

1 **Are you suppressed? Viral load test coverage for people living with** 2 **HIV in Mutare District, Manicaland Province, Zimbabwe, 2015-2017**

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Abstract

Background: The third 90-90-90 UNAIDS goal require that 90% of people living with HIV (PLHIV) on antiretroviral treatment (ART) achieve viral load (VL) suppression. This study assessed the proportion of VL suppression and related factors among PLHIV on 1st and 2nd line ART in Mutare District, Manicaland Province, Zimbabwe between 2015-2017.

Methods: A retrospective study using routine HIV programme data from the electronic monitoring system for nine health facilities in Mutare District. VL suppression was defined as < 1,000 copies/ml.

Results: Of 16,590 registered patients, 15,566(94%) were on first-line and 1024(6%) on second-line ART. Of those on 1st-line ART, 2856(18%) had a VL test result documented, while 367(36%) of 2nd-line ART patients had VL results. VL suppression rates were 86% among those on 1st-line and 45% in 2nd-line ART. Independent risk factors associated with VL non-suppression for those on 1st-line ART were age 0-9 years (adjusted relative risk, aRR=2.9; 95% confidence interval, CI=1.7-4.8;P<0.001), 10-19 years (aRR=2.2;95%CI=1.4-3.2,P<0.001) compared to those 20-49 years, concurrent TB (aRR=9; CI=3.0-29.7,P<0.001) and male gender (aRR=1.5,95%CI=1.1-2.1;P=0.02). There were no significant risk factors associated with VL non-suppression for 2nd-line ART patients.

Conclusion: For PLHIV on 1st-line ART in Mutare district, Manicaland, Zimbabwe, the frequency of reported VL results were only 18% among those on 1st-line ART, while the rate of VL suppression was near 90%. Viral Load testing coverage appears to be lagging behind current Zimbabwe goals and increased support is needed to improve the quality of HIV care and help reduce the threat of possible HIV drug resistance in the future.

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48 **Introduction**

49 In December 2013, the Joint United Nations Programme on HIV/AIDS (UNAIDS) proposed ambitious new
50 targets for HIV treatment scale-up beyond 2015. The new “90-90-90” goals for 2020 included 90% of all people
51 living with HIV (PLHIV) know their HIV status, 90% diagnosed with HIV infection receive sustained
52 antiretroviral therapy (ART) and 90% receiving ART will have durable viral load suppression.(1) UNAIDS data
53 from 168 countries reveal progress and gaps across the HIV testing and treatment cascade with approximately
54 82% of those on treatment virally suppressed. Fully achieving the “90-90-90” targets translates to 73% of PLHIV
55 virally suppressed; so far 7 countries including Botswana have already achieved or exceeded this target.(2)

56

57 In Zimbabwe, HIV prevalence has declined from 18% in 2009 to 14% in 2015(3) and there are an estimated 1.2
58 million PLHIV, with almost one million currently on ART. However, there remain challenges to achieving the
59 projected 90-90-90 UNAIDS goals. In response, the Zimbabwe Ministry of Health and Child Care (MOHCC) has
60 adopted viral load (VL) as the standard for ART monitoring, aiming to provide testing services to at least 90% of
61 PLHIV receiving ART by 2018. To facilitate the national rollout, the Viral Load Scale Up Plan 2015-2018 was
62 developed to assist in accelerating the scaling up of the VL testing through defined national testing targets and
63 timeframes for achieving those targets.(4)

64

65 Manicaland province started rolling out VL monitoring in 2015 with support from partners. Currently all the seven
66 districts within Manicaland are offering VL testing at selected high volume sites. Since 2015, Mutare Provincial
67 Hospital (MPH) has been providing VL testing to all sites in the province. To date, no studies have been done in
68 Manicaland to determine factors associated with non-suppression of VL.

69 Factors associated with VL non-suppression in other countries of sub-Saharan Africa (SSA) have included
70 children and adolescents, not adhering to treatment, active TB, male gender, Who stage 4 and lower CD4 at ART
71 initiation, while being on 2nd or 3rd line ART regimens were protective against non-suppression.(5)(6)(7)(8)

72 According to the Zimbabwe Population Based HIV Impact Assessment Survey 2015-2016 (ZIMPHIA), viral load
73 suppression among adult HIV patients (15-64 years) on ART in Zimbabwe was 86.5%, however for Manicaland it
74 was 61.5% for both PLHIV on ART and those not ART, the viral load suppression rates and non suppression for
75 those on ART in the province was unknown.(9) Thus the aim of this study was to determine the proportion with
76 non viral load suppression and related factors among PLHIV on 1st and 2nd line ART in Mutare District,
77 Manicaland Province, Zimbabwe between 2015-2017.

