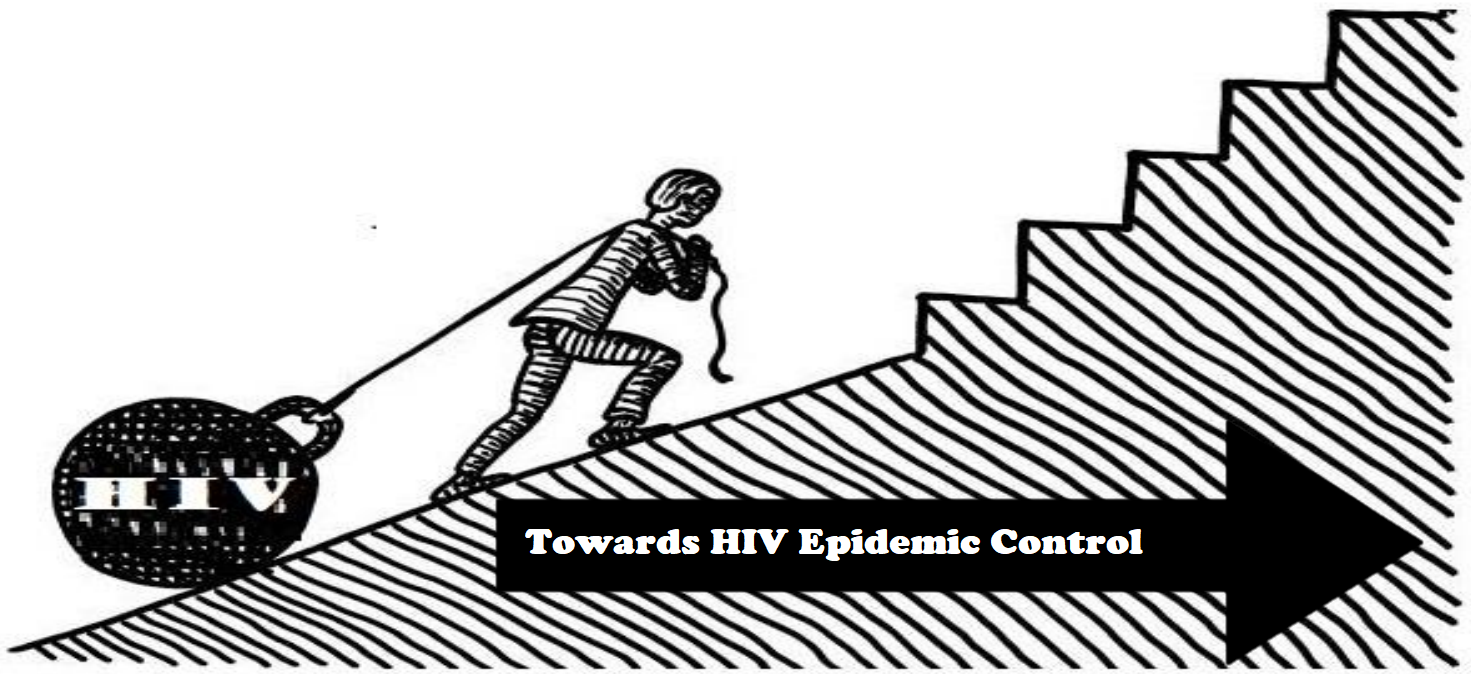
Should HIV Low-level viraemia Concern Us?



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Adapted from the H. E. Butt Foundation

Are we providing optimal HIV care?

Imagine an innocent man, who is taking his drugs very well and tests for viral load. The results are returned and are 400copies/ml (VL≥50 to <1,000 copies/ml). He is informed that the drugs are working very well and a few months later, he develops treatment failure!

Operational Definitions

- **Low-level viraemia:** A low but detectable VL (≥50 to <1,000 copies/ml)
- **HIV Viral load:** Number of HIV viral particles in each milliliter of blood.
- **Suppressed viral load:** A viral load less than 1,000 copies/ml of blood.
- **Non-suppressed viral load:** A viral load of 1,000 copies/ml or more.
- **Intensive adherence counselling:** Targeted counseling offered to PLHIV on ART with a non-suppressed VL.
- **Non-detectable viral load:** A viral load result below 50 copies per milliliter of blood (≤50 copies/ml)

Introduction

In 2022, Globally,

- 630,000 people died due to HIV related causes, and
- 1.3 million people acquired HIV

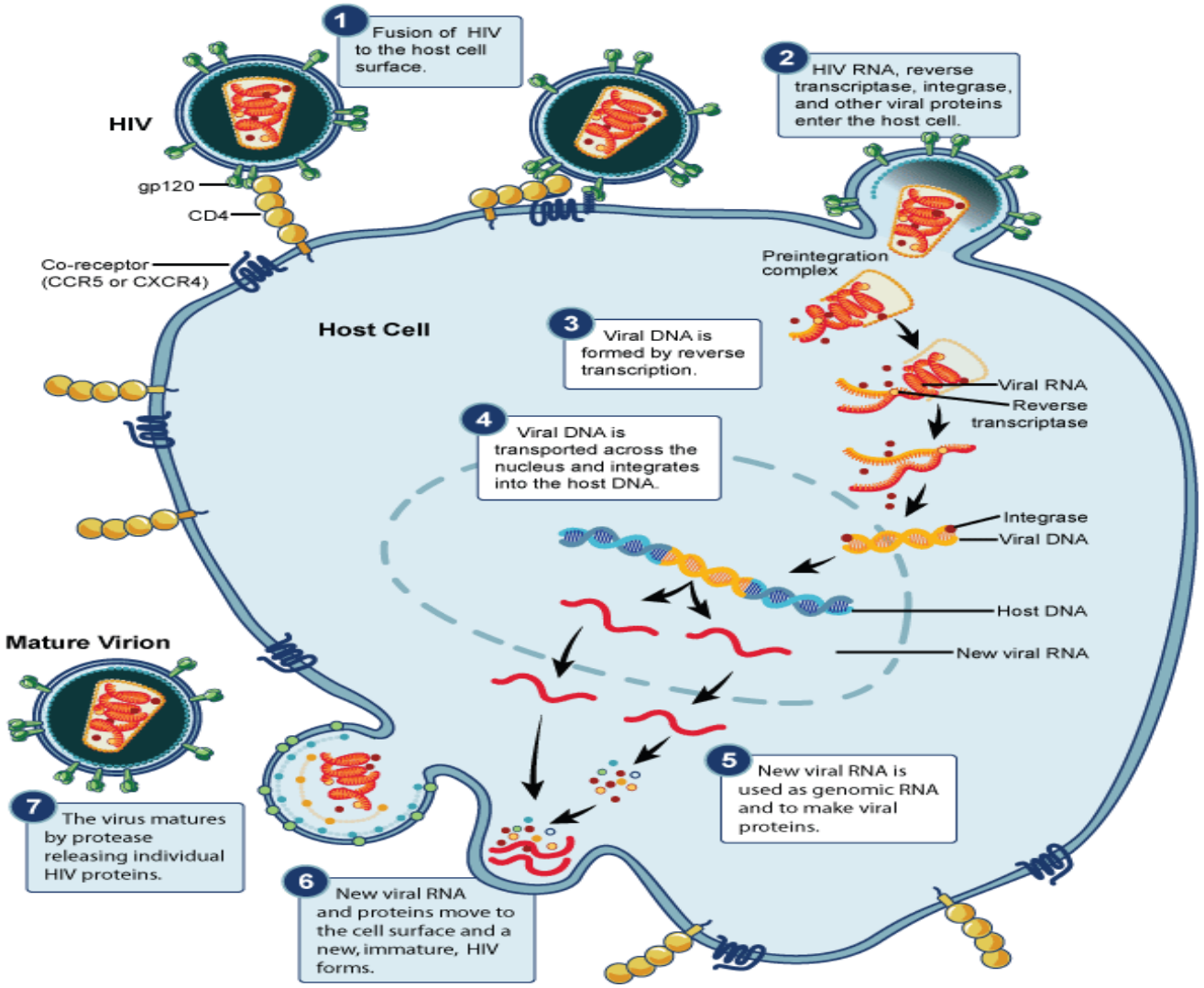
(UNAIDS 2023)

