Laboratory Challenges to Viral Load Implementation in Resource-Limited Settings

5 May, 2014
Lusaka, Zambia

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Many African countries are considering greater viral load use in public ART programs

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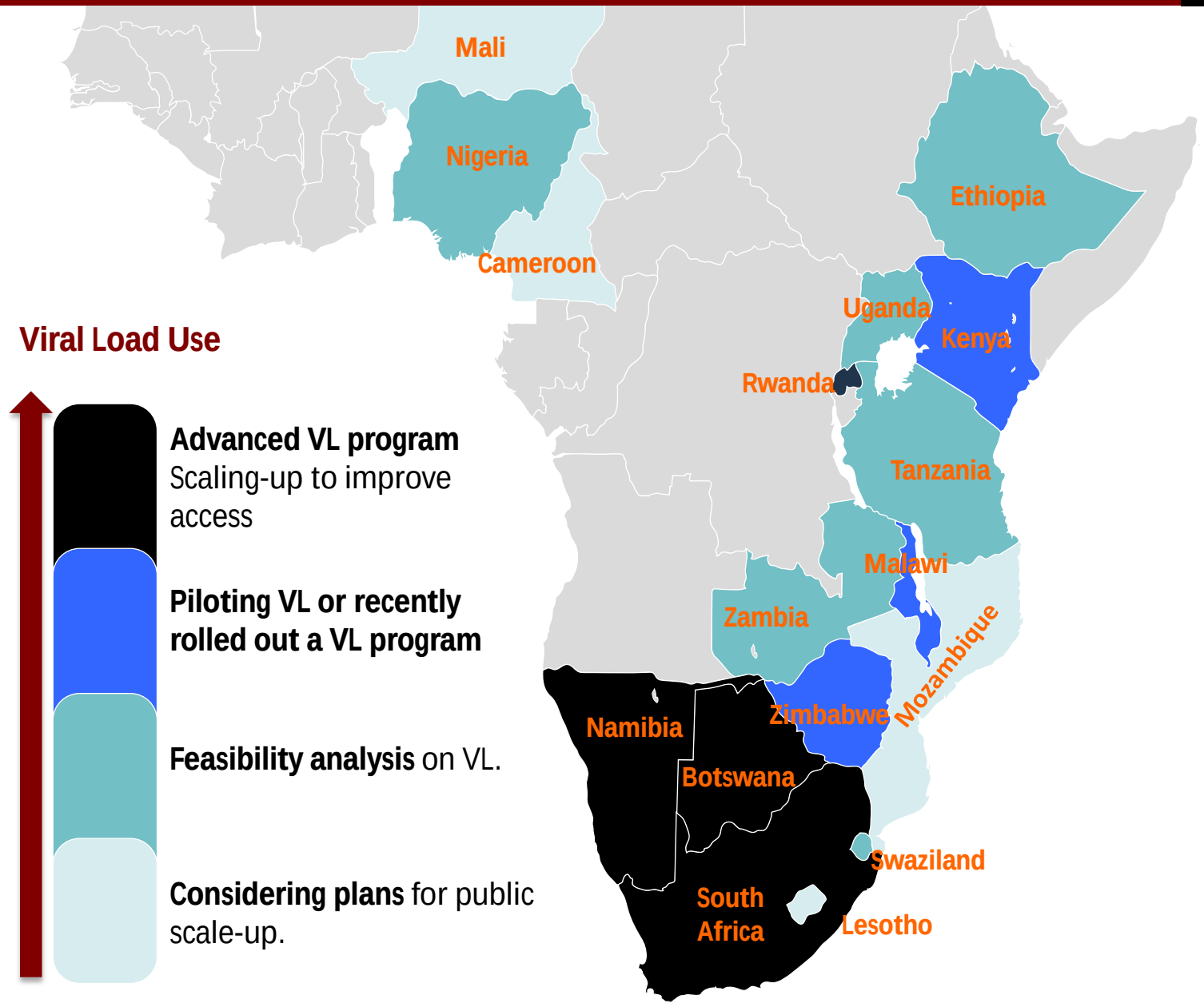