78 **Materials and methods**

79 **Design:** This was a retrospective study utilizing previously collected routine programmatic data from 2015-
80 2017.

81 **Setting:** Zimbabwe is a low income country in southern Africa with a high burden of HIV. The estimated
82 population of Zimbabwe is 16 million and healthcare is largely provided free of cost by MOHCC supported
83 facilities countrywide. Healthcare access remains a challenge, especially in rural areas, with a low physician and
84 nurse to patient ratio of 1.6/10,000 and 7.2/10,000, respectively.(10) Despite healthcare access difficulties, with
85 the support of multiple partners over the last decade, the cost of diagnosis and treatment with ART has been
86 essentially cost free to everyone.

87 Mutare District is one of the seven districts in Manicaland province which is in south eastern Zimbabwe, with the
88 provincial capital city, Mutare. The district (both urban and rural) has a population of 450,000.(11) All MOHCC
89 facilities provide HIV care based upon the current Zimbabwe HIV guidelines which are consistent with the WHO
90 2015 recommendations.(12)

91 **Specific Setting:** There are 53 health facilities in Mutare district of which 48 of these are offering routine
92 viral load testing. Ten of these sites, which are high volume, are supported by Médecins Sans Frontières
93 (MSF).(13) The sites started targeted VL testing in September 2015 and by August 2016 routine VL testing was
94 being done in 48 health facilities. For the ten high volume sites, HIV patient level data is captured in the MOHCC
95 supported Electronic Patient Monitoring System (EPMS).

96 VL suppression is defined as having a VL of <1000 copies/ml of blood while non suppression is having a VL of
97 >1000 copies/ml of blood. It is recommended that the first viral load test be taken at 6 months after ART
98 initiation, 12 months and yearly. If non suppressed Extended Adherence Counselling (EAC) is done and a repeat
99 test is done after 3 months, if it remains unsuppressed the patient is switched to second line ART according to the
100 national guidelines.(14)

101 All VL tests for Manicaland and Masvingo Provinces are completed at MPH laboratory on a single MSF-
102 supported VL platform. In 2017, MPH ran approximately 21,000 VL tests for both provinces. VL samples are
103 transported from facilities outside of MPH by either whole blood, plasma (if centrifuge is available) in EDTA
104 tubes requiring a cold-chain or by dried blood spot. VL sample transportation is specifically supported by
105 collaborating partners including USAID and the Global Fund. The MPH reported sample rejection rate was
106 approximately 2-3% in 2017. All MPH VL results are entered into the BIKA Laboratory Management Information
107 System (LMIS).

108 **Study Participants:** The study population included all PLHIV in 9 HFs within Mutare District during the
109 period from 2015-2017 who have been on either 1st line or 2nd line ART for at least 6 months. For ART patients
110 with multiple VL tests, the most recent result was considered for analysis.

111 **Data Variables:** Data from nine health facilities (HFs) within Mutare District was extracted from the EPMS
112 database into Excel (Microsoft, Redmond, WA, USA). Data variables included anonymised patient demographic

and clinical characteristics, including viral load results.

Statistical analysis: Data variables were imported into EpiData Analysis software (*v2.2.2.182, EpiData Association, Odense, Denmark*) analysed and presented in frequencies for categorical data and continuous variables were categorised for further analysis. Proportion with/without viral load suppression was presented with 95% confidence intervals (CIs). Factors associated with non-suppression of viral load were assessed using chi-square test at bivariate level and log-binomial regression at multivariate level (using Stata/SE 14.1, *StataCorp, College Station, TX, USA*). Only variables significant at bivariate level and those which improved the fit of the models to the data were included in the final models. Relative Risks (RRs) were used to calculate the measures of association, and presented with their 95% CIs. Levels of significance were set at $\leq 5\%$.

