Reshaping the HIV viral load testing and early infant diagnosis market – From market takers to market shapers

GHSC Summit 2024







Agenda

- I. Context and Problem Statement
- 2. Methodology and Work Timeline
- 3. Results
- 4. Conclusion

I. Context and Problem Statement

Context

- People living in LMICs are disproportionately affected by the HIV/AIDS epidemic
- Significant global advances in prevention, care, treatment, and viral load testing have the UNAIDS 95/95/95 targets within reach*
- Achievement of the 3rd 95 is only possible with efficient, available, cost effective, reliable, and high-quality viral load testing services
- Laboratory networks in LMICs struggle to perform given extensive constraints in funding, HR capacity, commodity availability, adequate infrastructure, and weak in-country private sector engagement

Context - USAID Introduces the Network Approach to Strengthening Laboratory Networks

- Aligns instrument capacity with patient demand and diagnostic equipment utilization
- Enables procurement and placement of molecular instruments through all-inclusive service level agreements
- Allows for costed implementation plans to create more efficient transport of patient samples
- Informs laboratory-related decision making at the national level, national laboratory policy, and vendor management of molecular instruments and commodities

Network Approach to Laboratory Service Elements

- Diagnostic network optimization (DNO)
- Sample Transport
- Forecasting and supply planning
- Procurement and strategic sourcing
- Performance management



Problem Statement

Applying the network approach to lab services, four major challenges in countries with high rates of HIV emerged.

- I. poor molecular diagnostic market dynamics;
- 2. lack of price transparency and wide variations in pricing by suppliers across countries;
- 3. lack of formal service contracts to allow supplier performance monitoring, and
- 4. lack of data transparency to monitor instrument network performance by laboratory users and donors.

Improving price transparency and service performance and building a healthy supplier market was key for PEPFAR to transform molecular laboratory testing and provide cost effective and efficient services for better health outcomes.

2. Methodology and Work Timeline

Reshaping the Viral Load Supply Chain – From market takers to Market SHAPERS

What is Market Shaping?

- Identifying systemic barriers that limit the availability of life-saving treatments.
- Strategic efforts to influence the supply and demand dynamics of health products or services
- Leading to improved access, affordability, and innovation.

Evolution of PEPFAR's global SLAs: The timeline



2019

Wave-I RFP kickoff

Global RFP initiated with focus on reagents and consumables for all countries and allinclusive services for six high-volume "Wave-I" countries

2020

Wave-I implementation

New global reagents and to cover services for consumables prices enacted. All-inclusive services pricing went into effect for six largest volume countries. Instrument operational data reporting began in Wave-I countries

2022

Wave-2 RFP kickoff

Global RFP extended additional 42 "Wave-2" countries, supported by PEPFAR

2023

Wave-2 implementation

All-inclusive pricing and KPIs go into effect for the Wave-2 countries with regular PEPFAR-supported purchases. Engagement occurs with the main public procurers (Global Fund, MOHs) for the remaining Wave-2 countries to make them aware the negotiated benefits

2024 **Support for SLA** adoption beyond **PEPFAR**

GHSC-PSM is helping to build capacity for SLA implementation, focusing on countries which demonstrated strong interest and readiness for it. Additional countries may need further support.























































Now, nearly 50 countries are included in the PEPFAR Global Viral Load Initiative



Zimbabwe

Mali

Leone

Rwanda

Problems with supply chain management and equipment maintenance can be tackled through these interventions:

Problem		Solution
Capital procurements and equipment graveyards	>	Instrument leasing instead of outright purchase, and upgrading of older equipment
Too many instruments (excess capacity) or inefficient utilization	>	Minimum utilization requirements on instruments Integration of testing – expansion to other disease areas
Provision of commodities only	>	Provision of commodities and services to include cost per patient test for reagents, consumables, controls and some wastage
Instruments with prolonged downtime and overdue maintenance	>	Maintenance terms and KPIs for performance monitoring and accountability
Reagents and consumables stocked out	>	Shifting more responsibility to vendor via different incoterms and/or vendor managed inventory
Data systems not available or with limited integration. Long TAT of results return	>	Holistic approaches to data ecosystems: interfaces between health information systems, laboratory information systems, instruments, use of KPIs and other data for decision making

The all-inclusive standard service package in SLAs include:

Category	What is included?
Instrument lease, installation and removal	Equipment lease and installation costs, including placement, delivery of machines to site, inspection of machines, initial end user training and instrument removal at end of life or end of contract
Service and maintenance, insurance, and ongoing end user training	All aspects of servicing and maintaining instruments and providing ongoing end user training, including insurance, preventative maintenance, repairs and replacements, and necessary updates
Connectivity and data reporting	Automated reporting of operational data from instruments
Commodity supply chain management	Freight and logistics of reagents and consumables delivered to an agreed place, per incoterms (e.g. the central medical store)
Equipment upgrades	Planned enhancements and upgrades to instruments

SLAs are as effective as they are monitored and managed against established service levels, hence the need for Key Performance Indicators (KPIs)



Category	Areas tracked in key performance indicators	
Service and maintenance, insurance, and ongoing end-user training	 Preventative maintenance visits per instrument per year Average response for equipment breakdown Average time to repair Instrument outages after regular maintenance Average uptime working days per quarter Average number rejected runs or failed tests 	
Connectivity and data reporting	 Average "uptime" of automated reporting systems at least once per day Quarterly Reports submitted on-time 	
Commodity supply chain management	 Share of reagents and consumables in a delivery with required shelf life remaining Share of reagents and consumables delivered in full and on time 	

Under the SLAs, suppliers are responsible for monitoring and reporting regularly on 10 key performance indicators.

