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Treatment Outcomes after Seven Years of Public-sector HIV treatment at the Themba Lethu Clinic in Johannesburg, South Africa

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Abstract

Objectives—To assess outcomes over the first seven years of antiretroviral therapy at Themba Lethu Clinic, Johannesburg, South Africa.

Design—Observational cohort study.

Methods—Patients are managed according to South African National Treatment Guidelines. Mortality is ascertained through linkage with the national vital registration system. Loss to follow-up is defined as 3 months late for the last scheduled appointment.

Results—Between April 2004 and March 2010, 13,227 patients initiated ART, increasing from 1,794 in the year 2004/5 to 2,481 in 2009/10. Median CD4 at ART initiation increased 39% between 2004 and 2009 (82 vs. 114 cells/mm³). The proportion who died within one year on ART was below 11% at all calendar years, while the proportion lost by one year increased from 8.5% in 2004 to 12.1% in 2009 (RR: 1.42; 95% CI: 1.18–1.71).

We followed the 1,794 patients initiated in April 2004–March 2005 through August, 2011 for 8,172 person-years. We estimated 25% of patients were lost and 16% died. The overall mortality rate was 3.59/100 PY (95% CI: 3.20–4.02). Of the 1,577 who completed 6 months of follow up, 213 (13.5%) failed first-line treatment in a median (IQR) of 25.9 (15.8–41.4) months on treatment.

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Authorship Statement: Matthew Fox designed the study and drafted the manuscript. Kate Shearer designed and conducted the analysis. Ian Sanne, Mhairi Maskew, William MacLeod, Patrick MacPhail and Pappie Majuba had significant input into the design of the study, suggested additional analyses and edited the manuscript.

Of those who failed, 141 (66.2%) switched to second-line for a rate of 48.5/100 PY (95%CI: 41.1-57.2).

Conclusions—Despite some improvements over seven years, more intervention is needed in the first year on treatment to reduce overall attrition.

Keywords

antiretroviral therapy; HIV; AIDS; mortality; resource-limited settings; sub-Saharan Africa

INTRODUCTION

Since the large-scale roll-out of public-sector antiretroviral treatment (ART) programs in resource-limited settings, over five million patients have been initiated onto ART, representing 36% of those in need in 2009.[1] Over the past decade, numerous treatment programs have demonstrated successful treatment outcomes in programs at scale,[2-4] and subsequent survival impacts.[5, 6] Still, substantial losses from care in the pre-ART period, [7-11] low CD4 counts at ART initiation,[12-15] increased mortality during early ART[16-18] and sustained attrition from HIV programs[12, 14] continue to prove difficult challenges for those implementing treatment programs in resource-constrained settings.

As HIV treatment programs mature, ever more patients are initiating ART. In some settings the accumulated experience managing and treating HIV has translated into better patient outcomes[3] while in others increasing demands on providers may prevent these gains from being realized. At the same time, to maintain the benefits associated with treatment, attention must be paid to keeping stable patients in care and adherent long-term. Given these competing needs are occurring in a setting of finite resources, decisions must be made as to where to focus efforts and new strategies must be developed to manage patients more efficiently.

To fully describe the short- and long-term experience managing and treating HIV at one of the largest HIV treatment programmes in the world, we report HIV treatment outcomes over seven years in a public-sector ART treatment program at the Themba Lethu Clinic (TLC) in Johannesburg, South Africa.

METHODS

TLC is located at Helen Joseph Hospital in Johannesburg. Care at TLC follows the national guidelines.[19, 20] During the period of this analysis patients initiated ART with a CD4 count <200 cells/mm³ or a WHO Stage IV condition.

Under the 2004 guidelines, standard first-line ART regimens included stavudine or zidovudine with lamivudine and either efavirenz or nevirapine. Switching to second-line ART was recommended after documented first-line treatment failure (two consecutive viral loads >1000 copies/ml). Standard second-line therapy included zidovudine, didanosine and lopinavir-ritonavir. Since other regimens are sometimes used, we defined second-line as a protease inhibitor-based regimen with 1 change in nucleoside reverse transcriptase inhibitor.

We included all ART naïve adults (>18 years) initiating first-line three-drug ART at TLC between 01 April 2004 and 31 March 2010. Patient data is collected using an electronic patient management system[4] to record data on patient demographics, clinical examinations, conditions, treatment regimens, and lab results. While initially data was collected on paper records and entered into the electronic system, since 2007 data is entered

by clinicians during patient encounters, except for visit booking and attendance which is entered by clinic staff upon arrival at the clinic.

