-ART site

The median time to report to pre-ART care from time of HIV diagnosis was lower in the immediate arm and leaflet arms - 7 days (IQR 1-18d ; IQR 7-9d respectively), whereas in the NC arm, median time to arrival at pre-ART site was 13 days (IQR 7-23d). Figure 1 Wilcoxon rank sum analyses were significant; immediate vs NC ($z = 1.972$; $p < 0.04$) and leaflet vs NC ($z = 1.935$; $p < 0.05$)

Univariate and Multivariate analysis

Univariate analysis showed that age, employment, nationality and source of referral could potentially be associated with likelihood of reporting to further care (Table 2a). After multivariate logistic regression, with reference age category 25-29yrs; age 19-<25yrs was associated with reduced engagement in further care. As age increased, so did an increased likelihood of enrollment in further care (Table 2b).

This association was confirmed by trend tests.

Losses to enrollment in further care

Observed losses were 50/81(62%) in the immediate arm, 48/72(67%) in the leaflet arm and 40/67(60%) in the NC arm for patients requiring pre-ART care.

In ART eligible patients, losses experienced were 15/43(35%); 22/35(63%) and 27/36(75%) in the immediate, leaflet and NC arms respectively. Figure 2

In the standard collection arms (NC and leaflet), 112/220 (51%) returned to collect their CD4. Comparison of this group of returnees with patients in the immediate arm showed that the returning patients were 1.98x more likely to present for pre-ART care (RR=1.98, 95% CI=1.42-2.75, p=0.0002).

Discussion

Pre-treatment loss to care continues to be a source of concern for health planners in South Africa. However, the reasons for this are complex and resolving the issue of linkage to care remains difficult. In this study, we have shown that decentralizing one aspect of the HIV care pathway by removing the need to send CD4 venous samples away for analysis has resulted in a partial reduction in loss to care. In patients who are eligible for ART, the receipt of an immediate CD4 result after HIV diagnosis increased the likelihood of patients starting therapy within three months of HIV diagnosis. On the other hand, for patients who are not yet eligible for ART, having knowledge of a CD4 count immediately after HIV diagnosis did not increase the numbers who enrolled in pre-ART care.

The provision of an information leaflet at the time of HIV diagnosis did not affect further care enrolment and appeared only to promote an earlier reporting to pre-ART care, where the detailing of services offered may have contributed. This finding indicates that there is likely to be value in researching the quality and content of information leaflets that assist patients to negotiate care pathways more effectively especially in the context of pre-ART care.

Interestingly, when we did compare the immediate arm group with patients that did return to collect their CD4 on their likelihood of reporting to further care; patients in the latter

group were more likely to attend for pre-ART care. This suggests that the positive health seeking behaviour exhibited by returning to collect CD4 may extend to improved reporting at these services. On the other hand, it also implies that for ART eligible patients, the influence of 'returning to collect' is diminished and perhaps superseded by immediate knowledge of CD4 and perceived need for treatment. This adds to our later contention that patient factors which promote engagement in care are likely to differ according to ART eligibility.

The likelihood of reporting for continued care increased with age. This is in line with other studies on loss to care^{5,7-10} and confirms persisting difficulties in engaging younger HIV infected patients in care. Type of employment was also shown to have an impact, with those in full time employment less likely to enroll for further care, suggesting that clinical services available at times which suit people in full time employment should be explored.

High pre-ART losses persist with almost 1 in 2 patients in this study failing to collect their laboratory CD4 result one week after HIV diagnosis. To mitigate this loss, the introduction of rapid CD4 testing with a short turnaround time for results has been proposed.⁶ However, even with the knowledge of a CD4 at time of HIV testing, only 40% enrolled for monitoring at the pre-ART/wellness clinic and 65% of those eligible for ART presented for treatment. Similar findings have been observed in other studies too. In another Johannesburg based study, 59% of those with CD4 counts between 251 and 350 cells/ μ L had not returned to care within 1 year²⁰ and in Zambia, only 11% of the non-ART patients returned.²¹ Loss to care is well described. Several studies have proposed

possible determinants for pre-treatment loss to care in patients eligible for ART. Such factors include death, fear of stigma, socioeconomic issues including financial, lack of transport, difficulty with being away from their place of employment, quality of provider-patient relationships, a history of TB treatment or male gender.^{5,7-10} However, it cannot be assumed that similar factors apply for retention in care in the non-ART patient without further investigation. Patients with relatively high CD4 counts are on the whole well and may not see engaging in care as a priority as has been proposed in other studies²². Contributing to this, is the paucity of effective models for pre-ART care which inform how this aspect of care can be delivered probably because resources have been directed at improving ART rollout at the expense of pre-ART care. Equally, health care professionals and as a consequence patients, may also perceive pre-ART care as less important than ART care. This has significant implications as South Africa has embarked on improving HIV counseling and testing rates and at the current CD4 count cut off for treatment, we are bound to observe an increase in patients needing pre-ART care; reaching this group of patients will need to be prioritized.

