Increasing access to routine viral load with nearly point-of-care SAMBA-1: Outcomes from a decentralized HIV program in Malawi.

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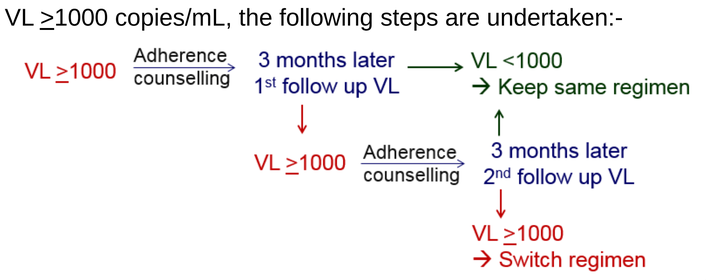
1. Introduction

- Routine Viral load (VL) testing is key to monitor ART success and early detection of treatment failures (TF) amongst people living with HIV/AIDS (PLHIV).
- To increase decentralized access to routine VL monitoring, Médecins sans frontières (MSF) with UNITAID funding piloted the implementation of SAMBA-1, a nearly point-of-care (POC) device for semi-quantitative VL testing.
- The key merits of POC technology is simplicity offering same day results and same day decision making.

Simple **AM**plification **B**ased **A**ssay
- Automated extraction process
- Amplification in closed system
- Visual dipstick readout.
- Cut-off :1000 copies HIV RNA/mL

- SAMBA-1 was implemented gradually from August 2013 in 1 district hospital (DHOS) and 4 health centres in Chiradzulu District, Malawi.
- Protocol in place in Chiradzulu recommends a VL test at 6 months on ART and every 2 years starting at 24 months on ART. If a patient has a VL ≥1000 copies/mL, the following steps are undertaken:-



- The objective is to report on achieved VL testing coverage using SAMBA-1 and describe the VL cascade from the first VL test ≥ 1000 copies/mL

2. Methods

Study design

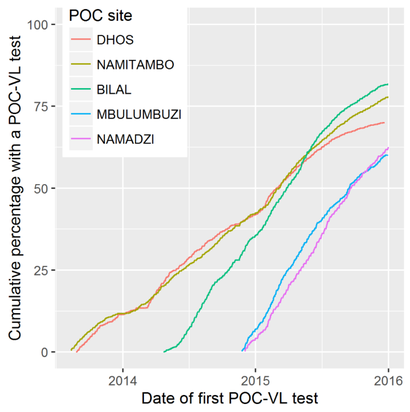
- Descriptive cohort analysis of sequence of POC-VL tests performed between **August 2013** and **December 2015** in 5 treatment sites equipped with SAMBA-1, in Chiradzulu district.
- Study inclusions were:-
  - All patients with at least 6 months on first line ART and followed at the 5 treatment sites
  - All POC-VL tests of selected patients and up-to 1 year after the initial VL≥1000 copies/mL.
- Data was collected routinely and prospectively and entered in a dedicated POC database by MSF program staff and merged with routine patient follow-up data for analysis.

Descriptive analysis

- VL Coverage: Number and % of patients with at least 1 POC-VL test.
- VL Cascade following a POC-VL≥1000 copies/mL
  - Number and % with follow-up (FU) VL tests.
  - Number and % who suppress (VL<1000 copies/mL at the 1st or 2nd follow-up VL test)
  - Number and % with VL≥1000 copies/mL at the 1st or 2nd follow-up VL test.
  - Number and % who switch regimen amongst those with 3 consecutive VL≥1000 copies/mL.
  - Median months [IQR] between tests, and between test and regimen switch
- Turn-around time between date of blood draw and review of test result
- Incomplete VL protocol: Number and % of patients missing VL tests according to MOH VL monitoring algorithm by patient outcomes at date of analysis (31 December 2015).

3. Results

VL coverage

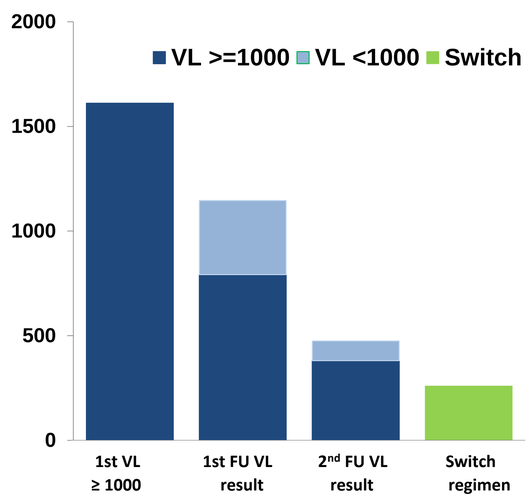


POC Site	POC start date	Number of patients eligible for POC-VL	VL Coverage n (%)	Months to achieve 50% coverage
DHOS	Aug. 2013	5557	3871 (69.7)	7.4
NAMITAMBO	Aug. 2013	5062	3911 (77.3)	9.4
BILAL	May 2014	3743	3041 (81.2)	4.7
MBULUMBUZI	Nov. 2014	2187	1305 (59.7)	2.6
NAMADZI	Nov. 2014	2487	1547 (62.2)	4.4

- Among 19036 first line ART patients, 13675 (72%) received at least 1 POC-VL test between August 2013 and December 2015.
- VL coverage ranged from 62% to 81% across POC-sites.
- Time to achieve 50% POC-VL coverage was between 3 to 5 months at the smaller sites and up-to 9 months at the larger sites reflecting the fact they were the first to implement.

