

Symposium 1 – Scaling up Access to Viral Load in Africa: Progress and Challenges

“Overview of Viral Load Capacity Across Africa”

ASLM2014

December 1, 2014

Cape Town, South Africa



Existing VL Capacity and Volumes

VL Forecast and Scale-Up Plans

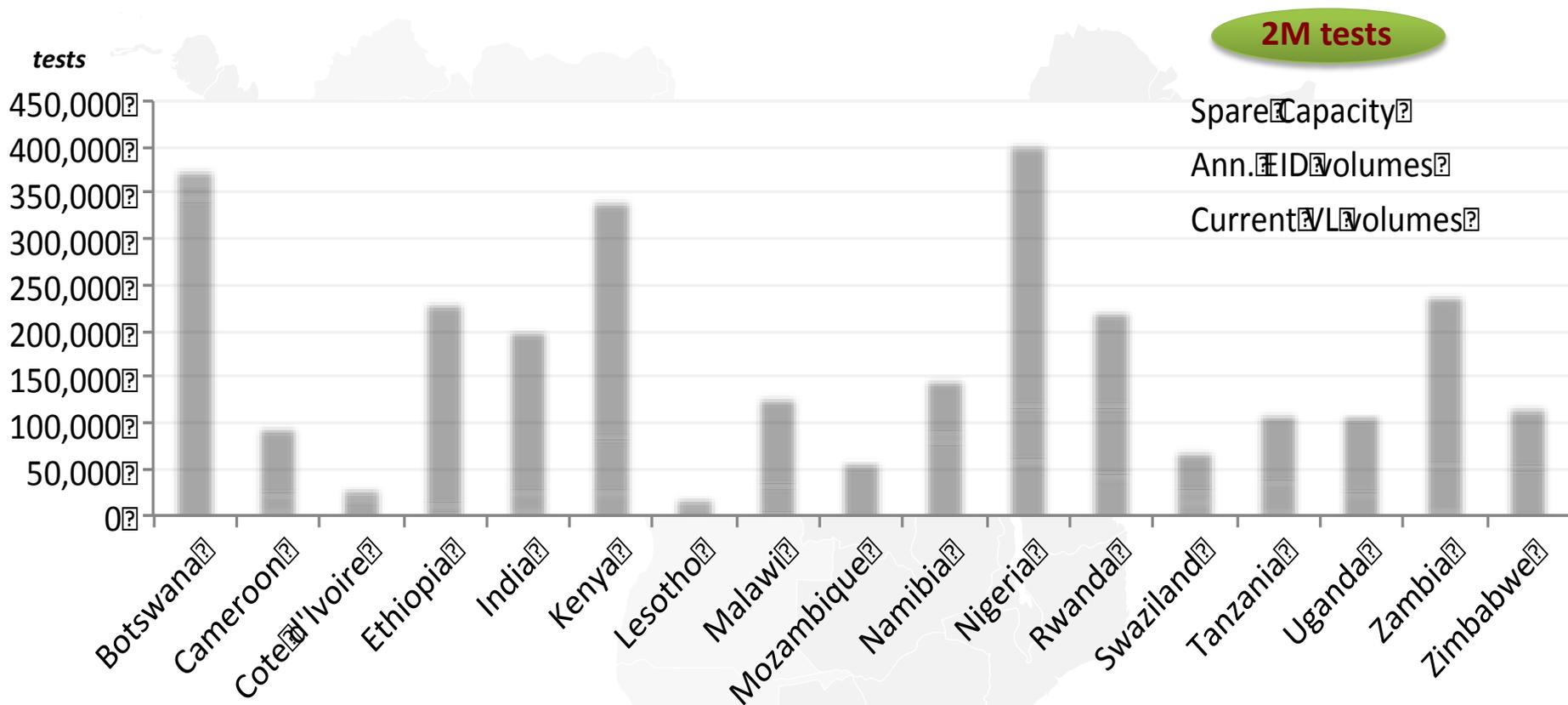
VL Price Reductions

Many countries where we conducted assessments have a large installed base of equipment, and have established aggressive VL scale-up plans

Country	# PCR Instruments	Tests in 2013	Scale-Up Plans		
			2014	2015	2016
Country 1	13	5,500	71,132	174,426	227,725
Country 2	12	70,000	100,000	150,000	200,000
Country 3	12	34,667	87,000	123,000	170,000
Country 4	27	71,500	100,000	125,000	150,000
Country 5	6	9,918	12,534	14,121	32,823
Country 6	6	31,829	100,000	200,000	400,000
Country 7	3	11,000	11,000	119,976	230,755
Country 8	7	7,000	50,000	TBD	TBD
TOTAL	86	241,416	531,666	906,523	1,411,303

NOTE: # PCR instruments only includes those placed in public sector labs; many countries plan to add additional instruments in the coming year.

