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PEPFAR

Scaling-up Viral Load testing: Procurement and Supply Chain Considerations

Jason Williams

Senior Laboratory Advisor, OHA/
SCH/USAID

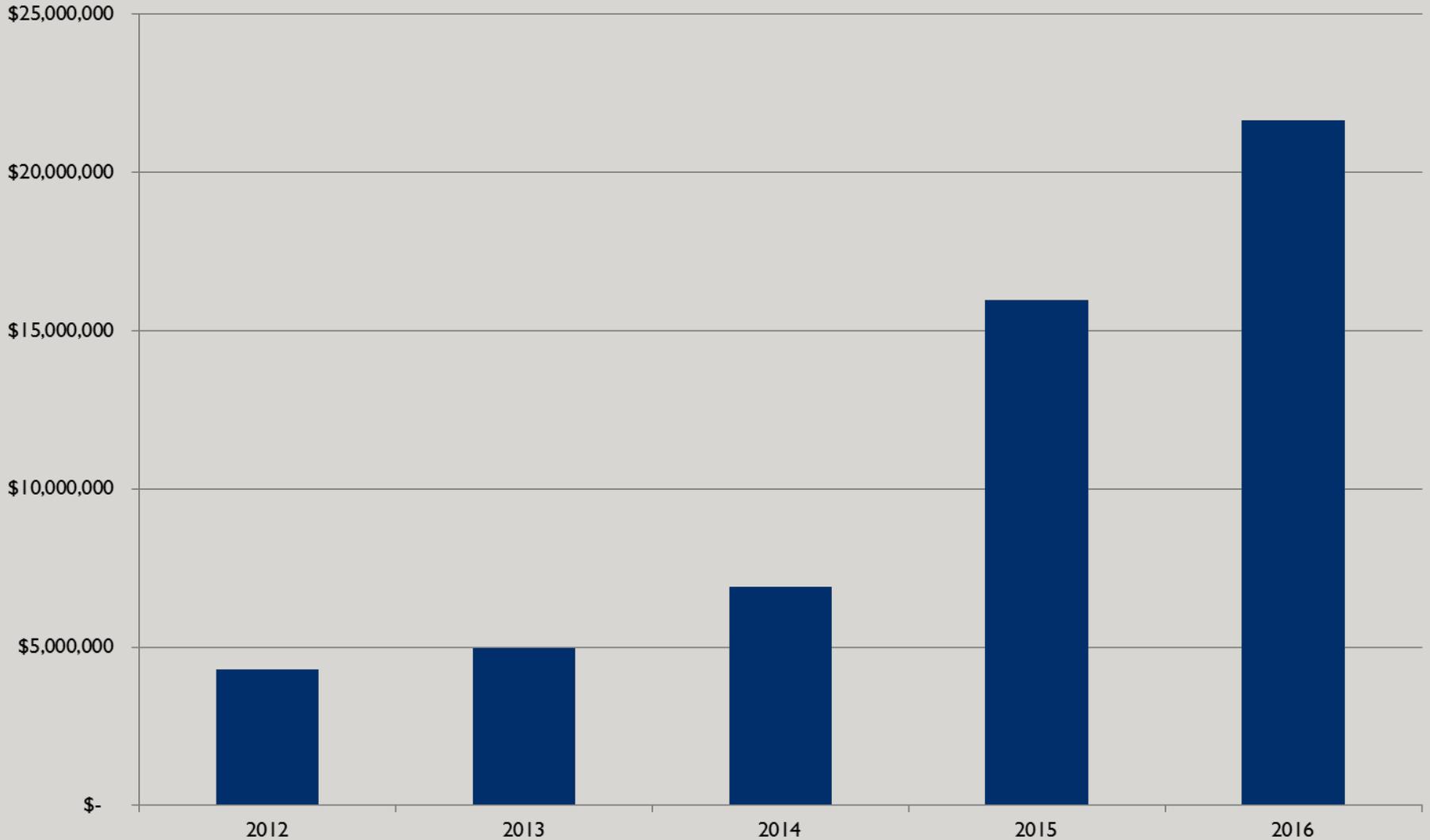
Namibia, Windhoek

September 13-16, 2016

Overview:

