

Effect and Implementation Experience of Intensive Adherence Counseling in A Public Hiv Care Center in Uganda: A Mixed-methods Study

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Abstract

Background: Non-adherence to anti-retroviral therapy (ART) is responsible for up to 75% of the unsuppressed viral load among people living with HIV (PLWH) on ART. Intensive adherence counseling (IAC) is an intervention recommended by the World Health Organization to improve adherence. In 2016, the Ugandan Ministry of Health introduced IAC to improve viral load suppression. This study evaluated the effect and experiences of providing IAC in an urban HIV care center in Kampala, Uganda.

Methods: This was a sequential explanatory mixed-method study that compared viral load suppression in the period with IAC intervention to a period without IAC at Kisenyi Health centre IV. Data were abstracted from patient files. The effect on viral load suppression of IAC and associated factors was analyzed using modified Poisson regression with robust standard errors. Using in-depth interviews and an inductive analysis approach in Atlas. ti, we also explored experiences of providing IAC among healthcare workers.

Results: A total of 500 records were sampled: 249(49.8%) in the intervention period and 251(51.2%) in the pre-intervention period. The mean age of clients was 34.8 years (SD±12.8), and 326/500 (65.2%) were females. Majority were on a Lopinavir/ritonavir based regimen [314 (62.8%)], and the median duration on ART was 30.8 months (IQR: 12.5–51.7). Over the intervention period, all eligible clients received IAC [249/249 (100.0%)]. Of those, 143 (44.1%) achieved viral load suppression compared to 46 (26.3%) in the pre-intervention period. Receiving IAC significantly increased viral load suppression by 22% (aPR = 1.22, 95% CI: 1.01–1.47). Participants on Lopinavir/ritonavir-based regimen were less likely to suppress (aPR= 0.11, 95%CI: 0.08–0.15) than those on Efavirenz or Nevirapine based regimens. All the interviewed healthcare workers lauded IAC for improving ART adherence. However, non-disclosure, social-economic constraints, lack of a multidisciplinary team and work overload hindered adherence during IAC.

Conclusions: The full potential of IAC in achieving viral suppression in this setting has not been reached, probably due to a combination of the health care system and patient-related factors. Provision of adequate IAC necessities and use of patient centered approach during IAC should be emphasized to obtain the maximum benefit of IAC.

Introduction

Globally 37.9 million people are infected with Human Immunodeficiency Virus (HIV) (1). Despite a 47% global decrease in new infections since the 1997 peak (1), the number of new infections and AIDS-related deaths is still high (1, 2). Eastern and southern Africa are the most affected regions(1). Over the past decade, significant progress has been made towards the world's vision of ending the HIV/AIDS pandemic by 2030. This achievement is reflected in a 34% decline in AIDs related deaths and an 18% decrease in new infections between 2010 and 2017 (3, 4). However, the progress toward the ambitious vision of ending the HIV/AIDS pandemic may be slower than envisioned due to the inadequate implementation of available effective strategies and interventions (5). Unsuppressed viral load (VL) is a major challenge in the management of HIV as it is responsible for the continued spread of HIV, drug resistance and HIV

related mortality (6, 7). Various interventions including test and treat strategy (8) have been directed towards achieving a suppressed VL of < 1000 copies/ml of blood which is regarded as essential for reducing HIV morbidity, mortality and transmission, particularly in sub-Saharan Africa (SSA) (9–12).

The World Health Organization (WHO) recommends life-long and periodic monitoring of VL to ensure viral suppression and address promptly the common issues for unsuppressed VL (13, 14). Poor Anti-retroviral therapy (ART) adherence is a major issue for unsuppressed VL. It is responsible for about 75% of detectable VL (VL > 1000 copies/ml) in people living with HIV (PLWH) on ART (15, 16). Since the primary role of ART in HIV management is to suppress VL (8, 13), there is a need to maximize the benefits of ART so that at least 95% of people on ART are suppressed (17). To improve adherence among PLWH on ART with unsuppressed VL, the WHO recommended intensive adherence counseling (IAC) in 2016 (8, 18). Studies done worldwide, including systematic reviews, have shown that IAC achieved viral suppression in over 70.5% of PLWH on ART with unsuppressed VL (19–22). The other reasons for unsuppressed VL include drug resistance, mal-absorption and drug-drug interactions, but these may require ART regimen change if they are to be addressed (23). Therefore, the WHO recommended that if the VL is high, IAC be carried out, followed by a repeat VL test after completing the intervention (8). If the repeat VL is suppressed (< 1000 copies/ml), the client continues with the current ART regimen. Otherwise, virological treatment failure is concluded; and the patient should be switched to another regimen after ensuring that all adherence issues have been addressed (19, 20).

In response to WHO and UNAIDs recommendations, Uganda implemented various strategies and interventions, including the 90–90–90 global targets (10), test and treat strategy and IAC (14, 20, 24). Following the implementation of these strategies, the number of PLWH on ART and virally suppressed PLWH increased (25). However, 12% of PLWH on ART remained virally unsuppressed in 2018 (1) despite the MoH having launched IAC in 2016 (20). The coverage, effects and factors associated with IAC implementation within a healthcare setting have not been formally evaluated. Moreover, behavioral interventions have been shown to vary from one context to another, and therefore context-specific evaluations are always needed for such interventions (20, 26). Poor quality of counseling, lack of skills among health workers, shortage of health care workforce, lack of patient's privacy at the facility, patients' type of regimen, and social demographics are reported to affect adherence intervention outcomes (15, 27–31). To ensure strategic implementation of IAC and maximize its benefits within healthcare settings, there is a need to assess its outcomes following implementation. Therefore, this study aimed to assess the effect and experiences of providing IAC in the first 23 months of implementation in a public urban HIV care center in Uganda.

