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Earlier referral to differentiated antiretroviral therapy delivery at six months after initiation: a retrospective cohort study in KwaZulu-Natal, South Africa

[version 1]

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Abstract

The World Health Organization revised eligibility for differentiated service delivery to requiring clients to be on antiretroviral therapy (ART) from 12 to six months with one suppressed viral load. South Africa adopted “early community-based ART” referral from April 2020. We aimed to evaluate the uptake and subsequent clinical outcomes through a retrospective cohort study using routine, de-identified data from 124 public clinics in KwaZulu-Natal province, South Africa. We included people with HIV aged ≥16 years, newly initiated on ART and virally suppressed (≤50 copies/mL) at 6 months. We assessed uptake of early community-based ART (referral < 270 days from ART initiation) among people initiating ART between 1 January 2020 and 1 December 2022, and clinical outcomes of not retained-in-care or died, and viraemia at 12 months. We used multivariable Poisson regression models with robust standard errors to compare outcomes between

‘early community-based ART referral’ versus ‘no early referral’. Among 27,855 people eligible for early community-based ART, 61% were women and the median age was 33 years. 3,427 (12.3%) received early community-based ART, at a median of 223 days after ART initiation. Rates of early community-based ART increased from 7.0% of those initiated in Q1 2020 to 20% in Q4 2022. Among 21,106 participants with outcome data, 9.5% received early community-based ART. The proportion not retained-in-care or died at 12 months was 3.9% for those with and 17.9% for those without early community-based ART (RR 0.49; 95% CI 0.39-0.61; $p < 0.05$). Among those retained-in-care, a 12-month viral load result was available for 83.4% patients, and of these 9.0% with and 10.5% without early community-based ART had viraemia (RR 0.88; 95% CI 0.75-1.04; $p = 0.128$). In conclusion: uptake of early community-based ART was low but associated with better retention and similar clinical outcomes.

Keywords
HIV, antiretroviral therapy, differentiated service delivery, retention in care, viral suppression, South Africa

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Introduction

There is growing evidence that, among clinically stable clients, using community-based antiretroviral therapy (ART) is as effective in maintaining retention-in-care and viral suppression as clinic-based care.[1–3] During the COVID-19 pandemic, the World Health Organization (WHO) revised its definition of clinical stability as a criterion for referral to community-based ART. The previous definition required clients to be on ART for at least 12 months with two suppressed viral loads (VLs) and no current illness[4]; this was changed to at least six months on ART with one suppressed VL post-initiation and no current illness.[5] Clients who achieved this clinical stability would be eligible for enrolment in community-based ART programmes.

We previously conducted a retrospective cohort study on people living with HIV (PLHIV) on first-line ART who were eligible for community-based ART (less frequent clinic visits with external pick-up points for ART's) and found that the number of clients eligible far exceeds the number referred.[3] Qualitative findings suggested that a lack of provider buy-in to the expansion of eligibility into these programmes was causing reluctance to refer clients eligible at six months,[6] despite the perceived benefits by stable patients.[7] Providers reported concerns about client readiness, fear that adherence would be worse, and the limited empirical evidence on outcomes following earlier referral. Therefore, we aim to evaluate the uptake of early referral to community-based ART programmes (early community-based ART) and to compare subsequent outcomes between people referred for early community-based ART, with those not referred.

Methods

Study design and participants

We conducted a retrospective cohort study using deidentified electronic health data from 124 public clinics in eThekwini, uMgungundlovu and uMkhanyakude districts in KwaZulu-Natal province, South Africa. We analysed two cohorts: one to evaluate uptake of early community-based ART, and one to evaluate subsequent outcomes. In the uptake cohort, we included adults (≥16 years) newly initiated on tenofovir disoproxil fumarate/emtricitabine/efavirenz (TEE) or tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) between 1 January 2020 and 1 December 2022, who did not have tuberculosis (TB), were not pregnant, and were virally suppressed (VL <50 copies/mL) 6 months after ART initiation. We excluded people who transferred-in after ART initiation due to unavailable ART initiation data, and people who became lost to follow-up before 9 months as they may not have had the opportunity to be referred for early community-based ART. For the outcome cohort, we used the same criteria as the uptake cohort, but excluded people initiated after 1 March 2022, as they did not have enough follow-up time to determine outcomes before the administrative data cut on 1 September 2023. We also excluded people who had been referred into community-based ART with a 12-month prescription,[3,6] as they would not have been scheduled a clinic visit before the end of follow-up and so retention-in-care could not be assessed.