In 2021, In Uganda,

- 17,000 people died due to HIV related causes, and
- 54,000 people acquired HIV in Uganda.

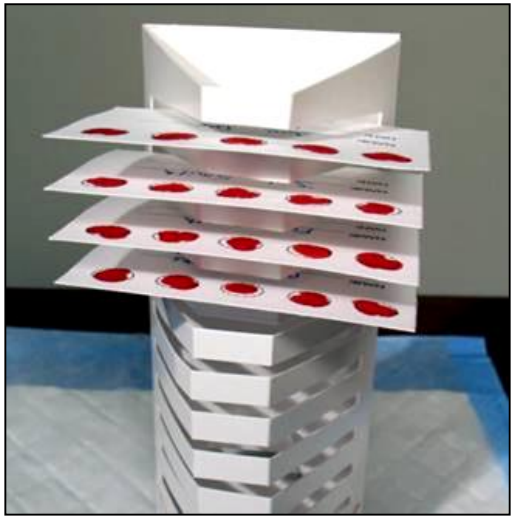
(Uganda AIDS Commission 2022)

As most of us are aware,



Why HIV Low-level viraemia was a big concern

- WHO recommended VL testing in 2013, and Uganda initiated VL testing in 2014
- A threshold of 1,000 is used for non-suppression in most SSA countries
- Increase in PLHIV with LLV in Uganda (CPHL, 2021).
- LLV associated with treatment failure (Ryscavage P et al., 2014)
- Sub-optimal Adherence is associated with LLV (Zhang et al., 2020)
- No intervention to address LLV among PLHIV in Uganda (MOH, 2020)



Paper I

African Journal of Laboratory Medicine
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AOSIS

Page 1 of 5 Review Article

Low-level viraemia: An emerging concern among people living with HIV in Uganda and across sub-Saharan Africa

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Attaining viral load (VL) suppression for over 95% of the people living with HIV on antiretroviral therapy is a fundamental step in enabling Uganda and other sub-Saharan African countries to achieve global Sustainable Development Goal targets to end the HIV/AIDS epidemic by 2030. In line with the 2013 World Health Organization recommendations, several sub-Saharan African countries, including Uganda, use a threshold of 1000 HIV viral RNA copies/mL to determine HIV viral non-suppression. The United States Centers for Disease Control and Prevention and the International Association of Providers of AIDS Care deem this threshold very high, and hence recommend using 200 copies/mL to determine viral non-suppression. Using 1000 copies/mL as a threshold ignores people living with HIV who have low-level viraemia (LLV; HIV VL of at least 50 copies/mL but less than 1000 copies/

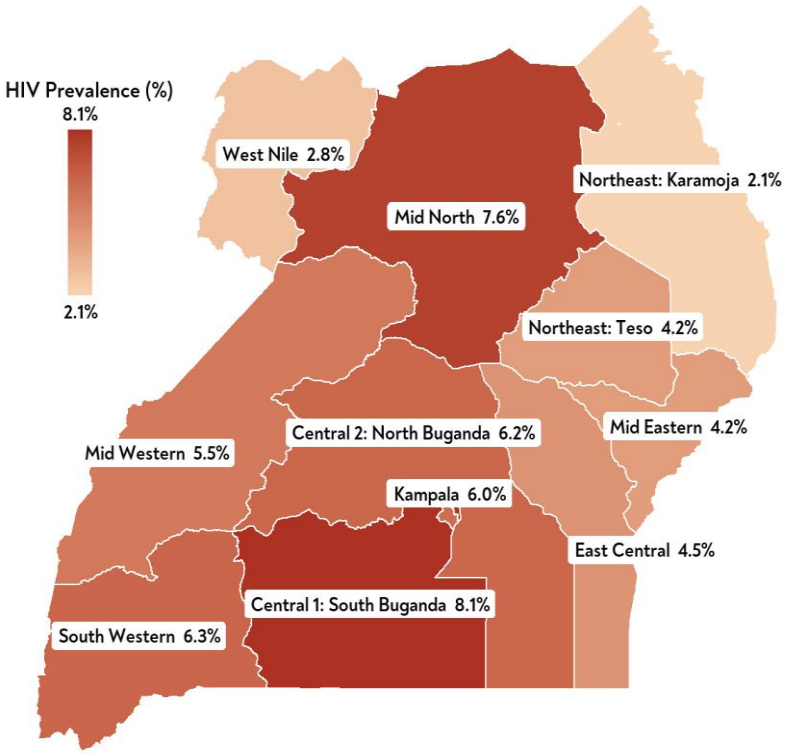
Rationale for the Study

The study results were anticipated to guide Ministry of Health and its partners to review the HIV guidelines; to effectively control and manage LLV in Uganda

Research Objectives

- To determine the association between low-level viraemia and viral non-suppression among PLHIV on ART from 2016 to 2020 in Uganda (Sub-study One).
- To explore the perceptions of low-level viraemia among PLHIV on ART and healthcare providers in Uganda (Sub-study Two).
- To determine the effectiveness of intensive adherence counselling in achieving a non-detectable viral load in the management of LLV among PLHIV on ART in Uganda (Sub-study Three).

Methods: Study Setting



- Study conducted in Uganda, with a population over 42 million people, as of July 2022 (UBOS, 2022)
- Prevalence of HIV among adults aged 15 to 49 years in Uganda is 6.7%
- 1.4 million people having HIV/AIDS, and about 1.2 million people were on ART by 2019 (UNAIDS, 2019).
- The viral suppression rate for 2022 was 93.7%, (Uganda Viral Load Dashboard, 2022).

