***Original Article***

**Outcomes of on-site antiretroviral therapy provision in a South African correctional facility**

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**Word count:** 2897 (max 3000)

**Abstract**

We evaluated a novel on-site antiretroviral therapy (ART) programme in a South African correctional facility using routinely-collected programme data, from a retrospective cohort of adult inmates starting ART between 03/2007-03/2009 followed-up to 09/2009. We report 1) mortality (using survival analysis); 2) retention to the programme (to 09/2009); and 3) virological suppression at six and 12months (<400copies/ml) following ART initiation. In total, 404 started ART (median age 33years; 91.3% male; median baseline CD4 count 152cells/µl [interquartile range 85-225]). Among 299 starting ART for the first time (ART-naïve), 23 deaths occurred during 252 person-years (median follow-up 9months). Mortality rates were 17.2 at 0-6months (95% confidence interval [CI] 10.9-26.9) and 2.8 at >6months (95%CI 1.1-7.5)/100person-years; p<0.001. On 09/2009, 35.6% (144/404) remained in the correctional facility, with 94.4% (136/144) retained to the programme; 38.4% (155/404) were released; and 20.0% (81/404) transferred to another facility. Among ART-naïve patients in care six and 12 months after ART initiation, 94.7% (124/131) and 92.5% (74/80) were virologically suppressed, respectively. High early mortality warrants the early identification and management of HIV-positive inmates. The high mobility of inmates necessitates systems for facilitating the continuity of care. Good virological responses and retention supports decentralizing HIV care to correctional facilities.

**N=199 (maximum 200)**

**Keywords**

Correctional facilities, inmates, antiretroviral therapy, HIV

**Running head**

On-site ART for South African inmates

**Introduction**

Human immunodeficiency virus (HIV) prevalence in inmates is higher than that of the general population1, 2. Correctional facility settings therefore provide an opportunity to deliver HIV testing, care and treatment, and prevention services2-7. This has individual and public health benefits, as HIV-positive inmates achieving viral suppression are less likely to transmit HIV to others in the community upon release.

Studies from resource-rich settings have demonstrated a good response to antiretroviral therapy (ART) in inmates who are provided with care and access to treatment within correctional facilities5, 8-16. HIV care and treatment for inmates in resource-limited settings was commonly provided through community HIV treatment programmes, to which inmates were transferred for clinic appointments. With the move towards decentralization to scale-up ART access17, many resource-limited countries have begun implementing HIV treatment programmes within correctional facilities, rather than using community services18-22. This aims to improve the access of HIV-positive inmates to ART services, while mitigating the logistic and safety concerns involved with the transfer of inmates to external ART clinics. Data from these programmes within correctional facilities in countries hardest hit by the HIV epidemic are mostly limited to the feasibility of services18-22. Studies from community settings have demonstrated ART use to be associated with decreased morbidity, mortality and HIV transmission23-25. However, poorly-designed programmes, with treatment interruptions, poor adherence and attrition, can lead to poor outcomes and the development of resistant HIV strains26-28. Therefore thorough evaluation of programmes serving a highly mobile at-risk population in high HIV burden settings is important.

South Africa has one of the highest incarceration rates in Africa at 316 per 100,000 population in 201129. It also has one of the highest burdens of HIV infection globally; in 2012 the estimated prevalence of HIV infection in adults aged 15-49years was 17.9%30. In 2007, through a partnership between The Aurum Institute and the Department of Correctional Services, South Africa, a Johannesburg correctional facility, housing approximately 12,000 inmates, became the first to be accredited for ART provision. Details of this partnership and the initiation of the President’s Emergency Plan For AIDS Relief (PEPFAR) funded on-site ART programme has been previously described22. Prior to this on-site ART programme, inmates at the correctional facility received ART through a large tertiary referral University Hospital ART clinic (results previously reported)31. We describe in this on-site correctional facility ART programme mortality; retention to the programme; and viral load suppression.

**Methods**

*The on-site ART programme*

The on-site ART programme (henceforth referred to as "the programme") within the correctional facility serves the entire inmate population, both the sentenced and awaiting trial population. HIV-positive inmates who are eligible for ART according to national guidelines32, 33 are referred to this on-site programme staffed by doctors and nurses with support from counsellors and dieticians, by the correctional facility medical team responsible for all other medical care for inmates. HIV counselling and testing services are available throughout the correctional facility, where confidential opt-in voluntary testing is provided to all inmates upon entry to the correctional facility, and periodically thereafter.

