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Time to first viral load testing among pregnant women living with HIV initiated on option B+ at 5 government clinics in Kampala city, Uganda: Retrospective cohort study

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ABSTRACT

Background: Timely viral load (VL) testing is critical in the care of pregnant women living with HIV and receiving anti-retroviral therapy (ART). There is paucity of data regarding the Time to First Viral Load (TFVL) testing in resource-limited settings.
Methods: We extracted clinical and VL test data from records of a cohort of ART-naïve pregnant women living with HIV who initiated Option B + and were retained in care between 01 Jan 2015 and 31 Dec 2015. The data were verified against laboratory VL registers. TFVL (in months) was calculated based on the time difference between the date of ART initiation and FVL test. Descriptive and Cox regression analyses of data up to 30 Sep 2017 (33 months later) were done.
Results: Of the 622 records retrieved, 424 women were retained in care. Of 424 women retained in care, 182/424 (43%) had at least one VL result post ART initiation while 242/424 (57%) had no VL performed. Only 30/182 (16.5%) had a second VL. At six, nine, and twelve months, only 8/424 (1.9%), 47/424 (11.1%), and 94/424 (22.2%) had VL testing performed respectively post ART initiation. The median TFVL testing was 12.7 months (95 CI 11.6-13.7) post ART initiation. Across the five clinics, patient factors (age, gravidity, gestational age, marital status, and adherence at 12 months) were not significant predictors.
Conclusion: A dismal 1.9% rate of achieving WHO-recommended TFVL testing and a median TFVL testing of twelve months post ART initiation were observed. The non-association of patient factors to these observations may suggest a serious need to review health system factors likely associated with these observations and their effective interventions.

Introduction

With the increased scale-up of anti-retroviral therapy (ART) in sub-Saharan Africa, the World Health Organization (WHO) in 2013 recommended viral load (VL) testing as the mainstay of HIV treatment monitoring (Organization WH, 2016). Timely VL testing is critical in the care of pregnant women living with Human Immunodeficiency Virus (HIV) for measuring treatment success and assuring elimination of mother-to-child transmission (eMTCT) of HIV to unborn children, as well as enabling clinicians to take appropriate action for those with unsuppressed HIV viremia resulting in early detection of virologic failure (Myer et al., 2017; Lecher et al., 2016). As a result, maternal morbidity and mortality is significantly reduced, which further assures survival among the HIV-exposed uninfected children. Despite the increased uptake of VL testing in resource-limited settings over the years, some implementation challenges still exist (Pham et al., 2017; Abuogi et al., 2018)

Since 2014, VL testing in Uganda is initiated at ART clinics, where a VL laboratory requisition form is completed for each specimen collected. The form includes patient demographic information, the type of specimen collected, and the health unit from which the sample has been collected and whether the requisition is for a routine or targeted VL test. After completion of the form, the specimen is transported to a hub (another health unit to which different health units bring their samples) before transportation to the Uganda National Health Laboratory Services (UNHLS/CPHL) where centralized VL testing is done. Upon receipt

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at UNHLS/CPHL, data from the requisition form are entered into the Laboratory Information System (LIS) and the specimen is placed in a testing queue. Following testing, the result is entered into the LIS and a report is printed for delivery back to the hub from which the referring clinic will obtain the result and give it to the patient (Peter et al., 2017). Based on the WHO guidelines, the Ministry Of Health (MOH) recommends Time to First Viral Load (TFVL) testing as 6 months post initiation of ART (Bulage et al., 2017; WHO, 2016).

Despite the above guidelines and recommendations, VL testing may not be done in a timely manner due to varied factors in resource-limited settings (El-Sadr et al., 2017). Individual level factors include lack of awareness among patients and clinicians as to the benefits of VL testing; facility level factors include poor adherence to current WHO guidelines on VL testing, high costs for VL tests, reagents, and consumables, inability to keep up with laboratory maintenance, weaknesses in sample transport and lab work flow, poor lab clinic interfaces, and low levels of staff training and quality assurance (Lecher et al., 2016; Phillips et al., 2015; Roberts et al., 2016). Most of these data on factors associated with VL are based on general HIV care and are not specific to eMTCT programs. The data are deficient in information regarding the actual time the patient gets his/her first VL test after ART initiation and the barriers/enablers of having the VL test done. We sought to establish the TFVL testing and associated facility and patient factors at five eMTCT clinics in Kampala, Uganda.

