And Opportunities

Laboratory Challenges

Viral Load Testing:

Scaling up

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MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

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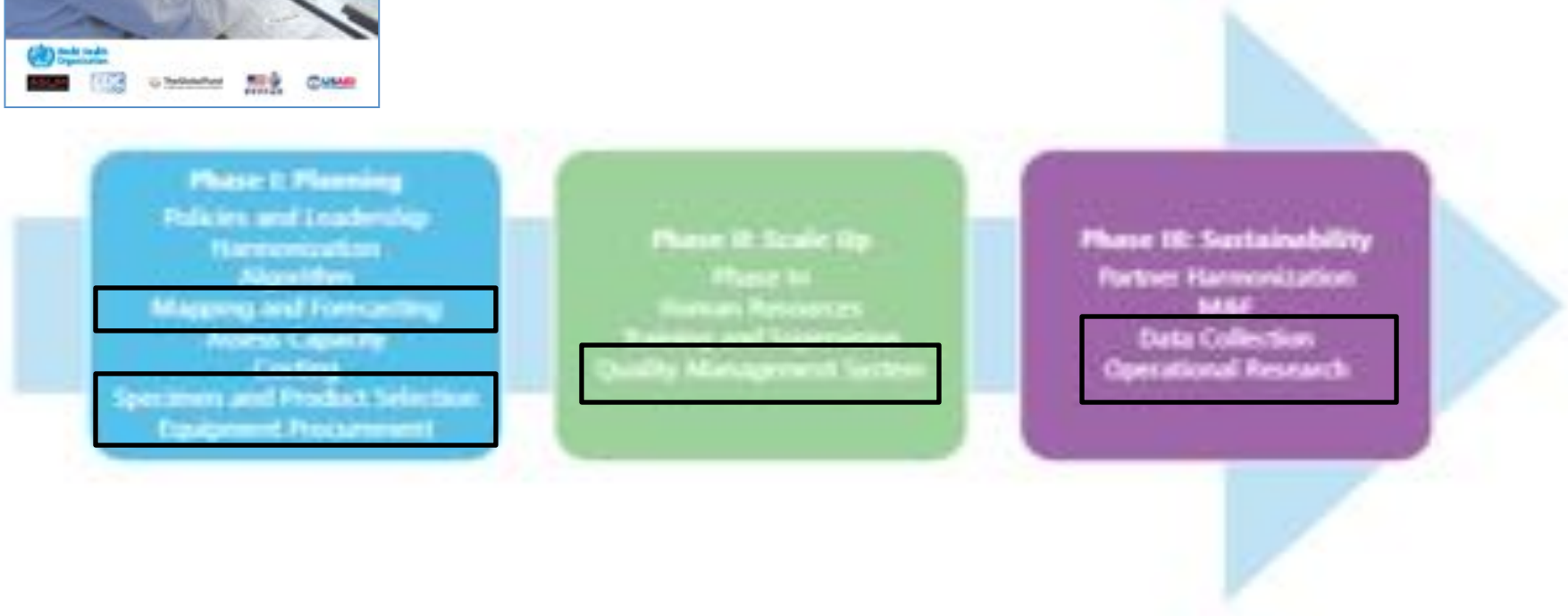
SAMU
SOUTHERN AFRICA MEDICAL UNIT

Phased Implementation of VL Testing

WHO provides guidance on implementing and scaling up viral load testing programmes for health ministries and implementing partners. It aims to inform national HIV programme managers and laboratory managers using a three-based approach: **(1) planning; (2) scale up; and (3) sustainability**



Viral Load Testing Network

- Determining the numbers of current and expected people receiving ART and tests needed + clinical algorithm