Objective One

Paper II

PLOS ONE

RESEARCH ARTICLE

The association between low-level viraemia and subsequent viral non-suppression among people living with HIV/AIDS on antiretroviral therapy in Uganda

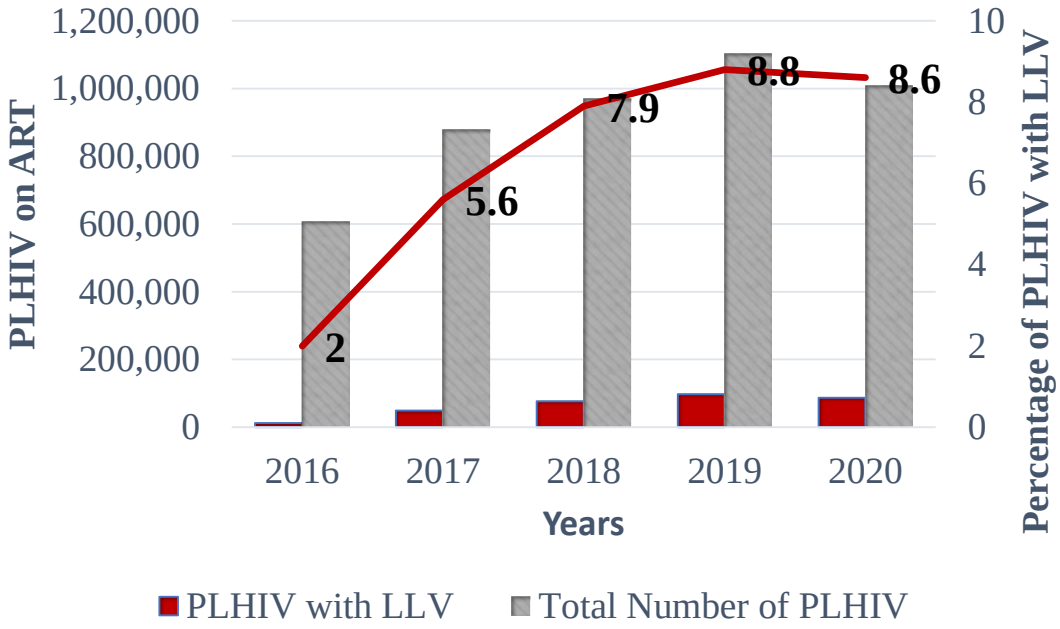
Nicholus Nanyeenya[1,2]*, Larry William Chang[3], Noah Kiwanuka[1], Esther Nasuuna[4], Damalie Nakanjako[5], Gertrude Nakigozi[6], Simon P. S. Kibira[7], Susan Nabadda[2], Charles Kiyaga[2], Fredrick Makumbi[1]

Methods: Determining the association between low-level viraemia and viral non-suppression among PLHIV on ART from 2016 to 2020 in Uganda.

Study Design	Study Population	Data Collection	Analysis	Outcomes
Retrospective cohort study	PLHIV on ART with a suppressed VL (<1,000 copies/ml) done between January 2016 and December 2016 using plasma samples	National VL program data from 2016 to 2020 used	▪ Participants characteristics summarized by descriptive statistics ▪ Multivariate logistic regression was used to determine the factors associated with LLV. ▪ Survival analysis methods namely Kaplan Meier and Cox Proportional-Hazards models used to determine the association between LLV and non-suppression. ▪ Multiple imputation used for missing data	▪ Proportions of PLHIV with VL non-suppression among the exposed and unexposed groups ▪ Time-to-non-suppression. ▪ Hazard ratios for non-suppression

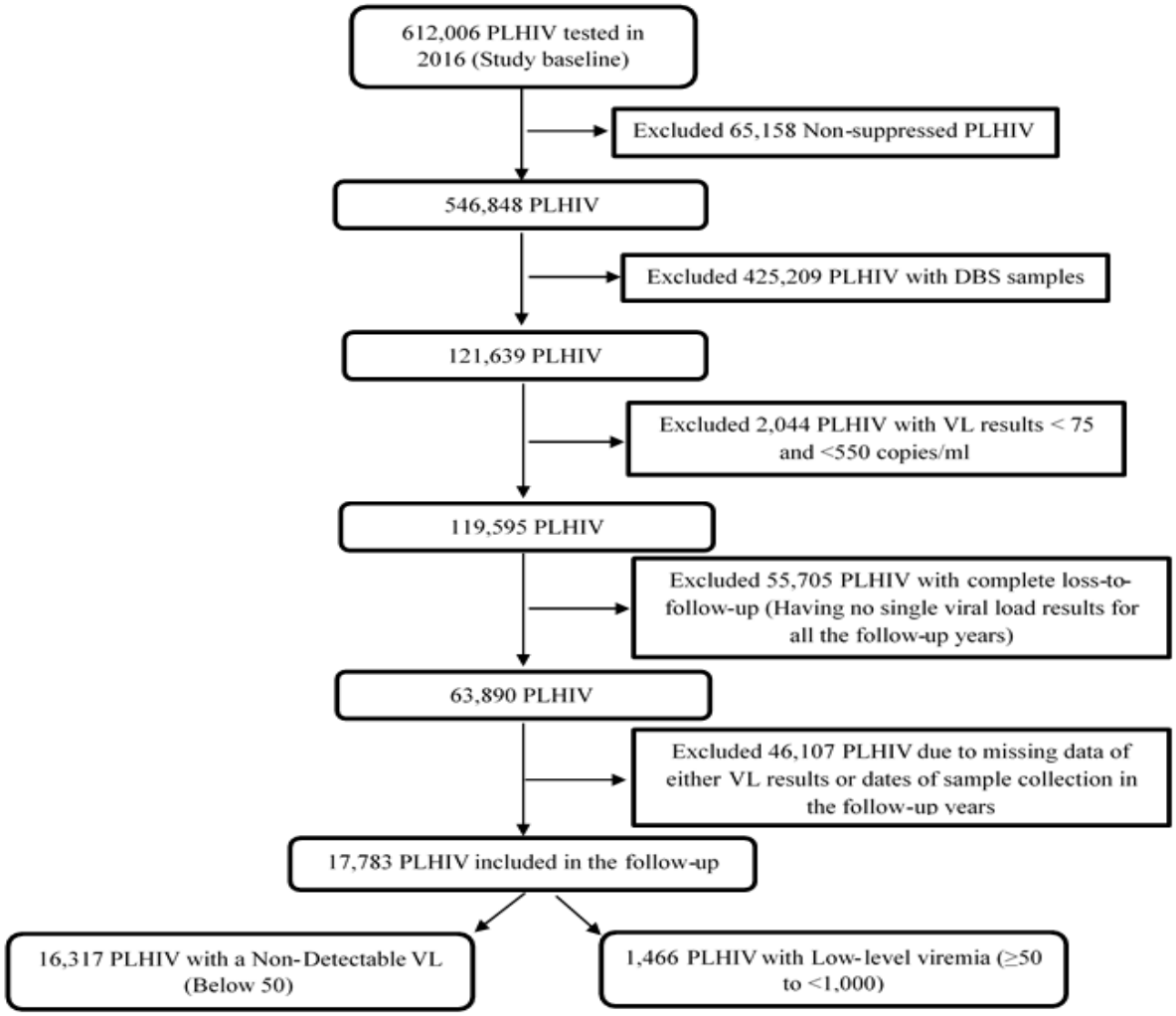
Prevalence of LLV from 2016 to 2020

There were increasing proportions of PLHIV with LLV from 2.0% in 2016 to 8.6% in 2020 (p-value = 0.072)