During the time period being reported in this paper, the programme followed the 2004 South African National ART Treatment Guidelines32 (now superseded33). The criteria for ART initiation were CD4 cell count <200 cells/μl irrespective of disease stage or World Health Organisation (WHO) stage IV illness irrespective of CD4 cell count. The first-line treatment regimen consisted of stavudine and lamivudine and one non-nucleoside reverse transcriptase inhibitor (efavirenz or nevirapine). Second-line treatment consisted of zidovudine, didanosine and lopinavir/ritonavir. All medication were self-administered. Following ART initiation, patients were seen at 2, 4, 8 and 12 weeks, and 3-monthly thereafter. CD4 cell count and viral load monitoring were conducted at baseline and six-monthly thereafter.

All patient information was collected on standardized data collection forms. These were single-entered on site into a password-protected Access database. When patients were transferred to another correctional facility or released, a transfer letter was provided from the programme detailing treatment history. Information on linkage to care in other correctional facilities and the community was not routinely collected as part of the programme.

*Variables and definitions*

Baseline information including age, sex, WHO disease stage and history of opportunistic infections were collected during the registration visit to the programme. Where WHO stage was not documented, this was calculated from information on previous or current opportunistic infections. Information on reasons for leaving the programme were routinely collected and included transfer to another correctional facility, released from the correctional facility to the general community, still in the correctional facility but stopped attending the programme and death.

Patients self-reporting any previous ART use were defined as ART-experienced. The baseline CD4 cell count was defined as the result from the sample closest to ART initiation (window: 90 days before to 15 days after). Baseline viral load was defined as the result from the sample closest to ART initiation (window: 90 days before to date of ART initiation). For six and 12 month viral load following ART initiation, the windows were 120 to 240 days, and 300 to 450 days from starting ART, respectively. If more than one measurement was available in a specified interval, that closest to the defined visit was chosen. Viral load suppression was defined as <400 copies/ml of blood. Patients were defined as retained in care if they were still in the correctional facility on the 31st of August 2009 and had been seen by the programme in the preceding six months.

*Descriptive and retrospective cohort analyses*

Mortality, retention and virological outcomes were ascertained for an open historical cohort of adults ≥18 years who commenced ART in the programme from 1st March 2007 to 1st March 2009, using routinely collected data. The cohort was restricted to patients with information on previous ART use. Follow-up was censored at 31st August 2009.

For each patient the total follow-up time on ART was calculated from the date of initiating ART to the earliest of (i) the date of leaving the programme (due to any reason) (ii) the date of their last recorded clinic visit if the date of leaving the programme was unknown or (iii) 31st August 2009. For those who had no subsequent clinic visit following ART initiation where the exact date of leaving the programme was unknown, a nominal follow-up time of seven days was assumed. Virological outcomes were determined for patients who were followed-up for at least six and 12 months following ART initiation.

Data were analysed using Stata version 11.0 (Statacorp, College Station, Tx). Analysis was undertaken separately for patients who were ART-naïve and ART-experienced. Categorical data are presented as frequencies and percentages and continuous data as medians and interquartile ranges (IQR). Comparisons by ART status were conducted using the Chi-square test or Fisher’s exact test for categorical data and the Wilcoxon rank-sum test for continuous data. The mortality rate was calculated for the periods 0-6 months and >6 months following ART initiation, among those ART-naïve. Kaplan-Meier curves were used to summarize time to death and Cox regression used to assess the effect of CD4 strata on time to death. Kaplan-Meier curves were used to summarize the proportion in follow-up in the programme, following ART initiation.

*Ethical approval*

Ethical approval for the study was obtained from the research ethics committees of the University of the Witwatersrand, South Africa (reference number M090801) and the London School of Hygiene and Tropical Medicine, United Kingdom (reference number 5602). Permission to conduct the study was obtained from the Department of Correctional Services, South Africa. As this analysis used routinely-collected programme data, with no patient contact or procedures beyond routine clinical care, informed consent was not obtained from patients. All ethics committees approved this analysis, without requiring individual informed consent.

**Results**

During the study period, 409 HIV-positive adults initiated ART in the on-site correctional facility ART programme. Information on previous ART use was available for 404/409 (98.8%) who formed the study cohort, of whom 299 (74.0%) were ART-naïve at baseline.

Table 1 summarizes the baseline characteristics of this cohort and compares those who were ART-experienced at enrolment to the programme with those who were ART-naïve. Those who were ART-naïve were more likely than those ART-experienced to be male (p=0.004) and younger (p<0.001). They had a lower median baseline CD4 cell count (p<0.001) and a lower proportion had a viral load <400 copies/ml (p<0.001). Of those who were ART-naïve, 43/238 (18.1%) had a baseline CD4 cell count ≤50 cells/µl.