Prior to ART initiation, patients are monitored every 3-6 months. On ART patients are seen monthly for the first six months on ART, then every two months if stable. Pharmacy visits occur at every visit, while medical visits occur six-monthly or as clinically indicated. CD4 and viral load monitoring was scheduled at six months, and six-monthly thereafter.

We define loss to follow-up (LTF) as 3 months late for a scheduled visit with no later visit. Deaths are identified through attempts by clinic counselors to trace lost patients. For patients who provide a valid South African National ID number (55%), we also ascertain deaths from the National Vital Registration system (September 2011).[21] Patients who die are included in the analysis until the date of death even if this occurs after leaving care and are coded as deaths, not losses.

The dataset was closed on August 2, 2011. Person-time began at ART initiation and ended at death or the earliest of: LTF; transfer; 7 years of follow up; or dataset closure. Comparisons by yearly cohorts (April 1st of each year to March 31st of the subsequent year) were conducted on one-year outcomes to allow cohorts to be comparable. We analyzed predictors of death and LTF with log-binomial regression using modified Poisson regression and robust error estimation.[22] We then describe seven-year outcomes for those initiated in the first cohort.

Approval for analysis was granted by the Ethics Board of the University of the Witwatersrand and by the Institutional Review Board of Boston University.

RESULTS

13,227 adult patients initiated treatment at TLC. In 2004, HIV treatment services rapidly scaled-up, with 1,794 patients initiating ART between April 2004 and March 2005 (Table 1). Yearly cohorts after that ranged from 1,996 to 2,617 patients. The median CD4 count at ART initiation for all cohorts was <120 cells/mm³ but a small, nearly consistent yearly increase was observed. From 2004/5-2009/10 the median CD4 count increased 39% (82 to 114 cells/mm³, $p<0.0001$). About 75-80% of all ART patients achieved viral suppression in a median (IQR) of 3.9 (3.7-5.0) months and 90% when limited to those with 6 months of follow-up (Table 1).

Much of the negative outcomes on ART occurred in the first year (Figure 1). Death was highest in the first 12 months at 24.3/100 person-years (95% CI: 21.6-27.4) in month 1 and 5.4/100 person-years (95% CI: 4.1-7.3) in month 12, but remained stable at under 5/100 person-years for each month thereafter. LTF (which cannot occur before month four) was also elevated in the first year (month 4: 53.2/100 person-years; 95% CI: 49.0-57.9; month 12: 6.6/100 person-years; 95% CI: 5.1-8.6) then stabilized at under 10/100 person-years through 72 months.

One-year Treatment Outcomes

After a year on treatment, 76.0% ($n=10,051$) of patients were alive and in care. 9.1% ($N=1,201/13,227$) of patients died within one year in a median (IQR) of 2.9 (1.1-6.1) person-months. One-year mortality was below 11% (7.5% to 10.6%) in all years. We identified several predictors of mortality at ART initiation over the first year on ART (Appendix 1), including CD4 count <50 (RR: 2.66; 95%CI: 2.06-3.44) and 50-99 (RR: 1.68; 95%CI: 1.28-2.21) compared to 200+, anemia (RR severe vs none: 2.79; 95%CI: 2.24-3.49),

low BMI (RR low vs. normal: 1.70; 95%CI: 1.49-1.94) and older age (RR 45+ vs. 18-29: 1.61; 95%CI: 1.35-1.92).

LTF over one year on ART occurred in 11.2% (N=1,477/13,227) of patients in a median (IQR) of 5.0 (4.0-7.6) person-months. While not perfectly monotonic, one year losses increased from 8.5% in 2004/5 to 12.1% in 2009/10 (RR: 1.42; 95%CI: 1.18-1.71). Anemia was a strong predictor of LTF (RR severe vs. none: 1.73; 95%CI: 1.45-2.06) (Appendix 1). Male sex (RR: 1.28; 95%CI: 1.15-1.43), young age (RR 18-29 vs. 45+: 1.40; 95%CI: 1.20-1.64), low BMI (RR low vs. normal: 1.33; 95%CI: 1.16-1.52) and initiating on a non-d4T based regimen (RR other vs. d4T-3TC-EFV: 1.35; 95% CI: 1.18-1.55) were also significant predictors of loss.

Seven-year Outcomes

1,794 patients initiated treatment the first year of the treatment roll-out in South Africa (2004/5) of whom 48.4% are in care, 9.9% transferred to another facility, 25.4% were lost and 16.3% had died. These patients have been followed for 8,172 person-years and a median (IQR) of 6.4 (1.7-6.8) years on treatment per-person. This gave us a rate of 3.59 deaths (95% CI: 3.20-4.02) and 5.57 losses/100 person-years (95% CI: 5.08-6.10). When including patients from all cohorts in a survival analysis we found overall 37.8% (36.2-39.4%) of patients were alive and in care at seven years.