Methods

Study area and design

This was a retrospective cohort study design that used secondary data collected from the Kampala City Council Authority (KCCA) clinics. These clinics, which are operated by the KCCA, are public health care centers located in respective administrative divisions of Kampala city. They are categorized as health center III's according to the Ugandan health systems categorization for health units. These include Kawala, Kisenyi, Kiswa, Kitebi, and Komamboga health centers.

They provide basic preventive, promotive, and curative care. The facilities have at least 18 staff who are headed by a senior clinical officer, who runs a general outpatient clinic and a maternity ward. There are provisions for laboratory services for diagnosis, maternity, and first level referral cover for each division. They serve Kampala City which is home to more than 3.7 million people during the day (UBOS, 2019). Each of these clinics provides HIV Care services on a daily basis to on average of 100 persons living with HIV/AIDS. Within the antenatal clinics at each health center are the EMTCT programs from which these data were obtained. These clinics in particular were chosen because they have similar pathways to VL testing and retesting.

The sample included women living with HIV receiving option B + triple ARVs enrolled from 01 Jan 2015 to 31 Dec 2015. This period was considered because it is this cohort of women who are expected to have had 2 V L test results based on guidance from the ministry of health and the KCCA clinics' team leaders. First VL testing is expected to be done at six months after ART initiation, and the second VL is expected to be done one year later. Following HIV diagnosis at the Antenatal Clinics (ANC), women receive counselling and are initiated on ARVs the same day. In 2015, the women would be initiated on Tenofovir/Lamivudine/Efavirenz as the preferred first-line regimen. In case one developed toxicities, she would be switched to Tenofovir/Lamivudine/Lopinavir/Ritonavir. Virologic monitoring was rolled out in Uganda in November 2014. VL testing at these clinics had been implemented by 2015, and testing was expected to be done at 6

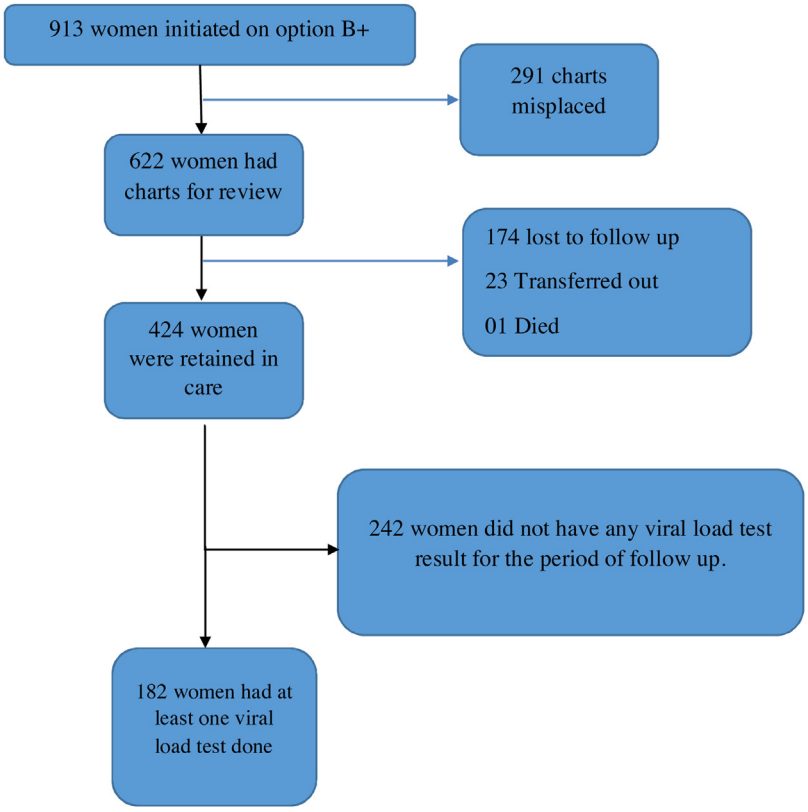

Figure 1. Flow chart showing numbers enrolled in the study.

months post ART initiation and annually after (Lecher et al., 2016; Bulage et al., 2017).