Altogether, Africa has more than 200 automated PCR instruments and more than 2m tests per year in unused testing capacity

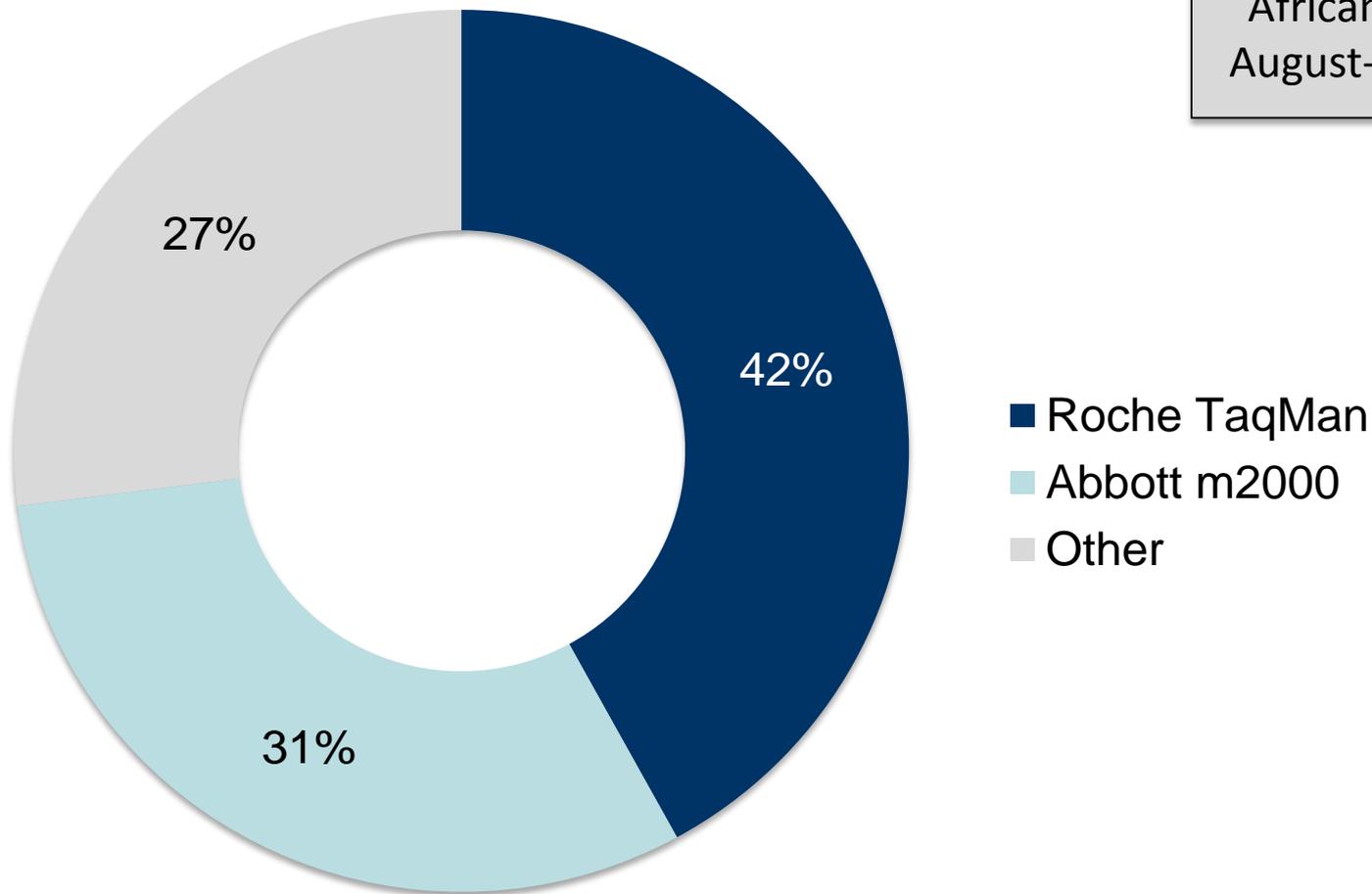


These existing instruments can be used to kick-start VL programs without significant infrastructure investment