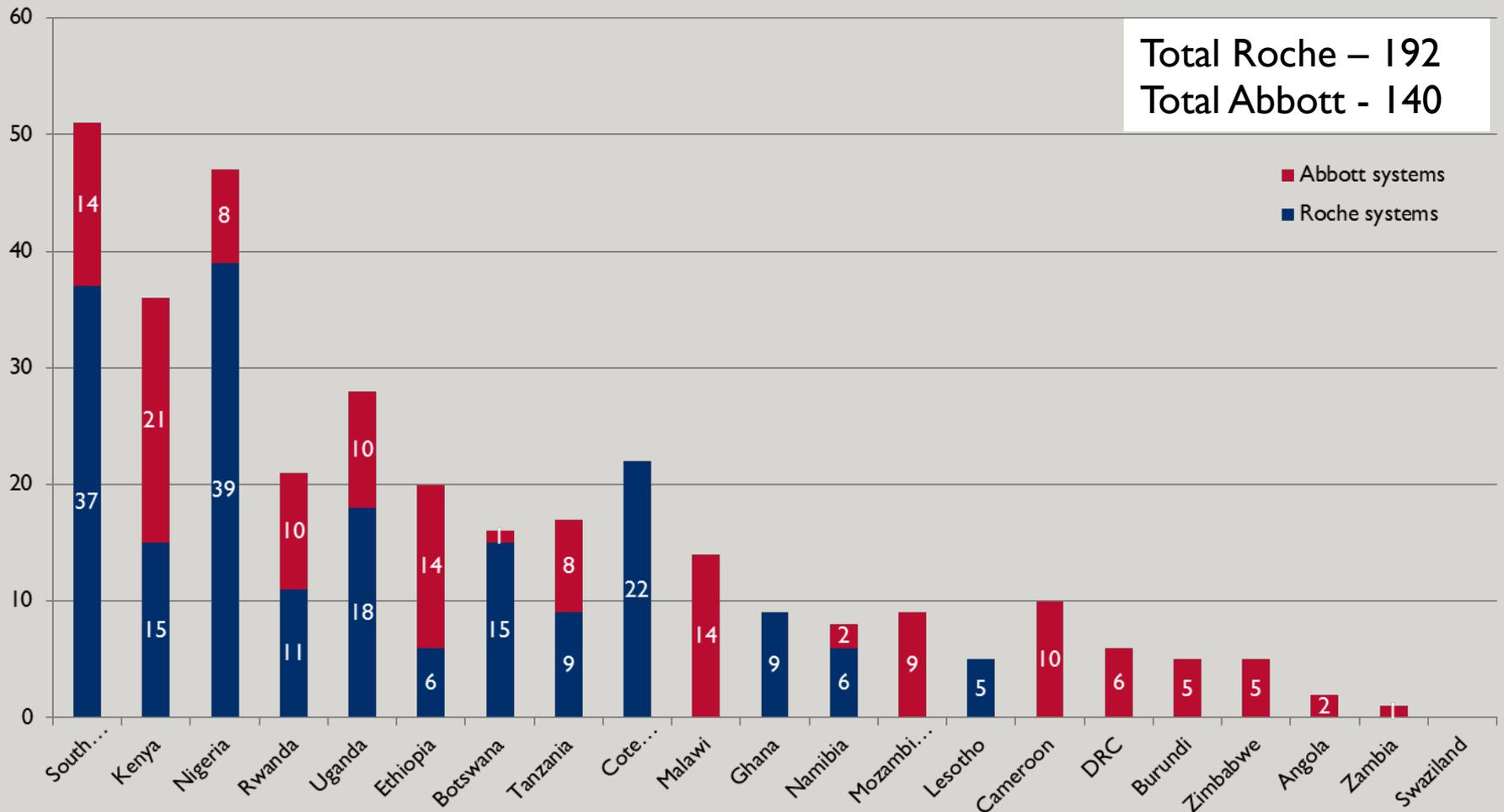
- Spend and current coverage
- Forecasting and Procurement
- Addressing maintenance challenges
- Understanding pricing variations
- Scale-up considerations
 - POC integration
- Donor and manufacturer engagement

Spend (SCMS – August 2016):