Graph showing the trend of low-level viraemia from 2016 to 2020

A cohort of 17,783 PLHIV was followed from 2016 to 2020



Study Cohort Characteristics and Factors Associated with LLV

- A cohort of 17,783 PLHIV was followed from 2016 to 2020, of which 1,466 (8.2%) had LLV
- Men had 1.3 times the risk of having LLV, as compared to women (p value < 0.001).
- PLHIV on 2nd line ART had 2.5 times the risk of having LLV, as compared to PLHIV on 1st line ART (p < 0.0001).
- Children had 3.1 times the risk of having LLV, as compared to adults (p value < 0.001).

Characteristics of the Study Cohort	n	%
Age		
<18 years	3,399	19.1
≥18 years	14,242	80.1
Missing	142	0.8
Gender		
Female	11,765	66.2
Male	5,765	32.4
Missing	253	1.4
Level of viraemia (copies/ml)		
Non-Detectable (Below 50)	16,317	91.8
Low-level viremia (≥50 to <1,000)	1,466	8.2
50 to 199	836	57.0
200 to 399	288	19.6
400 to 599	129	8.8
600 to 999	213	14.6
ART regimen		
First line regimen	15,741	88.5
Second line regimen	1,710	9.6
Other regimen	53	0.3
Missing	279	1.6
Mean Age (SD), years	33.8 (15.2)	
Mean Duration on ART (SD), years	5.0 (3.3)	

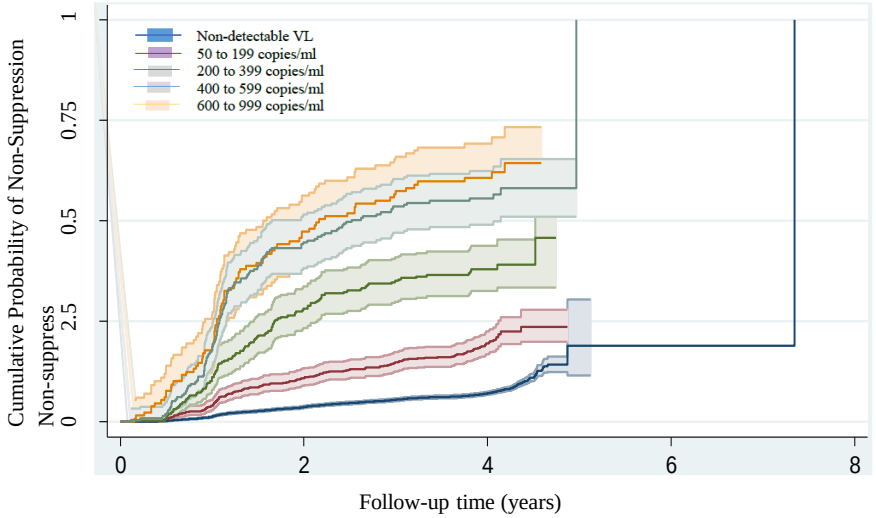
PLHIV with LLV had 4.1 times the hazard rate of developing viral non-suppression, as compared to PLHIV with a non-detectable VL

- The median follow-up time was 4.0 years (IQR 3.8 – 4.2), with a cumulative 67,931.8 (67739.8, 68123.9) person-years of follow-up.
- Nearly 1 in 10 PLHIV (9.7%, 1,730/17,7839) became non-suppressed during the follow-up period
- 32.5% (476/1,466) of the PLHIV with LLV became non-suppressed, as compared to 7.7% (1,254/16,317) of the PLHIV with a non-detectable VL (p value < 0.001).
- PLHIV with LLV had 4.1 times the hazard rate of developing viral non-suppression, as compared to PLHIV with a non-detectable VL (p < 0.001).

PLHIV with LLV (≥50 to <1,000) had increased hazards of Non-suppression, compared to PLHIV with a non-detectable VL (<50)

- The Kaplan-Meier:- PLHIV with LLV had increased probability of non-suppression at any given time, compared to PLHIV with a non-detectable VL and this increased with increasing ranges of viraemia.

- The log-rank test:- There was a significant difference in the probability of non-suppression at any time point between PLHIV with LLV and PLHIV with a non-detectable VL (p value < 0.001).



Number at risk

Non-detectable VL	16308	15710	7871	1	0
50 to 199 copies/ml	836	745	308	0	0
200 to 399 copies/ml	288	207	79	0	0
400 to 599 copies/ml	129	68	28	0	0
600 to 999 copies/ml	213	118	52	0	0

Kaplan-Meier estimator showing the association between LLV and viral non-suppression

Study I Conclusions

- Increasing PLHIV with LLV from 2.0% in 2016 to 8.6% in 2020
- PLHIV with LLV had 4.1 times the hazard rate of developing viral non-suppression, as compared to PLHIV with a non-detectable VL
- LLV was associated with male sex, second line regimen and lower age

Study I Recommendations

- **Ministry Of Health and its partners**
  - ❖ There was an urgent need to review the VL testing algorithm:- **The VL suppression threshold has been reduced from 1,000 to 200 and 400 copies/ml for plasma and dried blood spot samples respectively**

- **World Health Organization**
  - ❖ Review the recommendation of using 1,000 copies/ml to determine viral non-suppression in Sub-Sahara Africa

Objective Two

Paper III

PLOS GLOBAL PUBLIC HEALTH

RESEARCH ARTICLE

Hopes, joys and fears: Meaning and perceptions of viral load testing and low-level viraemia among people on antiretroviral therapy in Uganda: A qualitative study

Nicholus Nanyeenya[1,2*], Godfrey Siu[3], Noah Kiwanuka[1], Fredrick Makumbi[1], Esther Nasuuna[4], Damalie Nakanjako[5], Gertrude Nakigozi[6], Susan Nabadda[2], Charles Kiyaga[2], Simon P. S. Kibira[7]