The VL market is relatively competitive, with two main suppliers and some smaller players

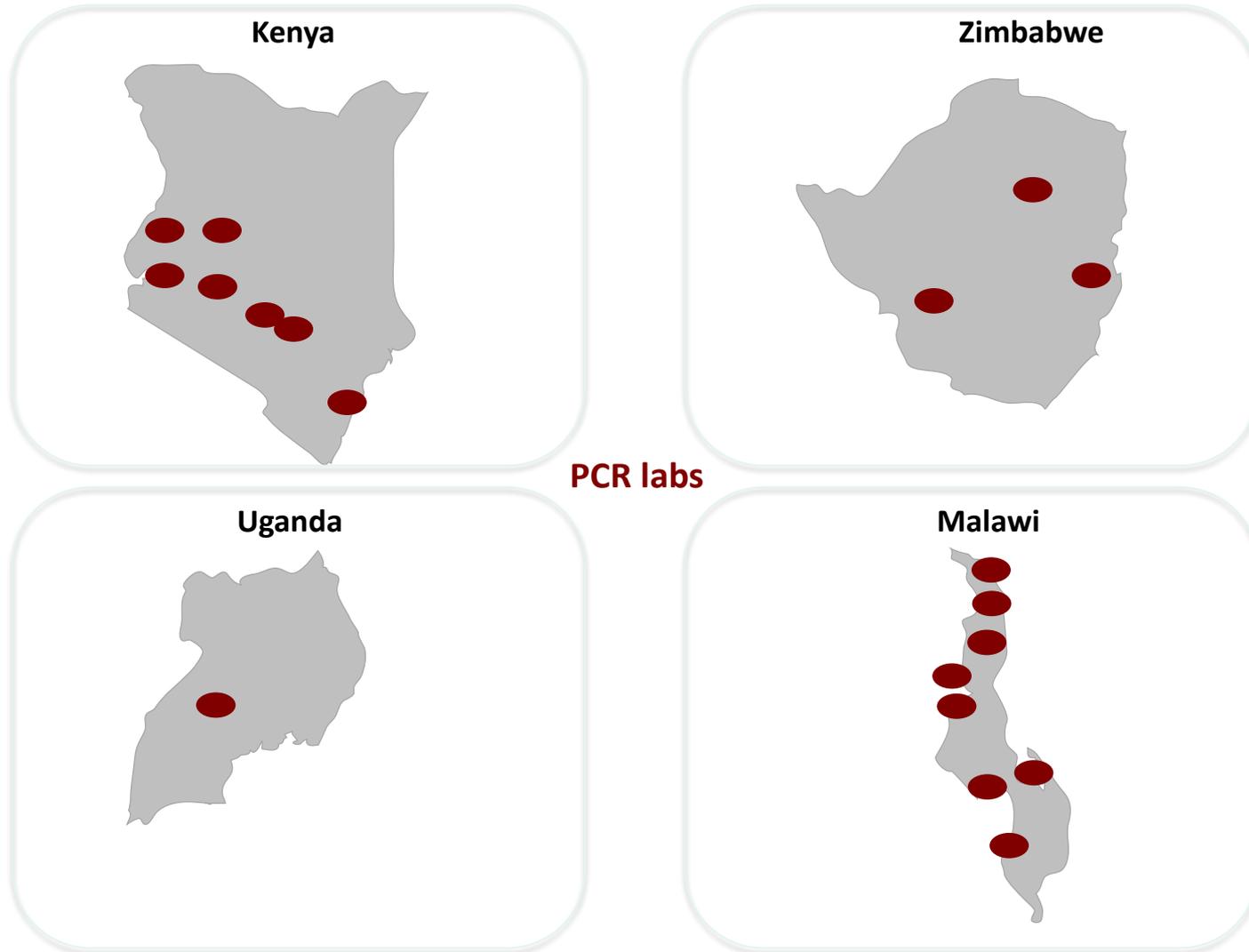
Current VL Instruments Placed

Data collected from 20 African countries in August-October 2014



NOTE: "Other" includes AB Gene Amp 9600, Roche Amplicor, bioMerieux, Siemens

The distribution of molecular laboratories allows for wide geographical coverage

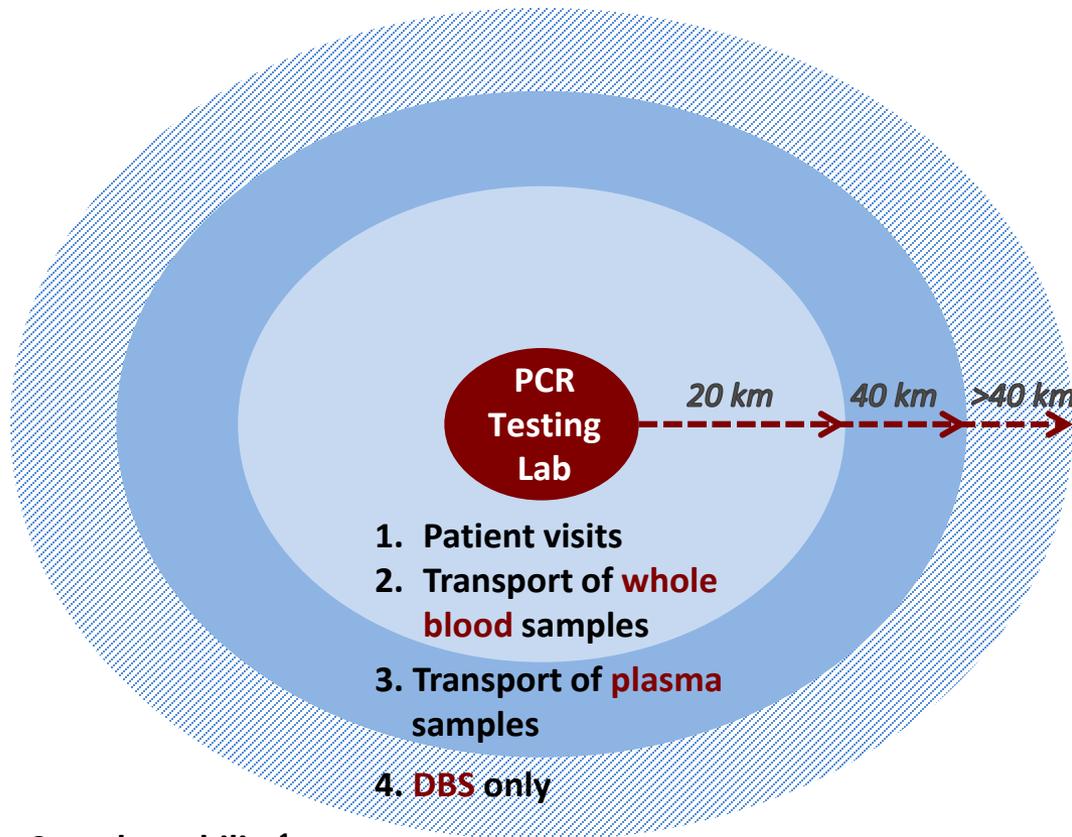


PCR labs

Note: this slide only reflects the PCR testing labs used for VL testing in the public sector. This excludes private PCR testing labs or those used for research purposes

VL testing laboratories are accessible to ART patients through a multi-tiered catchment area relying on various sample types to ensure stability