Transport and storage requirements

Human Resources

Sample type

VL Technology

Facility

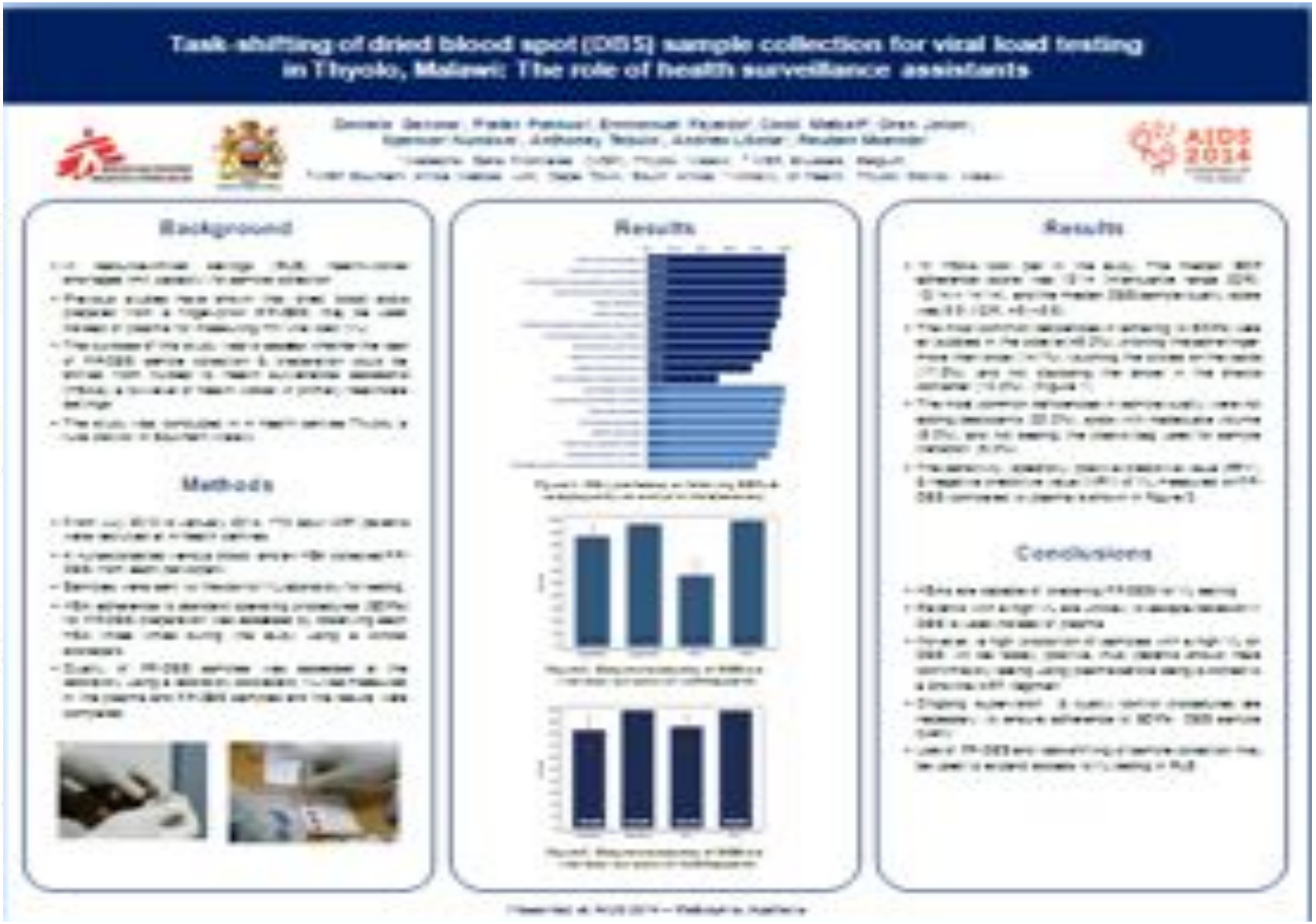
Throughput

Dried Blood Spots

Table 1. Provisional data on performance characteristics for commercially available molecular HIV viral load assays using dried blood spot specimens compared with plasma at 1000 copies/ml cut-off

Assay assessed	Sensitivity (mean %)	Specificity (mean %)	*n*
Abbott Molecular: Abbott RealTime HIV-1 (manual, m24sp and m2000sp) assays with m2000rt platform	95.24[a]	91.67[a]	1529
Biocentric: Generic HIV Charge Virale	94.86[a]	55.16[a]	531
bioMérieux: NucliSENS EasyQ® HIV-1 v2.0	84.37[a]	94.52[a]	1062
Roche Molecular Systems: COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0 [free virus elution protocol]	81.02[b]	96.74[b]	229
HIV-1 RNA 1.0 Assay (kPCR)	90.97[a]	87.76[a]	144

Dried Blood Spots



Task-shifting of dried blood spot (DBS) sample collection for viral load testing in Thyolo, Malawi: The role of health surveillance assistants

