

# HOME VS. SELF-INITIATED ART REFILL: CLINICAL, IMMUNOLOGICAL, AND VIROLOGIC OUTCOMES

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#### Introduction

Antiretroviral therapy (ART) delivery by courier to the patient's home (home refill) is a novel intervention that may improve clinical outcomes and reduce indirect costs for individuals in low- and middle-income countries (LMICs). We aimed to compare clinical and virologic outcomes for patients obtaining medication refills at their local pharmacy (self refill) vs. home refill in Aid for AIDS (AFA), a large South African private sector HIV/AIDS programme.

### **Methods**

Antiretroviral therapy (ART) delivery by courier to the patient's home (home refill) is a novel intervention that may improve clinical outcomes and reduce indirect costs for individuals in low- and middle-income countries (LMICs). We aimed to compare clinical and virologic outcomes for patients obtaining medication refills at their local pharmacy (self refill) vs. home refill in Aid for AIDS (AFA), a large South African private sector HIV/AIDS programme.

Retrospective cohort analysis of ART naïve HIV-infected adults in AFA who initiated first line NNRTI based ART regimen between January 2002 and July 2010 was performed. Patients were selected to switch to home refill based on the discretion of AFA. Primary endpoint was all-cause mortality; secondary endpoints were viral suppression (VL< 400 copies/mL) and median CD4+ T-cell response (cells/µI) (from baseline) at 6-month intervals. We compared the crude survival between self-refill and home refill using Kaplan–Meier plots and a log-rank test. We performed Cox regressions to model the individual and simultaneous effects of baseline variables and mode of ART delivery on all-cause mortality, adjusting for propensity score.

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40,939 patients, contributing over 100,000 years of follow-up were recorded. The most common first line regimen was efavirenz + lamuvidine + zidovudine, followed by efavirenz + emtricitabine + tenofovir in later years.

Emerging at 24 months, the home refill group had improved median CD4+ T- cell count response (451 vs. 387, respectively, p < 0.01) compared to the self-refill group – see figure 1. Equally, the likelihood of virologic suppression improved (81% versus 71%, respectively, p-value <0.001) compared to the self-refill group – see figure 2.



Figure 1: Comparing median CD4+ cell count (cells/µl) response from baseline to 60 months on antiretroviral therapy with interquartile ranges for home-refill by courier with (a) self-refill and (b) switching from self-refill to home-refill by courier

## Discussion

Home refill is associated with improved clinical, immunological, and virologic outcomes compared to self-refill for HIV-infected adults in this private AIDS programme in South Africa. Home refill offers a promising additional option to the growing ART service delivery models and should facilitate the UNAIDS 90-90-90 targets in LNICs.



Figure 2: Comparing median HIV viral load (copies/ml) response from baseline to 60

months on antiretroviral therapy with interquartile ranges for home-refill by courier with (a) self-refill and (b) switching from self-refill to home-refill by courier Home refill (vs. self-refill) was associated with better survival (adjusted hazard ratio = 0.90 [95% CI: 0.84-0.96] (Table 1), p-value for log-rank test < 0.001) (Figure 3).



Variables		Multivariate with p-score		Multivariate	
		Hazard ratio (95% CI)	p-value	Hazard ratio (95% CI)	p-value
Antiretroviral dispensing	home-refill	0.88 (0.82 to 0.95)	< 0.001	0.9 (0.84 to 0.96)	0.003
	self-refill	referent		referent	
Baseline NNRTI	efavirenz	1.13 (1.03 to 1.23)	0.012	1.14 (1.04 to 1.25)	0.006
	nevirapine	referent		referent	
Baseline NRTI	tenofovir	referent		referent	
	other	1.95 (1.26 to 3)	0.003	1.91 (1.24 to 2.94)	0.003
	zidovudine	1 (0.85 to 1.19)	0.957	0.87 (0.78 to 0.96)	0.008
	stavudine	1.09 (0.94 to 1.26)	0.255	0.99 (0.88 to 1.1)	0.813
Sex	female	referent		referent	
	male	1.04 (0.92 to 1.17)	0.562	1.15 (1.08 to 1.23)	<0.001
Age on starting antiretroviral therapy (years)	<25	0.81 (0.63 to 1.06)	0.121	0.74 (0.58 to 0.94)	0.014
	25-49	referent		referent	
	>50	1.5 (1.35 to 1.66)	<0.001	1.58 (1.45 to 1.73)	<0.001
Baseline viral load (copies/ml)	<100,000	0.71 (0.43 to 1.18)	<0.001	0.73 (0.44 to 1.21)	0.217
	100,000-999,999	referent		referent	
	>1,000,000	1.78 (1.15 to 2.76)	0.19	1.85 (1.2 to 2.85)	0.005
Basline CD4 category (cells/µL)	0-49	4.04 (3.53 to 4.62)	0.009	4.38 (3.92 to 4.89)	<0.001
	50-199	1.96 (1.75 to 2.2)	<0.001	referent	
	200-349	referent		2.02 (1.81 to 2.26)	<0.001
	>350	1.11 (0.87 to 1.42)	0.415	1.09 (0.85 to 1.39)	0.494
Year of starting antiretroviral therapy	2002-2003	2.4 (2.13 to 2.71)	<0.001	2.25 (2.03 to 2.49)	<0.001
	2004-2005	1.53 (1.38 to 1.71)	<0.001	1.55 (1.39 to 1.73)	<0.001
	2006-2007	1.16 (1.06 to 1.28)	0.002	1.19 (1.09 to 1.31)	<0.001
	2008+	referent		referent	
Body Mass index (kg/m2)	<18	1.52 (1.3 to 1.78)	<0.001	1.56 (1.33 to 1.83)	<0.001
	18-24	referent		referent	
	25-34	0.82 (0.72 to 0.93)	0.007	0.8 (0.7 to 0.91)	0.003
	35+	0.7 (0.53 to 0.92)	0.013	0.67 (0.51 to 0.88)	0.006

Table 1: Cox regression table comparing multivariate analyses with or without propensity score

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