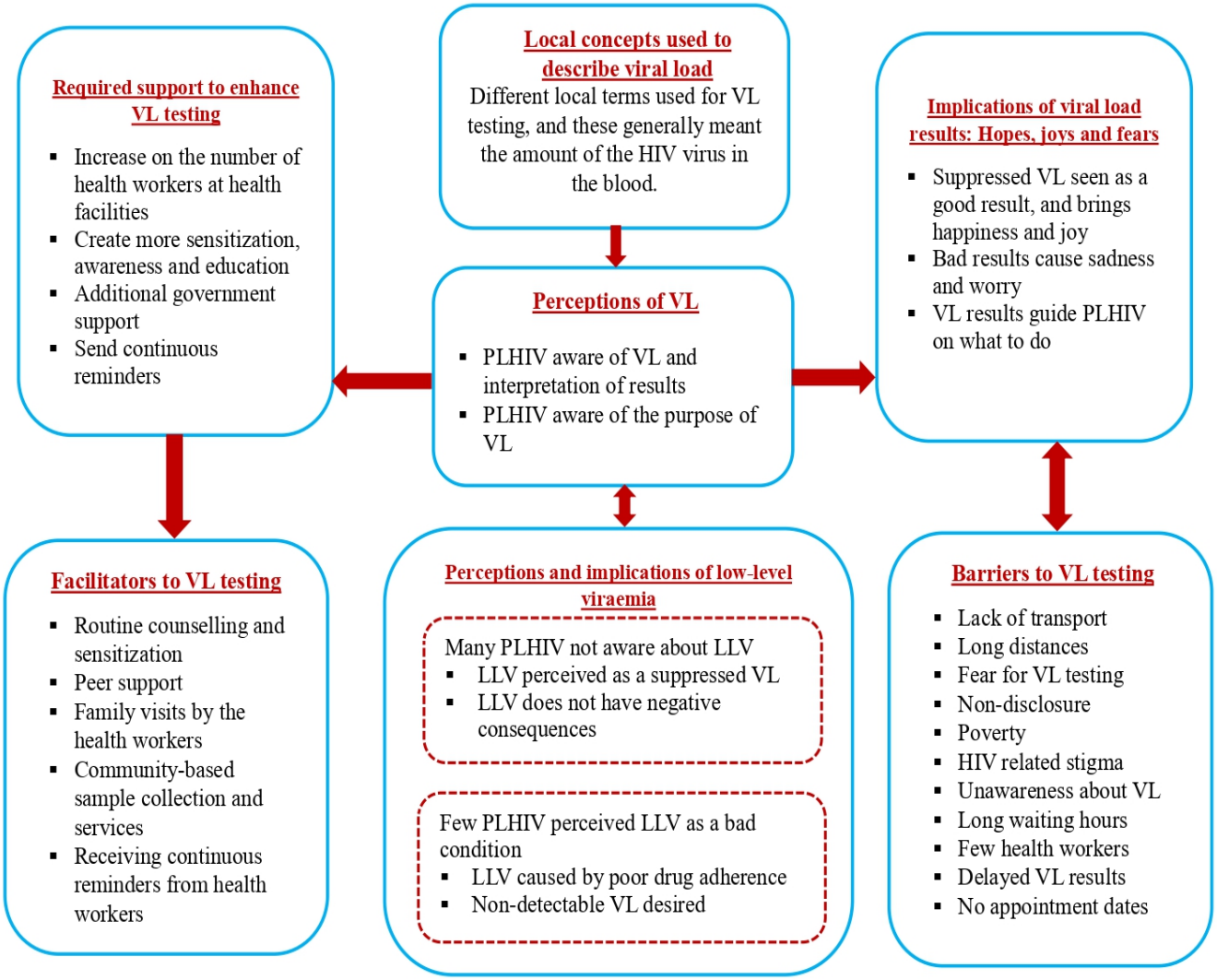
Methods: Exploring the perceptions of low-level viraemia among PLHIV on ART and healthcare providers in Uganda.

Study Design	Study Population	Data Collection	Analysis	Outcomes
Qualitative narrative study using the Health Belief Model	- PLHIV on ART for 6 months or more, 18 years and above, & able to speak either of; English, Luganda, Runyankore, Ateso or Acholi. - Healthcare workers providing HIV	▪ 32 IDIs with PLHIV ▪ 15 KIIs with healthcare workers ▪ Data collected from 8 high volume facilities with high number of PLHIV with LLV	Thematic analysis used, with the help of ATLAS.ti version 6.0 software to code and organise the data	▪ Perceptions of PLHIV and healthcare workers about LLV ▪ Meaning of LLV and VL among PLHIV ▪ Understanding of LLV and VL among healthcare workers

Study II Results: Participant Characteristics for the IDIs

Characteristics	(n = 32)
Mean Age (SD), years	38.4 (13.8)
Gender	
Female n (%)	17 (53.1)
Male n (%)	15 (46.9)
Mean Duration on ART (SD), years	5.0 (3.3)
ART regimen	
TDF/3TC/DTG n (%)	30 (93.8)
ABC/3TC/DTG n (%)	1 (3.1)
AZT/3TC/DTG n (%)	1 (3.1)
Level of viraemia	
Non-Detectable (Below 50) n (%)	28 (87.5)
Low-level viremia (≥50 to <1,000) n (%)	4 (12.5)
Marital Status	
Married n (%)	18 (56.2)
Single n (%)	11 (34.4)
Widowed n (%)	3 (9.4)
Education Level	
No education n (%)	2 (6.3)
Primary n (%)	12 (37.5)
O' Level n (%)	15 (46.8)
Tertiary n (%)	3 (9.4)
Occupation	
Peasant n (%)	19 (59.4)
Student n (%)	2 (6.3)
Other n (%)	8 (25.0)
Unemployed n (%)	3 (9.3)

Main themes identified from the IDIs



Meaning of LLV among PLHIV

- Most PLHIV were not aware of the term, 'low-level viraemia.'

- However many PLHIV with no or primary education perceived and interpreted a VL between 50 to 999 copies/ml as a decreased and suppressed VL, which they considered to be good and the goal of ART.

- These PLHIV did not consider this VL range to be harmful.
  - ❖ *"With low-level viraemia, one can go to the garden and do farming very well. However, if your VL is non-suppressed, you can go to the garden and your head will be spinning and therefore, you cannot do work because your body is too weak but if its lower, you can do everything, come back home from the garden, eat your food and if you want to return to the garden in the afternoon, you can still do, return home after because you are strong."*

  - ❖ *"If you achieve low-level viraemia, there will be a lot of joy and thanking God Almighty very much. After realizing that, you don't have to start worrying or doing other things but you have to keep your life very well as you ought to."*

Meaning of LLV among PLHIV (Continued…,)

- PLHIV with no or primary education believed they had already developed LLV. Maintaining LLV was reported as a motivation for taking ART

  - *"If the VL copies are low and you follow the advice of the healthcare giver, it means that the VL copies will keep reducing and will not rise up again. For example; when we just received the drugs recently, I had to make sure to keep taking those drugs so that the strength of virus is reduced completely."*

- A few PLHIV with secondary and tertiary education indicated that a VL between 50 to 999 copies/ml is not good, and caused by not taking drugs. They said that they desired to always have a non-detectable VL

  - *"Yeah, I have heard about that because I have also experienced it. When I was still in school, I was hiding my drugs and most times I would miss, and when they would do the VL test, I would have some copies like 50, 80, or 100. Yeah. So I know that when some copies are detected, it means that the adherence, it's not really good to what is expected of us, maybe we are missing out on our drugs, maybe we are taking them at the wrong time now and again and that makes us get some copies of the virus detected in blood."*

Meaning of VL testing among PLHIV

- PLHIV were aware of the term 'Viral load', and different local terms used to describe VL;
  - 'Obungi bwa akawuuka mu musaayi', which means the amount of the virus in the blood - Central
  - 'Etiai lo ekurut kotoma akuwan', meaning the amount of the virus in the body - Eastern
  - 'Pimo dwong onyo nok pa kwidi twojonyo iremo' meaning the number of virus - Northern

- PLHIV described the biomedical value of VL and related it to the numbers and counts of things in their bodies, that is, the amount of disease or copies of the virus in the body.