Ethics

The study was reviewed and approved by the Medical Research Council of Zimbabwe (Harare, Zimbabwe) and the International Union Against Tuberculosis and Lung Disease Ethics Advisory Group (Paris, France). Permission was granted by the Zimbabwe Ministry of Health and Child Care (Harare, Zimbabwe). There was no need for informed consent as we utilized anonymized data.

Results

There were 16590 patients registered within the 9 Mutare District health facilities between January 2015 – December 2017, of whom 15,566 (94%) were on first line and 1,024 (6%) on second line ART regimens. Of those on 1st line ART, 2856(18%) had a VL test results documented, while 367(36%) of 2nd line ART patients had VL results, see (**Fig 1**). Those patients on 2nd line therapy were significantly younger compared with those on a 1st line regimen (38 years (interquartile range, IQR: 19-48) vs 43 years (IQR 35-50), $P<0.001$), more likely to be female (55% vs 33%, $P<0.001$) and single (30% vs 17%, $P<0.001$) see **Table 1**.

Table 1. Demographic characteristics of HIV patients on 1st and 2nd line ART with viral load testing results in Mutare District, Manicaland Province, Zimbabwe 2015-2017 (N=3,223).

Variable	1 st line ART		2 nd line ART		Total	<i>p-value</i>
	N	(%)	N	(%)		
Age group (years)						
0-9	58	(2)	16	(4)	76	
10-19	137	(5)	82	(3)	229	
20-49	1881	(66)	190	(11)	1929	
≥50	780	(27)	79	(15)	845	
Total	2856	(100)	367	(100)	3223	<i>p</i> <0.001
Median age	43	IQR: 35-50	38	IQR: 19-48		
Gender						
Male	929	(33)	167	(46)	1096	
Female	1927	(68)	200	(55)	2127	
Total	2856	(100)	367	(100)	3223	<i>p</i> <0.001
Marital Status						
Married	1452	(55)	121	(39)	1573	
Divorced	224	(8)	26	(9)	250	
Single	400	(15)	107	(35)	507	
Widowed	586	(22)	53	(17)	639	
Total	2663	(100)	307	(100)	2969	<i>p</i> <0.001
Level of Education						
None	35	(3)	7	(5)	42	
Primary	318	(26)	43	(30)	361	
Secondary	785	(63)	79	(55)	864	
Tertiary	104	(8)	14	(10)	118	
Total	1242	(100)	143	(100)	1385	<i>p</i> =0.2

IQR = interquartile range

141 Patients on 2nd line ART were more likely to have presented with advanced WHO 3-4 stage disease than 1st line
 142 (48% vs 42%, $P=0.03$), a VL < 1000 (45% vs 14%, $P<0.001$) and CD4 count < 100 (48% vs 25%, $p<0.001$),
 143 compared to 1st line patients, see **Table 2**.

144
 145 **Table 2.** Clinical characteristics of HIV patients on 1st and 2nd line ART in Mutare District, Manicaland;
 146 Zimbabwe between 2015-2017 (N=3,223).

Variable	1 st line ART		2 nd line ART		Total	<i>p-value</i>
	N	(%)	N	(%)		
^aWHO Stage						
Stages 1-2	1650	(58)	189	(52)	1839	
Stages 3-4	1189	(42)	173	(48)	1362	$p=0.03$
Total	2839	100	362	(100)	3201	
^bTB Status						
Current TB	7	(<1)	2	(<1)	9	
No TB	2847	(99)	365	(99)	3212	$p=0.3$
Total	2854	100	367	(100)	3221	
Viral Load						
VL<1000	2457	(86)	202	(55)	2659	
VL>1000	399	(14)	165	(45)	564	$p<0.001$
Total	2856	(100)	367	(100)	3223	

CD4 Count					
<350	1198	(87)	123	(84)	1321
>350	172	(13)	23	(16)	195 <i>p=0.3</i>
Total	1370	100	146	(100)	1516
<100	346	(25)	70	(48)	416
>100	1022	(75)	75	(52)	1197 <i>p<0.001</i>
Total	1368	100	145	(100)	1736

