Article

Research

Immediate and early engagement of same-day antiretroviral therapy initiation among newly diagnosed people living with HIV in urban Zambia: a retrospective cohort study

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Abstract

Introduction: as Zambia moves towards attaining human immunodeficiency virus (HIV) epidemic control, it is clear significant efforts are required to facilitate achievement of UNAIDS treatment targets by 2030. To accelerate progress towards global target of 95% of people living with HIV (PLHIV) knowing their status, country is promoting community-based HIV testing and same-day antiretroviral therapy (ART) initiation. However, there are uncertainties of how this strategy affects immediate and early engagement in program settings. To address this research gap, we analysed R programme data of PLHIV newly diagnosed and initiated on ART in community and health facility settings. Study objectives were; to estimate the proportion of immediate engagement, to estimate early engagement among newly diagnosed PLHIV and to examine factors independently associated with immediate and early engagement in care among newly diagnosed PLHIV offered same-day ART initiation. *Methods:* we included all newly diagnosed PLHIV aged 18 years or older and provided same-day ART initiation between October 2018 and January 2019 in Lusaka District. Immediate engagement was estimated as proportion of newly diagnosed PLHIV who visited the health facility at least once within 14 days after same-day ART initiation, whereas early engagement as proportion of newly diagnosed PLHIV active 6 months after same-day ART initiation. Pearson's chi-squared test was used to assess association of outcomes with key background characteristics. *Results:* of 12,777 newly diagnosed PLHIV who initiated same day ART 7,943 (62%) were tested and initiated in the community. Overall, 6,257 (49%) engaged within 14 days (median 15, IQR: 13-37). Older individuals (36-49 years) were more likely to be engaged at 14 days (aRR 1.29; 95%CI 1.06 - 1.18; p<0.001) and retained at 6 months (aRR1.27;95%CI 1.21-1.34P<0.001) whilst risk of attrition at 6 months was highest in younger ages (18-24 years) (aRR 0.79;95 %CI 0.76-0.82; p<0.001).

Conclusion: to adequately address the HIV epidemic targeted engagement approaches are required particularly in the younger ages.

Introduction

Human immunodeficiency virus (HIV) epidemic control remains a public health concern, despite substantial progress made in the last two decades. The race to achieve HIV/AIDS elimination by 2030 has been set as the UNAIDS 95-95-95 global targets (i.e. ninety-five percent of all people living with HIV (PLHIV) know their HIV status, 95% of all people with diagnosed HIV infection receive sustained antiretroviral therapy (ART), and 95% of all people receiving ART have viral suppression) [1]. Zambia is striving to achieve HIV epidemic control, and efforts have contributed to lowering HIV prevalence however, current estimates of 71-88-89 among 15-59-year-old PLHIV fall short of satisfying the global target of 95-95-95 by 2030 [2]. The gaps in attaining these treatment targets, particularly the first and second 95, underscore the need for intensive efforts towards attaining UNAIDS 2030 treatment targets [3].

The Zambian Government has mandated universal HIV testing services (HTS), which provides an opportunity to screen all individuals for HIV and immediately treat all HIV-infected individuals regardless of cluster of differentiation 4 (CD4) count or world health organisation (WHO) clinical stage. Whilst primarily conducted at health facilities, HTS also occurs outside the health facility in the "community" to expand individuals' knowledge of their HIV status, accelerate linkage to care, improve ART initiation, limit the spread of infection, reach priority and key vulnerable populations (KVPs) and consequently ensure that no one is left behind in the fight against HIV [2]. The HTS package provides a full range of services including pre-and post-test counselling, linkage to appropriate HIV prevention, treatment, and care services; and referral to other appropriate clinical and support services. Additionally, individuals who

test positive are initiated on ART and provided with antiretroviral medication for 14 days, in which the newly initiated PLHIV must visit a health facility within 14 days of initiation to collect a 1-month supply and thereafter 3-month supply.