Background

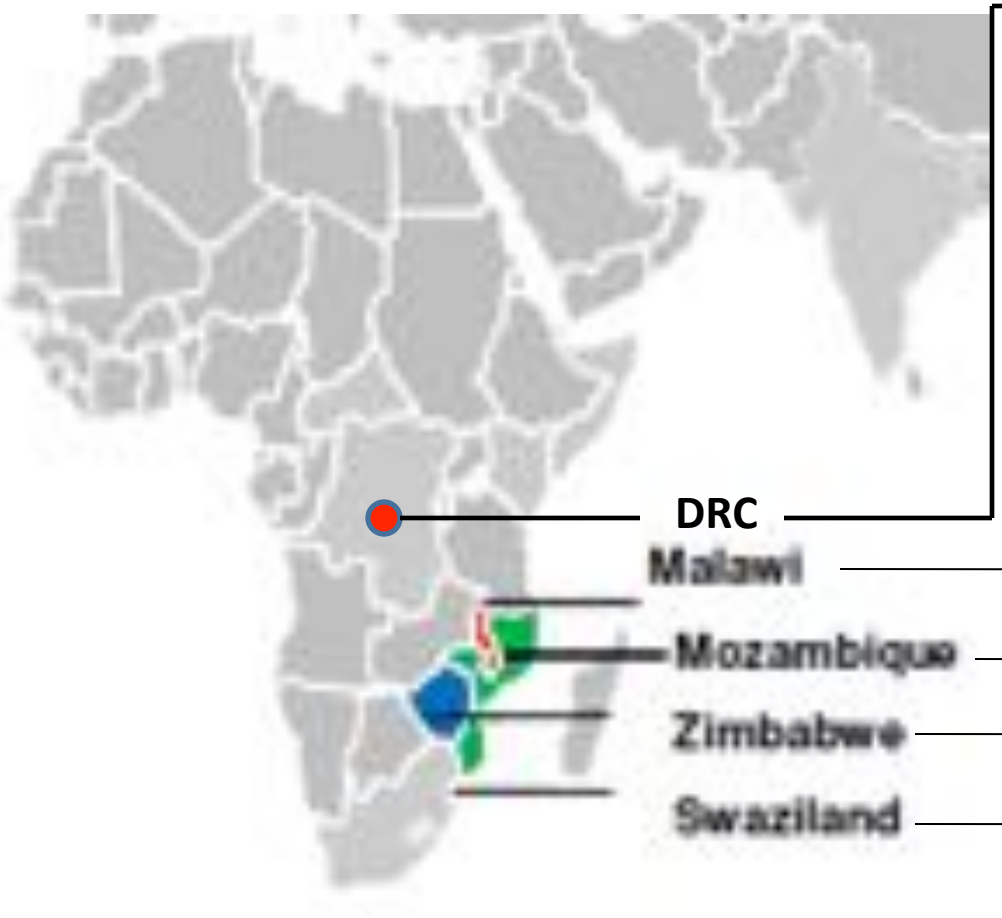
Methods

Results

Results

Conclusions

Setting-up the Laboratories



- Urban District Hospital **(Abbott - Plasma)**
- Rural District Hospital **(BioMerieux - DBS)**
- Rural District Hospital
- Health Centre Lab **(SAMBA - plasma)**
- Urban General Hospital **(BioMerieux - DBS)**
- National Reference Lab **(BioMerieux - DBS)**
- Rural District Hospital **(Biocentric - plasma)**

Lesotho, Guinea, South Sudan, CAR → **DBS** → **External Laboratory**

DBS Kits

- Cheaper **filter paper alternatives**
- **Perforated filter paper** to reduce cross-contamination
- **Finger prick DBS kit** (lancet + volumetric microsafe pipette)
- **EDTA DBS kit**