Methods

Study design and population

This was a sequential explanatory mixed-methods study. The quantitative part was a pre-post intervention evaluation. The qualitative part was a phenomenological assessment of health care worker

experiences. The pre-post evaluation involved reviewing records of all PLWH on ART who had a VL \geq 1000 copies per ml on a test done between Jan 2015 and October 2018. Records of patients who were no longer active in the clinic were excluded. The phenomenological assessment involved healthcare workers, including clinicians and counselors involved in the provision of IAC at Kisenyi Health center IV (KHCIV)

Study setting

Uganda is the country in the East African region with a total population of about 45 million, of which 1.45 million (5.7%) are the PLWH (1, 32). The government of Uganda adopted the WHO recommendations (IAC), and the program was implemented as stipulated by the MoH guidelines(33) at KHCIV. KHCIV is the largest urban public HIV care center in Kampala, serving approximately 11,500 PLWH. Of these, about 1200 were estimated to have a VL > 1000 copies at the end of 2018(1). The facility is supervised by Kampala Capital City Authority (KCCA); and the Infectious Disease Institute (IDI) is the implementing partner for HIV services. The facility serves about 2,000,000 people (34) from the Kampala suburbs, especially informal settlements.

The program of VL monitoring at KHCIV stipulates performing VL test for all PLWH who have been receiving ART for at least six months. Those whose VL is \geq 1000 copies/ml undergo three IAC sessions one month apart, after which the VL test is repeated. If the repeat VL is suppressed (< 1000 copies per ml), the client continues with the current treatment and repeats the VL after one year. If VL is unsuppressed (\geq 1000 copies per ml), clients are considered for a switch to a second or third-line regimen after ensuring that all adherence issues have been addressed. Testing possible resistant HIV strains is reserved for suspected failure on a second line regimen before switching to a third regimen(14).

Following the confirmation of its effectiveness in earlier studies, IDI started implementing the IAC strategy in the health facilities where it supports HIV services across the country, including KHCIV. Implementation of IAC at KCHIV started in early 2016 where some unsuppressed clients on ART VL would receive IAC, while others receive routine counseling (regular counseling). When the MoH adopted and launched the intervention in December 2016, KHCIV continued with strategy by making it available to all targeted clients. The Healthcare workers (nurses, clinicians and adherence counselors) at the facility initiate the IAC. For children and adolescents, the sessions are conducted together with the children and their caregivers (Fig. 1). Expert clients (individuals on ART who are suppressing well and are volunteering in the ART clinic) also conduct the IAC sessions after orientation. These are supervised by the healthcare workers (HCWs). Those undergoing IAC are scheduled for monthly sessions for three consecutive months. At these sessions, an effort is made to understand the client's drug administration, the barriers to adherence, social support, and opportunities to improve adherence using the 5 As (assess, advise, assist, agree, arrange) approach (33, 35). All the information is recorded in the counseling notes and monitored. When the third session is done, the client is given a one-month appointment (4th visit). At the 4th visit, if adherence is consistently good (\geq 95%) for the previous three consecutive visits, a client is prepared for VL testing at this visit. Otherwise, a 4th IAC session is conducted. For pregnant clients, VL testing is done at the 3rd visit.

VL tests are run at one central laboratory for the whole nation, the Central Public Health Laboratories (CPHL) in Kampala city. Therefore, the VL test samples drawn from clients at KHCIV are sent to CPHL for analysis. The results should be available within two weeks of dispatch for delivery to clients at a subsequent clinic visit. If a client is currently on a second-line regimen and has two detectable VL test results, they are considered for a resistance test. All these steps are routinely registered in MOH tools (the viral load register, the non-suppressed VL register, and the client files), all of which were source documents for this evaluation.

Procedures

Data from all eligible records were collected and analyzed. Using 01st December 2016 as midpoint (launch of IAC by the MoH), data were divided into two comparable groups; 23 months before the introduction of IAC (01st January 2015–30th November 2016) and 23 months after the introduction of IAC (01st December 2016-31st Oct 2018). A pre-tested data abstraction form was used to collect data on the variables of interest from the source documents (viral load register, the non-suppressed VL register, and the client files/charts). A list of the ART clinic numbers of eligible participants was extracted from the VL register. Their corresponding clinical charts were retrieved and reviewed for additional information, including; age, date of birth, ART start date, the current ART regimen. Other information collected included the viral load test result and date of the result, whether or not the client had IAC, the dates for the IAC sessions, and the repeat VL test result at the end of IAC. The study outcomes extracted were; (1) participant's receipt of IAC or not, (2) participant's achievement of viral suppression following IAC (or an adherence counseling) or not. The factors associated with viral suppression were also determined. Health care workers involved in the provision of IAC were contacted, and their individual interviews were arranged.

Sample size and sampling procedures

Using a formula for two proportions(36), $Z_{\alpha/2}$ as the standard normal value corresponding to the level of significance (e.g., for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Z_{β} as the standard normal value corresponding to 90% confidence interval, β of 0.215 and the critical value was 1.645, and at the power of 80% (0.84). P_1 is the proportion of participants expected to have viral suppression before the introduction of IAC (Jan 2015 to Nov 2016). P_2 is the proportion of participants expected to have viral suppression after the introduction of IAC (Dec 2016 to Oct 2018); q_1 is the proportion of participants before the introduction of IAC (Jan 2015 to Nov 2016), while q_2 is the proportion of participants after the introduction of IAC (Dec 2016 to Oct 2018) who would not have viral suppression, $P = q_1P_1 + q_2P_2$. N is the total number of participants. Assuming clients never used to suppress before the introduction of IAC, therefore $P_1 = 0\%$. Using 70.5% effect of IAC in achieving suppression(22), hence $p_2 = 0.71$. Taking equal numbers in the two groups, hence $q_1 = q_2 = 0.5$, therefore $N \approx 244$.

Considering records with incomplete or unclear information, X, of 27%(37) and N, the estimated sample size, and substituting into the formula, $n = \frac{N}{1-X}$ a total sample size of 289 was obtained. In addition, a design effect of 1.5 was considered to adjust for the spread nature of the sample across the two groups. This brought a sample size to about 500, i.e., 250 in each group.