^aWHO, World Health Organization clinical stage; ^bTB, Tuberculosis

Log-binomial regression analysis was completed to determine the independent strength of risk factor association with viral load non-suppression among those on 1st line ART, see **Table 3**. 1st line ART patients had three times the risk of VL non-suppression if they were in the 0-9 years' age group (adjusted RR=2.9; CI=1.7-4.8, *P*<0.001) and two times the risk if in the 10-19 years' age group (adjusted RR=2.2, CI=1;4-3.2, *P*<0.001) compared to those 20-49 years. Additionally, 1st line patients were at significantly higher risk of VL non-suppression if they had concurrent TB (adjusted RR=9.4; CI=3.0-29.7, *P*<0.001) and were male (adjusted RR=1.5; CI=1.1-2.1, *P*=0.02). There were no other significant associations among the 1st line ART patients. A regression analysis completed among risk factors for viral load non-suppression for 2nd line ART patients found no significant differences.

Table 3. *Multivariate analysis of factors associated with viral load suppression among HIV patients on 1st line ART Mutare District, Manicaland; Zimbabwe 2015-2017 (N=2856).*

Variable	Total 1 st	Viral Load Not		crude RR	adj RR	95%CI	<i>p-value</i>
	Line ART N	Suppressed N (%)					
Age group							
(years)							
0-9	58	33 (57)		4.2	2.9	1.7-4.8	<i>p</i> <0.001
10-19	137	58 (42)		3.1	2.2	1.4-3.2	<i>p</i> <0.001
20-49	1881	256 (14)		<i>Reference</i>			
≥ 50	780	11 (1)		0.4	0.3	0.1-0.7	<i>p</i> =0.007
	2856	358 (13)					
Marital Status							
Married	1452	155 (11)		<i>Reference</i>			
Divorced	224	26 (12)		0.8	0.8	0.5-1.4	<i>p</i> =0.5
Single	400	116 (29)		1.9	1.4	0.9-1.9	<i>p</i> =0.07
Widowed	586	586 (9)		0.7	0.9	0.6-1.3	<i>p</i> =0.5
	2663	348 (13)					
Gender							
Male	1927	155 (17)		1.3	1.5	1.1-2.1	<i>p</i> =0.02
Female	929	244 (13)		<i>Reference</i>			
	2856	399 (14)					
Level of Education							
None	35	12 (34)		<i>Reference</i>			
Primary	318	40 (32)		0.9	0.7	0.5-1.1	<i>p</i> =0.1

Secondary	785	108 (14)	0.9	1.1	0.8-1.4	$p=0.5$
Tertiary	104	12 (11)	0.8	0.8	0.4-1.7	$p=0.5$
	1970	172 (14)				
WHO Stage						
Stages 1-2	1650	226 (14)	<i>Reference</i>			
Stages 3-4	1189	171 (14)	1.0	0.8	0.7-1.0	$p=0.1$
	2839	397 (14)				
TB status						
Current TB	7	4 (57)	4.1	9.4	3.0-29.7	$p<0.001$
No TB	2847	395 (14)	<i>Reference</i>			
	2854	399 (14)				

CD4 was dropped from the model because of missing data which would have weakened the model. adj OR, adjusted odds ratio; CI, confidence interval.

Discussion

Our study provides the first look at the most recent HIV outcomes since implementation and scale-up of routine viral load testing in Mutare district, Manicaland, Zimbabwe. The results reveal that there remains a significant amount of under-reporting and documentation of routine HIV VL monitoring in a district that is the capital of a province in Zimbabwe.

While the rate of reported VL suppression is close to the WHO 90% goal, at 86% for 1st line ART patients, only 18% had reported VL results. Likewise, VL reporting was a challenge among 2nd line ART patients, with only 35% having available VL results. The multivariate analysis revealed that those with unsuppressed VL among 1st line patients were more likely to be < 20 years old, male, or have concurrent TB. The results suggest that

173 increased programmatic focus on patients with these risk factors is needed to reduce the frequency of VL non-
174 suppression.

175 The findings are unique because they provide “real-world” field perspective into the successes and challenges still
176 facing a remote province in southern Zimbabwe and are likely comparable in other parts of the country and
177 similar contexts elsewhere. The strengths of this study include the use of a district-wide implemented electronic
178 patient monitoring tool for data sourcing and support from collaborative partners for VL sample transport, VL
179 platform resources and medication supply.