Viral load test volumes will grow significantly

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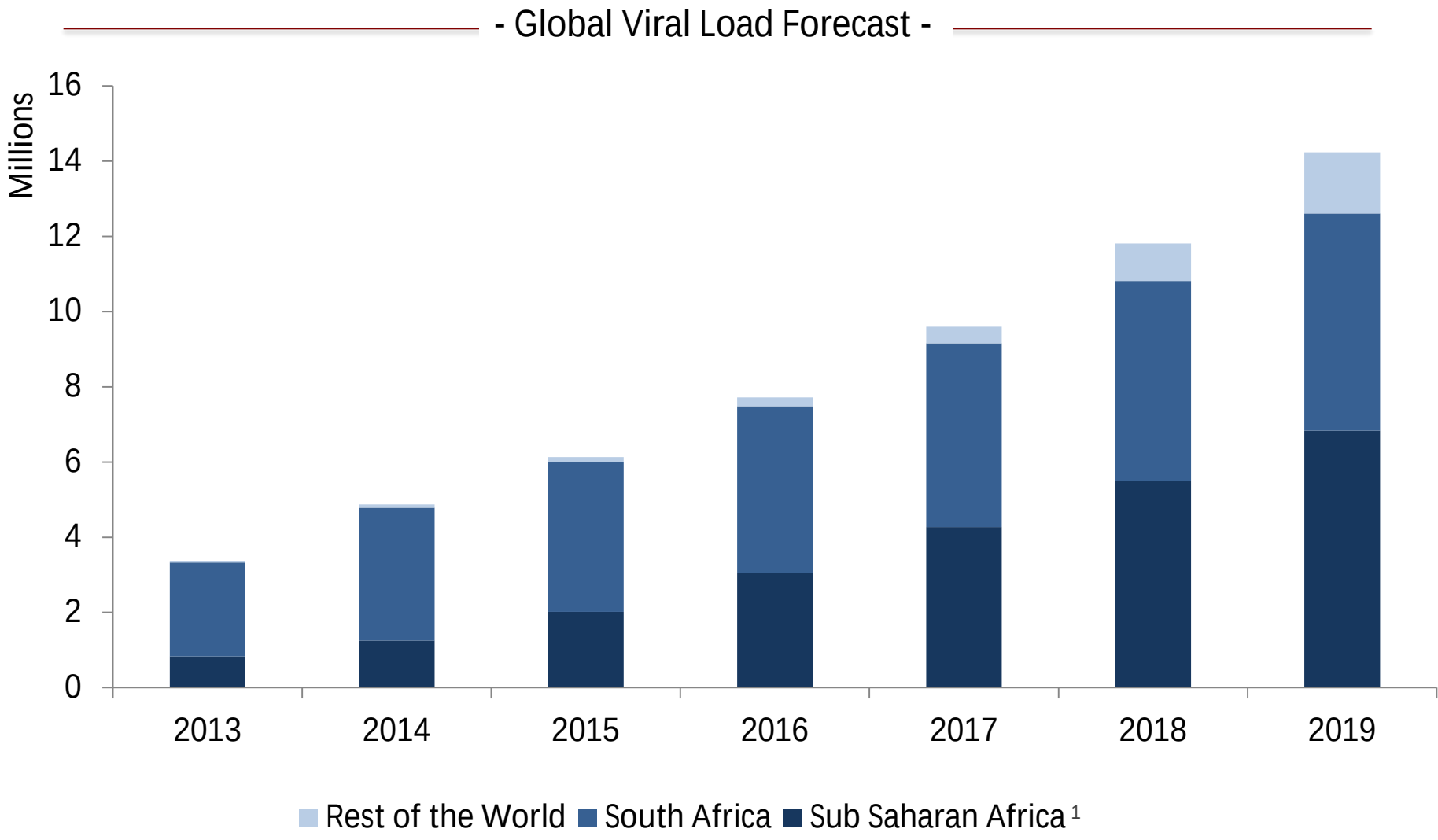