We reviewed records of women who were ART naïve and enrolled into the PMTCT clinics since 01 Jan 2015 to 31 Dec 2015 for possible inclusion into the study. Study data collection was done from Jun 2017 to September 2017. The period of follow-up under review begins in 2015 to 2017 (from enrollment into the program through September 2017). All HIV-positive pregnant /lactating women who initiated ART between 01 Jan 2015 and 31 Dec 2015 and were active at the respective five government-aided PMTCT clinics in KCCA were included. Pregnant/lactating women living with HIV who were already on Highly Active Antiretroviral Therapy (HAART) in 2014 and before were excluded. We reviewed each patient's VL test results and verified them using the laboratory VL register. Completion of the data collection tools was done by the investigator and protocol-trained research nurses. The lists of potential participants for the study were generated at the different health centers. Lost to Follow-up is defined as cases not seen at the HIV treatment clinic for six months and for whom vital status (alive or dead) was not already known.

Statistical analysis

The baseline characteristics of this retrospective cohort were summarized using frequencies (for categorical variables) and medians (for numerical variables), which were presented in tables. The characteristics included maternal age at enrollment into the clinic, time from first HIV diagnosis (difference in time at conduct of the study and time of first positive HIV test result), baseline WHO stage, baseline CD4 cell count, gravidity, gestational age/ lactating age at first registration, marital status, number of pregnancies since HIV diagnosis, prior exposure to nevirapine for PMTCT, initial ART regimen at registration, and health center.

TFVL (in months) was calculated based on the time difference between date of ART initiation and that of first VL test. The relationship between time to first VL testing and the independent variables was determined using Cox proportional hazards. Bivariable and multivariable analyses were done to obtain the adjusted and unadjusted hazard ratios. Every variable with a p value of less than 0.5 in the bivariable analysis was added in the multivariable analysis. In addition, we used biologic plausibility to decide on which other variables to include in the multivariable model. Variables included in the multivariable analyses were chosen based on prior research on risk factors, clinical associations, and biological plausibility. The Cox proportional hazard model of best fit was determined. We used backward elimination to obtain variables to include in the model. However, some variables were added even if they had been eliminated based on biological plausibility. The 95% confidence interval and the p value of less than 0.05 were used to determine significance. The data were analyzed in STATA 13.

Ethical considerations

Institution Review Board (IRB) approval was obtained from the Makerere University Higher degree Ethics and research committee. Administrative permission to conduct this study was obtained from the KCCA public health directorate. Access to data was restricted and participant identification numbers (PID) on study data collection tools were used instead of participant names to ensure confidentiality. An informed consent waiver was obtained from the IRB as this was retrospective data.

Results

A total of 913 women were initiated on option B + during the specified period based on the master lists generated by the data manager for the five health centers. Of 913 women, 622 (68.1%) had charts available for review, as shown in Figure 1. The remaining 291 (32%) were misplaced. Throughout the 33-month follow-up period, 174/622 (27.9%), 23/622 (3.7%), and 1/622 (0.16%) women were lost to follow-up, transferred out, and died, respectively. Of 424 women retained in care, 182/424 (43%) had at least one VL result post ART initiation, while 242/424 (57%) had no VL performed. Only 30/182 (16.5%) had a second VL test done during the months of follow-up.