Data sources and management

We used de-identified data from TIER. Net, an electronic health register containing demographic, clinical, and visit data for clients in South Africa's public ART program.[8] TIER. Net provides information on clinic visits, referral for community ART delivery within the Central Chronic Medicines Dispensing and Distribution (CCMDD) programme, ART regimens, prescription durations, outcomes and CD4 and VL measurements.

Variables

The primary exposure was a binary variable of early community-based ART referral (defined as receiving a community ART referral to an external pickup point within 270 days of ART initiation), or no early referral. Baseline variables in TIER. Net considered as potential confounders were age, sex, ART regimen, and CD4 count at initiation.

The primary outcomes were not retained-in-care or died, and viraemia at 12 months post-initiation. Clients were classified as not retained-in-care or dead at 12 months if they missed a visit by more than 90 days or died, within 9-15 months of ART initiation. Viraemia was defined as a VL >50 copies/mL, using the VL closest to 12 months within a window of 9 to 15 months post-initiation.

Statistical analysis

We first described overall uptake of early community-based ART in the uptake cohort. Then, in the outcome cohort, we used univariable and multivariable logistic regression analyses to examine associations between the primary exposure of early community-based ART referral and the outcome of not retained-in-care or died at 12 months. Among those retained-in-care with a 12-month VL, a second analysis assessed viraemia at 12 months. We used generalized linear models (GLMs, Poisson family) with robust standard errors, reporting risk ratios with 95% confidence intervals. In the multivariable analyses, we adjusted for the potential confounders of age, gender, CD4 count, and ART regimen.

Ethical approval

This work was approved by the University of KwaZulu-Natal Biomedical Research Ethics Committee (BE646/17), the KwaZulu-Natal Department of Health's Provincial Health Research Ethics Committee (KZ_201807_021), and the eThekwini Municipality Health Unit, with a waiver for informed consent for analysis of anonymized, routinely collected data.

Results

Client characteristics

Across the 124 clinics, 70,551 ART-naïve adults initiated on ART between 1 January 2020 and 1 December 2022 and were not pregnant or diagnosed with TB. 42,696 (60.5%) were excluded as they were not on a TEE or TLD regimen (n = 392), were lost to follow-up (n = 23,623) or missed a visit by ≥90 days (n = 3,441) in the firsts 9 months, did not have a VL measurement recorded at 6 months (n = 8,990), or were not virally suppressed <50 copies/mL (n = 6,250) (Figure 1). Among 27,885 people eligible for early community-based ART and included in the uptake cohort, 17,111 (61%) were women (Table 1) and the median age was 33 years (IQR 27-40). 3,427 (12.3%) received early community-based ART, at