*sub-Saharan Africa (sSA) includes the following countries: Botswana, Cameroon, Cote d'Ivoire, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe

Source: CHAI

However, these will likely fall short of testing need

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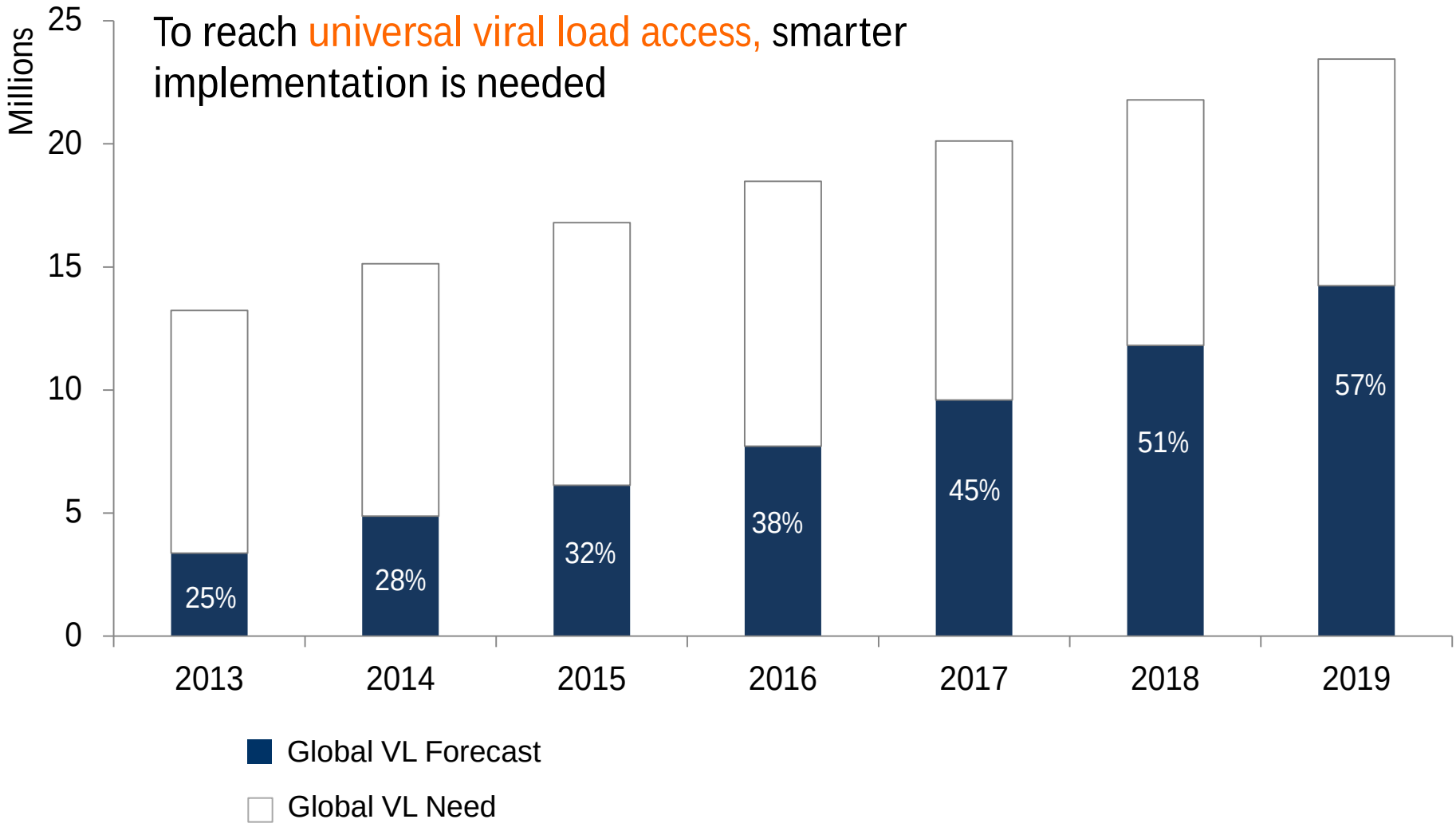
- Coverage of Global Need -