Baseline Characteristics

At enrollment into the clinics (Table 1), the median age of the women was 24 years (IQR 22-28 years). Most of them—89/182 (52%)—were having their first pregnancy as shown by the median gravidity of 1. The median gestation age was 20 weeks (IQR 14-24), median CD4 cell count was 480 cells/μl, and 98.9% of the women

Table 1
Baseline characteristics of the study period.

Characteristics of enrolled participants (N = 182)		n (%) or Median (IQR*) VL≤12months (94)	VL>12 months (88)	P value
Age at Enrollment (Years)		24 (22-27)	24.5(22-28)	0.56
Gestational age (Weeks)		20 (14-24)	20 (14-24)	0.59
Baseline CD4 cell counts (Cells/μl)		491.5 (323-695)	467 (287-656)	0.70
Gravidity				
	1	41 (43.6%)	48 (54.6%)	0.17
	2-3	42 (44.7%)	27(30.7%)	
	4 and above	6 (6.3%)	7(8.0%)	
	Missing	5 (5.4%)	6(6.7%)	
WHO Clinical stage	Stage 1	92 (97.9%)	88 (100%)	0.50
	Stage 2	2 (2.1%)	0 (0.0%)	
Prior Nevirapine Exposure	Yes	9 (9.6%)	4 (4.6%)	0.19
	No	85 (90.4%)	84(95.5%)	
Marital Status	Married	61 (64.9%)	60(68.2%)	0.5
	Cohabiting	11 (11.7%)	11(12.5%)	
	Single	14 (14.9%)	7(8.0%)	
	Others	8 (8.5%)	10(11.4%)	
ART regimen	Tenofovir/Lamivudine/Efavirenz	92 (97.9%)	85(96.3%)	0.8
	Tenofovir/Lamivudine/Lopinavir/Ritonavir	0 (0.0%)	1(1.1%)	
	Other Non-Tenofovir based	2 (2.1%)	2(2.3%)	

IQR* Interquartile range

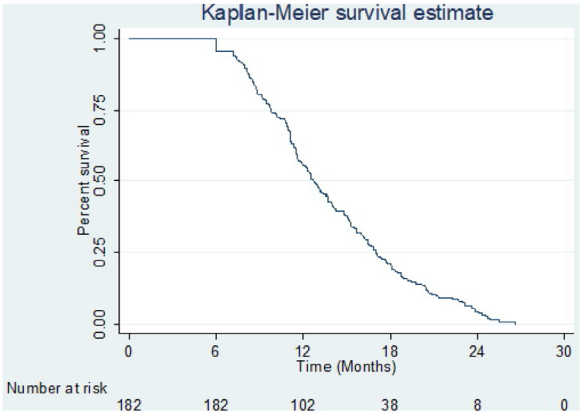

Figure 2. Time to First Viral Load testing in Months.

were in WHO clinical stage 1. Most of them were on Tenofovir/Lamivudine/Efavirenz (613/622 (98.6%)), and the majority were married 362 (58.4%).

Time to first viral load test

At the end of 6 months post ART initiation, which is the Uganda MOH recommended time point for first VL testing, only 8/424 (1.9%) women retained in care had had the first VL test done. This number rose to 47/424 (11.1%) at the end of 9 months, reaching 94/424 (22.2%) by 12 months. It took up to over 20 months for all (182) to have had at least one VL result. The median time difference between ART initiation and the actual time of first VL testing was 12.7 months (95 CI 11.6-13.7), as shown in Figure 2 below. The median Time to first VL testing based on the time since HIV diagnosis was 13.42 (95% CI: 12.43-14.51). A total of 94/182 (51.7%) women had their first VL test done within the first 12 months post ART initiation.

Between six and 12 months, about 87/94 (92.7%) of those who had a VL test done had a VL less than 1000 copies/ml. On average, 167/182 (91.2%) of all women who had a first VL were virally suppressed (Table 2).