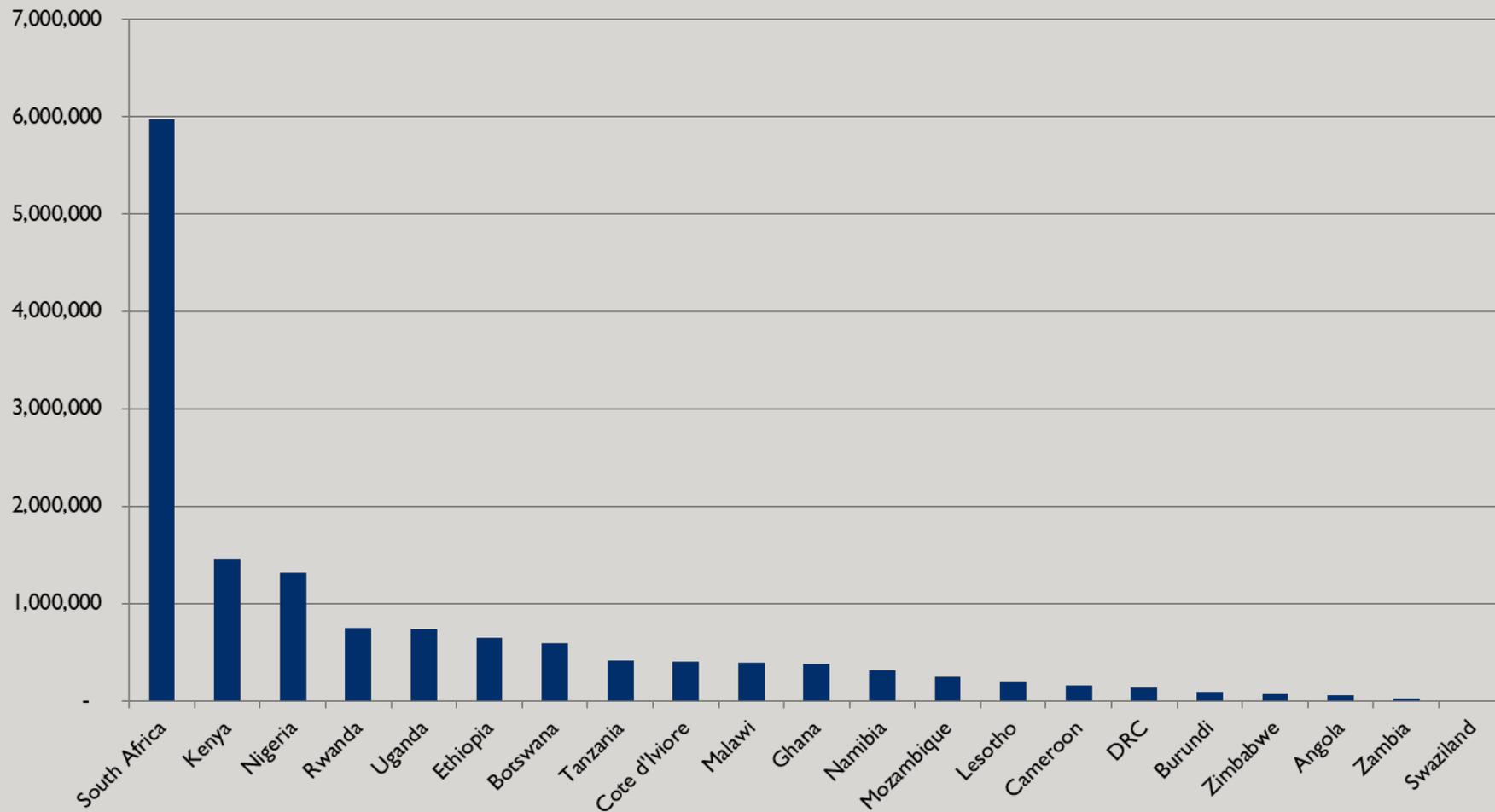
System footprint: Number of Abbott/Roche systems by country (Africa) 2016

(Source: Abbott/Roche, May 2016)



Included: Rwanda (10) and Tanzania (5) new Abbott platforms to be installed 2016
Nigeria's PEPFAR capacity reduced – pivot to 11 labs, not adjusted

Roche/Abbott molecular testing capacity (2016)



Included: Rwanda (10) and Tanzania (5) new Abbott platforms to be installed 2016
Nigeria's PEPFAR capacity reduced – pivot to 11 labs, not reflected

Components of Successful VL Scale Up

Lab

- Platforms
- Plasma and DBS
- Staffing & Training
- Quality Assurance
- Result Return



Logistics

- Forecasting & Procurement
- Reagent Storage & Cold Chain Distribution
- Maintenance
- Sample Transport

Clinical

- Provider Training
- Patient /Community Education
- Systems for Sample Collection, Results Return, Documentation, Interpretation/Utilization, QA/ Mentorship

M&E

- Forms & Registers
- M&E System (LIS, Logistics & Clinical) Integration

Challenges associated with VL forecasting

- Quickly changing guidelines and system adjustments
 - Test and start, CD4 transitions, MMS, rapid VL scale-up
- No historical data for new programs – unknown uptake, system limitations and capacity
- Use of demographic/target based forecasts, traditionally overestimate commodity demands
- Rapid instrument deployments and network expansion
- High level of instrument failures
- M&E (LIMS/LMIS) systems are required to capture testing uptake to inform adjustments to supply plans