Using “2” as the “ K^{th} ” number, ($\frac{1200}{500(\text{sample size})} \approx 2$). Thus, we selected the 2nd record in the generated list of all potential participants. The first record was randomly selected in each year of the study period (2015, 2016, 2017, and 2018). After that, records in the subsequent even number positions were selected. On average at least 100 records were selected each year depending on the number of potential participants.

For qualitative sampling, we used the principles of sufficient information power (38) and purposefully selected counselors and clinicians involved in the provision of IAC. A total of five interviews exploring experiences of providing IAC at KHCIV were conducted. Interviews were conducted face to face in calm and private settings away from distractions. Participants were recruited until the point of saturation (39), when no new themes emerged. The interviews lasted between 15 to 30 min. The first author (Z.L.) conducted all the interviews in English. All the interviews were audiotaped and transcribed by a professional.

Data management and analysis

Data from the field was entered into excel sheets by a data clerk. Data cleaning was done and then transferred to Stata version 14.0 (Stata corp) for analysis. Data were checked for normality and transformation. Frequencies were generated using Stata version 14.0-(Stata Corp) for the number of participants who received interventions (IAC and routine counseling) before and after introduction of IAC, and the number of participants who suppressed before and after introduction of IAC.

Using “as treated” analysis strategy, frequencies of those who received IAC in either group were obtained. Baseline characteristics were summarized and described into frequencies and percentages for the categorical variables. Descriptive statistics included either mean (\pm SD) or median with the corresponding interquartile range for continuous variables. Categorical variables were summarized as frequencies and percentages. We determined the factors associated with the viral suppression using the modified Poisson model with robust standard errors to obtain prevalence ratios (PR) and their corresponding 95% confidence intervals. Independent variables with a $p < 0.2$ at bivariable level, those known to be associated with viral suppression from literature and those considered plausible although not significant, were entered into a multivariable model to determine the independent factors associated with viral suppression.

The qualitative analysis started in the field and was an iterative process guided by qualitative content analysis (40, 41). The analysis included identifying meaning units, abstracting the content of meaning units, and summarizing their importance (Table 1). Words, sentences, or paragraphs that relayed a similar

message were grouped as meaning units, condensed, and labeled with a code. We aggregated similar codes to form categories. Categories were made mutually exclusive whenever possible and included all the information related to the content area being discussed. Categories were further analyzed to form manifest sub-themes and themes. We used Atlas.ti 8 (ATLAS.ti Scientific Software Development GmbH, Berlin- Germany). We methodologically triangulated(42) the collected data (interviews) with quantitative results at thematic analysis stage, which increased the perspectives and deepened the understanding of the meanings attached to providing IAC at KHCV.

Table 1

Examples of meaning units, codes, categories and themes from qualitative content analysis of interviews about experiences of providing IAC at KHCV

Meaning units/quotes	Codes	Category	Theme
<i>"We have to be very sure that the adherence is above 95% or the adherence is good so we continue our adherence counseling reason why I told you we give an allowance of three to six months to conduct intensive adherence counseling. For adults, we are doing the 3 sessions, one month apart. Then at the third session if the adherence is good, we give them a one-month appointment to come back for a repeat viral load"</i>	Ensuring good ART adherence	IAC is done to ensure good adherence	IAC is the recommended strategy for PLWH with unsuppressed viral load
<i>"then we are having this category of men and women having disclosure issues, maybe a son or daughter fears to tell the father or mother and in that they keep dodging around; today he or she takes, tomorrow he/she doesn't take; so generally adherence has those dynamics"</i>	Non-disclosure hinders ART adherence	Factors that hinder ART adherence during IAC	Patient related factors affecting ART adherence during IAC
<i>"At the facility level I can say long time waiting for example; some clients come knowing he/she is going to leave early but takes a whole day at the facility."</i>	Long waiting time at the facility	Issues at the facility affecting client adherence to drugs and clinic appointments	Health care system related factors affecting ART adherence during IAC
<i>"So if we engage these peers, give them the training and mentorship, they can do the counseling very well; so that is what is missing here."</i>	Peer Educators administering IAC	Reducing the workload of health workers during the provision of IAC	Improving provision of IAC

Ethical consideration

The study was approved by Makerere University Institute of Public Health Higher Degrees, Research and Ethics Committee (HDREC). Permission to conduct the study was sought from the KCCA administration. Since this was a retrospective analysis of de-identified data, a waiver of consent was also obtained from

the same IRB. However, for qualitative interviews, informed consent was obtained from the health workers.

Results

Proportions recruited and analyzed

Overall, more participants received IAC 325(65.0%) compared to 175(35.0%) who received routine counseling as summarized in Fig. 2.

Participant characteristics

Data from 500 participants was analyzed. The mean age was 34.8 (\pm 12.8), more were female 326 (65.2%), most were married 260 (52.0%) and the median baseline CD4 was 220 (IQR = 97–356). The initial ART regimen for majority was Efavirenz-based 317 (63.4%) and the current regimen for majority Lopinavir/ritonavir based 314(62.8%). The median number of days on ART was 924(375–1552). Majority had switched ART regimens once 298 (59.6%). The median first unsuppressed VL in HIV care was 15,331 (IQR = 4420–51587) as shown in Table 1.

Intensive adherence counseling coverage

After introduction of IAC (Dec 2016), all participants with unsuppressed VL received IAC, 249(100.0%). Among those who received IAC, the median number of sessions received was 4 (IQR = 4–5), and the median number of days to the first IAC session was 50.5 (IQR = 23–84). The median number of days during IAC was 102(85–142), See Table 2

Table 2
Descriptive characteristic of participants

Characteristic	Frequency(N)	Percentage (%)
Cohorts		
Jan 2015 to Nov 2016 cohort	251	50.2
Dec 2016 to Oct 2018 cohort	249	49.8
Age in years, mean (SD)	34.8 (12.8)	
Sex		
Male	174	34.8
Female	326	65.2
Marital status		
Married	260	52.0
Casual partner	7	1.4
Single	192	38.4
Children	41	8.2
Baseline CD4, median (IQR)	220 (97–356)	
Initial Regimen		
Efavirenz-based regimen	317	63.4
Nevirapine-based-regimen	175	35.0
Lopinavir/ritonavir(PI)	7	1.4
DTG	1	0.2
Current regimen		
Efavirenz-based regimen	102	20.4
Nevirapine-based-regimen	8	1.6
Lopinavir/ritonavir(PI)	314	62.8
DTG	76	15.2
Regimen switching		
0	197	39.4
1	298	59.6
VL suppression and factors associated		