Second viral load testing

Only 30/182 (16.5%) women had a second VL test following ART initiation. Among those who had a second VL test, 15/182 (8.2%) women had a VL greater than 1000 copies/ml following the first VL test (Table 2). Only 5/15 (33/3%) women with high VL above 1000 copies had a second VL test done as follow-up. The remaining 10/15 (66.7%) of the women with high VL above 1000 copies per ml were still being supported through intensive adherence counselling, which is well above 6 months since the first high VL result was obtained. The time between the first and second high VL tests was above the 4-month WHO-recommended time point for a follow-up VL test after the first high VL result. Only 15/182(8.2%) women had their routine annual VL test done.

Factors associated with first viral load testing

Health center was a statistically significant predictor of having a VL test done both in the bivariable and multivariable analyses. Conversely, patient factors (age, gravidity, gestational age, marital status, and adherence at 12 months) were not significant predictors (Table 3).

When compared to women receiving HIV care from Kawaala Health center (HC), those receiving care from Kisenyi HC, Kiswa HC, and Kitebi HC were 47%, 66%, and 59% less likely to have a VL test done, respectively. In contrast, a 17% higher chance of having a VL test was observed for women receiving HIV care from Komamboga compared to those receiving care from Kawaala. These associations related to health center were not significant except for Kiswa health center both in the bi-variable and multivariable analyses. The time to first VL test seemed to vary between centers at different time points (Figure 3).

Age, gravidity, gestational age, and marital status were not significant predictors in both bi-variable and multivariable analyses. Women aged 25 years and below had a 68% high chance of having their VL test done, while those aged 25-30 years were 2 times more likely to have their VL test done in comparison to those aged 30 years and above (Figure 4).

Discussion

We found that only 1.9% of the women had had the first VL test done in time, and yet it was expected that each woman would have had a VL test done at 6 months and 18 months by the time of conduct of the study. The median time difference between ART initiation and the first VL test was about 12 months. This reflects significant delays in VL testing and is consistent with other literature in other resource-limited settings. A review by Abuogi et al. assessing the gaps, progress, and research needs with regard to achieving UNAIDS 90-90-90 targets for pregnant and postpartum women in sub-Saharan Africa highlighted the need for timely VL testing and the paucity of programmatic data regarding the same. This review, however, is not able to provide data regarding the time to the first VL testing in the 9 studies reviewed. These data also suggest that women are rarely having VL testing during pregnancy and few receive testing six months postpartum (Abuogi et al., 2018).

Such delays in VL testing may result in late detection of virologic failure, increase maternal morbidity, mortality, and HIV drug resistance. We noted that only 50% of the women who had a second VL test done were those who had a high VL above 1000 copies/ml. This further underscores the need to critically examine the VL testing cascade at the different health centers so as to identify the gaps and create interventions to resolve them. Delays in VL testing undermine programmatic efforts to achieve the UNAIDS 3rd 95%

Table 2
Time to first viral load testing and level of viremia.

Time to first viral load test post ART initiation in months	Level of viremia		
	<1000	>1000	Total
6-12	*87 (92.6%)*	*7 (7.4%)*	*94 (51.7%)*
13-19	*56 (90.3%)*	*6 (9.7%)*	*62 (34.1%)*
>20	*24 (92.3%)*	*2 (7.7%)*	*26 (14.3%)*
Total	*167(91.8%)*	*15(8.2%)*	*182(100%)*