Outside health facility "community-based" as well as facility-based strategies of rapid ART initiation are being utilized to test as many people as possible so as to expand the HIV status knowledge, address the poor linkage of care and ensure that no one is left behind [4-8]. Whilst the advantages of immediate and sustained ART treatment are well established, the benefits do not fully materialize due to delayed and intermittent engagement in care among PLHIV who may feel well or face other psychosocial, structural, and health system barriers [9-11]. There is conflicting evidence regarding the acceptability and appropriateness of immediate ART initiation. While Sharma *et al.* (2015) and Katirayi *et al.* (2016) demonstrated > 90% acceptance rates for immediate ART, Katirayi and colleagues (albeit among pregnant women) reported that issues such as denial, shock, life-long treatment, or the requirement for partner consultation hampered uptake and adherence to rapid ART initiation [12,13]. Furthermore, randomized controlled studies conducted in Zambia and Malawi revealed that at treatment initiation individual factors (e.g., fear of lifetime commitments and side effects, denial, substance abuse), household factors (e.g. power relations, livelihood demands), and health system factors (e.g., distance to the clinic, congestion, poor record-keeping, health care workers attitude) undermined engagement in care [14,15]. These factors, coupled with traditional approaches to the delivery of health services, led to attrition of >30% early loss within one month of initiation [14-16].

Current evidence on interventions that promote engagement of PLHIV following rapid ART initiation is limited [5,12,17]. Significant questions persist about how the universal test and treat (UTT) strategy affects the engagement in HIV care of newly diagnosed PLHIV furthermore, what factors affect engagement of newly diagnosed PLHIV in routine settings [4]. To address this research gap, we analysed programme data of PLHIV newly diagnosed and initiated on ART in community and health facility settings. Using the definitions offered by Grimsrud *et al.* (2021), we defined the study objectives as to estimate the proportion of immediate engagement (i.e. newly diagnosed PLHIV who continue with ART 14 days after same-day ART initiation), to estimate early engagement (i.e. newly diagnosed PLHIV who continue within the first six months of same-day ART initiation) among newly diagnosed PLHIV and to examine factors independently associated with immediate and early engagement in care among newly diagnosed PLHIV offered same-day ART initiation.

Methods

Study design: this was a retrospective cohort study of newly diagnosed PLHIV who were offered same-day ART initiation during community-based or facility-based HTS.

Participants: we included all newly diagnosed PLHIV individuals, aged 18 years or older and initiated on ART between October 2018 and January 2019.

Setting: all thirty-four MoH ART facilities that offered comprehensive HIV services including HIV Testing Services (HTS) in Lusaka District. Lusaka, the capital city of Zambia, is the most inhabited city in the country and home to approximately 3.5 million people [18]. While national HIV prevalence among adults aged 15-59 years is 12.0%, prevalence in urban Lusaka district is higher at 15.7% [2].

Data sources and variables: in February 2020 we extracted health facility data on registrations, HIV testing, new HIV-positive diagnoses, HIV-positive individuals already on ART, and date of ART initiation from registers and the national electronic medical record (EMR) database. To reliably determine the site of ART initiation, for

every newly diagnosed PLHIV initiated on ART during the period of interest, we physically searched for corresponding evidence in the enrolment registers using the ART number (and matching age for confirmation). The outcomes were immediate engagement at 14 days and early engagement at 6 months. Immediate engagement was defined as a newly diagnosed PLHIV who visited the health facility at least once within 14 days after same-day ART initiation, whereas early engagement was defined as a newly diagnosed PLHIV who was found active (collected a drug refill) in the EMR 6 months after same-day ART initiation.

Statistical methods: we summarized baseline characteristics (age and gender) using frequencies and proportions. Health facility size was categorized as number of active PLHIV; (large (>10,000 PLHIV), medium (5,000-10,000 PLHIV), small (1,000 - 5,000 PLHIV), and very small (<1,000 PLHIV). The differences in proportion by the site of initiation were assessed using the chi-squared test. We estimated immediate engagement by dividing number of newly diagnosed PLHIV who visited the health facility at least once within 14 days of same-day ART initiation by total number of newly diagnosed PLHIV and early engagement by dividing number of newly diagnosed PLHIV found active in EMR 6 months after same-day ART initiation by total number of newly diagnosed PLHIV. Pearson's chi-squared test was used to assess association of the outcomes with key background characteristics. Poisson's regression with robust standard errors was used to determine factors independently associated with immediate and early engagement in HIV care at 14 days and 6 months, respectively. Statistical significance was set at p-value <0.05. In a secondary analysis, the Kaplan-Meier method was utilized to estimate the time to immediate engagement and compared time to immediate engagement between the site of initiation using the log-rank test. All analyses were performed using Stata 17 MP8 (StataCorp, College Station, TX, USA).