SOPs and training package for DBS collection

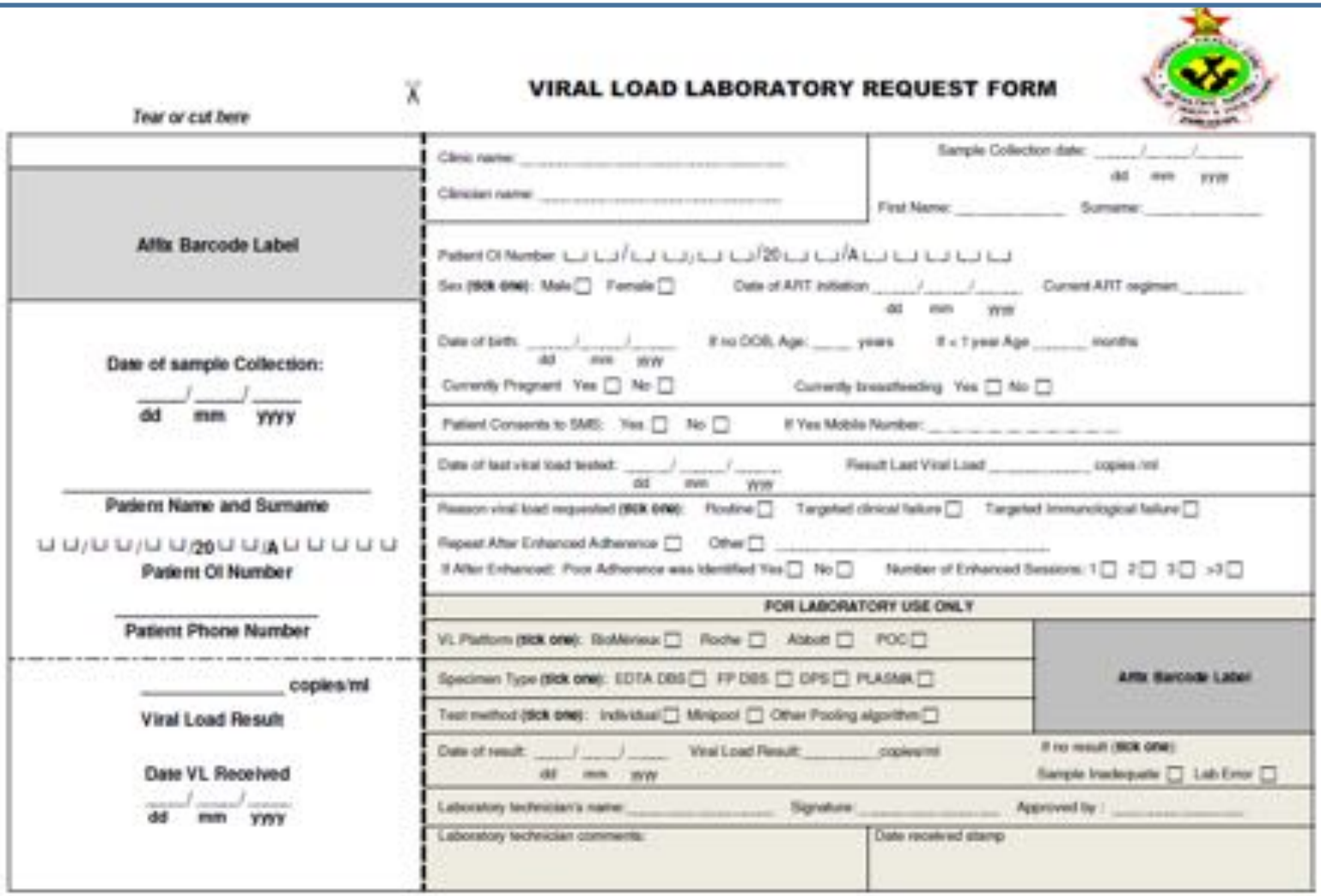
- DBS sample collection using **EDTA venous blood**
- DBS sample collection using **finger prick**
- Powerpoint **training materials** on sample collection and documentation

Quality Assurance

- Before routine operations, **verification procedures** were carried out
- Commercial controls (positive and negative controls) for **daily internal control**, were used but due to costs we implemented in-house controls using samples already tested
- Enroll in a **proficiency testing programme** with the CDC : **dried tube specimen**
- However, **DBS proficiency testing programmes** are not available to date

Data Management

Zimbabwe and Mozambique = **Viral Load Information System (VLIS)**
Malawi = **Laboratory Information Management System (LIMS)** = CHAI = connectivity