Table 3
Cox regression analysis for factors associated with viral load testing

VARIABLE		[a]cHR			[b]aHR		
		Value	95%CI	P value	Value	95%CI	P value
Age category	<25 years	1.24	0.76-2.02	0.40	1.68	0.87-3.23	0.12
	25-30 years	1.41	0.83-2.41	0.20	2.00	0.98-3.94	0.06
	>30 years	1.0	-	-	1.0	-	-
Gravidity	1	1.0	-		1.0	-	
	2-3	1.03	0.57-1.84	0.93	1.18	0.82-1.68	0.37
	≥4	1.26	0.69-2.28	0.45	1.05	0.50-2.22	0.89
Gestational age	<28 weeks	1.0	-				
	≥28 weeks	1.48	0.84-2.62	0.18	0.97	0.52-1.81	0.93
CD4 cell count (*cells/ul*)	<500	1.0	-				
	≥500	1.03	0.76-1.39	0.89	-	-	-
Marital status	Married	1.0	-		1.0	-	
	Cohabiting	0.83	0.50-1.37	0.46	0.92	0.50-1.71	0.80
	Single	0.75	0.39-1.40	0.36	1.19	0.70-2.02	0.52
	Other	0.89	0.47-1.68	0.71	1.03	0.57-1.86	0.92
Time since HIV diagnosis		1.00	0.99-1.02	0.86			
Prior NVP exposure	Yes	1.40	0.99-1.02	0.51			
	No						
Baseline ART	Non-TDF regimens	1.0	-				
	TDF/3TC/EFV	1.38	0.51-3.75	0.53			
	TDF/3TC/LPV/r	1.45	0.16-13.07	0.74			
Breastfeeding status	at 6 months	1.03	0.65-1.64	0.88			
	at 18 months	0.97	(0.47-1.97)	0.93			
Adherence at 12 months	Good (≥95%)	1.0	-				
	Fair (85-94%)	4.73	0.42-52.91	0.21	0.18	0.02-1.60	0.18
	Poor (<85%)	1.78	0.44-7.19	0.42	0.29	0.03-2.87	0.44
	Lost	2.77	0.59-12.89	0.20	0.07	0.00-1.52	0.21
	Missed	1.63	0.15-18.08	0.69	0.09	0.00-1.69	0.11
Health center	KAWAALA	1.0	-		1.0	-	
	KISENYI	0.76	0.38-1.53	0.44	0.53	0.23-1.22	0.13
	KISWA	0.53	0.33-0.85	0.008	0.34	0.15-0.79	0.01
	KITEBI	0.37	0.23-0.60	<0.0001	0.41	0.16-1.05	0.06
	KOMAMBOGA	0.45	0.25-0.80	0.007	1.17	0.48-2.88	0.73

[a] cHR - crude Hazard Ratio,
[b] aHR - adjusted Hazard ratio, Nevirapine (NVP), Tenofovir (TDF), Lamivudine (3TC), Efavirenz (EFV), Lopinavir/ritonavir (LPV/r).

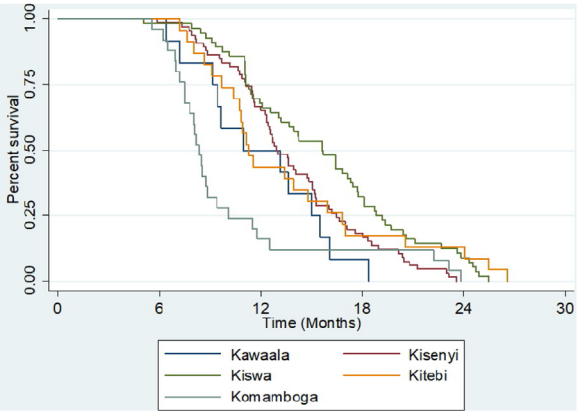

Figure 3. Time to first viral load testing by health center.

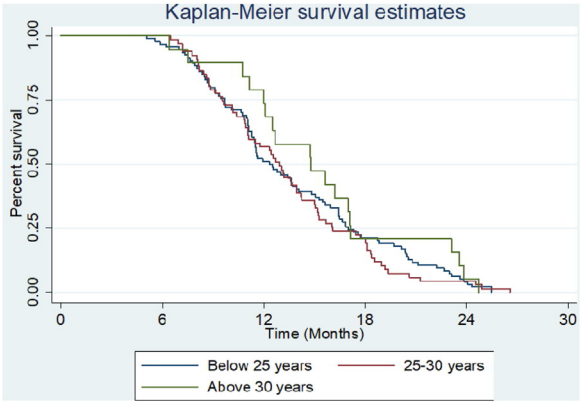

Figure 4. Time to first viral load testing by age category.

goal of sustained viral suppression and optimize maternal health and prevention of vertical and sexual HIV transmission (Petersen et al., 2014).