Ethical consideration: approval to review existing, deidentified, routinely collected programmatic data was provided by the U.S. Centers for Disease Control & Prevention (2018-381), University of Zambia Biomedical Research Ethics Committee (011-12-17), University of North Carolina at Chapel Hill, USA (18-0854) and the Institutional Review Board at Washington University, St. Louis, USA (2019-11143).

Results

Characteristics of the study population at the time of ART initiation: a total of 12,777 newly diagnosed PLHIV from 34 urban health facilities in Lusaka District who were provided same day ART between October 2018 and January 2019 were included, of whom 7943 (62%) were initiated into HIV care from the outside the health facility "community" and 4834 (38%) from the health facility (Figure 1). Overall, the median age at ART initiation was 32 years (IQR 27-39) and 36 years (IQR 28-45) and 31 years (IQR 26-36) when disaggregated by facility and community respectively. More females initiated on ART in the community (62%) and at the facility (58%). Among the newly diagnosed PLHIV initiated in the community, a significant majority were between 25-35 years old (53%), compared to 33% in the facility, followed by those aged between 36-49 years old (26%), compared to 41% in the facility. In both the facility and community, the older individuals 50+ years initiated the least (Table 1).

Immediate and early engagement at 14 days and 6 months of same-day ART initiation: overall, 49% (n = 6257) immediately engaged in care within 14 days of testing and same-day ART initiation, with no differences in proportions of engagement by facility (49%) and community (49%) initiation (Table 2). Immediate engagers were male (p=0.013), aged 36-49 years old (p<0.001), and received ART services from large health facilities (p<0.001). At 6 months, overall engagement increased to 58% with strong evidence of differences by age, sex, site of initiation and health

facility size. Early engagement increased with age, with the lowest observed among adults aged 18-24 years (49%) and highest in the older adults 50+ years old (63%; (p<0.001)). Males were significantly more engaged at 6 months (60%; p<0.001) whilst PLHIV who received ART services from large health facilities had the lowest early engagement rates (52%; p<0.001) (Table 2).

Factors associated with immediate and early engagement: in the Poisson regression, immediate engagement was independently associated with age, with those between 36-49 years (aRR 1.12; 95% CI 1.06-1.18) most likely to be engaged and the youngest age group (18-25 years of age) least likely to be immediately engaged (Table 3). The pattern of immediate engagement varied by health facility size, with individuals accessing ART services from large facilities (>10,000 PLHIV) more likely to engage (aRR 1.08; 95% CI: 1.03-1.13; p-value <0.001) and those from health facilities (1,000-5,000 PLHIV) least likely to engage. There were no differences of immediate engagement by gender or site of ART initiation. At 6 months, newly diagnosed PLHIV engaged in the ART program were more likely to be older than 35-49 years (aRR 1.27; 95% CI 1.21-1.34; p<0.001). The younger age group (18-24 years) and PLHIV receiving care from large facilities (RR 0.79; 95% CI 0.76-0.82; p <0.001) were less likely to be engaged. For most individuals, time from ART initiation to immediate engagement was short, 15 days median time (IQR 13-37). Survival patterns were similar with no differences in time to immediate engagement between newly diagnosed PLHIV who initiated from the facility compared to those initiated from the community (p>0.05) (Figure 2).

Discussion

The study showed that out of facility "community" same day test and treat reached a higher proportion of PLHIV (62%) than facility same-day test and treat, with non-significant differences in the engagement at 14 days and 6 months by the site of initiation. These study findings align with the CASCADE trial, which promotes out-of-facility testing and treatment initiation to optimally address the first and second 95 treatment targets [19]. We found that <50% of PLHIV initiated on the same day ART immediately engaged within 14 days (49% in both community and facility) whilst at 6 months, 57% engaged in community and 56% facility respectively). This gradual increase in engagement over time is supported by findings from Grimsrud *et al.* (2020) and Rivka R *et al.* (2020) who acknowledged that newly diagnosed PLHIV require time and continued support to accept their diagnosis following testing and treatment initiation [3,16].