*Mortality following ART initiation: ART-naïve patients*

The median follow-up time of the 299 ART-naïve patients was 9.3 months (IQR 2.4 – 16.3). There were 23 deaths during 252 person years (pyrs) of follow-up giving an overall mortality rate of 9.1 per 100 pyrs (95% confidence interval [CI] 6.1 – 13.7) (Figure 1). Mortality rates in the intervals 0-6 and >6 months following ART initiation were 17.2 per 100 pyrs (95% CI 10.9 – 26.9) and 2.8 per 100 pyrs (95% CI 1.1 – 7.5), respectively (p<0.001). Among 238/299 (79.6%) with CD4 cell count results, there was an increased hazard of death over the total duration of follow-up, for those with CD4 cell counts ≤100 (hazard ratio [HR] 1.82, 95% CI 0.66 – 5.02; 10 deaths; mortality rate 14.2 per 100 pyrs) and similar HR for those with CD4 cell counts >200 (HR1.00, 95%CI 0.25 - 4.00; 3 deaths; mortality rate 7.2 per 100 pyrs) versus 101-200 cells/μl (6 deaths; mortality rate 7.2 per 100 pyrs). However, confidence intervals were wide and there was no evidence for a difference in mortality by CD4 cell count strata (p=0.43).

Among 105 ART-experienced patients, the median follow-up time was 5.6 months (IQR 1.4 – 9.5). There was one death during 60.9 pyrs of follow-up, giving an overall mortality rate of 1.6 per 100 pyrs (95% CI 0.2 – 11.7).

*Retention in the on-site ART programme*

By 31st August 2009, 144 of the original 404 (35.6%) inmates remained in the same correctional facility, with 136/144 (94.4%) retained in care (Figure 2)). Of the remaining, 155/404 (38.4%) were released back into the general community, 81/404 (20.0%) were transferred to another correctional facility and 24/404 (5.9%) had died. Of those commenced on ART, 241/404 (59.7%) were in follow-up at six months following ART initiation, and by 12 months, the proportion fell to 137/404 (33.9%) (Figure 3).

*Viral load suppression*

Of the 191/299 (63.9%) ART-naïve patients followed-up for at least six months following ART initiation, six-month viral load measurements were recorded for 131/191 (68.6%), of whom 94.7% (124/131) were virologically suppressed. Of the 120/299 (40.1%) followed-up for at least 12months following ART initiation, 12-month viral load measurements were available for 80/120 (66.7%); 92.5% (74/80) were virologically suppressed. Among 43 ART-experienced patients with viral load results following ART initiation (31 at six months and 12 at 12 months), only one patient was not virologically suppressed (at six months).

There was no difference in age or baseline CD4 cell count between patients that did and did not have viral load measurements undertaken at six and 12 months (data not shown).

**Discussion**

As far as we are aware, this study is the first to evaluate ART outcomes among patients in an on-site correctional facility ART programme in a resource-limited setting. Early mortality was high in those who were ART-naïve at baseline. Losses from the programme due to leaving the correctional facility were high. However of the patients still in the correctional facility, retention in the programme was excellent.

Virological suppression among those on ART was >90% at six and 12 months following ART initiation. While there are no on-site correctional facility ART programme data from other resource-limited settings to compare our findings against, our results are comparable to those from ART programmes in South Africa31, 34-37. In addition our findings are comparable to results from the tertiary referral University Hospital ART clinic where inmates received ART prior to the on-site ART programme; N=148 adults started on ART among whom viral load suppression at 24 and 48 weeks of treatment was 91%31. Findings from within the correctional facility ART programme which are comparable to best practice tertiary care provided to inmates is very encouraging. Longitudinal follow-up of patients in the programme is required to ensure that these early findings are sustained.

The early mortality rate in ART-naïve patients was high. It is comparable to rates seen in the community, where early mortality is associated with lower CD4 cell counts34, 38-40. While a higher mortality rate was seen in those with CD4 cell counts ≤100 in our study, confidence intervals were wide and overlapping due to the relatively small number of deaths. Although data on the causes of death in this population were unavailable, tuberculosis is known to be major cause of death among HIV-positive patients in sub-Saharan Africa41, 42. It is also known that tuberculosis prevalence is higher among inmates that the general population43 and is common in this correctional facility, especially among those who are HIV-positive44. Therefore it is likely that tuberculosis is an important cause of death in this population. The median baseline CD4 cell count of 133 cells/μl in the ART-naive cohort was higher than that seen in a community programme in Johannesburg45 but similar to that seen in programmes from other parts of South Africa34, 46, 47, over the same calendar period. Nearly a fifth of those who were ART- naïve had a baseline CD4 cell count ≤50 cells/μl. Data suggests early initiation of ART decreases morbidity and mortality48. Therefore inmates who are HIV-positive need to be identified urgently after incarceration with appropriate linkage to HIV care and tuberculosis investigated and managed appropriately49, 50. Correctional facilities provide additional opportunities to engage patients with HIV into treatment and care.