Characteristic	Frequency(N)	Percentage (%)
2	5	1.0
Days on ART, median(IQR)	924(375–1552)	
First detectable VL, median (IQR)	15331 (4420–51587)	
Intervention		
Standard of Care	175	35.0
Intensive Adherence Counseling	325	65.0
Coverage of IAC after Dec 2016(%)	249(249)	100.0
Number of IAC sessions, median (IQR)	4 (4–5)	
Days to first IAC, median (IQR)	50.5 (23–84)	
Relapse after IAC	29	10.0
VL suppression and factors associated		

On bivariate analysis, 499 participants had VL results following adherence counseling in both groups. Participants in the group after introduction of IAC were 68% more likely to achieve viral suppression (PR = 1.68, *P-value* > 0.001) compared to those before introduction of IAC. Females participants were 12% more likely to achieve viral suppression PR = 1.12, *P-value* = 0.349) compared to males, however, this was not statistically significant. Those who were single were 22% less likely to achieve viral suppression (PR = 0.78, *P-value* = 0.042) compared to married ones. Those who had a CD4 + count above 500 cells/ μ L were more likely to suppress (PR = 1.37. *P-value* = 0.04) compared to those with a CD4 + count below 500cells/ μ l. Those initially on Efavirenz based regimen were 36% more likely to suppress (PR = 0.64, *P-value* = 0.001) compared to those on non-Efavirenz based regimen. Those currently on protease inhibitor (PI) based regimen were 90% less likely to achieve viral suppression (PR = 0.1, *P-value* = 0.001) compared to those on Efavirenz or Nevirapine based regimen. In the final adjusted model, those in the group after introduction of IAC were 22% more likely to achieve viral suppression (aPR = 1.22, 95% CI: 1.01–1.47) compared to those before introduction of IAC. Those who were currently on PI based regimen were 89% less likely to achieve viral suppression (aPR = 0.11, 95%CI: 0.08–0.15) compared to those on Efavirenz or Nevirapine based regimen. Crude and Adjusted Risk Ratios are shown in Table 3.

Table 3

Viral suppression following unsuppressed Viral Load from Jan 2015 to Oct 2018 and associated factors

Variable	Not suppressed (n = 310)	Suppressed (n = 189)	Crude PR	P- value	adj PR	95%CI	P- value
Intervention							
SOC	129 (73.7)	46 (26.3)	1		1		
IAC	181 (58.9)	143 (44.1)	1.68	> 0.001	1.22	1.01–1.47	0.04
Age in years	34.6 (13.1)	35.1 (12.5)	1.01	0.666	1	0.99–1.01	0.949
Sex							
Male	113 (36.5)	61 (32.3)	1		1		
Female	197 (63.6)	128 (67.7)	1.12	0.349	1.06	0.08–1.28	0.559
Marital status							
Married	150 (48.4)	110 (58.2)	1				
Single	133 (42.9)	65 (34.4)	0.78	0.042			
Children	27 (8.7)	14 (7.4)	0.81	0.349			
CD4 count							
≤ 500	226 (87.6)	120 (80.4)	1				
> 500	32 (12.4)	29 (19.5)	1.37	0.04			
First Viral load	43982 (35011.1)	34107.7 (18072.5)	0.99	0.496			
Initial Regimen							
Efavirenz-based regimen	178 (57.4)	138 (73.0)	1				
Non-Efavirenz-based regimen	132 (42.6)	51 (27.0)	0.64	0.001			
Current regimen							
NNRTI	13 (4.2)	97 (51.3)	1		1		
Protease Inhibitors(PI)	285 (91.9)	29 (15.3)	0.1	< 0.001	0.11	0.08–0.15	< 0.001
DTG-based regimen	12 (3.9)	63 (33.3)	0.95	0.429	0.96	0.85–1.09	0.543

Variable	Not suppressed (n = 310)	Suppressed (n = 189)	Crude PR	P- value	adj PR	95%CI	P- value
First detectable viral load	70203.2 (199420.7)	90402.5 (289995.8)	1	0.32			
Days on ART	1131.3 (1034.2)	1053.0 (1005.2)	0.99	0.411			

The Health Care Worker experiences of providing intensive adherence counseling in Kisenyi Health Center IV

In exploring experiences of providing IAC among Health care workers involved grouping of words, sentences and paragraphs of similar message to form meaningful units. Similar meaningful units were condensed to form codes; similar codes were aggregated to form categories which were eventually grouped to form themes. The major themes included; IAC intervention is an effective intervention recommended for PLWH on ART with unsuppressed viral load, patient related factors affect ART adherence and health care system related factors affect adherence.

IAC intervention is an effective recommendation for PLWH on ART with unsuppressed viral load

The findings from health workers' experiences indicate that IAC is an intervention that has fully been embraced at KHCIV and it was noted as a very useful tool in enabling ART adherence and VL suppression.

"We have to be very sure that the adherence is above 95% or the adherence is good so we continue our adherence counseling reason why I told you we give an allowance of three to six months to conduct intensive adherence counseling. For adults, we are doing the 3 sessions, one month apart. Then at the third session if the adherence is good, we give them a one-month appointment to come back for a repeat viral load".

"[said a Clinician with 7 years of experience]

They all exhibited a clear understanding of the program as it is provided to those clients with unsuppressed VL (VL > 1000 copies). They said that a patient is considered suppressed with the intervention when the VL is less than 1000 copies/ml. This is determined after the repeat VL after the third session. The main sessions conducted were reported to be 3 but in case the adherence of that particular client is not above 95% then a fourth session is considered. They also said that if poor adherence persists, even after the fourth session, the decision is left to the clinician, otherwise the entire process is repeated, although this rarely happens.