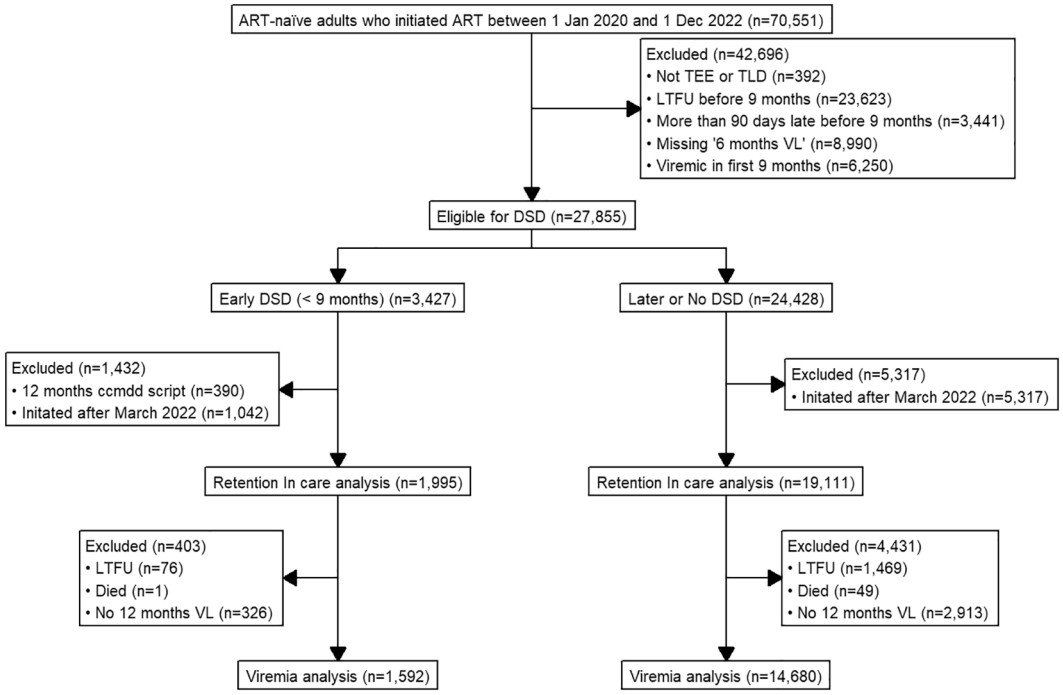

Figure 1. Flow diagram of patients eligible for early community-based ART and retention in care between January 2020 and December 2022 in 124 clinics in KZN, South Africa. LTFU: lost to follow-up.

Table 1. Baseline characteristics in the uptake cohort.

	Overall n = 27,855[1]	Early community ART n = 3,427[1]	No or later community ART n = 24,428[1]
Gender			
Male	10,744 (39%)	1,257 (12%)	9,487 (88%)
Female	17,111 (61%)	2,170 (13%)	14,941 (87%)
Age group (years)			
16-20	1,183 (4.2%)	124 (10%)	1,059 (90%)
21-30	9,813 (35%)	1,263 (13%)	8,550 (87%)
31-40	10,317 (37%)	1,242 (12%)	9,075 (88%)
41-50	4,618 (17%)	577 (12%)	4,041 (88%)
>50	1,924 (6.9%)	221 (11%)	1,703 (89%)

Table 1. *Continued*

	Overall n = 27,855[1]	Early community ART n = 3,427[1]	No or later community ART n = 24,428[1]
Quarter of initiation			
Q1 2020	3,717 (13%)	259 (7.0%)	3,458 (93%)
Q2 2020	2,368 (8.5%)	147 (6.2%)	2,221 (94%)
Q3 2020	2,324 (8.3%)	213 (9.2%)	2,111 (91%)
Q4 2020	2,387 (8.6%)	229 (9.6%)	2,158 (90%)
Q1 2021	2,654 (9.5%)	351 (13%)	2,303 (87%)
Q2 2021	2,393 (8.6%)	253 (11%)	2,140 (89%)
Q3 2021	2,023 (7.3%)	258 (13%)	1,765 (87%)
Q4 2021	2,001 (7.2%)	344 (17%)	1,657 (83%)
Q1 2022	2,463 (8.8%)	493 (20%)	1,970 (80%)
Q2 2022	1,917 (6.9%)	266 (14%)	1,651 (86%)
Q3 2022	2,197 (7.9%)	338 (15%)	1,859 (85%)
Q4 2022	1,411 (5.1%)	276 (20%)	1,135 (80%)
Initiation CD4 count (cells/μL)			
<=200	4,663 (17%)	469 (10%)	4,194 (90%)
201-350	5,386 (19%)	638 (12%)	4,748 (88%)
351-500	5,110 (18%)	708 (14%)	4,402 (86%)
>500	9,150 (33%)	1,248 (14%)	7,902 (86%)
Missing	3,546 (13%)	364 (10%)	3,182 (90%)
ART regimen			
TLD	23,192 (83%)	3,110 (13%)	20,082 (87%)
TEE	4,663 (17%)	317 (6.8%)	4,346 (93%)
Days to first VL			
	184 (169, 200)	176 (168, 195)	186 (169, 201)

[1]n (%); Median (Q1, Q3).

a median of 223 days (IQR 199 to 242) after ART initiation. The proportion with early referral to community-based ART increased from 7.0% of those initiated in Q1 2020 to 20% of those initiated in Q4 2022 (Table 1).

Outcomes retained in care and viral suppression

A further 6,749 people were excluded from the outcome cohort as they initiated after March 2022 (n = 6,359) or received a 12-month script when starting community-based ART (meaning they would have no scheduled visits during the follow-up period with which to assess retention-in-care, n = 390). The remaining 21,106 people had initiated ART between 1 January 2020 and 1 March 2022, were eligible for early community-based ART and were included in the outcome cohort (Figure 1). Of these, 1,995 (9.5%) received early community-based ART and 19,111 (90.5%) did not (Figure 1). The proportion not retained-in-care or died at 12 months was 77/1,995 (3.9%) for those with and 1,518/19,111 (7.9%) for those without early community-based ART (multivariable adjusted Risk Ratio (RR) 0.49; 95% CI 0.39-0.61; $p < 0.05$; Table 2). For the viremia analyses, among people retained-in-care, VL data was available for 16,272/19,511 (83.4%) patients, and of these 143/1,592 (9.0%) with and 1,546/14,680 (10.5%) without early community-based ART had viraemia (RR 0.88; 95% CI 0.75-1.04; $p = 0.128$; Table 2).