VIRAL LOAD LABORATORY REQUEST FORM

Tear or cut here

Affix Barcode Label

Date of sample Collection:
____/____/____
dd mm yyyy

Patient Name and Surname

Patient OI Number

Patient Phone Number

____ copies/ml
Viral Load Result

Date VL Received
____/____/____
dd mm yyyy

Clinic name:
Clinician name:
Sample Collection date: ____/____/____ dd mm yyyy
First Name: Surname:
Patient OI Number
Sex (tick one): Male Female Date of ART initiation ____/____/____ dd mm yyyy Current ART regimen
Date of birth: ____/____/____ dd mm yyyy If no DOB, Age: ____ years If < 1 year Age ____ months
Currently Pregnant Yes No Currently breastfeeding Yes No
Patient Consents to SMS: Yes No If Yes Mobile Number:
Date of last viral load tested: ____/____/____ dd mm yyyy Result Last Viral Load ____ copies /ml
Reason viral load requested (tick one): Routine Targeted clinical failure Targeted Immunological failure
Repeat After Enhanced Adherence Other
If After Enhanced: Poor Adherence was Identified Yes No Number of Enhanced Sessions: 1 2 3 >3

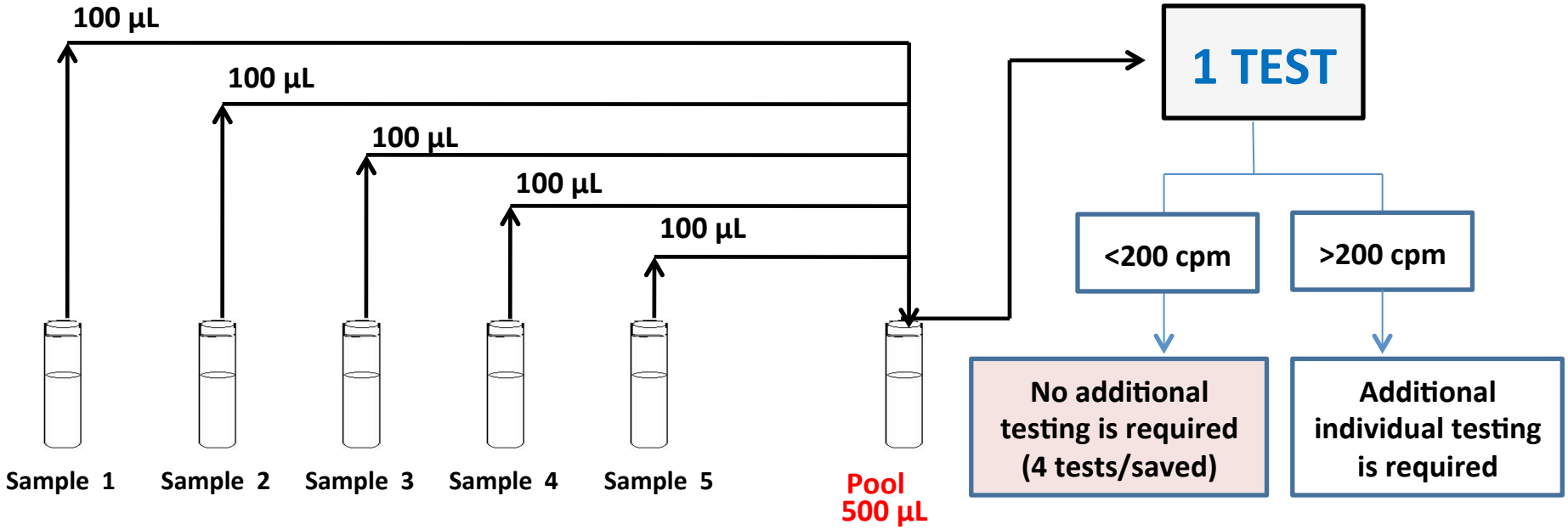
FOR LABORATORY USE ONLY

VL Platform (tick one): BioMerieux Roche Abbott POC
Specimen Type (tick one): EDTA DBS FP DBS DPS PLASMA
Test method (tick one): Individual Minipool Other Pooling algorithm
Affix Barcode Label
Date of result: ____/____/____ dd mm yyyy Viral Load Result: ____copies/ml
If no result (tick one): Sample Inadequate Lab Error
Laboratory technician's name: Signature: Approved by :
Laboratory technician comments:
Date received stamp

Te$t Co$t Reduction$

- Although the increase in testing volumes has lead to cost reductions in the price of the test, our volumes remain relatively low (district programmes)

- Innovative strategies are required to drop test prices, and we identified sample pooling as a potential solution.