Nearly half (46%, n=825) experienced 1 drug substitution exclusive of switching to second-line. Of the 1,577 who completed 6 months of follow-up, 213 (13.5%) failed first-line in a median (IQR) of 25.9 (15.8-41.4) months. Of those who failed, 141 (66.2%) switched to second-line for a rate of 48.5/100 PY (95%CI: 41.1-57.2). Switching occurred in a median (IQR) of 5.0 (1.8-16.8) months after failure. The median gain in CD4 count from baseline to last CD4 count conducted was 339 cells/mm³.

DISCUSSION

In South Africa, as with many resource-limited countries, scale up of the national ART program began in 2004[19]. Over the past seven years, the program has grown to include roughly 1.5 million patients on ART[1]. As South Africa's national ART programs continue to mature, the challenges of maintaining patients who have been on ART for a substantial period of time are being balanced against the demands of increasing patient volumes, higher ART initiation thresholds, and changes to preferred ART regimens[20, 23].

In our cohort of over 13,000 patients, we demonstrated positive one-year outcomes (mortality, LTF, suppression etc.) over the six cohorts, despite increasing clinic size from under 2000 patients in 2004/5 to >9000 in 2009/10. We found most patients (90% of those with 6 months of follow-up) suppressed the virus, and 76.0% (n=10,051) were still alive and in care after a year on treatment. One year mortality was below 11% in all cohorts. After the first twelve months on treatment monthly rates of death and loss decreased strongly and remained fairly constant further underscoring the need for intervention targeted towards getting patients through the critical first year.

Among patients on treatment since the first year of the clinic's inception, roughly half are still in care and a further 10% have been transferred to another facility. While this is less than ideal, given the emergency mindset of getting as many patients on treatment as possible at that time, this is still a remarkable success. Our long-term findings are in line with another South African cohort [3]. Like that program we saw increasing LTF over time and increasing CD4 counts at ART initiation. However, unlike their program we did not observe

decreasing mortality over time. It is, however, possible they were able to identify more deaths than we were among those lost using linkage to the registry.

Our study, which includes roughly twice as many patients as the Khayelitsha analysis, confirms that the benefits of ARV treatment can continue to be realized even as programs expand. As TLC has grown in patient size, the size of the clinical staff has remained stable over the past years with roughly 6-8 doctors and 2-3 nurses while funding for the clinic has not increased at the same pace. Instead new strategies have been devised to cope with the increasing patient load and maintain outcomes. These include rearrangement of the patient flow of the clinic, implementing SMS reminder services, use of the electronic patient record system to track patients through the clinics, and down-referral of stable patients to clinics supported by nurses.[24, 25] Future efforts to reduce costs will need to be explored to achieve universal access.

Our study limitations include missing data and limited information on treatment adherence and other potentially important covariates. Also, there is likely some misclassification of death leading to underestimated mortality rates and overestimated LTF rates. In addition, we can only track patients after ART initiation and cannot comment on pre-ART outcomes. Finally this study represents only one clinic and results may not be generalizable to all settings.

While the future of HIV treatment funding remains unclear, the benefits of massive investment in treatment are clearly evident. This seven-year follow-up evaluation demonstrates that resources being invested in large-scale HIV treatment are achieving substantial gains.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
 Monthly rates of mortality, loss to follow-up and transfer over 84 months at an HIV treatment program at the Themba Lethu clinic in Johannesburg, South Africa*
 * LTF = loss to follow-up

Table 1

Patients characteristics and treatment outcomes of patients enrolled in an HIV care and treatment program at the Themba Lethu Clinic in Johannesburg, South Africa between April 1, 2004 and March 31, 2010