Few studies have reported on immediate and early engagement after same-day ART initiation in the community. Overall, our findings on immediate and early engagement in Lusaka compare well with a Nigerian study that reported that 51% of newly diagnosed adult PLHIV were lost to follow-up (LTFU) within the first 30 days following ART initiation compared to 30% among the previously diagnosed PLHIV (p<0.0001) [20]. Furthermore, a South African study reported significantly higher program losses at six months among same-day PLHIV initiators compared to PLHIV initiating ART 1 day after HIV diagnosis (30.1% vs 21.4%).[16]. However, in both studies, PLHIV were initiated on same-day ART within health facilities. We report that 58% of newly diagnosed PLHIV were engaged within 6 months of ART initiation, contrary to findings of improved engagement and retention after home-based testing and ART initiation reported in other studies [21-25]. However, these studies that demonstrated significant improvement in engagement and retention after same day testing and ART initiation in the community provided incentives and nudges such as transport vouchers, telephone messages, and tracing of PLHIV who did not link to care [21-25]. Therefore, the lower engagement we found in routine settings amplifies that significant efforts are required to adequately address the unique requirements of newly diagnosed PLHIV [26].

The finding of no difference in immediate engagement by the site of ART initiation ("community" vs health facility) runs counter to Labhart *et al*. randomized controlled trial (RCT), which showed that adult PLHIV initiated on ART in the community in rural Lesotho were significantly linked to care and engaged at 3 months when compared to those initiated at health facilities (68.6% (94) versus 43.1% (59)) [19]. The contrast between the two studies may be explained by differences in the local context, clinical procedures, and study methodologies that may affect linkage and engagement. The Labhart *et al*. study randomized participants whilst this was an observational cohort study, thus subject to selection bias, as individuals enrolled in the community may be different from those enrolled in the health facility. Furthermore, Labhart *et al*. conducted the study in a rural setting, sampled a small number of individuals (278), and used trained nurses to provide ART initiation at home. Whereas this study was conducted in an urban setting with ART initiation in the community provided by trained Lay Health Personnel. Additional research is therefore necessary to understand the substantial heterogenicity of linkage and engagement in care in different settings.

Our study supports the recommendations of providing targeted interventions that support engagement along the HIV care cascade [3]. We found that immediate engagement varied among the age groups, with the 18-24 years old delaying while the 36-49 years old engaged in care quicker. These findings are corroborated by the PopART study that observed differences in linkage into care by age groups with older adults >45 years linked earlier than those aged 15-25 years old [27]. Furthermore, our study showed significant differences in 6-month early engagement by health facilities size, with attrition highest in large facilities with PLHIV load > 10,000 (aRR 0.79; 95% CI 0.76-0.82). The East African (EA)-IeDEA Consortium's retrospective cohort study in 29 affiliated sites equally showed that clinical burden

was associated with increased loss to follow-up among those who engaged with care thus underscoring the effects of high patient load on successful engagement of PLHIV [28]. Considering the health system pitfalls in public health facilities and rapid scale-up of ART in the country, this study supports guidance that clinical burden may be addressed to a certain extent by differentiated service delivery (DSD) models tailored for newly initiated PLHIV [29].

Our study has various strengths that should be recognized, we analysed programmatic data thus provided an opportunity of describing immediate and early engagement of newly initiated PLHIV initiated on the same day ART in real-life settings thereby adding valuable insights to "community" HTS and ART initiation as well as supplement the knowledge provided by the CASCADE RCT [19]. Furthermore, the utilization of routine data from multiple health facilities in urban Lusaka resulted in a large sample size that is likely to be representative of PLHIV who initiated ART in urban health facilities in the country although may be extrapolated with caution to many urban setting in SSA. The study however had some limitations, data only included PLHIV that had started ART during October 2018 - January 2019, this short period increased the possibility of biases due to temporal factors that could not be adjusted for. There is no information on individuals that did not engage, it is possible that these individuals were already on ART and did not want to disclose their status. Additionally, there was incomplete information and substantial missingness in routine data therefore, key variables such as the viral load, CD4, body mass index (BMI), WHO disease staging, education level and other sociodemographic characteristics could not be examined, thus resulted in few variables analysed and limited adjustment of these potential confounders that may affect immediate and early engagement in HIV care. Notably, the engagement outcomes were not affected by data missingness. Lastly, the study setting was urban, and findings may lack generalizability to populations in rural areas. Given

these limitations, larger cohort studies with longer observation times and more attention to optimal data collection are required to confirm these results.