This study has some limitations. Firstly, we cannot be certain that patients lost to our follow up did not access care elsewhere, as newly diagnosed patients are not assigned unique identifiers and are therefore not traceable within the health care system. Moreover, with the possible overestimation of loss to care as proposed in other studies²³, the outcomes of this study could be affected. In addition, without continued follow up of our cohort, we are unable to show that our observations persist beyond initial presentation at the further care site particularly as attrition rates post ART initiation have been well documented.^{5,7,8} Finally, this study did not explore the cost effectiveness of immediate

CD4 count provision after HIV diagnosis, as the focus was on assessing the impact of the intervention on patient care. Effective decentralization of CD4 diagnostics would need to be informed by cost-benefit analyses when evaluated against current CD4 count delivery models.

In summary, we found that loss to ART initiation was decreased through making a CD4 result immediately available after HIV diagnosis but the use of an information leaflet did not have an impact on retention rates. In addition, retaining younger HIV infected individuals continues to be a concern suggesting that our current models of care remain suboptimal and need review. Basing HIV care after diagnosis around CD4 cut-offs necessitates that HIV infected patients will be assigned to either of the two models of care currently available – pre-ART care or ART initiation. How patients engage depends on whether they receive pre-ART care or ART and losses are especially high in those who are staged for pre-ART care. With the likely expansion of HIV infected numbers after the HIV counseling and testing campaign, research priorities will need to be targeted at understanding factors that can improve engagement in pre-ART care as well as developing evidence-based models for pre-ART care. Underpinning all of this, is the urgent need for unique identifiers for all HIV infected patients so that monitoring efforts of how and when patients are accessing care are better informed.

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Authorship

M Faal was involved in the implementation of the study, data analysis and interpretation, writing and editing of the manuscript

N Naidoo was involved in the conceptualization and implementation of the study, as well as data analysis and editing of the manuscript

DK Glencross was involved in implementing and coordinating on-site and laboratory CD4 testing and editing the manuscript

WDF Venter was involved in study design and editing of the manuscript

R Osih conceptualized the study, supervised implementation and assisted with data analysis, writing and editing the manuscript

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Table 1:

Relative likelihood of reporting to further care sites by intervention arm

	ART initiation	Pre-ART care	ART initiation / pre – ART care
Immediate vs Standard*	2.1 <i>p=0.0004;95%CI=1.39-3.17</i>	1.02 <i>p=0.899;95%CI=0.72-1.45</i>	1.41 <i>p=0.011;95%CI=1.08-1.84</i>
Immediate vs NC[#]	2.6 <i>p=0.0004;95%CI=1.42-4.78</i>	0.92 <i>p=0.663;95%CI=0.62-1.36</i>	1.44 <i>p=0.023;95%CI=1.04-1.99</i>
Immediate vs leaflet	1.75 <i>p=0.014;95%CI=1.08-2.84</i>	1.14 <i>p=0.525;95%CI=0.75-1.76</i>	1.39 <i>p=0.04;95%CI=1.01-1.91</i>

*= NC & leaflet arms returned 1 week later for CD4 count and staging (standard of care) ; #= normal collection (NC): standard of care; no leaflet

