

Early experience with implementation of SAMBA HIV viral load testing in a rural district - Malawi

Charlie Masiku

Deputy Medical Coordinator

MSF HIV Project, Chiradzulu, Malawi

Capetown 22nd September 2014



MSF- MoH Project

- Malawi: rural district
 - Population ~ 300,000, HIV prevalence 17%
 - Chronic lack of health HR
 - Program very decentralised in 10 HIV clinics + 1 hospital
 - 28 802 patients followed-up on ART (> 80% decentralised)

- Until sept 2013: VL requested only for suspicion of treatment failure
- 1.7% only on second line regimen

SAMBA – VL

SAMBA

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

- A Simple Nucleic Acid Testing platform
- Semi-quantitative plasma VL (\geq or $<$ 1000 copies/mL)
- Qualitative EID (ongoing field clinical trials)
preliminary results in Uganda and Kenya
presented at IAS 2014

SAMBA I platform



SAMBA prep

SAMBA amp

- Isothermal amplification with simple visual detection
- 300 μ L of plasma needed
- Preloaded reagents in closed cartridges
- Heat stable freeze-dried reagents
- TAT = 105 minutes (without centrifugation)

Easy read-out on a dipstick



≥ 1000 cop/ml

<1000 cop/ml

Invalid

Protocole in use for VL

- From date of ART start (defines the milestones)
 - 1 VL at M6
 - 1 VL every 2 years
 - Additional if patient suspect of failure
- In addition (MSF)
 - 2 VL/yr for children and adolescents
 - 2 VL/yr for second line
- Definition of failure for ART switch
 - VL > 1000 copies/mL x 3 times
 - In between: reinforcement of adherence counselling

Lessons learned



Lessons learned - SAMBA 1 system

- Easy to install
- Moderate footprint
- All consumables included
- Short training : lab techs autonomous after 4-5 runs
 - CHW would need longer training and closer supervision
- Nb of theoretical runs depend on the nb of equipment and the working hours

Theoretical optimised throughput

	1 SP + 1 SA		1 SP + 2 SA		1 SP + 3 SA	
	Nb tests	Duration	Nb tests	Duration	Nb tests	Duration
1 run	4	2 h 20	6	2 h 20	6	2 h 20
2 runs	8	3 h 45	8	2 h 50	12	2 h 55
3 runs	12	5 h 15	14	3 h 35	18	4 h 00
4 runs	16	6 h 40	16	3 h 55	24	4 h 35
5 runs	20	8 h 05	22	4 h 40	30	5 h 10
6 runs			24	5 h 10	36	6 h 15
7 runs			30	5 h 55	42	6 h 50
8 runs			32	6 h 25	48	7 h 25
9 runs			38	7 h 10		
10 runs			40	7 h 40		

Lessons learned - SAMBA 1 system

- Volume of the kits : 12 tests = 14 litres
- Waste to be considered (but no toxic chemicals)
- Instrument adaptation ongoing
 - Tolerance above 35°C (room ventilation/insulation)
 - Mechanical problems (blockages) with SAMBA prep
 - Design of the mobile arm modified on SAMBA prep version 2
 - Design of the adaptor modified
- Invalid rate extremely low:
 - 6903 samples tested
 - 19 non-repeatable invalid (0.3%)
 - 1 repeatably invalid



Current versus needed VL throughput

With 1 SAMBA prep & 3 SAMBA amp

	ART Cohort Q1, 2014	VL Needed /year (0,66/pat/yr)	Observed current throughput /day	Estimation VL done in the HC /year	Difference VL done vs needed	Percent
Hospital cohort	4671	3083	24	6048	+ 2965	+ 49.0%
HC 1 cohort	4239	2798	8	2016	- 782	- 38.8%
HC 2 cohort	3300	2178	14	3696	+ 1518	+ 41.1%

**With improved patient and sample flow,
the observed throughput progresses regularly.**

Reaching an optimised throughput

- Get the samples to reach the clinic laboratory early
 - Blood drawing early, when patients arrive for result/action the same day
 - **Or** VL requested at previous consultation and result/action at next visit
- Clinicians issues
- Train specialised community workers from the villages to perform SAMBA (& other POC?)
 - No time lost due to lab tech transportation to/from their work place
 - Operational Research planned on task-shifting to TCW

Breakdown by type of requests

Type of request	Number of tests	< 1000		≥ 1000
6 months ART	197	180	(91.3%)	17
« Routine » ART FU	2915	2588	(88.8%)	327
Suspicion treatment failure (CD4)	824	491	(59.6%)	333
After enhanced adherence counselling	41	24	(58.5%)	17
Other	211	176	(83.4%)	35
Total	4188	3459		729

Impact of VL on clinical management

- More straight-forward clinical decision making on treatment strategy than looking at CD4 trends
- Reduction of clinic workload / Optimised use of scarce HR
 - Spacing of clinical appointments for patients < 1000 copies /mL
 - Longer consultation time with experienced staff for more vulnerable patients
- Failing patients are recognised on time and switched

SAMBA 2



Assay Module

Display Module

- A whole blood VL semi-quantitative test is being developed (plasma separation included in the preparation cartridge)
- In near future, both VL semi-quantitative and EID qualitative test with one platform (only cartridge is different)
 - Same day result for EID → immediate ART start if positive → impact on HIV + infant mortality

Conclusion

- SAMBA 1 system is **much simpler** than currently available Nucleid Acid Testing technologies
- SAMBA 1 cartridge tightly closed → **prevents contamination** of the environment by amplicons
- **Staff training** requirements for SAMBA 1 is **minimal**
- SAMBA 1 **can be implemented in lower healthcare levels** such as district hospitals or health centres with a basic laboratory **that has electricity**

Thank you

Acknowledgements:

- The patients and the staff of Malawi clinics and laboratories
- UNITAID for the grant to operationalise the VL POC
- Epicentre
- MoH Malawi