Source: CHAI

VL programs should learn from experience with CD4 & EID

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- Challenges -	- Lessons Learned -
Weak Supply Chain and funding instability	• ***Best practices for forecasting and procurement*** *of Dx commodities need to be developed and adopted*
Weak Sample Logistics	• Investments on improving sample transportation are needed to reduce TAT and increase testing, especially when requiring cold chain (CD4)
No POC tests	• POC technologies are key for decentralizing tests and expand access
Inadequate patient access	• Low retention and many patients missed by current clinical systems
Inefficient utilization of equipment	• Workflow at clinics and labs should be optimized though training clinics and labs staff • Appropriate instrument placement strategies needs to be developed before procurement

EID/CD4

ASLM Viral Load Consultation

In April 2013 convened an expert meeting on consensus strategies and recommendations for increasing access to HIV viral load in Africa.

A. Clinical strategies
B. Implementation policy issues
C. Lab strengthening priorities
D. Role of point-of-care testing

Meeting report available at: http://www.aslm.org/resource-centre/hiv-viral-load-testing/

- 130 attendees: clinicians, policy-makers, scientists
- 20 Ministries of Health
- Representatives from WHO, UNAIDS, SAA, US CDC, NHLS, KEMRI, APIN, Dream Project, CHAI, APHL, others
- Diagnostics companies

ASLM Viral Load Consultation

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Countries represented:

- South Africa
- Nigeria
- Ethiopia
- Kenya
- Senegal
- Uganda
- Malawi
- Tanzania
- Botswana
- Mozambique
- Sudan
- Cameroon
- Cote d'Ivoire
- Zambia
- Zimbabwe
- Lesotho
- Morocco
- Togo
- Algeria
- Liberia

Meeting Co-chairs:

- Sagie Pillay, NHLS, South Africa
- Wendy Stevens, NHLS, South Africa
- Nathan Ford, WHO
- Laura Broyles, CDC
- Alash'le Abimiku, IHVN Nigeria
- Richard Enzama, IHVN Nigeria
- Matilu Mwau – KEMRI, Kenya
- Madisa Mine, MOH Botswana
- Rosanna Peeling, LSHTM
- William Ampofo, University of Ghana
- Jessica Justman, ICAP
- Teri Roberts, MSF
- Shaffiq Essajee, CHAI

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World Health Organization REGIONAL OFFICE FOR Africa

UNAIDS

SOUTHERN AFRICAN HIV CLINICIANS SOCIETY

SAA www.saafrica.org SOCIETE AFRICAINE ANTI-SIDA SOCIETY FOR AIDS IN AFRICA

Key Meeting Findings

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- ***Many countries are starting to implement viral load***
  - Testing policies are being updated and adoption is starting
- ***Laboratory capacity exists to start many national programs***
  - Existing EID and VL laboratories have significant spare capacity (2M tests)
  - Existing lab staff require modest additional training
- ***Significant viral load expertise and best practice exists in Africa***
  - South Africa and Botswana provide long-term experience of high volumes and both centralized and decentralized testing
  - Many smaller scale viral load programs across Africa – e.g. some MoHs, MSF, Dream Project, research programs, centers of excellence
- ***Testing scale-up skills exist***
  - Prior investment in CD4 and EID laboratory strengthening has produced experienced program managers, policy makers, technologists, clinicians
  - Lab systems best practice exists – supply chain, quality assurance, maintenance

Stabilized sample options and improved referral networks

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The use of Dried Blood Spot samples or other sample stabilizing technologies could facilitate decentralized test access

