

Evaluation of SAMBA Viral Load point-of-care test operation by trained non-health workers in rural Health Centers, Chiradzulu District, Malawi

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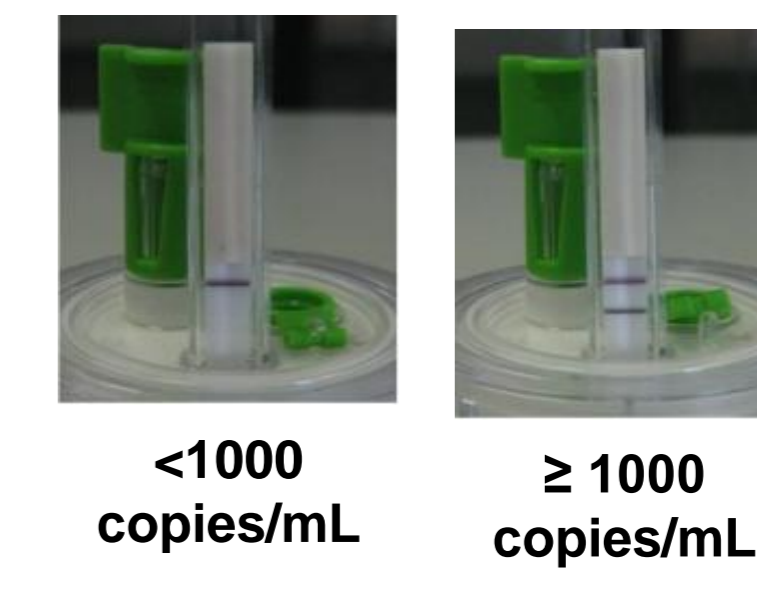
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Introduction

- Since more than a decade Médecins Sans Frontières (MSF), in collaboration with the Ministry of Health, provides antiretroviral treatment (ART) in 10 rural health centers (HCs) in Chiradzulu District, Malawi.
- HIV Viral Load (VL) testing using the SAMBA HIV-1 point-of-care VL test is implemented at four health centers since August 2013 to create decentralized access to VL monitoring for PLHIV on ART
- Shortage of health care- and laboratory staff is an issue in rural Chiradzulu District.
- We assessed task-shifting of SAMBA VL test operation to non-health workers living in the community around the HCs.

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- Sample preparation - automated extraction process
- Amplification and detection - isothermal amplification in closed system with visual dipstick visual readout
- Semi-quantitative detection around 1000 copies HIV RNA/mL cut-off
- Total time to result is approximately a 105 min

Methods

Study Design: prospective field evaluation of operator-dependant performance of SAMBA POC VL test.

Sample Size: N=250 plasma samples from EDTA whole blood for routine VL test from patients ≥ 18 years

Study sites: Two rural health centres (HC): Namitambo and Bilal, in Chiradzulu District, Malawi.

Methods: Each sample was assessed with SAMBA VL by a lab technician (LT) and by a trained community worker (TCW) in the HC mini-laboratory, respectively. In addition, Viral load was also assessed for each sample with Generic real-time PCR assay from Biocentric.

Objectives: To evaluate the performance of trained non-health community worker operation of the SAMBA HIV-1 Semi-Q test for VL testing at POC compared to lab technicians

Ethics: The study has been approved by French and Malawian ethics committees.

Training of community workers : Four non-health workers from the community around the health centers received a 12 days structured training on SAMBA VL POC operation. Required qualifications: Secondary school certificate.

In each of the two HCs two Trained Community Workers (TCWs) and one Lab technician (LT) participated to the study.

Statistical analysis:

VL Results by SAMBA (trained community workers) versus SAMBA (lab technician):

- Kappa coefficient to assess the agreement in classification of viral load < and ≥ 1000 RNA copies/ml plasma
- Percent agreement and misclassification, and sensitivity, specificity when classifying viral load < and ≥ 1000 RNA copies/ml plasma.

SAMBA invalid-rate, sample processing and sample throughput-time, and operator acceptability/ease of use of SAMBA (qualitative questionnaire)

- Percent agreement and misclassification < or ≥ 1000 copies/ml, for: SAMBA (trained community workers) versus reference method (Biocentric) SAMBA (lab technician) versus reference method (Biocentric)

Results

Between April and June 2015, 271 venous blood samples of ART-patients attending routine VL-testing after informed consent.

Characteristics of study samples – tested by SAMBA

	N (%)
Total	271 (100)
Namitambo health center	141 (52.0)
Bilal health center	130 (48.0)
Invalid results	0
Total VL ≥ 1000 copies/ ml (LT)	51 (18.8)
Total VL ≥ 1000 copies/ml (TCW)	54 (19.9)

Characteristics of study samples – Quantitative VL (Biocentric)

VL (copies/mL)	N (%)	
not detected/below threshold	220 (82.2)	Median VL: 12 799 copies/mL
390 -1000	4 (6.3)	IQR: 3,656 – 97 136 copies/mL
1 000 – 10 000	19 (7.0)	
10 000 – 100 000	16 (5.9)	
> 100 000	12 (4.4)	
<1000	224 (82.7)	
≥1000	47 (17.3)	

Good agreement between SAMBA operators

TCW	LT		Total
	≥ 1000	<1000	
≥ 1000	46	8	54
< 1000	5	212	217
Total	51	220	271

- Agreement : 95.2% (CI95%: 91.9-97.4)
- Kappa Coefficient: 0.85 (95%CI : 0.76-0.93)
- Discordance: 4.8% (CI95%: 2.6-8.1)

Community Workers: Operator questionnaire feedback:

- SAMBA operation rated 'easy' or 'very easy' by trained community workers
- Confident that community workers can do the job with sufficient training
- Recognition of the value of regular supervisory visits from a lab technician
- Identified the activity as providing ownership of VL testing to the community
- Identified the need to be trained in phlebotomy to further optimize task-shifting approach

Good agreement of SAMBA operators with quantitative VL

SAMBA copies/ml	Biocentric VL (cps/ml)				
	<500	500 - 999	1000-1999	>2000	
LT					95.9% agreement (92.8%-97.9%)
≥ 1000	7	2	6	37	
< 1000	214	1	1	4	
TCW					96.3% agreement (93.3%-98.2%)
≥ 1000	8	2	6	39	
< 1000	213	1	1	2	

Values between 500-2000 copies/ml by quantitative PCR were considered concordant with any of the SAMBA results, taking into account the accuracy range around the 1000 copies threshold (+/- 0.3 log for NAT methods)

LT-SAMBA versus quantitative method:
11 samples discordant: 7 false positive, 4 false negative

TCW-SAMBA versus quantitative method:
10 samples discordant: 8 false positive, 2 false negative

Conclusion

- Adequately trained community workers delivered SAMBA VL POC results equivalent to lab technicians
- Task shifting of simplified VL POC-technologies to non-health workers can be a key strategy to overcome health worker shortage and to ensure sustainable access to routine VL testing in decentralized settings.