  - *'Viral load is when some substances or blood samples are taken from you for testing and later, the machines will produce the test results. The health care provider is able to explain to you the amount of the virus in your blood. That is what viral load testing is."*

Understanding the purpose of VL testing

- The purpose of VL was described in terms of four main categories including;
  a) the ability of a VL test to show the amount of HIV in the body

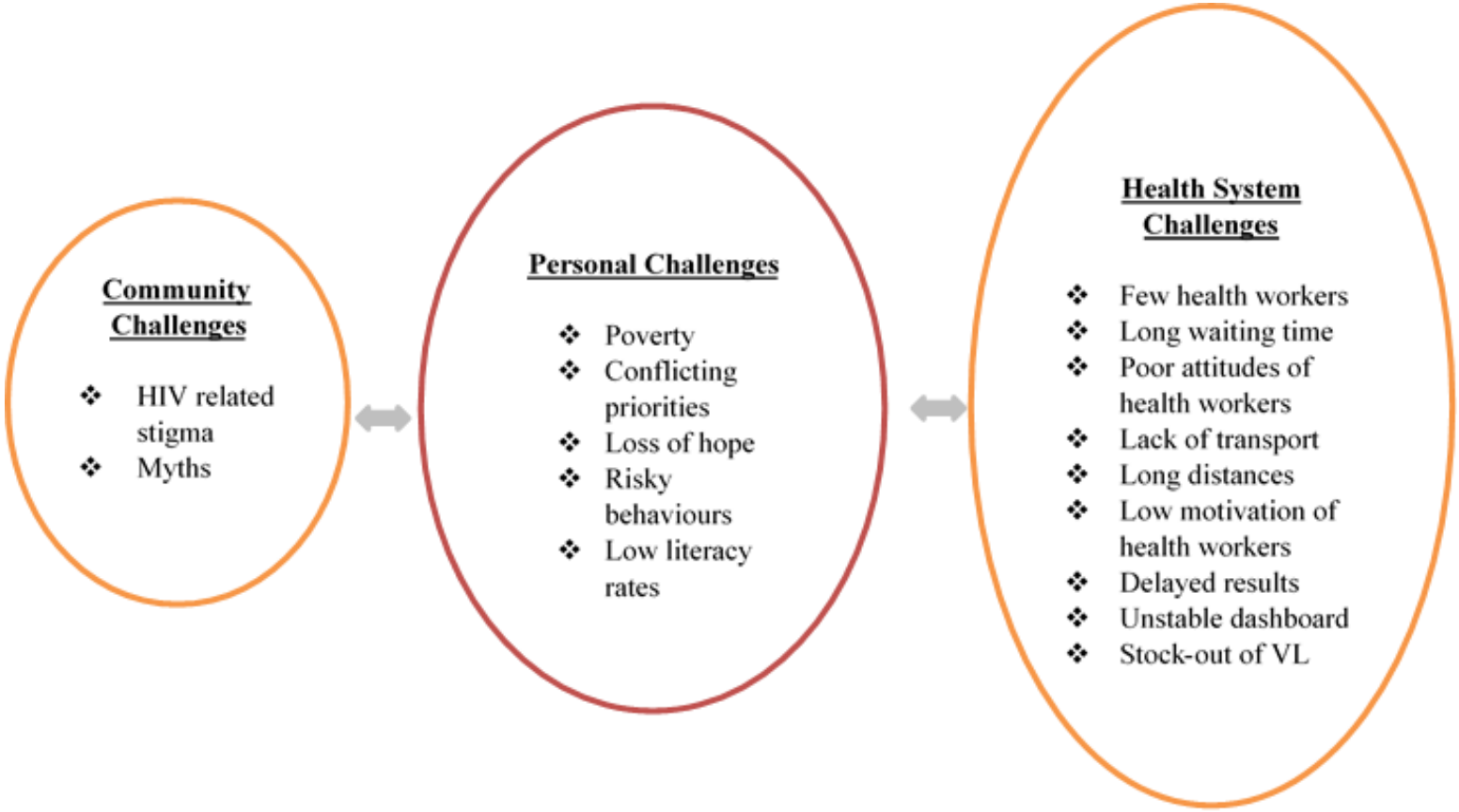
  a) how the patient is taking his/her drugs

  a) whether the drugs are working very well or not

  a) guide the next treatments steps for the patient.

  ❖ *"We were told, VL testing is how health workers are able to know the amount of the virus in your body after starting treatment and it is also how they are supposed to know if the medicine you are taking is really doing well for you or not? That is what actually they always tell us and why they remove our VL so that they see whether to continue with the same drugs, or they change to see, that the virus becomes suppressed."*

Barriers to VL testing



"There are those times when one knows that he/she is due for viral load testing appointment, and may be one fails to come at the facility for testing due to lack of transport especially like us women who are taking care of ourselves and also taking care of our big families."

Facilitators to VL testing

- Increase on the number of health workers at health facilities
- Create more sensitization, awareness and education

"The number of healthcare providers should be increased so that all these people can easily be worked on quickly before they get exhausted of waiting and go back home without being tested."

- Additional government support
- Send continuous reminders

"I wanted to request that let the government see how to help us as people who are living with HIV because we don't have any support. But let the government help us in any way possible and that is what I wanted to say to you. Help us and deliver our report to the government for some support because if you follow it closely, the government seems to have forgotten us."

Understanding of LLV among Healthcare Workers

- Nearly all the healthcare workers could not define the term 'Low-level viraemia'. Many interpreted it as having a suppressed VL.

❖ *For me the way I understand it, is like when an HIV positive patient is having viral load less than 1000 copies, sometimes we normally say that this person is suppressed, and that is how I can say it. You are having a viral load which is equivalent to or below 1000 copies of the virus which we normally say it is suppressed. (26 years old male clinician from Northern region)*

- When LLV was described as a range of viraemia between 50 to 999 copies/ml , many health workers reported that this range of viraemia was caused by sub-optimal drug adherence among PLHIV.

❖ *From your explanation, I am not comfortable with my patient having low-level viraemia. If they are properly adhering to the drugs, then their viral load test results would come back undetectable or at least less than 50 viral copies per micro litre of blood. (41 years old male counsellor from Eastern region)*

Perceptions of LLV among Healthcare Workers

- Health workers indicated that PLHIV with LLV had increased risk of viral non-suppression and HIV transmission.