However current sample referral systems are fragmented and data on performance of DBS for VL needs further review and assessment

A. Clinical strategies - Recommendations

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Virologic failure thresholds

- Better guidance needed on use of **dried blood spots and POC VL assays** – a research and policy priority
- **Different thresholds** for DBS or different VL platforms may not be easy to implement
- Normative bodies and industry should consider **standardizing viral load biomarkers and thresholds**

Future role of CD4

- **CD4 will still be needed** for:
  - Prioritizing patients for ART initiation
  - Informing need for OI prophylaxis
  - Confirming immune reconstitution post ART-initiation
- Important not to neglect CD4 but further **operational research** and **guidance on future role in monitoring** is needed

A. Clinical strategies - Recommendations

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Implementation priorities

- Routine monitoring for all ART patients is preferred, but if resources are limited, **prioritize** the following (WHO guidelines):
  - Confirmation of clinical or immunological failure
  - Pregnant and breastfeeding women
  - Sero-discordant couples
  - Newly initiated patients (within 6 months)
  - Infants and adolescents

Strengthen adherence

- To maximize the benefit of viral load, investment is needed in:
  - Strengthened, innovative and cost-effective **adherence support systems** integrated into clinic workflow
  - **Patient education**, e.g. via patient networks

B. Implementation policy - Recommendations

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Deployment planning is essential

- **Plan and budget** rational and cost-effective phase-in and scale-up
- Understand full **budget implications**, e.g. additional 2nd and 3rd line line drug use
- **Leverage existing viral load early infant diagnosis testing capacity**
- **Use both current laboratory and future point-of-care** platforms to ensure efficiency, equity and access

Reliable, cost-effective testing

- Make **accreditation** of viral load laboratories a requirement
- Strengthen **regulatory systems for** in-vitro diagnostic (IVD) products
- Establish **policies** to facilitate new **product adoption and product switches**
- Adopt **procurement best practice**
  - Standardize equipment
  - Lease expensive instruments
  - Consortium purchasing for volume-based discounts
  - Bundle maintenance and reagent pricing

Standardized, volume-based VL pricing is needed, as for CD4

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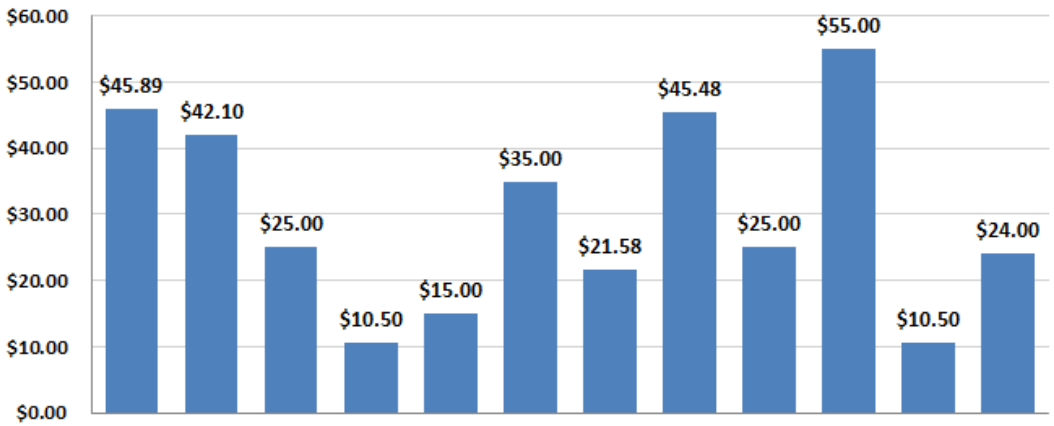
The cost per-test of viral load commodities varies greatly with volumes and is still generally much higher than CD4 cost.