Conclusion

This retrospective cohort study on same-day ART initiation of newly diagnosed PLHIV in the community reinforces the concept that immediate and early engagement may differ by gender, age, and local context. Advocating for targeted approaches in the implementation of same day ART initiation that can motivate key actors to improve routine program performance and accelerate attainment of UNAIDS targets.

What is known about this topic

- *Our study supports the recommendation that to improve immediate and early engagement in HIV care, individuals who receive same day ART should be characterized to make targeted interventions that support engagement along the HIV care cascade;*
- *This gradual increase in engagement over time supports suggestion that PLHIV require time and continued support to accept their diagnosis following testing and treatment initiation.*

What this study adds

- *Study analyzed programmatic data thus provided an opportunity to describe ART immediate and early engagement in real-life settings, adding valuable insights to community test and treat interventions as well as improving on knowledge provided by randomized control studies;*
- *Few studies have reported on immediate and early engagement after same-day ART.*

Competing interests

The authors declare no competing interests.

Authors' contributions

Mpande Mukumbwa-Mwenechanya: lead author, framed the study and wrote the first draft. Obvious Nchimunya Chilyabanyama: conducted data analysis. Estella Kalunkumya: supervised the data collection. Godwin Nyirenda: assisted the underlying data processes. Kombatende Sikombe: assisted with implementation process. Violet Kunda: advised implementation details. Jake Pry: assisted with the analysis. Mwansa Lumpa: Assisted the underlying data processes. Samuel Bosomprah: lead advisor on data analysis. Anjali Sharma: assisted with the writing. Carolyn Bolton-Moore: lead for implementation process.

Acknowledgments

Tables and figures

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Figure 1: enrollment flow chart

Figure 2: Kaplan Meier Curve comparing time to first ART visit, among patients who are newly diagnosed with HIV, between those in the community and those from the facility in the first 100 days of diagnosis; the log rank test is used to compare equality of the survival curves in each study arm

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Table 1: baseline characteristics of the study participants

	n(%) of Total	Facility Initiated n(%)	Community Initiated n(%)	[a]P-value
Age at ART start				
18-24 years	2142(17)	686 (14)	1456 (18)	
25-35 years	5814 (46)	1607 (33)	4207 (53)	<0.001
36-49 years	4061 (32)	1981 (41)	2080 (26)	
50+ years	760 (6)	560 (12)	200 (3)	
Sex				
Female	7756 (61)	2801 (58)	4955 (62)	<0.001
Male	5021 (39)	2033 (42)	2988 (38)	
Facility size				
1000-5000	2158(17)	835 (17)	1323 (17)	
5000-10000	5187(41)	1942 (40)	3245 (41)	0.76
<1000	291(2)	107 (2)	184 (2)	
>10,000	5141(40)	1950 (40)	3191 (40)	
Total	12777 (100.0)	4834(100)	7943(100)	

ART, antiretroviral therapy [a]P-values were calculated using the Pearson's chi square test

Table 2: proportion of participants who engaged in treatment immediately and those who engaged in treatment within 6 months (early engagement)

Background characteristics	n(%) of Total N=	Immediate engagement n(%)	[a]P-value	Early Engagement n(%)	[a]P-value
Age at ART start					
18-24 years	2142 (17)	984(46)		1043(47)	
25-35 years	5814 (46)	2796(48)	<0.001	3304(57)	<0.001
36-49 years	4061 (32)	2100(52)		2560(63)	
50+ years	760 (6)	377(50)		452(63)	
Sex					
Female	7756 (61)	3730(48)	0.013	4348(56)	<0.001
Male	5021 (39)	2527(50)		3011(60)	
Site of Initiation					
Facility	4834 (38)	2386(49)	0.494	2875(59)	0.001
Community	7943 (62)	3871(48)		4484(56)	
Facility Size					
1000-5000	2158(17)	1084(50)		1420(66)	<0.001
5000-10000	5187(41)	2249(43)	<0.001	3115(60)	
<1000	291(2)	142(49)		160(55)	
>10,000	5141(40)	2782(54)		2664(52)	
Total	12777 (100.0)	6257(49)		7359(58)	