❖ *Yes, low-level viraemia is an issue because first of all our goal is to have zero copies from our viral load tests. If there are copies, that means there is a problem and it is somewhere with adherence. The presence of copies increases risk of HIV transmission and worse more if not managed early enough, the patient could backslide into non-suppressed which we don't want. (43 years old male clinician from Central region)*

- They reported that they were occasionally doing supplementary counselling to PLHIV with LLV to improve their drug adherence and manage the LLV. However, they reported that this counselling was informal and unstructured, being offered to PLHIV at will.

❖ *In fact in most cases, when the results come when the viral copies are above 50, we talk to such a patient. We counsel them to change whatever they are not doing right to make changes. In most cases the person taking the pills knows where the issue is. (36 years old male counsellor from Northern Uganda)*

Study II Conclusions

- Many PLHIV were unaware about LLV, and did not understand its risks

- Healthcare workers did not fully understand LLV and its implications

Study II Recommendations

- **Ministry Of Health and its partners**
  - ❖ Sensitize health workers and PLHIV about LLV and its risks
  - ❖ Create strategies to reduce HIV related stigma, and improve turnaround time for viral load results

- **World Health Organization**
  - ❖ Design strategies to guide countries to create awareness for LLV

Objective Three

Paper IV

HIV MEDICINE | BHIVA British HIV Association

ORIGINAL ARTICLE

Effectiveness of intensive adherence counselling in achieving an undetectable viral load among people on antiretroviral therapy with low-level viraemia in Uganda

Nicholus Nanyeenya, Damalie Nakanjako, Fredrick Makumbi, Gertrude Nakigozi, Fred Nalugoda, Godfrey Kigozi, Esther Nasuuna, Simon P. S. Kibira, Susan Nabadda, Charles Kiyaga, Mutyaba Huzaifah, Noah Kiwanuka ... See fewer authors

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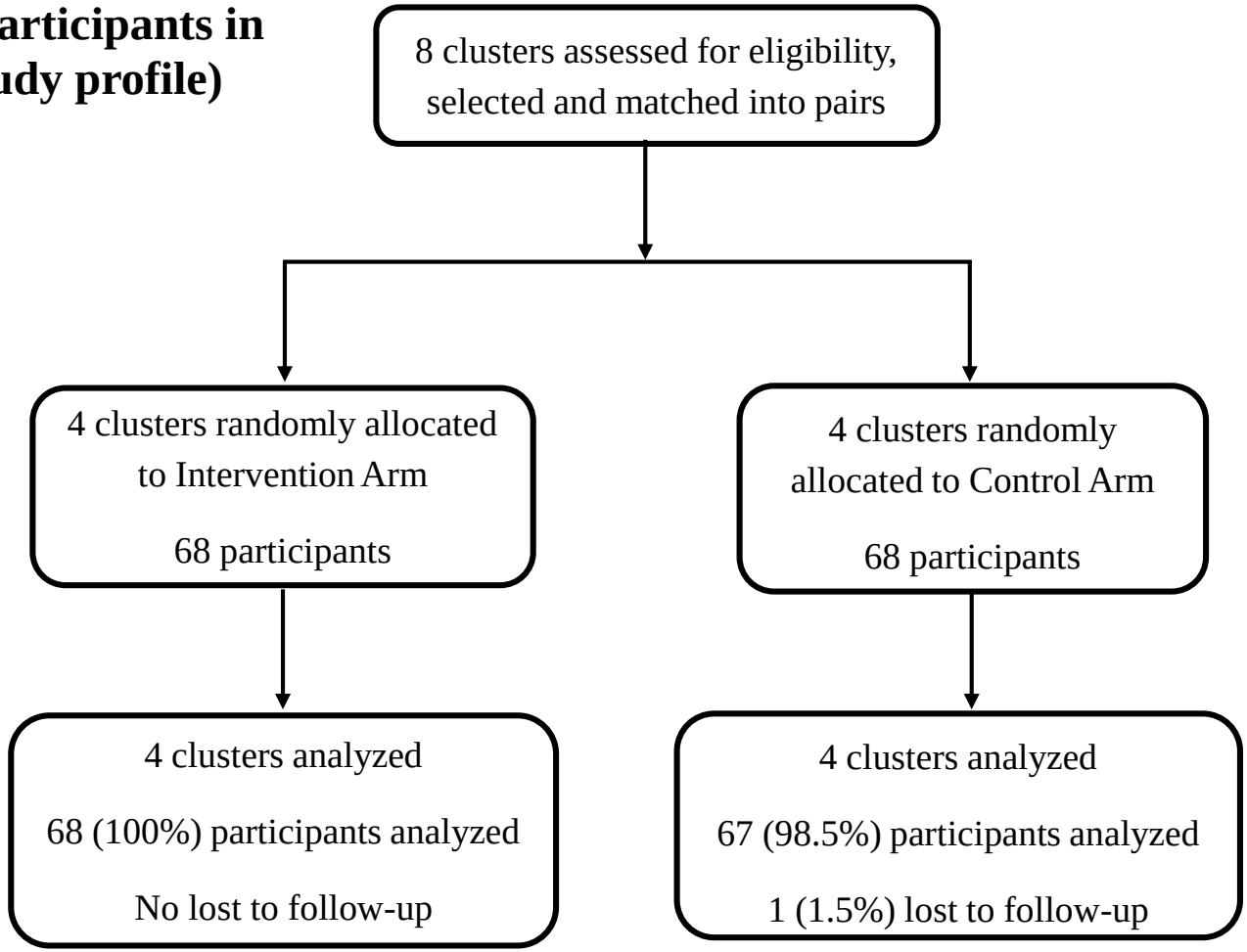
Methods: Determining the effectiveness of intensive adherence counselling in achieving a non-detectable viral load in the management of LLV among PLHIV on ART in Uganda.

Study Design	Study Population	Data Collection	Analysis	Outcomes
Cluster-randomized clinical trial	PLHIV on ART who had recent VL results with LLV (tested from July 2022 to October 2022)	▪ 8 HIV clinics matched using the Goldilocks approach, followed by randomization. ▪ Each cluster had 17 participants, (136) ▪ Intervention clusters had 3 IAC sessions, and Control clusters had standard of care ▪ VL was repeated after 3 months of the study	▪ Participants characteristics summarized by descriptive statistics ▪ Bivariate analysis and Modified Poisson ▪ Cox PH regression model used	▪ Proportions of PLHIV with LLV achieving a non-detectable VL (VL < 50 copies/ml) in both groups ▪ Risk ratios ▪ Hazard ratios

Results: Effectiveness of Intensive Adherence Counselling in Achieving a Non-detectable VL among PLHIV on ART with LLV

Flow of the participants in the study (Study profile)