Concern exists over the incremental funding required to scale-up viral load

Viral Load Reagent + Consumable Pricing
Per test, in a selection of countries



CD4 Reagent + Consumable Pricing
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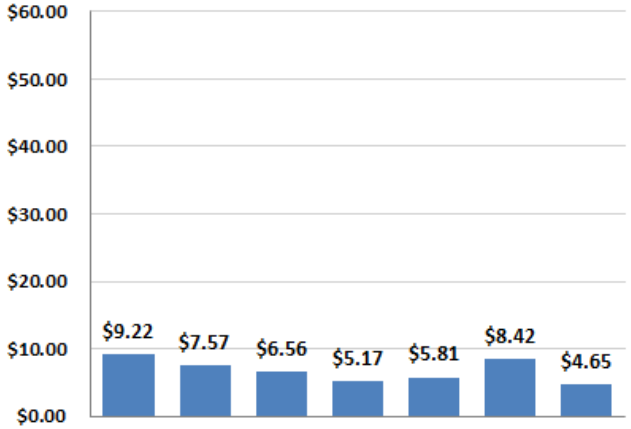

Exisiting VL and EID equipment can be used to start scale-up

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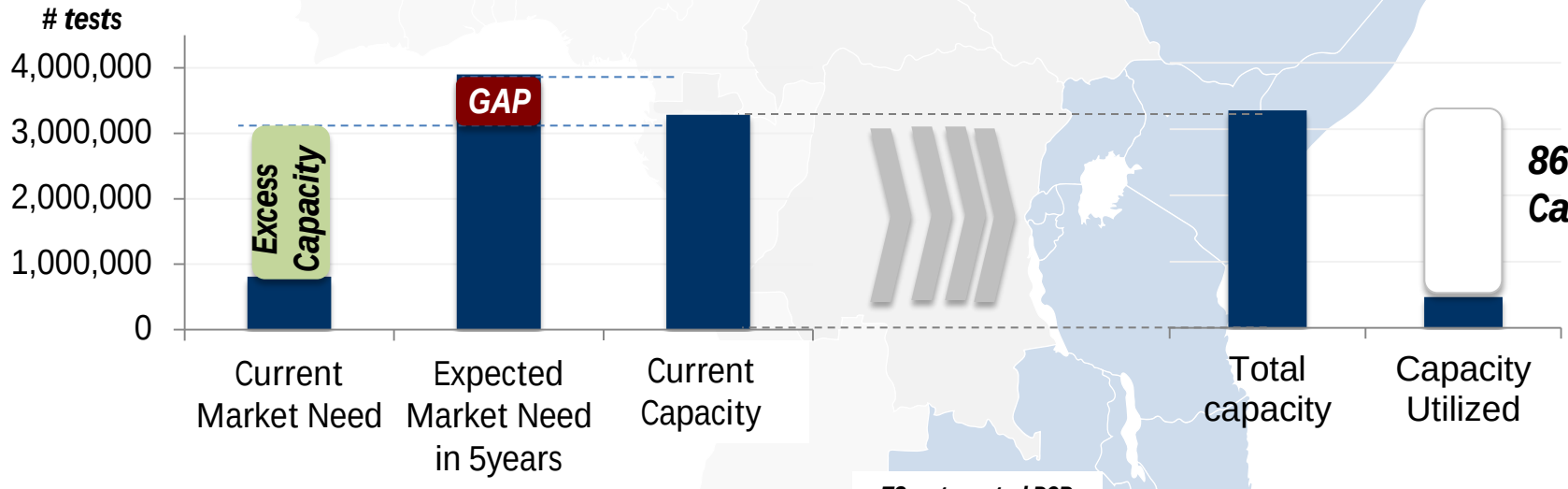
- Equipment Capacity[3] vs Market Need -



- Utilization of Equipment Capacity[4] -

73 automated PCR

Existing equipment capacity exceeds current market need, but more instruments need to be procured to cover the expected demand for VL tests in 5 years if the algorithm includes 2 VL tests per year