Only health center was a significant predictor of having a VL test done in time. Although our data showed Kiswa health center as the only center with a significant association, these data suggest high rates of missed VL testing across the centers. VL testing processes appeared to vary at different time points between health centers (Figure 3). More research is needed to establish the actual reasons for the differences in testing practices. The literature shows that this is a common occurrence in HIV care centers in sub-Saharan Africa and may be a major hindrance to achieving the UNAIDS 2030 strategy toward attaining the 3rd 95 (Roberts et al., 2016; Ehrenkranz et al., 2019). Health facility factors cited as barriers to timely VL testing include poor adherence to current WHO guidelines on VL testing, high costs for VL tests, reagents, and consumables, inability to keep up with laboratory maintenance, weaknesses in sample transport and lab work flow, poor lab clinic interfaces, and low levels of staff training and quality assurance (Lecher et al., 2016).

There were noticeable differences in patient age relatedness to first VL testing (below 30 vs above 30 years) as early as 7 months

post ART initiation suggesting that the younger women below 30 years received their VL testing earlier when compared to the ones older than 30 years.

However, despite gravidity not being significant, women who had more than one pregnancy appeared to receive VL testing. This is possibly due to having higher chances of interacting with the health system through the antenatal period through to delivery. Other patient factors like gestational age, marital status, and adherence at 12 months were not significant predictors of having a VL test done. Most women were in the 2nd trimester and therefore could have failed to return to the facility due to fatigue of pregnancy or delivery before their scheduled visits. One would expect good adherence to be associated with VL testing as women with good adherence will often be adherent to clinic visits as well as to their ART. However, the self-reported adherence as obtained in this study may not have been accurate thus potentially affecting the association with VL testing. About 67% of the women in this cohort were married, and this factor was not a significant predictor of VL testing. Being unmarried in other cohorts of African women has been associated with poor virologic outcomes (Atuhaire et al., 2019). Being lost to follow-up was another individual reason for non-timely VL testing. In general, there is scarcity of data on what patient factors are responsible for untimely VL testing. The literature underscores the need to address the optimal timing and frequency of VL monitoring in pregnant and postpartum women (Abuogi et al., 2018).

The strength of this study is that this is program eMTCT data which represents real-life situations in the implementation of the WHO test and treat policy and VL monitoring in resource-limited settings. These data underscore the challenges that need urgent attention from the program heads. One limitation of this study is the small sample size of women who had VL tests done which resulted from high loss to follow-up but also possible system inefficiencies regarding VL monitoring at the centers. Relatedly, this being a retrospective study, there was a chance of selection bias because the possibility of being retained in the cohort was not known in this setting. This may have led to an underestimation of the study outcome. In addition, even if these data are old, there is a need for further system evaluations to improve uptake in both rural and urban centers (Nakalega et al., 2020). Coverage of VL testing may have improved over the years with the 2018 WHO guidelines of mandatory VL testing at first pregnancy registration.

Non-timely VL testing majorly related to the facility, coupled with poor retention and other health system inefficiencies, remains as a major limitation in HIV care and treatment among women in their reproductive age on lifelong HAART. The non-association of patient factors to these observations may suggest a serious need to review health system factors likely associated with these observations and their effective interventions. The program managers need to emphasize the importance of timely VL monitoring and consistently review EMTCT program VL data as part of the persistent struggle to attain the UNAIDS 3rd 95 by 2030 in this significant population.

Ethical Approval

Institution Review Board (IRB) approval was obtained from the Makerere University Higher degree Ethics and research committee. Administrative permission to conduct this study was obtained from the KCCA public health directorate. Access to data was restricted, and participant identification numbers (PID) on study data collection tools were used instead of participant names to ensure confidentiality. An informed consent waiver was obtained from the IRB as this was retrospective data.

Conflict of interest statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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