"Actually the third session will be the determinant to go to the fourth one. After the 3rd session if you see that this person has really scored 95%, you can stop on the 3rd one and the fourth visit is just for review

and then you forward for VL testing. But if you see that he/she is still in 80 or 70% adherence, then you do the fourth session.” [Said a Counselor with 5 years of experience]

Health care workers felt that this kind of intervention has really done a commendable job in improving adherence levels. Majority said that only about 20%-30% fail to achieve suppression following IAC. And this can majorly be due to several factors which can be both patient and health care related. These are expounded below;

Patient related factors

Non-disclosure

The major patient factor highlighted was non-disclosure. Participants said that most clients, when they learn about their HIV status they start imagining how they would tell others especially their partners. This makes them start taking their ARVs while in hiding and on some occasions it gets tough to hide and they choose not to take it.

“ There are situations that come in for a client to tell you that I am not ready for ARVs for example non-disclosure; this is something that comes to them maybe like a shocker to them and so they start imagining you are telling them they are going to take ARVs for life, how am I going to go to my partner, how am I going to keep this medicine. Yes you can give them the medicine because the guidelines say they should take the medicine. It should be noted that all those who fail to disclose, it also gets difficult for them to explain why they would opt for safe sex; this keeps exposing them” [said a Clinician with 7years of experience]

“...then we are having this category of men and women having disclosure issues, maybe a son or daughter fears to tell the father or mother and in that they keep dodging around; today he or she takes, tomorrow he/she doesn't take; so generally adherence has those dynamics.” [said a Counselor with 5 years of experience].

Social-economic life of the client

It was reported that this is quite key when it comes to adherence. Patients report challenges like lack of food. Some clients do not have jobs and hence cannot afford a living.

Some say that they can't take medicine on empty stomachs.

“...a mother is going to tell you am not working, we do not have food so I cannot take medicine on an empty stomach; so if the mother is not taking medicine automatically the child will not take medicine if they are also infected and if their issue is food, that is something we might not solve at the facility.” [said a Counselor with 10 years of experience]

“ Yes, because they have their other issues. You can do the counseling very well but they go back home some have challenges of food; they say they cannot take this drug when they have not eaten anything.”

[said a Counselor with 4 years of experience]

It has been very difficult for the health workers to address some of these challenges of socio economic constraints. They have linked a few clients especially vulnerable children to some projects but these can't take on all the clients, as they support a limited number.

"But then for the children, Orphans and vulnerable children (OVC) is the program we have here. Children and adolescents that are unsuppressed are linked to this program for support. If it is food, they give them some food but sustainability, the issues of sustainability." [said a Clinician with 7 years of experience].

We have the OVC program but it only look after children yet there are also adults who are badly off." [said a Counselor with 4 years of experience].

Other support encouraged by health workers is psychosocial support from family members or relative but this is difficult especially for those who have not disclosed. Other support is also sought from some organizations.

"We are working with some community based organizations(CBOs) but of course they also make things very long, some say we are full like world vision said we are full" [said a counselor with 4 years of experience].

New barriers setting in

Participants reported that some clients, after suppressing, they may come back later with poor adherence and this can be due to new barriers setting in. This can involve some clients relocating and later return after lost to follow-up, peer pressure, getting new partners, gender-based violence (GBV) and others.

"...you are kind of like, you used to do well, what could be the problem! It could be behavior change, it could be nature of work, it could be travelling, it could be distance, and it could be some other things like GBV, so surely it depends. So client is like health worker I used to have a good job, so I used to be well. Others are like they changed marriage and having non-disclosure issues so they are hiding drugs." [said a Counselor with 10 years of experience].

However, the major barrier that had caused unsuppressed VL during the period when this study was conducted was COVID-19 pandemic outbreak.

"...because people were in lock down, for about two months some were not taking drugs and they were saying that no car was allowed to move and there were no nearby health facilities to some client for drug refills. Many will tell you the lock down got me deep in the village and there is no nearby facility so I was not taking and currently we have got some mothers who are giving birth to positive children because they were not taking drugs during the lock down." [said a Counselor with 4 years of experience].

Health care system related factors

It was reported that determining the readiness of the patient to start ART is very key to ensure that they achieve a sustained adherence throughout their lifetime. And this is done with a checklist to determine a client's readiness. However, there healthcare-system related factors that influence this.

Counselors' ability/skill to manage the client's barriers

It was reported that building rapport with the client is key in solving their ART adherence barriers. If a counselor fails to have a good relationship with the client, then it becomes very difficult for the client to follow their instructions.

"...you know with counseling you need to be closer to the patient as much as possible but as you know government health care workers for some, that is not part of their job; theirs is to come, quickly see patients, give them drugs, and then go. So when it comes to ideal counseling there is a gap there." [said a Counselor with 10 years of experience].

Additionally, health workers may be transferred and the new health workers may require building trust and relationship with the clients which usually take quite some time. Therefore, in the event a counselor fails to build a good relationship with the client, the adherence barrier will continue affecting the patient.

Client load or workload

The patient-health worker ratio is so low resulting in a health worker attending to many clients a day. This causes fatigue to a health worker as well affecting the clients in terms of the waiting time.

"At the facility level I can say long time waiting for example; some clients come knowing he/she is going to leave early but takes a whole day at the facility.

Another thing I say is manpower; the staff's ratio to the patients is really not matching, you are a team of twenty and you are looking at a thousand of patients." [said a Counselor with 5 years of experience].

Due to fatigue among health workers, some clients may not be attended to as expected and this affects adherence because the client's barrier to adherence will not have been discussed and solved.

"Of course it is important. The very first encounter of a health worker if you find this health worker very tired, their attitude may not be good." [said a Clinician with 7 years of experience].

Lack of privacy

Due to many clients, the facility environment may not ensure client confidentiality. This causes clients fear to open up in presence of fellow clients. This especially happens during group counseling or when the health workers share a clinical room.

"You know sometimes we share offices like in my room I have a colleague I sit with; the counselors also share offices; when the numbers are many they decide to give a group counseling session forgetting that

people have got individual issues. So in that group counseling a client may not open up.” [said a Clinician with 7 years of experience].