Table 2. Univariable and multivariable risk ratios of early versus no or later community ART referral and the outcomes for not retained in care or died at 12 months and viremia.

Not retained or died at 12 months n/N (%)		RR univariable	p	RR multivariable	p
Early community ART referral					
No	1518/19111 (7.9)	1	-	-	-
Yes	77/1995 (3.9)	0.49 (0.39-0.61)	<0.05	0.49 (0.39-0.61)	<0.05
Gender					
Male	683/8130 (8.4)	1	-	-	-
Female	912/12976 (7.0)	0.84 (0.76-0.92)	<0.05	0.76 (0.69-0.84)	<0.05
Age group (years)					
16-20	82/880 (9.3)	1	-	-	-
21-30	660/7499 (8.8)	0.94 (0.76-1.18)	0.609	0.93 (0.74-1.15)	0.493
31-40	589/7871 (7.5)	0.80 (0.64-1.00)	0.051	0.75 (0.60-0.93)	<0.05
41-50	201/3450 (5.8)	0.63 (0.49-0.80)	<0.05	0.58 (0.45-0.74)	<0.05
>50	63/1406 (4.5)	0.48 (0.35-0.66)	<0.05	0.45 (0.33-0.62)	<0.05
Initiation CD4 count (cells/μL)					
<=200	239/3553 (6.7)	1	-	-	-
201-350	280/4157 (6.7)	1.00 (0.85-1.18)	0.988	0.98 (0.83-1.16)	0.808
351-500	251/3859 (6.5)	0.97 (0.81-1.15)	0.700	0.95 (0.80-1.13)	0.550
>500	561/6872 (8.2)	1.21 (1.05-1.40)	<0.05	1.23 (1.06-1.42)	<0.05
Missing	264/2665 (9.9)	1.47 (1.25-1.74)	<0.05	1.45 (1.23-1.72)	<0.05
ART regimen					
TLD	1265/16582 (7.6)	1	-	-	-
TEE	330/4524 (7.3)	0.96 (0.85-1.07)	0.451	0.95 (0.84-1.07)	0.372
Viremia n/N (%)					
Early community ART referral					
No	1546/14680 (10.5)	1	-	-	-
Yes	143/1592 (9.0)	0.85 (0.72-1.00)	0.056	0.88 (0.75-1.04)	0.128
Gender					
Male	815/6093 (13.4)	1	-	-	-
Female	874/10179 (8.6)	0.64 (0.59-0.70)	<0.05	0.75 (0.68-0.82)	<0.05
Age group (years)					
16-20	68/670 (10.1)	1	-	-	-
21-30	481/5693 (8.4)	0.83 (0.65-1.06)	0.136	0.77 (0.60-0.97)	<0.05
31-40	693/6071 (11.4)	1.12 (0.89-1.42)	0.329	0.90 (0.71-1.14)	0.394
41-50	325/2703 (12.0)	1.18 (0.93-1.52)	0.179	0.92 (0.71-1.18)	0.493
>50	122/1135 (10.7)	1.06 (0.80-1.40)	0.689	0.84 (0.63-1.11)	0.209
Initiation CD4 count (cells/μL)					
<=200	459/2847 (16.1)	1	-	-	-
201-350	382/3288 (11.6)	0.72 (0.64-0.82)	<0.05	0.76 (0.67-0.86)	<0.05
351-500	293/3038 (9.6)	0.60 (0.52-0.69)	<0.05	0.65 (0.56-0.74)	<0.05
>500	370/5248 (7.1)	0.44 (0.38-0.50)	<0.05	0.49 (0.43-0.56)	<0.05
Missing	185/1851 (10.0)	0.62 (0.53-0.73)	<0.05	0.66 (0.56-0.77)	<0.05
ART regimen					
TLD	1410/12789 (11.0)	1	-	-	-
TEE	279/3483 (8.0)	0.73 (0.64-0.82)	<0.05	0.82 (0.73-0.93)	<0.05

Discussion

Using a large retrospective cohort of adults initiated on ART with viral suppression at 6 months, we assessed uptake of early community-based ART and compared clinical outcomes of clients who received early community-based ART vs those who did not. We found that among those eligible for early community-based ART, only 10% were referred. Although uptake increased from 7% in 2020 to 20% in 2022, it remained relatively low. Twelve-month retention-in-care was higher among clients who received early community-based ART compared to those who did not, and viral suppression was similar.