DB$ Viral Load Pooling

RAPID COMMUNICATION

OPEN

Pooled HIV-1 Viral Load Testing Using Dried Blood Spots to Reduce the Cost of Monitoring Antiretroviral Treatment in a Resource-Limited Setting

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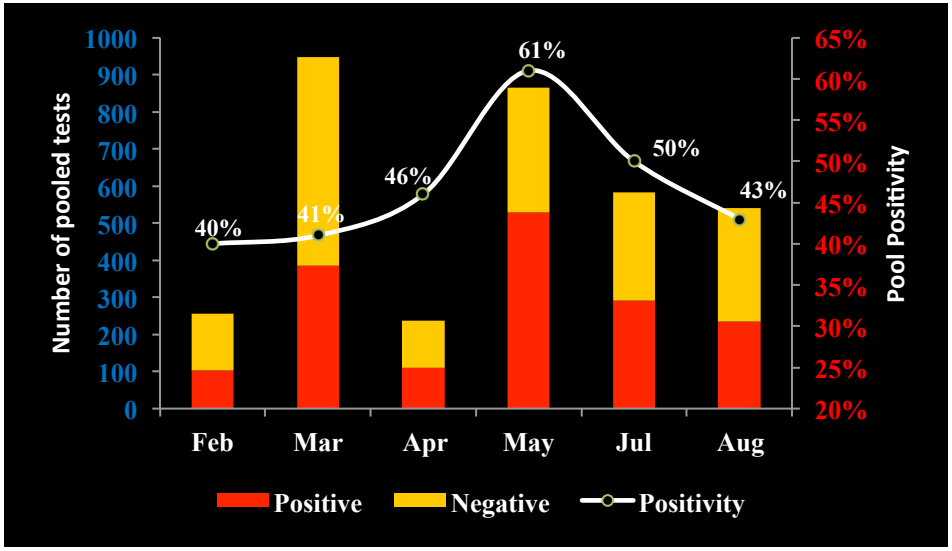
In this MSF study in Malawi we showed that using pooling resulted in a reduction of **30%-50%** tests required to be analyzed. This reduction could translate in significant cost savings ($160.000 - $290.000 / year) for the scale-up of viral load testing in Thyolo District

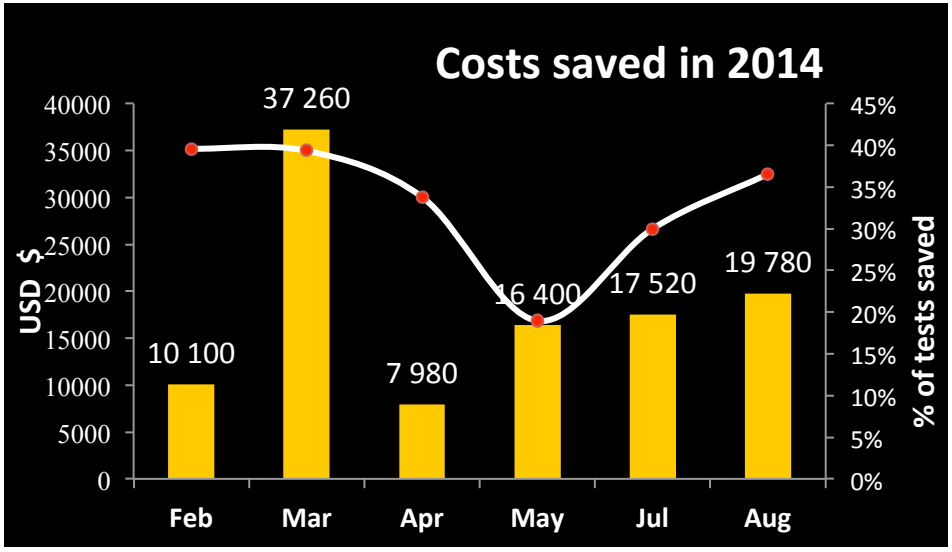
Pilot Implementation VL Pooling



Pooled testing initiated routinely in February 2014 in Malawi. The lab pools plasma samples (Tyholo District Hospital) and DBS samples (Health Centres)

Pool positivity (>200 cpm) (DBS + plasma)