“ here we have very big numbers so some clients have stigma; so when they come here and realize that the numbers are too big,they fear to be seen and thereafter start defaulting their appointments.” [said a Counselor with 10 years of experience].

Lack of a multidisciplinary team

Despite the fact that IAC requires a multidisciplinary team involving various cadres right from peer educators, counselors, clinicians, pharmacists, psychologists and family members, this has not been possible and in most cases it’s only one person or two are available to handle a client’s adherence barrier.

“Okay, ideally intensive adherence counseling involves the multidisciplinary team but I have told you that it is hard to collect that team together;. in our setting here the team is supposed to involve a clinician, a counselor, a pharmacist, an expert client, a family member and a support group.. But bringing these persons together to talk to this client is something hard and some are not available.” [said a Clinician with 7 years of experience].

This means that the workload would be much and one might not be trained enough to do the work of the other. This leaves the patient with scanty information.

Other barriers

These include drug side effects and language barrier. Despite not vividly highlighted, it was reported that a few clients may fail to contain the side effects and hence opt for drug holidays. Additionally, the location of KHCIV has many refugees who only speak their own languages and this affect the communication with health workers. The other health care related barriers included drug resistance, drug stock-out, and results turn-around time.

Facilitators of IAC provision at KHCIV

Use of peer educators, this has enabled to reduce workload of health care workers “ You know us health workers we tend to think that these peers or expert clients will not give the right information but if these people are empowered, they give that starter information before they proceed to the counselor because this is a person who has been in the same situation before so they will educate this client basing on what they have gone through.” [said a Clinician with 7 years of experience].

However, there are some things missing in the use of peer educators strategy at KHCIV such as lack of adequate training and mentorship “*So if we engage these peers, give them the training and mentorship, they can do the counseling very well; so that is what is missing here.” [said a Counselor with 10 years of experience].*

Assigning special clinic days and sessions to special groups or clients

In order to reduce the workload and provide more time to special groups of clients. There is a need to have less numbers at a time so that special clients with adherence difficulties are given more time .At KHCIV, special clinic day and session strategy has been developed and utilized.

“Tuesday is for those with unsuppressed viral load. So when these patients come in we let them have a group session with expert client first; then a clinician chip later and there after they are sent to the counselor. Pregnant and breastfeeding clients also have their own sessions; clients also have their family support sessions where they are given some information before they go to the counselor.” [Said a Clinician with 7 years of experience]

Improving IAC provision at KHCIV

In order to improve the implementation of the IAC and its performance, health workers suggested a few things to fix.

Intensifying the IAC

Majority of the health workers agreed that there is need to intensify the IAC intervention, they said that this could be done by improving the multidisciplinary nature of the IAC team by availing more health care workers or or professional cadres.

The other way of improving IAC is by increasing the number of sessions beyond three. It was reported that increasing sessions allows continuous counseling and health education talks which provide the ability to continuously identify new barriers.

“...we maybe probably need to add things like maybe the sessions, sometimes you feel like maybe the three sessions are not be enough depending on a particular client forexample the adolescents.[said a Counselor with 10 years of experience].

Discussion

This programmatic study showed that IAC has been embraced in a public HIV care center and there is a clear understanding of the program among HCWs. Despite a significant relative effect in improving viral suppression and optimal coverage, IAC did not produce the expected 70% viral suppression. Being on PI based regimen as the current regimen reduced the likelihood of viral suppression. Non-disclosure, social economic constraints, relocations, gender based violence, lack of privacy at the facility, lack of skills among HCWs and lack of a multidisciplinary team during counseling hindered viral suppression during IAC. The implications of these results are as follows;

The optimal coverage of IAC was probably due to an adequate understanding of IAC and its procedures among HCWs. Additionally, IDI being an implementing partner at this facility may have influenced IAC coverage. This is because it's a private not-for-profit organization that is more likely to have specific targets to meet under various projects and programs. On the contrary, Nassuna et al. found a lower

coverage of 68% in various facilities supported by IDI in Uganda(43). This could have been attributed to different study periods because Nasuuna et al's study was done from Jan 2015 to Dec 2016, which is the period before IAC was launched by MoH. During this period, IDI was still piloting the IAC strategy in various health facilities. Relatedly a study done in Zimbabwe also found lower coverage of 75.7%. This could also be attributed to the study period because the study was done in the first year of the Zimbabwe National ART program adopting the 2016 WHO guidelines on IAC strategy(15). During this short implementation period, HCWs might not adequately have understood IAC procedures. Therefore our findings may imply that once HCWs understand IAC procedures, they can optimally avail it the target population.

Besides improving viral suppression in 44.1% of the targeted population, IAC had a significant relative effect of 22% in achieving suppression compared to the counseling strategies that were used before it was introduced. To the best of our knowledge, this is probably the first study in Uganda and the region to assess the relative effect of IAC in routine HIV care program. IAC improving viral suppression in 44.1% of the target population is similar to Bonner et al findings which showed that patients with unsuppressed VL suppress following an adherence intervention(22). However, in this study, IAC did not produce the expected viral suppression (above 70%) as reported in Bonner et al (22). Our findings are similar to Nassuna et al and Bvochora et al's findings which also produced lower viral suppression of 23% (43) and 31.2% (15) respectively. Therefore, our findings imply that, IAC sub-optimally improved viral suppression at KHClV despite optimal coverage. There is a need to assess the quality and fidelity of IAC counseling sessions and procedures to probably ascertain the reasons for this gap in performance of IAC.