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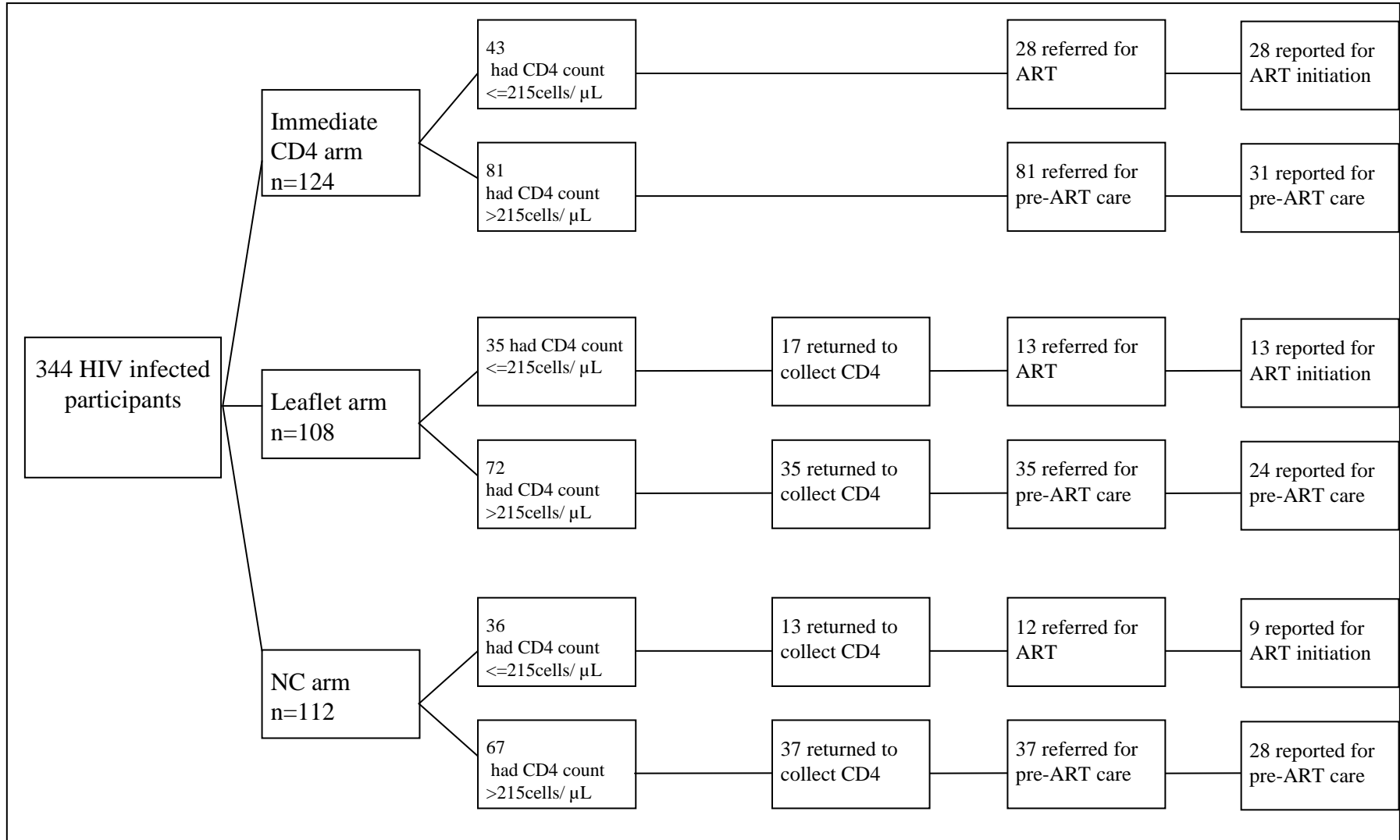
Table 2a: Univariate analysis of baseline characteristics on reporting to further care

Variable	Categories	OR	P	CI
Gender	Female	1		
	Male	1.04	0.847	0.66-1.64
Age	>=19 & <25yrs	0.2	0.037	0.04-0.91
	>=25 & <29yrs	1		
	>=29 & <34yrs	1.39	0.267	0.78-2.47
	>=34 & <39yrs	1.86	0.059	0.98-3.54
	>=39yrs	2.35	0.011	1.21-4.56
Education	none/primary	1		
	some secondary school	0.91	0.772	0.49-1.70
	completed sec. sch. or higher	1.28	0.457	0.67-2.44
Employment	Full time	1		
	Non full time	1.58	0.049	1-2.5
Residence	Local to clinic	1		
	Not local to clinic	0.76	0.294	0.45-1.27
Nationality	South African	1		
	Not South African	0.69	0.101	0.45-1.07
HIV test	First time tester	1		
	Re-tester	0.85	0.49	0.55-1.34
Source of referral	Self	1		
	Other	0.58	0.093	0.31-1.09

Table 2b: Multivariate model showing predictors for reporting to further care

Variable	Categories	OR	P	CI
Age	>=19 & <25yrs	0.21	0.044	0.05-0.96
	>=25 & <29yrs	1		
	>=29 & <34yrs	1.39	0.266	0.78-2.50
	>=34 & <39yrs	1.78	0.084	0.93-3.42
	>=39yrs	2.24	0.019	1.14-4.37
Employment	Full time	1		
	Non full time	1.45	0.121	0.91-2.32

Figure 1: Flow diagram of patient flow in study showing attrition at every stage



Patients in the immediate arm were staged on the same day as HIV diagnosis. Those requiring ART needed to have three sessions before referral to the ART initiation site. Some patients do not complete all three sessions and explains the discrepancy between number of ART eligible patients and actual numbers referred. Patients requiring pre-ART care were referred on receipt of CD4 count.

Figure 2: Time taken from diagnosis to arrival at pre-ART care