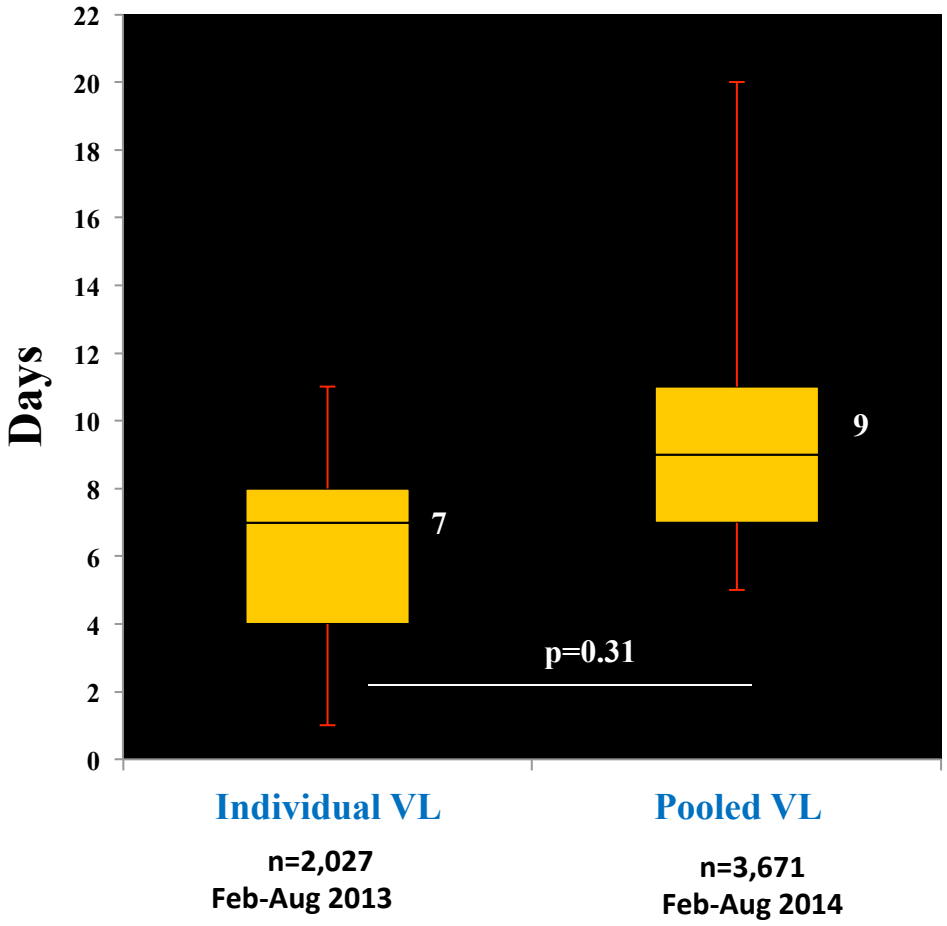
Average = 48%



The project has saved a total of 5,452 VL tests thanks to sample pooling; considering a price of USD $20/test, this translates in a cost-saving of **USD $109,040**, to date, in Thyolo.

Pilot Implementation VL Pooling

Lab Turn-around time



There were concerns/perception that pooling would lead to a significant increase in the TAT of results due to repeat testing.

TAT= date sample received in the lab – date result generated in the lab

As seen in the comparison between pre- and post-pooling phases the TAT only increased an average of 2 days, and this wasn't statistically significant.

Challenges

- Frequent breakdown of the VL instruments
- Delays with technical support (servicing, maintenance)
- Backlog of work
- Long turn-around-time to results
- High frequency of invalid results due to the use of DBS
- Ruptures of cold-chain during reagent delivery (2^0C – 8^0C)
- Lack of private companies for liquid waste management
- Contamination problems in the lab
- Stock ruptures and expiration of reagents
- HR issues

Laboratory OR Needs

1. Stability of EDTA whole blood and plasma at room temperature
2. Stability of whole blood and plasma using stability solutions
3. Clinical evaluations of new DBS protocols
4. Feasibility of DPS at the point of collection
5. Development of DBS-based proficiency testing for EQA
6. Feasibility of task-shifting phlebotomy to low cadres
7. Accuracy and clinical impact of Point-of-Care VL technologies

Conclusions

- Currently, DBS is the most practical and affordable alternative to increase access to VL testing
- Selecting the appropriate technology for given healthcare settings is essential
- Scale-up of VL testing requires adequate planning and monitoring
- Strengthening transport system, rapid delivery of results and laboratory network is critical
- Further research on the pre-analytical aspects of VL is needed

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