On average, only 14% of capacity is being used

3: The total capacity in 9 countries (Ethiopia, Kenya, Tanzania, Mozambique, Malawi, Swaziland, Zimbabwe, Zambia, Uganda) is a multiple of instruments and automated equipment capacity (supplier approved) per year - Roche CAP/CTM and Abbott M2000 system are 45,000 samples/year and bioMérieux NucliSENS EasyQ is 25,000 .
4: The capacity in 9 countries (Ethiopia, Kenya, Tanzania, Mozambique, Malawi, Swaziland, Zimbabwe, Zambia, Uganda) which is currently utilized is the sum of existing viral load and EID testing volumes.

C. Lab strengthening priorities - Recommendations

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Product Regulatory Systems

- **Harmonize regulatory approvals** under the Pan-African Harmonization Working Party (PAHWP) guidelines – accelerate adoption of improved technologies
- Establish **regional centers-of-excellence to generate high-quality evaluation data** for new technologies using standardized protocols

Laboratory Networks

- **Strengthen sample transport** and implement **SMS**-based result delivery systems.
- Implement WHO-AFRO SLIPTA accreditation and EQA programs
- Implement remote real-time monitoring of testing

Training

- **Train clinicians** on test use and interpretation
- Establish **public-private partnerships** for test operator training
- Prepare to train **non-laboratory POC test operators**

Equipment Maintenance

- Ensure **uninterrupted service and maintenance** coverage
- Track breakdowns in real-time
- Ensure availability of **service capacity** in country for fast turn-around repairs

D. Point-of-Care Viral Load - Recommendations

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Regulatory & Market surveillance

- PAHWP to develop **standard protocols for evaluation** of new point-of-care viral load technologies
- Develop **guidelines for post-market surveillance** of point-of-care tests
- Consider **remote device monitoring** and post-market surveillance via wireless networks
- Provide **ongoing mentorship** to POC testing facilities

Rational Deployment

- **Map** populations and health facilities that would benefit from access to lab vs. point-of-care viral load
- Determine **budget impact and cost-effectiveness** of introducing point-of-care testing
- Develop generic **implementation guidelines** to adapt to specific country settings as appropriate

Summary Meeting Recommendations

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- ***Scale-up should be proactive but well planned***
  - >6 million ART patients in Africa without access to viral load testing
- ***Use best practice***
  - Learn from existing viral load programs and experience with CD4 and EID
  - Implementing partner coordination is essential
- ***Viral load should be reliable and accessible***
  - Accredit viral load laboratories
  - Harmonize regulatory approval of new viral load technologies
  - Scale-up both lab and point-of-care tests
  - Clarify use of dried blood spots samples
- ***Viral load should be financially feasible***
  - Consolidate procurement to access price discounts
  - Utilize existing instrument capacity, e.g. for EID
  - Plan for increased 2nd and 3rd line drug needs

ASLM recommends a framework for viral load implementation

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	Stakeholder Consultation	Resources and Needs Assessment	Update guidance and algorithms	Impact Analysis	Laboratory networks and systems strengthening	Ensure cost-effectiveness	Monitoring and Evaluation
Activities	• Set-up TWGs to understand partner roles/responsibilities • Agree on a coordinated approach	• Assess existing resources (infrastructure, equipment, HR etc.) • Estimate the cost of integrating viral load into existing ART programs	• Revise national ART-related testing policies, local normative guidance and clinical algorithms	• Understand implications of scaling up VL for the whole health system	• Increase network capacity where needed • Strengthen laboratory systems to ensure a sustainable scale up • Lab accreditation	• Consortium procurement, instrument rental agreements, and public-private partnership initiatives with industry, etc • Rational test deployment	• Perform routine review and evaluation • Implement improvements and recommendations
Objective	Obtain **strong commitment and political will**	**Leverage existing resources and secure funding**	Create a **normative framework** conducive to VL access	**Anticipate and address challenges**	Ensure **sustainability**	**Optimized use of available resources**	Identify and share **best practices**