ART, antiretroviral therapy; [a] p-values were calculated using the Pearson's chi square test

Table 3: factors independently associated with immediate and early engagement of newly diagnosed HIV patients

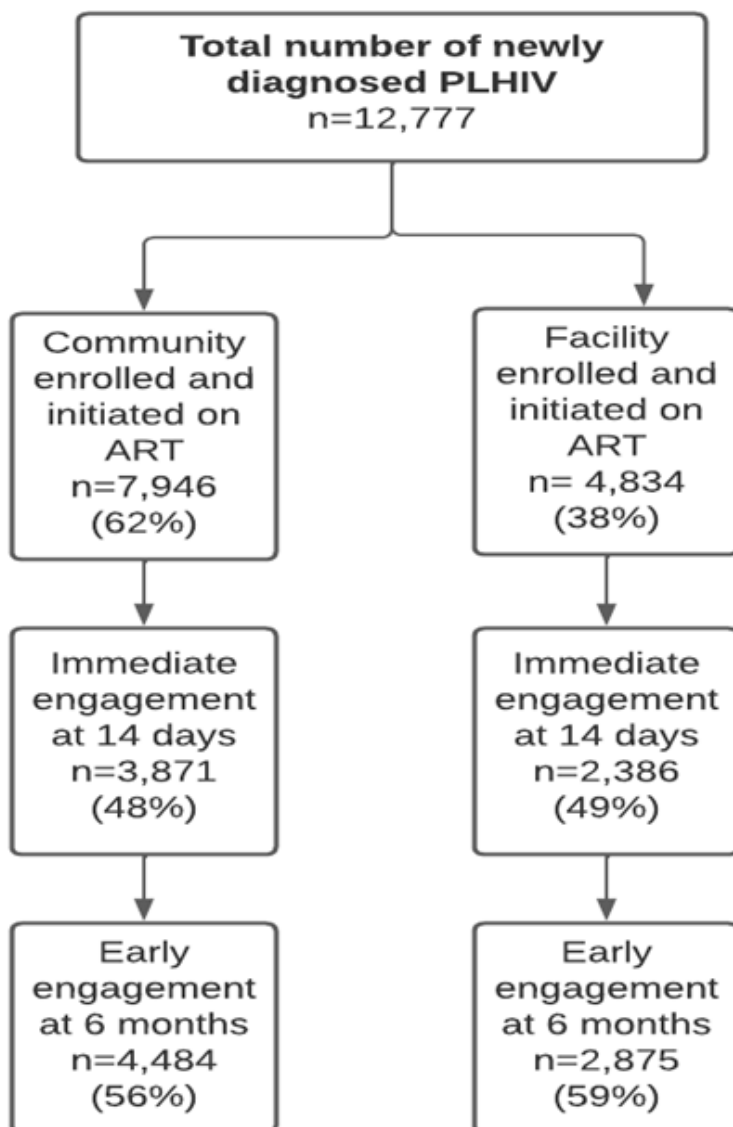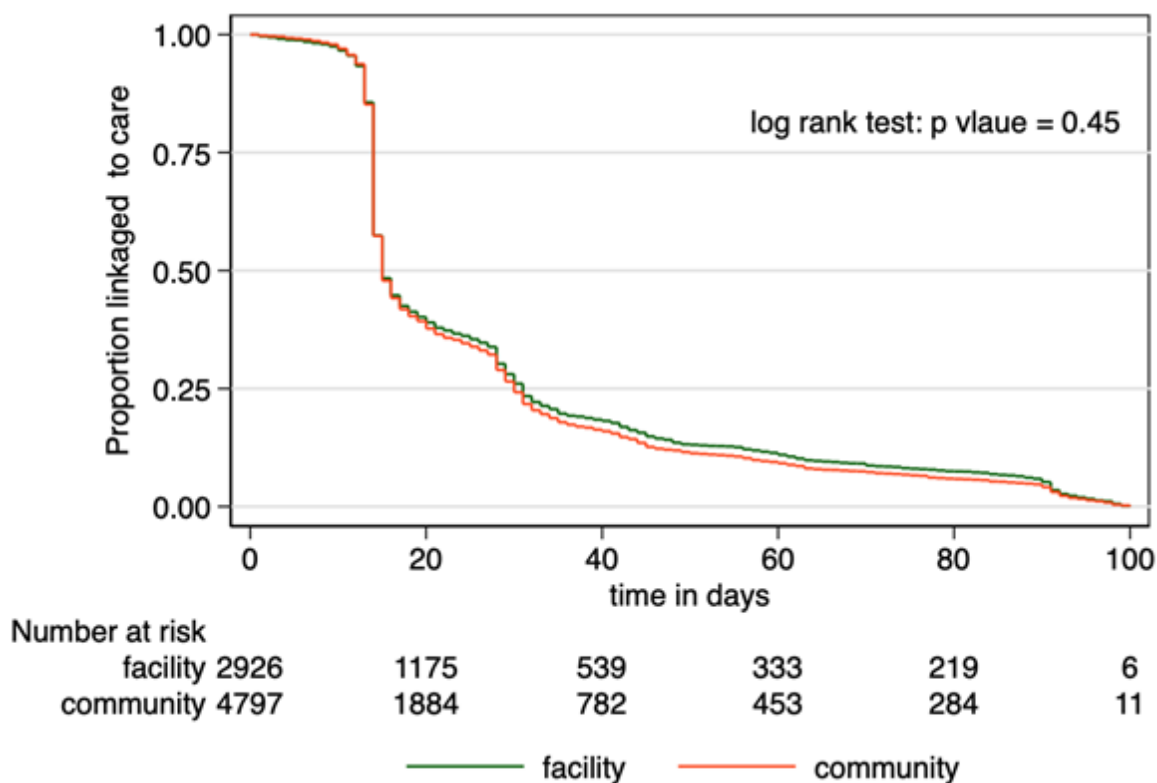|	Immediate engagement				Early engagement			
	RR (95% CI)	[a]P-value	ARR (95% CI)	[a]P-value	RR (95%CI)	[a]P-value	ARR (95%CI)	[a]P-value
Age								
18-24 years	Ref		Ref		Ref		Ref	
25-35 years	1.05(0.99-1.1)	<0.001	1.05(0.99-1.1)	<0.001	1.17(1.11-1.23)	<0.001	1.16(1.1-1.22)	<0.001
36-49 years	1.13(1.07-1.19)		1.12(1.06-1.18)		1.29(1.23-1.36)		1.27 (1.21-1.34)	
50+ years	1.08(0.99-1.18)		1.07(0.98-1.16)		1.22(1.14-1.31)		1.20 (1.11-1.29)	
Sex								
Female	Ref		Ref		Ref		Ref	
Male	1.05(1.01-1.08)	0.013	1.03(0.99-1.07)	0.135	1.07(1.04-1.1)	<0.001	0.93(0.86-1)	0.06
Site of ART initiation								
Facility	Ref		Ref		Ref		Ref	
Community	0.99(0.95-1.02)	0.493	1(0.97-1.04)	0.848	0.95(0.92-0.98)	0.001	0.97(0.94-1)	0.088
Facility size								
1000-5000	Ref		Ref		Ref		Ref	
5000-10000	0.86(0.82-0.91)	<0.001	0.86(0.82-0.91)	<0.001	0.91(0.88-0.95)	<0.001	0.91(0.88-0.95)	<0.001
<1000	0.97(0.86-1.1)		0.97(0.86-1.1)		0.84(0.75-0.93)		0.83(0.75-0.93)	
>10000	1.08(1.03-1.13)		1.08(1.03-1.13)		0.79(0.76-0.82)		0.79(0.76-0.82)	
ART, antiretroviral therapy; RR, rate ratio; ARR, adjusted rate ratio								

Figure 1: enrollment flow chart

Figure 2: Kaplan Meier Curve comparing time to first ART visit, among patients who are newly diagnosed with HIV, between those in the community and those from the facility in the first 100 days of diagnosis; the log rank test is used to compare equality of the survival curves in each study arm