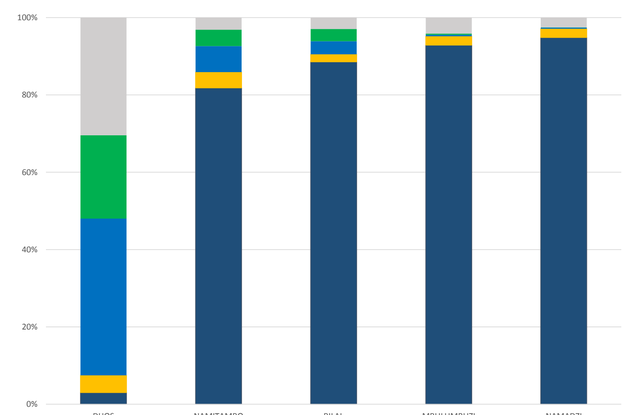
VL cascade

- 12064 (88%) of the 13675 first line ART patients tested by POC had a VL<1000 copies/mL and 1611 (12%) had a VL ≥1000 copies/mL .
- Among the 1611, 1146 had a 1st FU test and 475 had a 2nd FU test following VL testing protocol.
- **VL <1000 copies/mL**
  - 354/1146 (31%) at 1st FU test
  - 94/475 (20%) at 2nd FU test
- **VL ≥1000 copies/mL**
  - 792/1146 (69%) at 1st FU test
  - 381/475 (80%) at 2nd FU test



- Suppression at 1st FU test was 31% and by including a 2nd FU test, overall suppression increased to 39% amongst those with at least 1 FU test.
- 259/381 (68%) switched regimen following 3 consecutive VLs ≥1000 copies/mL
- Median months between tests: 3.2 [IQR 2.8–4.6]
- Median months between 2nd FU test and switch: 1.0 [IQR 0.0–3.1]
- Median months from 1st VL ≥ 1000 copies/mL and switch : 7.8 [IQR 6.2 – 10.4]

Turn-Around Time



- **At the 4 peripheral health centres** >80% of tests were reviewed by clinician on the same day as blood draw.
- **At District Hospital (DHOS)** ~ 2/3 of tests were reviewed more than 1 month later and ~1/3 of tests had missing data

Incomplete VL Monitoring Protocol

	Patients not VL tested		Patients Missing FU VL test		Patients Not Switched		Total	
Outcome	n	%	n	%	n	%	n	%
Died	86	1.6	11	1.4	0	0.0	97	2.0
Transferred	84	1.6	4	0.5	1	0.8	89	1.0
LFU	1333	24.9	132	16.9	12	9.8	1477	24.0
Followed	3858	72.0	635	81.2	109	89.3	4602	73.0
Total	**5361**	100	**782**	100	**122**	100	**6265**	100

- 6265/19036 (33%) patients were identified as not completing the VL monitoring protocol.
- Majority of those with incomplete protocol were still followed in care (73%) in Dec-2015
- A higher percentage of patients with no VL or missing FU VL test were LFU compared to those waiting to switch after 3 consecutive VLs >1000 copies/mL.

4. Key Findings

- Following over two years of POC-VL implementation, the programme attained high VL testing coverage.
- Good treatment outcomes with 88% of patients with VL<1000 copies/mL
- Fast turn-around-time with > 80% of VL results reviewed on the same day as blood draw at peripheral health centres
- 71% of patients with VL≥1000 copies/mL had a 1st follow-up test.
- Amongst patients who were switched to an alternative regimen, switch was within a median of 7.8 months after 1st VL>1000 copies/mL
- The main bottleneck was lack of follow-up tests after an initial high VL result: 63% of patients with VL≥1000 copies/mL result received no follow-up VL tests.
- The VL algorithm of 3 tests showed minimal gain in virological suppression whilst a large number of patients remained on a potentially failing regimen.

5. Conclusion

- Access to routine viral load using POC technology is feasible at the health-centre level and can satisfactorily service the population.
- Follow-up remains a major challenge which can be addressed by active monitoring and evaluation of the VL cascade and increasing VL literacy amongst healthcare workers and PLHIV.
- One follow-up test at 3 months after high VL seems sufficient to confirm treatment failure. This will simplify the process and may lead to improvement in VL monitoring cascade and HIV treatment outcomes.

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