Four-tier catchment area reflecting various levels of sample collection



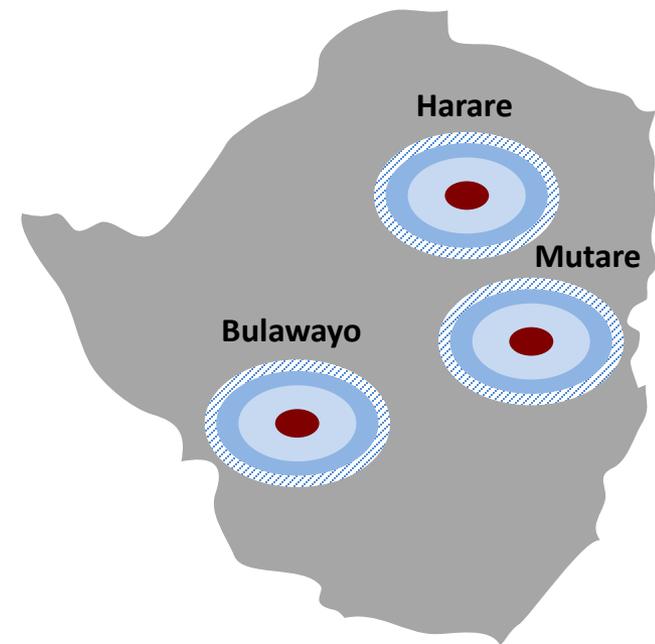
Sample stability¹

Whole blood in EDTA: 6 hours at room temperature

Plasma in EDTA : 24 hours at 2-8°C

Plasma in PPT: 24 hours at room temperature or 5 days at 2-8°C

Country example



¹ - These specifications can vary according to the PCR testing platform used

Using only whole blood and plasma samples, VL testing coverage can reach ~15-25% of patients; the remainder will need DBS and/or POC

Kenya

Zimbabwe

PCR Network

Testing Labs 7

Testing Labs 3

Catchment area

1-2 3

Tier	# ART patients	
	2014	2015
1 – patient visits	122,354	135,323
2 – whole blood		
3 - plasma	23,828	26,353
Total	146,182	161,676

Tier	# ART patients	
	2014	2015
1 – patient visits	117,699	228,653
2 – whole blood		
3 - plasma	56,138	163,580
Total	173,838	392,233

Total ART patients	763,685	844,033
Coverage	19%	19%

Total ART patients	725,866	830,812
Coverage (incl. new labs coming online in 2014-2015)	24%	47%

If considering existing testing capacity at single lab: **13%** **18%**

Using only whole blood and plasma samples, VL testing coverage can reach ~15-25% of patients; the remainder will need DBS and/or POC

Uganda

Malawi

PCR Network

Testing Labs 1

Testing Labs 7

Catchment area

1-2 3

Tier	# ART patients	
	2014	2015
1 – patient visits	104,943	136,425
2 – whole blood	8,919	11,595
3 - plasma		
Total	113,862	148,020
<hr/>		
Total ART patients	741,485	963,930
Coverage	15%	15%

Tier	# ART patients	
	2014	2015
1 – patient visits	62,543	68,797
2 – whole blood	50,277	55,304
3 - plasma		
Total	112,819	124,101
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Total ART patients	487,543	536,297
Coverage	23%	23%