A surprisingly large proportion of the cohort were ART-experienced. This highlights the challenges posed to correctional facilities in coping with the rapid community scale up of ART services; larger proportions of inmates will be ART-experienced and require timely identification and continuation of care on imprisonment. Of the ART-experienced cohort accessing care, three-quarters were virologically suppressed at enrolment to the programme, suggesting that the programme is identifying ART-experienced patients promptly and linking them to care. Previous studies have shown that ART discontinuation is common among people imprisoned51, 52. In a review by Wilson *et al*, 15% of inmates enrolled onto a correctional facility ART programme in Thailand were treatment experienced, with all having discontinued ART on imprisonment21. It is not possible to know if those accessing care in our study are a highly motivated group, and not representative of the ART-experienced HIV-infected correctional facility population. Work to facilitate access to HIV care within correctional facility systems is needed.

Losses from the programme were high due to movement out of the correctional facility, highlighting the importance of linkage to continuing care either in the community or in the receiving correctional facility. It is unclear if any releases from the correctional facility were on compassionate grounds, due to HIV/AIDS. Discontinuation of ART, which may occur on release from correctional facilities, reverses the successes gained by providing ART within correctional facilities8, 9, 53-55. Interventions aimed at improving linkage to care in the community (e.g. pre-release discharge planning) for HIV-positive inmates in the United States, has been shown to increase access to community-based HIV services and decrease recidivism56-60. Similar interventions are needed, tailored to African settings. Among those ART- naïve, a high proportion had a baseline viral load of <400 copies/ml of blood. Previous ART status was determined by self-report. As approximately 1% of ART-naïve patients would be expected to have very low viral loads without ART61, it is likely that reporting bias with misclassification of patients by previous ART status occurred. This further highlights the importance of linkage and seamless flow of information between community and correctional facility programmes62.

Our study has several limitations. It is not possible to know to what extent our results are generalizable to all HIV positive patients in the correctional facility who require ART; our cohort could represent highly-motivated inmates accessing care. There was a large proportion (>30%) of missing viral load data; the reasons for this are unclear. Therefore virological outcomes should be interpreted with caution. However there was no difference in those that did and did not have laboratory data by age and baseline CD4 count. The short duration of follow-up prevents us from being able to comment on the long-term outcomes of the programme. Patients were defined as retained in care if they were still in the correctional facility on the 31st of August 2009 and were seen by the programme in the preceding six months. As many studies use three months as a cut off, with this also being current WHO recommendations63, 64, the proportion retained in our study will be an overestimate if comparisons are made. However, a recent analysis of data from 19 countries to determine a standard lost to follow-up definition, identified that a cut off of 180 days since the last clinical visit resulted in the fewest misclassifications65.

In conclusion, our study demonstrates that provision of ART services within correctional facilities is feasible, with excellent retention and good virological outcomes of those remaining in the correctional facility. This supports the decentralization of HIV care to correctional facilities. The high early mortality emphasises the need for prompt identification of HIV-positive inmates upon entry to the correctional facility, and intensive management of patients at high risk of death around the time of initiating ART. High losses from the programme reflect the mobility of inmates emphasising the need for systems which facilitate continuity of care in resource-limited settings.

**Acknowledgements**

We would like to acknowledge the Department of Correctional Services of South Africa and the Department of Correctional Services team at the Aurum Institute.

**Declaration of conflicting interests**

The authors declare that there is no conflict of interest.

**Funding acknowledgement**

Subjects in this study were enrolled in treatment programs supported by the U.S. President's Emergency Plan for AIDS Relief and by Cooperative Agreement Number PS024055 from the Department of Health and Human Services/Centers for Disease Control and Prevention (CDC), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Global AIDS Program (GAP). The content of this manuscript are solely the responsibility of the authors and do not necessarily represent the official views of CDC. Professor Grant was supported by a UK Department of Health, Public Health Career Scientist award. Salome Charalambous was supported by grants from the Ernest Oppenheimer Memorial Trustee (EOMT 17073/03).

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