Characteristics of the Study Participants According to the Randomization Arm

Characteristics	Intervention Arm (n = 68)	Comparison non-intervention arm (n = 68)
Mean Age (SD), years	43.4 (11.5)	43.2 (12.5)
Gender, n (%)		
Female	41 (60.3)	36 (53.0)
Male	27 (39.7)	32 (47.0)
Mean Duration on ART (SD), years	7.1 (4.6)	7.2 (4.7)
Marital Status, n (%)		
Married	41 (60.3)	38 (55.8)
Single	6 (8.8)	5 (7.4)
Divorced	11 (16.2)	14 (20.6)
Widowed	10 (14.7)	11 (16.2)
Mean Level of viraemia (SD), copies/ml	139.1 (124.0)	166.3 (172.5)
Education Level, n (%)		
No education	8 (11.8)	7 (10.3)
Primary	48 (70.6)	35 (51.5)
Secondary	10 (14.7)	18 (26.5)
Tertiary	2 (2.9)	8 (11.7)
ART regimen, n (%)		
First line regimen	66 (97.1)	68 (100.0)
Second line regimen	2 (2.9)	0 (0.0)

Participant Retention

- The average follow-up time for PLHIV in the intervention arm was 3.7 months (SD – 0.2)
- 100% of the participants (68/68) completed all the 3 sessions of the IAC and did a repeat VL
- The average follow-up time in the comparison non-intervention arm was 3.5 months (SD – 0.1)
- 98.5% of the participants (67/68) did a repeat VL test in the comparison non-intervention arm.
- A total of 59 PLHIV (43.7%) out of 135 PLHIV achieved a non-detectable VL during the study follow-up period.

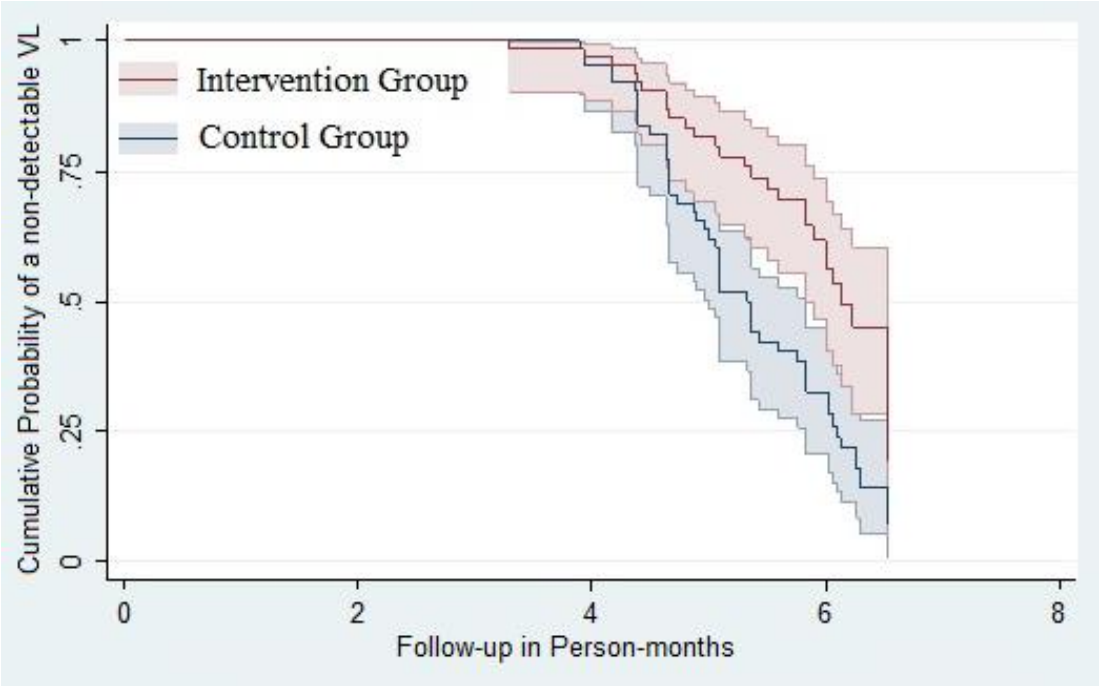
PLHIV offered IAC were 1.9 times more likely to achieve a non-detectable VL, as compared to PLHIV in the Control arm

- The effect of IAC on attaining a non-detectable VL was nearly twice as high in the intervention arm (57.4%, 39/68), as compared to the non-intervention arm (29.9%, 20/67), adj. RR = 1.9 (1.0, 3.5), p = 0.037.

	Adjusted RR (95% CI)	p value
Comparison non-intervention arm	1 (Reference)	
Intervention Arm (IAC Arm)	1.9 (1.0 – 3.5)	0.037
Age	1.0 (0.9 – 1.0)	0.943
Sex: Male	0.9 (0.8 – 1.2)	0.668
Marital Status (Married)	1 (Reference)	
Single	1.5 (0.7 – 3.3)	0.336
Divorced	1.2 (0.8 – 1.6)	0.330
Widowed	0.7 (0.3 – 1.6)	0.409
Duration on ART	1.0 (1.0 – 1.1)	0.025

PLHIV offered IAC had 3.2 times the hazard rate of achieving a non-detectable VL, as compared to PLHIV in the Control arm

- PLHIV in the intervention arm had 3.2 times the hazard rate of achieving a non-detectable VL, as compared to PLHIV in the comparison non-intervention arm (adjusted hazard ratio was 3.2, 95% CI: 1.3 to 7.8, p = 0.010),



Study III Conclusions

- IAC doubled the likelihood of achieving a non-detectable VL among PLHIV with LLV

- Giving an incentive like a transport refund improved retention of PLHIV in IAC sessions

Study III Recommendations

- **Ministry Of Health and its partners**
  - ❖ Need to institute IAC as an intervention to manage PLHIV with LLV:- **IAC has been instituted to manage PLHIV with LLV**
  - ❖ Urgent need to conduct other implementation science studies to design effective and sustainable interventions to manage PLHIV with LLV, in addition to the use of IAC

- **World Health Organization**
  - ❖ Give elaborate and clear guidance about the use of IAC to manage PLHIV with LLV

Study Strengths and Limitations

Strengths

- First multi-methods study looking at LLV in Uganda
- Accessed data from the national VL program from 2016 to 2020
- Experienced team of mentors from MakCHS, MOH, JHU, and RHSP including Epidemiologists, Biostatisticians, Clinicians and Policy makers who guided the research

Limitations

- Lack of data for HIV drug resistance testing in Study I
- Measurement bias for Study I
- Data missingness of 72% in Study I
- Social desirability bias in Study II
- Missing out HIV drug resistance testing in Study III

Policy implications from the study

- Reduction of the VL suppression threshold is key in reduction of PLHIV with LLV
- Sensitization of PLHIV about LLV and its related risks is key in management of LLV
- Education of healthcare workers about LLV is important in addressing LLV
- Institution of IAC in management of LLV
- Need to use VL testing platforms with lower limits of detection

Implications for future research

- Research to determine the prevalence of HIV drug resistance among PLHIV with LLV
- Follow-up studies to understand the cause of LLV among PLHIV who fail to achieve a non-detectable VL following IAC
- Interventional studies to improve the effectiveness of IAC in management of LLV
- Implementation science studies to design other cost-effective interventions to manage PLHIV with LLV

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Thank You