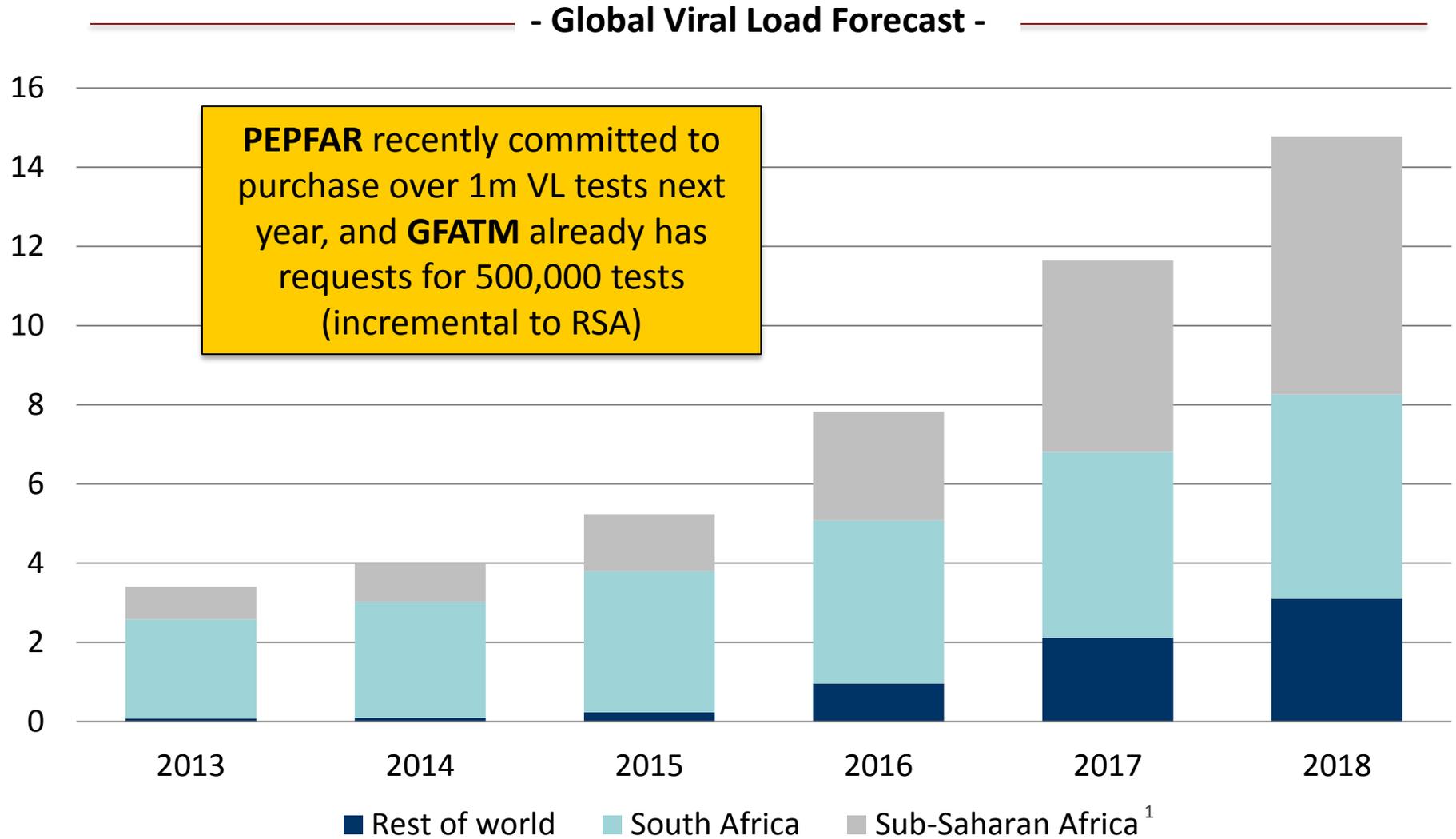
Agenda

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VL Price Reductions

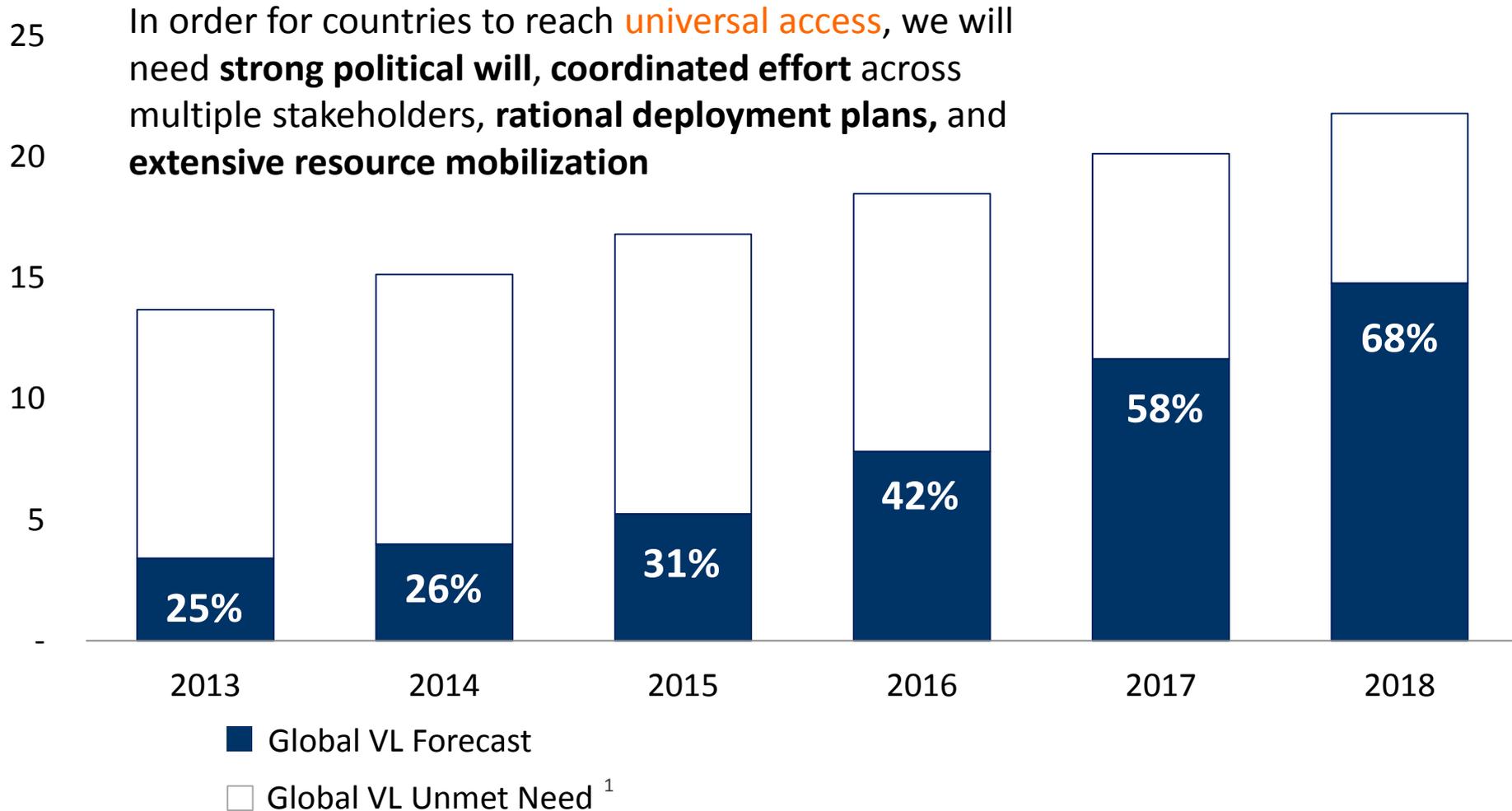
Based on “bottom up” country forecasts, taking into account current capacity and scale up plans, we can expect over 14m VL tests in 2018