Forecasting:

- New version in development



Procurement:

- New USAID mechanism (GHSC-PSM)

Procurement challenges:

- Procurement coordination and visibility
- In-country vendor capacity
- Lack of adherence to supply plans and making adjustments
- Aligning instrument deployments with commodity needs
- Protocol transitions
 - Commodities and software roll-out

Procurement: Protocol clarifications



Comparison Open mode DBS vs. CE DBS

	'Old' DBS HIV-1 viral load Open Mode protocol	'Optimized' DBS HIV-1 viral load Open Mode protocol	DBS HIV-1 viral load protocol CE
Instrument	m2000sp/rt		
DBS paper Type	0.5 inch (12-millimeter) circles; perforated Munktell TFN card or equivalent (e.g. Whatman 903)		
Abbott RealTime HIV-1 reagents	2G31-90	2G31-90	2G31-10
Number of DBS Per Sample	2	1	1
Blood Volume Per DBS	50	70	70
DBS Treatment Buffer	mLysis Buffer LN 2N77-01(1.7 mL)	DBS Buffer 8N80-01 (1.3 mL)	DBS Buffer 9N02 (1.3 mL)
No of Sample Tubes Per DBS	2 (DBS treatment tube & m2000sp sample input tube)	1 m2000sp sample input tube (ABBOTT Master Mix tube 4J71-80)	
Incubation	20 min at room temperature	30 min at 55 degree Celsius in heat block	
Automated DBS Eluate Transfer	No	Yes	
Sample Input Rack	Regular 13 mm calibration	Special rack calibration needed	13 mm Sample Racks with the DBS rack barcode label (ID 613; List 09N03-001) only
Internal Control per Lysis bottle	500 ul	750 ul	
Quantitation	Above 550 cp/mL	1- 10000000 cp/mL	See design goals
Data Reduction & Result Reporting	Specific for Open-Mode	Specific for Open-Mode	App Specs CD LN 01L68-013

CHOOSE TRANSFORMATION

Abbott

Addressing maintenance challenges:

- Limited data use to inform maintenance strategies
- Limited coordination and alignment in instrument management strategies (lease vs. purchase)
- Agreements are many times not negotiated system wide
- Adherence to contracts are not normally monitored, nor is vendor performance
- There is limited capacity and consistency in managing and negotiating maintenance contracts
- Vendor capacity can quickly be exceeded with rapid instrument scale-up
- Spare part availability and ability to import

Types of maintenance solutions:

- Reactive – pay as you go
- Instrument based – negotiated rate per instrument
- Reagent+S&M (bundled) – negotiated reagent premium inclusive of S&M – used with existing machines and newly purchased instruments
- Reagent Rental/Lease – negotiated reagent premium inclusive of S&M and rental costs for instrument

Recommended approaches moving forward:

- Reagent rental/leasing over purchase
- Reagent bundling (S&M) for existing instruments
- Amortizing instruments in reagent costs?
- Leverage data to negotiate contract terms and best fit solutions for existing instruments
- Back-up laboratory contingency plans

Set yourself up for **competition!**

Understanding price:

- Significant variation in commodity pricing (comparing apples to apples)
- Global access pricing vs. Local vendor procurement
- Demand – volume of testing
- Amortization of instruments included in price
- Reagent bundling (inclusive service and maintenance)
- Single brand platform use limits price negotiations
- **A need to focus on an 'all-in' cost**
- **Revisit and renegotiate agreements**

Ongoing manufacturer engagement:

PEPFAR, GF, and UNITAID involvement - purpose:

- Quarterly meetings to address country specific challenges
- Protocol enhancements and technology updates
- Development of responsive maintenance strategies
- VMI (vendor management inventory)
- Reagent rental/leasing options – regional contracts?
- Strengthening local vendor capacity – alignment with in-country scale-up ambitions
- Improved visibility and coordination
- POC integration, procurement and maintenance strategy development

Take Aways!

- Strengthen data mechanisms to inform forecasts and procurement adjustments
 - Develop data driven maintenance strategies
 - Investigate reagent rental/leasing, bundling options
 - Ensure local vendor capacity alignment
 - Establish integrated POC strategies
 - Strategies should not be static
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- We are working with manufacturers to address issues – but, we need your input!



Thank you

Jason Williams
Senior Laboratory Advisor
OHA/SCH/USAID