Viral load monitoring with SAMBA-1, a semi-quantitative nearly point-of-care method in Arua, a rural district, Uganda.

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1. Introduction

- Point-of-care (POC) systems for viral load (VL) monitoring have considerable potential but evidence from 'real-life' use is limited.
- In September 2013, Médecins sans frontières, with UNITAID funding implemented SAMBA-1, a semi-quantitative (1000 copies threshold) nearly point-of-care VL test system in the Regional Referral Hospital of Arua, a rural district, Uganda.
- A high proportion of patients followed in the clinic comes from neighbouring countries, mainly DRC.

Simple **AM**plification **B**ased **A**ssay

- Automated extraction process
- Amplification in closed system
- Visual dipstick readout.
- Cut-off :1000 copies HIV RNA/mL

- The objective was to provide access to routine VL testing to approximately 9000 ART patients followed by Ministry of Health (MOH). We describe the VL cascade to highlight successes and challenges in the first 3 years of implementation.
- MOH protocol for VL monitoring follows WHO 2013 guidelines and recommends a VL test at 6 and 12 months on ART and every year thereafter.

"The key merits of POC technology is simplicity offering same day results and same day decision making."

2. Methods

Study design

- We performed a retrospective observational cohort analysis using routine patient monitoring data.
- We describe the sequence of VL tests performed between September 2013 and November 2016 for patients followed with at least 6 months on ART (eligible for VL), and outcomes up-to 1 year after an initial VL≥1000 copies/ml.
- Study inclusions were:-
  - All patients with at least 6 months on ART and followed at the clinic from the date of POC implementation.
  - 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 eligible patients with at least 1 POC-VL test.
- VL Cascade following a POC-VL≥1000 copies/mL
  - Number and % with a repeat VL test.
  - Number and % who suppress (VL<1000 copies/mL at the repeat VL test)
  - Number and % with VL≥1000 copies/mL at the repeat VL test.
  - Number and % who switch regimen amongst those with 2 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 (30 November 2016).

3. Results

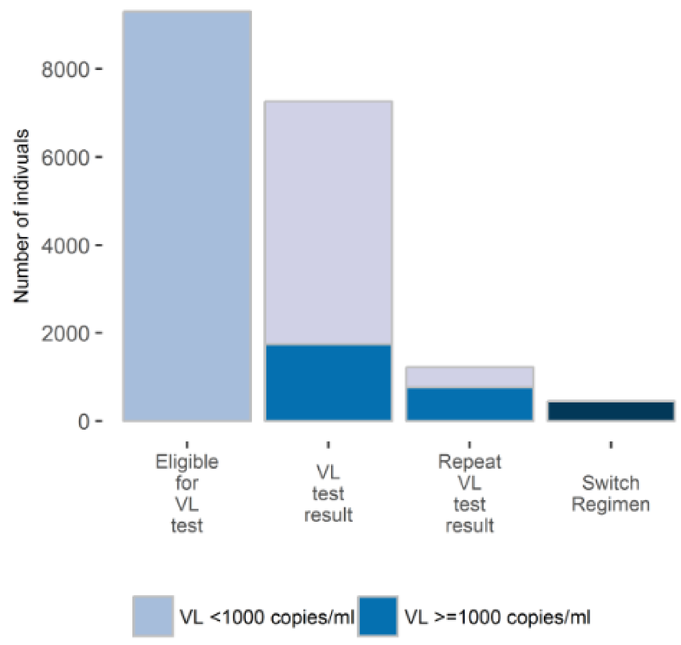
Cohort Profile & VL Coverage

- Over the study period, 9,305 patients were eligible for a VL test.
- Overall VL coverage was 78% (n=7,263).
- Median time from eligibility to first test was 5 months |IQR 0-21].
- >90% of tests ordered under routine testing and <1% as suspicion of treatment failure.
- Coverage was similar across gender and age and lower amongst patients with <1 year on ART.
- Coverage was also similar amongst those coming from Arua District or neighbouring countires (predominantly DRC), but lower amongst those from other Ugandan districts.

Characteristics		Cohort Profile		VL coverage
		n	%	%
	Total	9305	100	
Gender				
	Female	6066	65	80
	Male	3239	35	77
Age group (years)				
	<20	928	10	78
	≥20	8377	90	78
Months on ART				
	≥6 to <12	3326	36	72
	≥12 to <24	1108	12	77
	≥24	4871	52	83
District of origin				
	Arua district	4346	47	79
	Other districts	1200	13	72
	Neighbouring countries*	3759	40	79

**98% of the 3759 are from DRC*

VL Cascade



- Of the 7,263 patients tested, 1,748 (24.1%) had a VL ≥1000 copies/ml, and of these, 1,221 (69.9%) received a repeat VL test.
- Median time to repeat VL was 6 months [IQR 4.7-7.1] (following MOH protocol), at which 457 (37.5%) suppressed, 763 (62.5%) remained with a VL≥1000 copies/ml.
- Of the 763 patients with two consecutive VLs >1000 copies/ml, 449 (58.9%) were switched to the next ARV line in a median of 7.2 months [IQR: 2.9-12.7] following the repeat VL>1000 copies/ml test result.

Turn-Around Time

- Clinical review was same day for 96% of tests.
- The proportion of clinical review done on the same day of the test did not vary according to the geographical origin or VL test result.

Adherence to VL Monitoring Protocol

Patients' outcomes by incomplete or complete protocols

	Complete		Incomplete	
	n	%	n	%
Died	37	0.6	43	1.5
Transferred out	230	3.5	428	15.2
LFU by 2 months	1028	15.8	1447	51.4
Followed	*5194*	*80.0*	*898*	*31.9*
Total	**6489**		**2816**	

- National VL testing protocol was incomplete for 2816 (30.3%) eligible patients.
- Patients with incomplete protocol are less likely to be followed at date of analysis: 32% compared to 80% followed among those with a complete protocol

Description of non-followed patients with incomplete VL monitoring protocol

Median months [IQR]	Total N=1918	No VL N=1577	At least 1 VL N=341
Eligibility to Last visit	3.7 [0.4-12.2]	2.4 [0.1-7.7]	17.1 [8.8-27.4]
Eligibility to 1st VL test	-	-	4.8 [2.3-8.2]

- The vast majority of patients, not followed and with an incomplete VL protocol were those with no VL (82%). Amongst these, 50% had their last visit within 2.4 months of eligibility, indicating a reduced probability of being offered a VL test.
- 50% of the patients with at least 1 VL but an incomplete VL protocol had their first VL within 5 months and had their last visit within 17 months after the date of VL eligibility.

4. Conclusion

- POC VL testing achieved good VL-testing coverage, permitted same-day clinical review of results and timely follow-up.
- However, ensuring every patient gets their VL test remains a challenge in a dynamic cohort. Close program monitoring and support to staff is essential to identify and address gaps in the VL monitoring cascade.
- Not everyone identified as treatment failure switched regimen. Key constraint is reluctance, by clinicians to switch patients based on semi-quantitative results and by some patients even after failure confirmation. The issue could be overcome by improving clinicians' knowledge on the validity of the 1000-threshold, patients' education and psychosocial support

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