¹sub-Saharan Africa (SSA) includes the following countries: Botswana, Cameroon, Cote d'Ivoire, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe

Despite adoption of new WHO guidelines, it will take many years to approach universal access to VL testing

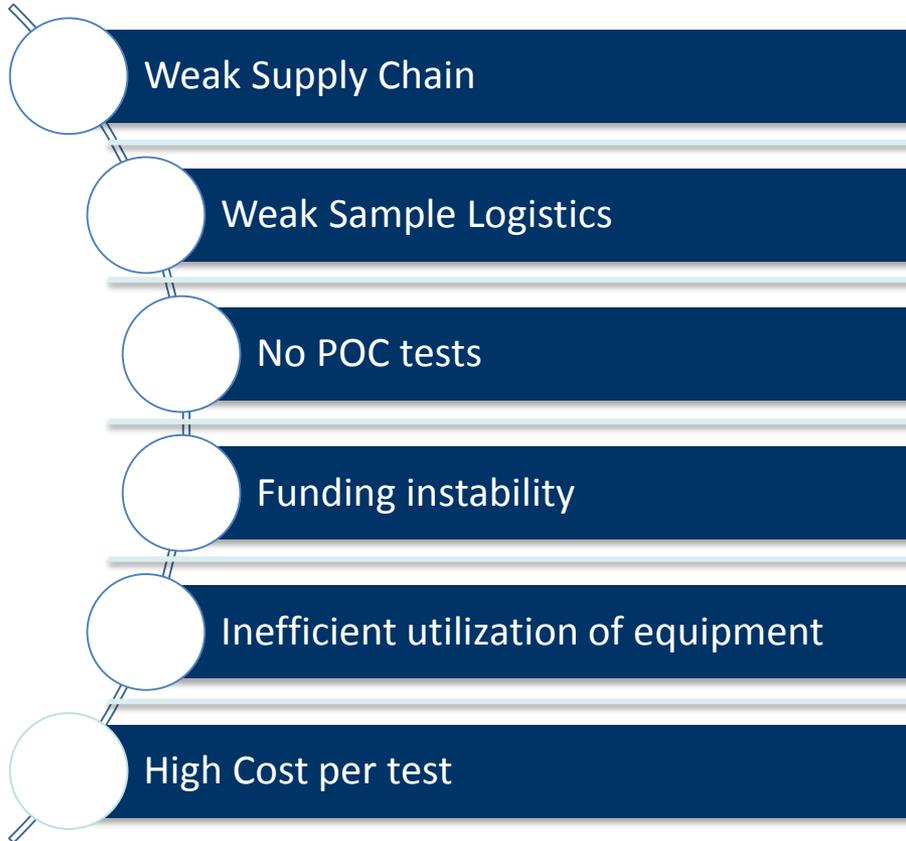
- Coverage of Global Need -



Note: The unmet need is defined by the total number of patients expected to receive ART monitoring in a country based on CHAI forecasts and the WHO guidelines. For several countries, national guidelines are used to define need rather than the WHO guidelines.