		Cohort of Patients Initiating ART between April 1 of Calendar Year Until March 31 of Following Calendar Year					
Variable	Exposure	2004/5	2005/6	2006/7	2007/8	2008/9	2009/10
Total N		1794 (100%)	2154 (100%)	2617 (100%)	1996 (100%)	2185 (100%)	2481 (100%)
Characteristics at ART initiation							
Sex	Male	555 (30.9%)	716 (33.2%)	955 (36.5%)	773 (38.7%)	811 (37.1%)	1038 (41.8%)
	Female	1239 (69.1%)	1438 (66.8%)	1662 (63.5%)	1223 (61.3%)	1374 (62.9%)	1443 (58.2%)
Median (IQR) age		35.3 (30.5-41.8)	34.5 (30.1-40.5)	35.5 (30.7-42.1)	36.2 (31.0-42.3)	36.9 (31.4-43.6)	37.2 (31.8-44.3)
Tuberculosis	No	1548 (86.3%)	1697 (78.8%)	2153 (82.3%)	1716 (86.0%)	1927 (88.2%)	2149 (86.6%)
	Yes	246 (13.7%)	457 (21.2%)	464 (17.7%)	280 (14.0%)	258 (11.8%)	332 (13.4%)
Median (IQR) CD4 count	(cells/mm ³)	82 (36-143)	90 (32-157)	83.5 (28-157.5)	82 (32-153)	99 (36-168)	114 (46-186)
CD4 count (cells/mm ³)	Missing	53 (3.0%)	37 (1.7%)	65 (2.5%)	30 (1.5%)	22 (1.0%)	52 (2.1%)
	0-24	317 (17.7%)	449 (20.8%)	584 (22.3%)	410 (20.5%)	406 (18.6%)	351 (14.1%)
	25-49	252 (14.0%)	275 (12.8%)	324 (12.4%)	290 (14.5%)	259 (11.9%)	286 (11.5%)
	50-99	447 (24.9%)	408 (18.9%)	521 (19.9%)	416 (20.8%)	417 (19.1%)	454 (18.3%)
	100-199	611 (34.1%)	776 (36.0%)	837 (32.0%)	687 (34.4%)	781 (35.7%)	865 (34.9%)
	200-349	102 (5.7%)	188 (8.7%)	252 (9.6%)	143 (7.2%)	267 (12.2%)	412 (16.6%)
	350+	12 (0.7%)	21 (1.0%)	34 (1.3%)	20 (1.0%)	33 (1.5%)	61 (2.5%)
Baseline ART regimen	d4T_3TC_EFV	1494 (83.3%)	1669 (77.5%)	2123 (81.1%)	1666 (83.5%)	1768 (80.9%)	2068 (83.4%)
	d4T_3TC_NVP	165 (9.2%)	122 (5.7%)	190 (7.3%)	139 (7.0%)	152 (7.0%)	155 (6.2%)
	d4T_3TC_LPVr	97 (5.4%)	284 (13.2%)	196 (7.5%)	49 (2.5%)	62 (2.8%)	65 (2.6%)
	AZT_3TC_EFV	25 (1.4%)	64 (3.0%)	79 (3.0%)	70 (3.5%)	90 (4.1%)	50 (2.0%)
	AZT_3TC_NVP	4 (0.2%)	4 (0.2%)	9 (0.3%)	8 (0.4%)	12 (0.5%)	8 (0.3%)
	TDF_3TC_EFV	1 (0.1%)	3 (0.1%)	5 (0.2%)	47 (2.4%)	74 (3.4%)	96 (3.9%)
	Other	8 (0.4%)	8 (0.4%)	15 (0.6%)	17 (0.9%)	27 (1.2%)	39 (1.6%)
Total Person Years		8172	7952	8286	5160	4555	3571
Outcomes on ART							
Achieved viral suppression	% (Median months to event)	79.8% (4.7)	74.8% (3.9)	76.2% (3.9)	74.6% (3.7)	77.7% (3.7)	76.3% (3.8)
Failed first-line ART	% (Median months to event)	11.9% (25.9)	11.4% (21.0)	8.4% (24.2)	6.2% (20.0)	4.5% (18.6)	2.7% (13.5)
Switched to second-line after first line failure	% Yes (Median months to event)	66.2% (5.0)	69.5% (3.6)	67.7% (2.3)	65.3% (2.7)	54.6% (3.2)	53.0% (1.1)
Outcome	Alive	868 (48.4%)	956 (44.4%)	1237 (47.3%)	1016 (50.9%)	1297 (59.4%)	1620 (65.3%)
	Dead	293 (16.3%)	357 (16.6%)	373 (14.3%)	277 (13.9%)	290 (13.3%)	239 (9.6%)
	Lost to follow-up	455 (25.4%)	617 (28.6%)	733 (28.0%)	516 (25.9%)	429 (19.6%)	474 (19.1%)
	Transferred	178 (9.9%)	224 (10.4%)	274 (10.5%)	187 (9.4%)	169 (7.7%)	148 (6.0%)

* d4T = stavudine, EFV = efavirenz, 3TC = lamivudine, NVP = nevirapine, AZT = zidovudine, LPVr = lopinavir-ritonavir, ART = antiretroviral therapy, TB = tuberculosis