In this study PI based ART regimens were associated with reduced viral suppression compared to other regimens despite requiring less adherence percentage levels (80% versus 95%) (6, 7, 44). This may probably be due to the fact that these are a 2nd line regimens in most cases that are always given to patients who have failed on the initial regimen; and most these patients are switched due adherence difficulties(45). It is possible that such difficulties may be worsened by the twice dosing demands of the regimen. Our findings are contrary to Bvochora et al's findings in Zimbabwe where patients on 2nd line ART were 65% more likely to re-suppress compared to those on 1st line regimen following adherence counseling(15). Similarly, another study in South Africa also showed that viremic patients on second-line ART usually achieve a suppressed VL after targeted IAC(45, 46). Jobanputra et al did not find a statistical difference in achieving re-suppression between patients on first and 2nd regimen(23). However, all these studies were non comparative compared to the current study. Therefore, our results imply that HCWs should take caution and be more vigilant while offering IAC to unsuppressed PLWH on PI regimen.

Patient related factors including non-disclosure, social economic constraints, relocations and gender based violence; and health system related factors including lack of privacy at the facility, lack of skills among HCWs and lack of a multidisciplinary team affect viral suppression during IAC. These results imply that these factors may hinder viral suppression during IAC. Our findings are similar to previous findings where it was reported that ; non-disclosure is a major barrier in achieving ART adherence and eventually viral suppression (47–50), social economic constraints may act as a barrier for transportation

to the facility for drug refills or lead to a patient fear of taking medication on empty stomach due to lack of food(31, 51–53), relocations may lead to lost to follow up(54, 55) and gender based violence (50, 56–59) may lead to psychological stress to a patient. Additionally, *Health care system related factors* have been reported to be barriers to ART adherence especially in resource limited settings (60) despite not being directly related to patient or medication; for example Odokonyero et al reported that healthcare infrastructure and health care work force are vital in effectiveness of a health intervention or strategy (29). Health care system related factors such as lack of client privacy during HIV care and lack of skills among HCWs(30, 31, 50) (61), poor quality of counseling sessions(27) and shortage of health workers or cadres or lack of multidisciplinary team (62–64) reduce the chances of adherence to lifelong medications such ART.

Strengths and limitations

This is one of the few studies to assess the effect of an adherence intervention using a comparison group. The study is limited by the fact that, we used routine program data of which conclusions are limited by issues of data quality and missing values or variables. The study used “as treated analysis” strategy which may have biased results in favor of the IAC intervention period due to the fact 76 participants in the pre-intervention period (Jan 2015-Dec2016)received IAC. However, this may have had minimal effect due to the fact that the study aimed at the effect of the intervention not the effect of the randomization or grouping. The study did not look at the clients who were no longer active in the clinic follow up which would positively favor the effectiveness of IAC if most of those who were no longer active in the clinic follow up had a non-favorable outcome of unsuppressed VL following IAC. However, non-active clients were not considered in both groups hence possibly equal effect on both groups.

Conclusion And Recommendation

At KHCIV, IAC being fully embraced and optimally provided to target population. However, its full potential is not yet reached probably to a combination of patient and health care system related factors. Clients on PI based regimen are less likely to suppress during IAC probably due to dosing demands of the regimen. The findings highlight a need;

- For HIV care facilities and programs to always avail adequate requirements for providing IAC as stipulated in IAC program manuals and guidelines including a multidisciplinary team, health care workers and privacy
- For health care workers to be more cautious and use client or patient centered approach while handling specific client adherence difficulties such as being on PI based regimen, non-disclosure, financial constraints and gender based violence etcetera

Abbreviations

- AIDs

- ART
- GBV
- HDREC
- HCWs
- HIV
- IAC
- IDI
- KCCA
- KHCIV
- OVC
- PLWH
- PI
- PR
- SSA
- VL
- WHO

Declarations

- **Ethics approval and consent to participate**

The Higher Degree Research and Ethics Committee (HDREC), Makerere University School of Public Health, reviewed and approved the protocol. Permission to conduct research was obtained from Kampala Capital City Authority's Directorate of Public Health and Environment. Written informed consent was obtained from interviewed participants. Participant safety was ensured throughout the study.

- **Consent for Publication declaration**

Not applicable

- **Data Availability Statement**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

- **Conflict of Interest**

No conflict of interest was reported

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- **Author Contributions**

ZL: conceptualized the study, participated in data collection and management and drafted the manuscript and participated in data analysis. KT: supported drafting manuscript and conducted the analysis. DM: guided analysis and conceptualization. AS& SE: supported and guided conceptualization, data collection and management and manuscript drafting. RW: provided overall technical guidance to the conceptualization process. All authors reviewed the manuscript and provided substantial input, and all approved the final manuscript