In addition to investment in equipment and other commodities, strong systems are needed

- Challenges -



- Solutions -

- **Best practices for procurement** of Dx commodities needs to be developed and adopted
- Investments on improving **sample transportation** are needed to reduce TAT and increase testing, especially when requiring cold chain
- **POC** technologies are key for **decentralizing testing** and expanding access
- Donors needs to be more coordinated to ensure **continuity of funding**
- **Workflow** at clinics and labs should be optimized. Appropriate **instrument placement strategies** needs to be developed before procurement
- **Cost of reagents and consumables** has historically been >\$25 per test in several countries, limiting countries' capacity to scale up

Key systems needed for VL scale up

- Cost per test
- Cost of maintaining the system infrastructure
- Resources mobilization (GFATM, PEPFAR, etc.)

- M&E system
- Connectivity
- Laboratory Information System (LIS)
- Patient tracking
- Linkages between diagnosis and treatment



- DBS vs plasma
- PoC vs conventional
- Platform selection
- CD4 shift
- Integration EID/VL
- QA and ISO standards
- Instruments maintenance
- Clinical and lab workflows

- Staffing and training
- Task shifting
- Turnover

- Policies and algorithm
- SOPs
- Policy dissemination
- Product registration and regulatory requirements
- Patient education
- Service delivery models
- Public/Private partnerships

- Forecasting
- Procurement
- Distribution
- Sample referral network
- Return of results

Agenda

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VL Price Reductions

Viral Load Access Pricing



\$9.40
reagents + consumables



Media Release

Basel, 26 September 2014

Roche launches Global Access Program for HIV viral load testing

Program expands access to care supporting the Diagnostics Access Initiative

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the launch of a new Global Access Program for HIV viral load testing, created in partnership with UNAIDS, the joint United Nations Programme on HIV/AIDS, the Clinton Health Access Initiative (CHAI), the President's Emergency Plan For AIDS Relief (PEPFAR) and the Global Fund to fight AIDS, TB & Malaria, at a high-level side event held during the 69th session of the United Nations General Assembly in New York, USA.

- **40% reduction in price**
- **\$150 million in costs savings over 5 years**
- **Dramatic improvement to the quality of care for over 31 million people living with HIV in LMICs**



Access pricing, along with aggressive scale-up plans, will help achieve global target of 90% of all people on ART with viral suppression



diagnosed

of all people living with HIV will know their HIV status



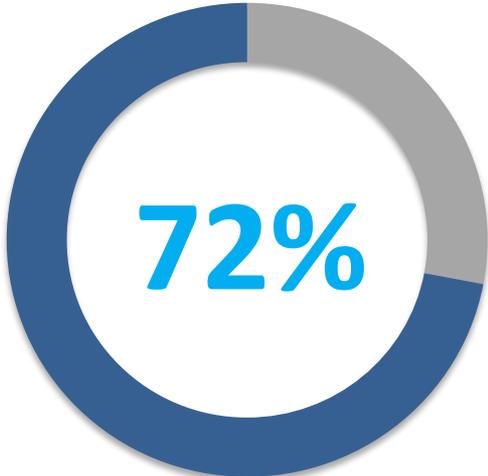
on treatment

of all people diagnosed with HIV will receive ARVs



virally suppressed

of all people receiving ARVs will be virally suppressed



of all people living with HIV will be virally suppressed



Viral Load Access Pricing and Scale-Up Plans Will Help, but Increased Investment Is Needed

Thank You

- MOHS – Ethiopia, Kenya, Malawi, Nigeria, South Africa, Tanzania, Uganda, Zambia, Zimbabwe
- Charles Kasipo, Paolo Maggiore, Naoko Doi and Meghan Wareham