180 The primary limitation is the lack of reported viral load results for both 1st and 2nd line ART patients which
181 directly limits the ability to determine the true rate of VL suppression. There are likely several reasons for the lack
182 of VL results being documented. First, there is a single VL platform based at Mutare Provincial Hospital (MPH).
183 The MPH lab is the sole provider of all VL results for ART patients in both Manicaland (population 1.7 million)
184 and Masvingo (population 1.5 million).(15) With a conservative estimate of 10% prevalence of HIV within these
185 two provinces, that leaves approximately 300,000 patients needing at least yearly VL results provided by MPH,
186 which is not technically feasible with current resources, regardless of partner support.

187 Second, VL sample transport has been reported to be a significant problem on several levels. (16) Mutare district
188 is currently using a combination of whole blood or plasma VL samples for closer facilities and dried blood spot
189 (DBS) samples from further distances. These samples need to be delivered to the MPH laboratory within specific
190 time constraints, which is especially true for whole blood and plasma samples, requiring a secure cold-chain in
191 place and can lead to increased rates of sample rejection(17)

192 Third, increased laboratory turnaround times have been previously reported as a limiting factor in reporting VL
193 results in a timely fashion.(16) Fundamental to reaching the UNAIDS 90-90-90 HIV goals has been the scale-up
194 and decentralization of VL testing platforms.(18) However, VL testing devices require significantly costly
195 reagents that frequently require sponsored support, additional training and personnel to manage. Reagent stock-
196 outs for VL testing remains challenging in many African contexts and maybe a key contributing factor at

197 MPH(19) The MPH laboratory has limited human resources which can affect both the time to process incoming

198 VL samples and VL result entry into the Laboratory Management Information System (LMIS). Lastly, increased
199 turnaround times can paradoxically lead to reduced VL sample submission.(16)

200 The exact amount of VL access to those PLHIV on ART in Zimbabwe is currently uncertain. Previously, it has
201 been reported that only 5.6% of ART patients had access to VL testing in 2015 in Zimbabwe.(19) Our study
202 found that 18% of 1st line patients had documented VL results, which demonstrates an improving trend, but far
203 from the 90% target by the end of 2018 set by the Zimbabwe HIV Viral Load Scale-Up Plan 2015-2018.(4) More
204 concerning is the increased risk of drug resistance mutations leading to HIV drug resistance that are more likely to
205 occur in patients with undetected continued viremia secondary to the lack of VL testing(20)

206 Our study findings demonstrate near 90% VL suppression among those on 1st line ART within the Mutare District
207 of Manicaland. However, the lack of adequate VL testing coverage appears to be of significant concern on
208 multiple levels. These results suggest that there is an urgent need for increased support for the Zimbabwe VL
209 scale-up plan from collaborative partners which should likely target multiple components of testing system.
210 Further study is needed determine exactly where the greatest gaps are in VL scale-up and our findings must serve
211 as a call for others to assist in this effort. It is highly likely that these challenges in viral load monitoring are not
212 isolated to Mutare district or to Zimbabwe alone.

213 **Conclusions**

214 For those people living with HIV on 1st line ART in Mutare district, Manicaland, Zimbabwe, the frequency of
215 reported viral load results were found to be only 18% among those on 1st line ART, while their rate of viral load
216 suppression was near 90%. Viral load testing coverage appears to be lagging behind current Zimbabwe goals and
217 increased support is needed to improve the quality of HIV care and help reduce the threat of possible HIV drug
218 resistance in the future.

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274

275

276 **List of Figures**

277 Fig 1 Numbers and proportions of HIV clients included and excluded at each stage for final
278 analysis, Mutare District, Manicaland Province, Zimbabwe 2015-2017.

279

280 **Supporting information**

281 S1 Registered HIV Patients Mutare (XL)

282 S2 Mutare HIV patients 1st line (XL)

283 S3 Mutare HIV patients 2nd line (XL)

16590 HIV Clients were registered in EPMS

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graph TD; A[16590 HIV Clients were registered in EPMS] --> B[15566(94%) were on 1st line ART]; A --> C[1024(6%) were on 2nd line ART]; B --> D[2856(18%) had viral test results]; C --> E[367(36%) had viral load test results];
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15566(94%) were on 1st line ART

1024(6%) were on 2nd line ART

2856(18%) had viral test results

367(36%) had viral load test results