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Figures

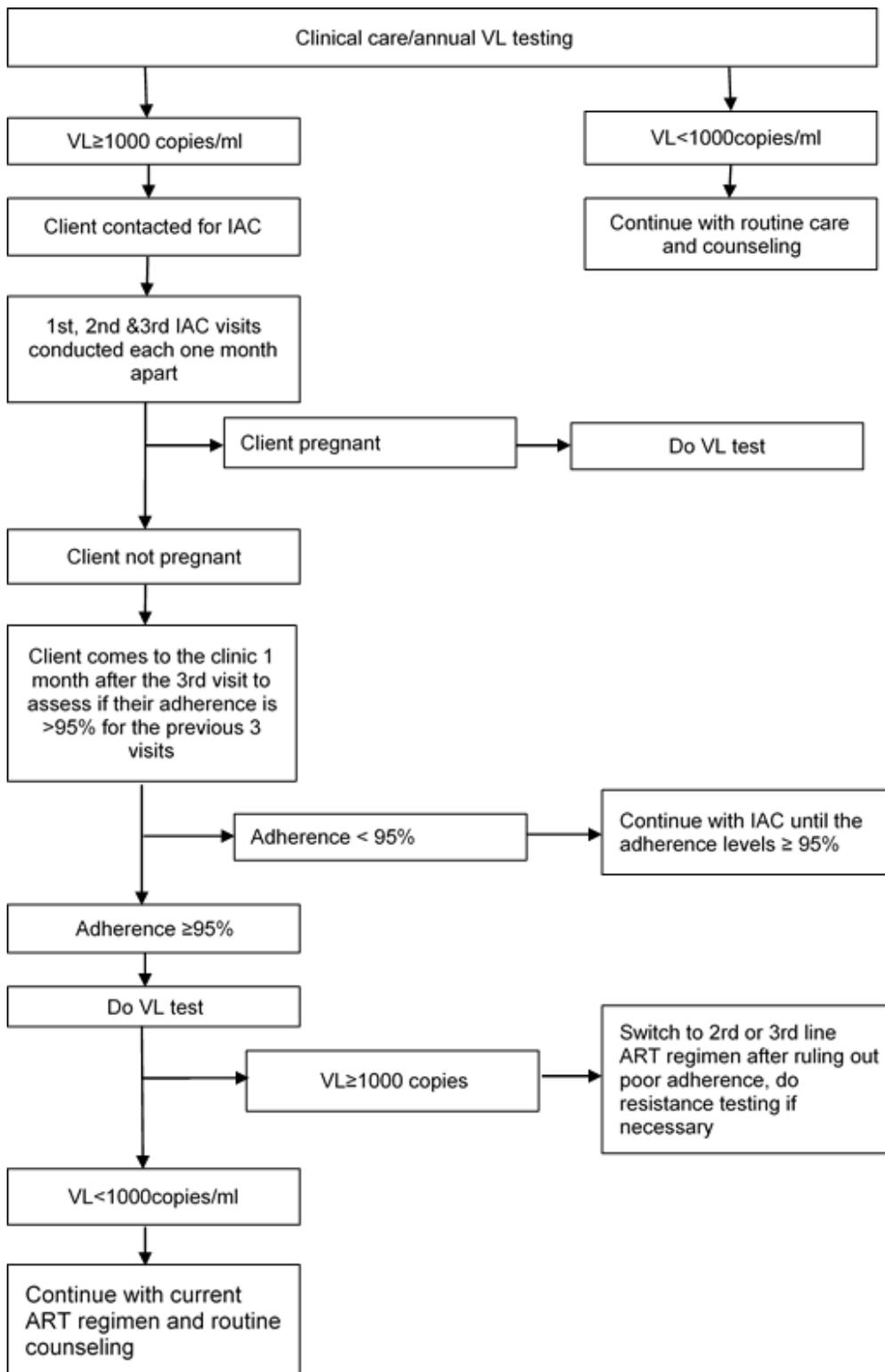


Figure 1

Intensive adherence counseling algorithm at Kisenyi Health center IV

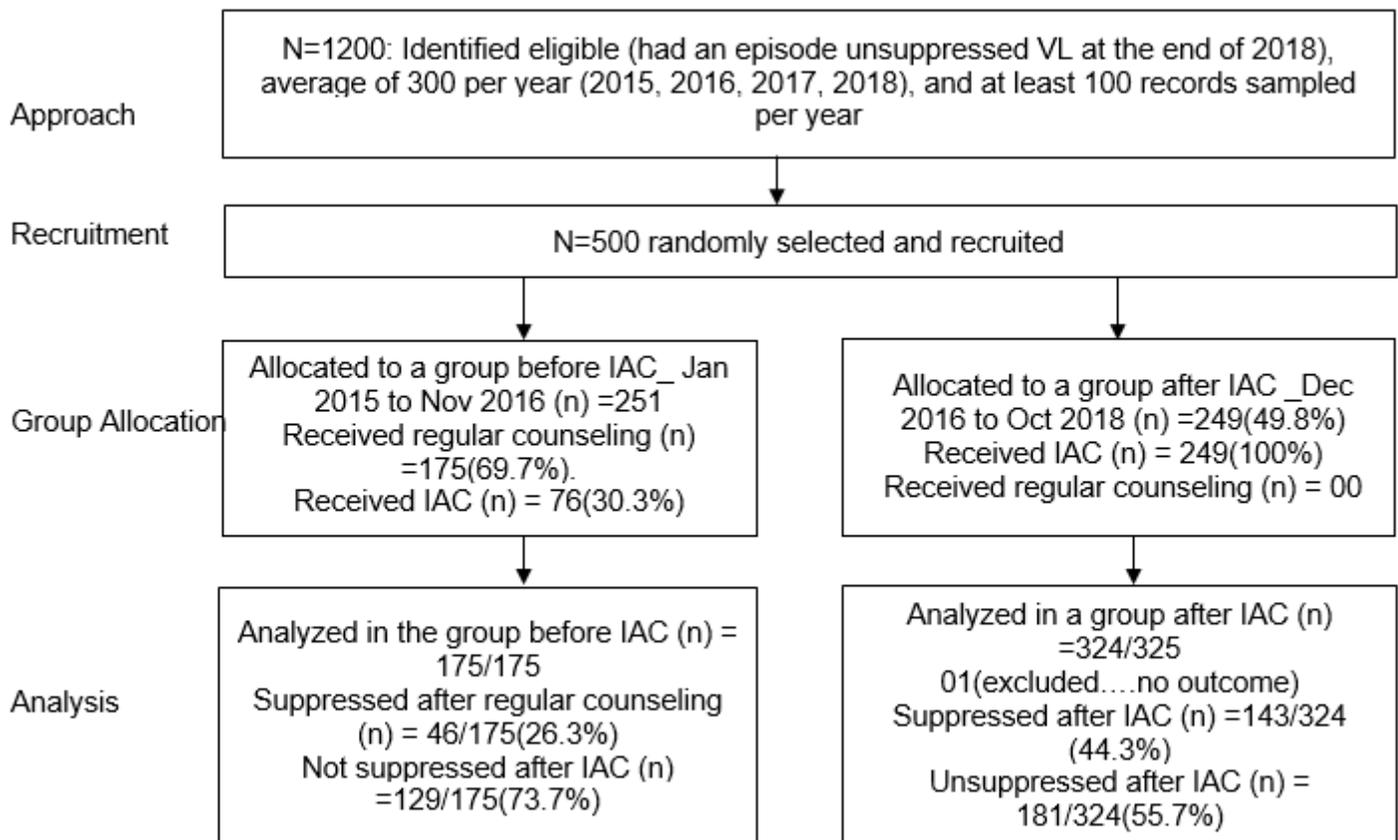


Figure 2

Numbers and proportions of participants at each stage of the study