While there is limited evidence specifically assessing early referral to community ART delivery programmes in South Africa, our findings are consistent with existing research showing low uptake of community-based ART regardless of the timing of referral. A retrospective cohort study by our team found that the number of clients eligible for community-based ART far exceeded the number of those actually referred.[3] We are unable to determine the reasons for this using our data, however, in a qualitative study by our team, healthcare workers reported that they did not think 6-month referrals were appropriate stating that although clients were virally suppressed at that point, they had not yet fully understood the treatment and struggled with adherence often forgetting their doses for several nights.[6] Qualitative evidence from Uganda suggests potential barriers to differentiated service delivery (DSD) implementation to span across multiple levels – individual, health system, community, and context – where challenges such as client preferences and insufficient health system resources impact referrals.[9]

Our findings on retention-in-care are also consistent with other existing research. Evidence from a retrospective cohort study in Zambia reported very low loss to follow-up rates at 18 months among early (<6 months, 3%) and established (≥6 months, 5%) enrollers into six DSD models, including both facility- and community-based models. These findings suggest a strong retention overall, although significantly better among early enrollers.[10] Various other studies have also shown that the use of various DSD models not limited to community-based ART is associated with improved retention-in-care.[11,12] A retrospective cohort study in Mozambique evaluating the effect of three-monthly versus monthly ART dispensing on HIV care retention found that three-monthly dispensing was associated with higher retention, including among people who were enrolled early at <6 months on ART.[11] However, a cluster-randomized clinical trial in Lesotho reported contrasting evidence, suggesting that certain client groups may still face challenges with engagement despite community-based ART.[13]

With regards to viral suppression, while our results showed similar, high viral suppression at 12 months between clients who received early community-based ART and those who did not, a pilot randomized controlled trial in Rwanda found that viral suppression rates were higher at 12 months among participants who entered DSD at six months with either one or two suppressed viral loads, compared to those who received the standard of care, although the study was not powered for a formal comparison.[14] Generally, various forms of community-based ART have been successful in improving viral suppression.[12] Altogether, these findings suggest that stable ART patients can start community-based ART early without affecting viral suppression.

One of the key strengths of this study is the large dataset derived from 124 clinics across both urban and rural regions of the province of KwaZulu-Natal, enhancing the generalisability of our findings. However, a limitation of this study is the exclusion of approximately one-third of the patients due to missing VL data at the 6-month follow-up. This exclusion introduces the potential for bias, as those without follow-up data may differ in important ways from those included in the analysis, potentially skewing the study's outcomes. Additionally, the possibility of unmeasured confounding, especially if clinicians selectively referred patients for early community-based ART who they anticipated would have better outcomes, cannot be ruled out. This could influence the observed results and should be considered when interpreting the findings.

The findings of this study have several implications for policy and research. The low uptake of early community-based ART highlights the need for interventions targeted at improving referral rates. Policy efforts should prioritise addressing barriers affecting referrals, such as addressing healthcare worker concerns about client readiness and strengthening training to improve their confidence in implementing early referral to community-based ART. To support these efforts, further research is needed to better understand and quantify barriers to uptake of early community-based ART and explore ways of improving healthcare worker confidence and patient readiness for early referral. Future studies should also focus on ways to up-scale the implementation of early community-based ART. The South African 2023 ART clinical guidelines now support even earlier referral (<6 months on ART),[15] and we plan to assess uptake and subsequent outcomes of this change in policy.

Conclusion

In conclusion, our findings suggest that early referral to community-based ART does not result in worse outcomes. Since DSD models are generally preferred by clients and help ease the burden on clinics, early referral could be a valuable approach to improving HIV care. While uptake remains relatively low, further work is needed to scale up early referral to community-based ART. Understanding and addressing barriers to uptake will be critical in optimizing early community-based ART and other DSD models. Refining policies and strengthening research efforts can help ensure that early community-based ART is implemented effectively for long-term benefits in HIV care outcomes.

Data availability statement

We cannot publicly share the data used for this analysis because of the legal and ethical requirements regarding the use of routinely collected clinical data in South Africa. Interested parties can request access to the data from the KwaZulu-Natal Provincial Department of Health, the eThekwini Municipality Health Unit and the South African National Department of Health TB/HIV Information System (contact details obtainable upon request to JD).

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