This enables countries to hold them accountable for their performance and quality of services

Note: Additional detail can be found on the appendix

3. Results – Price and Service

Price - The global SLA implementation by GHSC-PSM has had a measurable impact on pricing for all VL/EID reagents and consumables and on the laboratory supply chain towards services which are more cost effective, efficient, and responsive to patient needs

>65 million

VL and EID **tests procured** by PEPFAR 2020-2024 under the global all-inclusive SLAs with Abbott, Roche and Hologic

>\$235 million

Cumulative savings on these orders since 2020, compared with pre-global RFP prices

\$2.5 - \$3.5

Average savings
per test across the
PEPFAR portfolio



Supplier performance KPIs tracked under global SLAs and issues being identified and rectified in a timely manner. Instances of backlogs due to poor instrument performance reduced



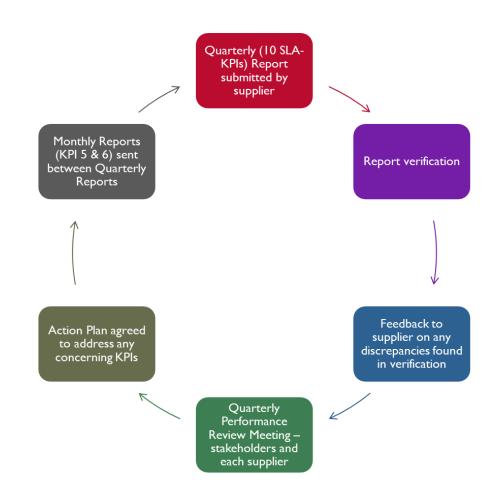
Instruments automatically reporting operational data to the suppliers' instrument data platforms and PSM's global dashboard



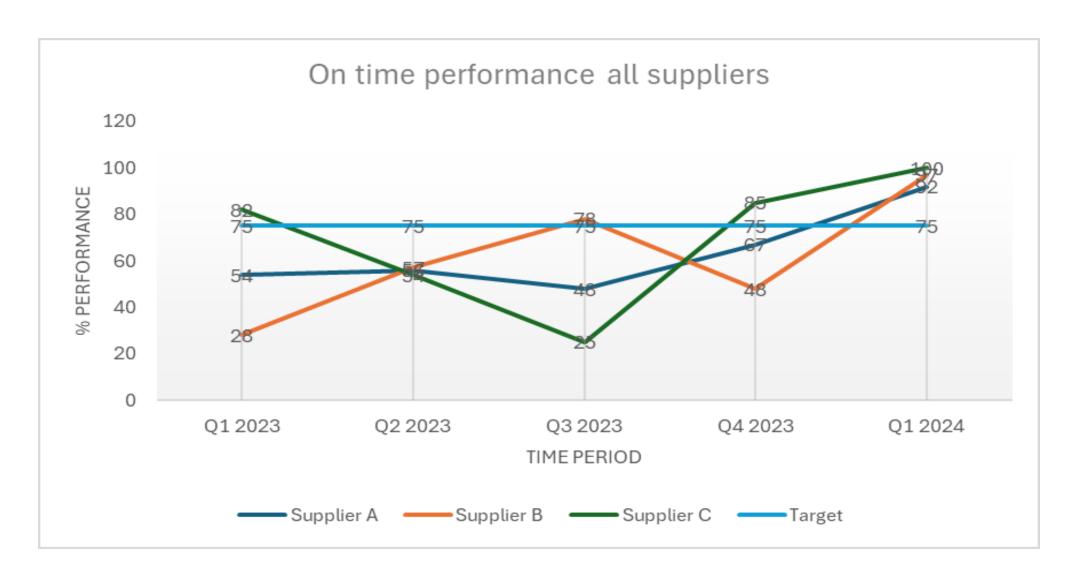
The relationship between GHSC-PSM and diagnostics manufacturers has changed from transactional, ad hoc-procurement activities to a long-term, mutually beneficial strategic partnerships

In-country supplier performance improvement through KPI Management – Process

- Suppliers submit a quarterly report,
- 2. Validation and concurrence on that report
- 3. Feedback to suppliers on discrepancies found in verification
- 4. Hold quarterly performance review meeting (QPR) with each supplier,
- 5. Action plan to address any concerning KPIs or service interruptions,
- 6. Review performance on monthly reports (for Uptime and Error Rates) and monitor adherence to any established action plans or action items. This cycle repeats quarterly.



In-country supplier performance improvement through KPI Management - Results



4. Conclusions

Supply chain innovations – such as all-inclusive pricing and data can be transformative - can improve molecular testing service quality and availability

- Introduction of Network Approach and strategic sourcing through Global RFP process has demonstrable and transformative effect on responsiveness and surveillance networks in supported countries
 - Impacts include cost savings, improved service availability, and market shaping that other procurement agents - donor and host country - have and can benefit from
 - Commodity + service based pricing and strategic partnerships can be adopted to benefit wide range of molecular testing assays and platforms
 - Strategic sourcing, strategic partnerships, data availability and monitoring, create environment for sustained response



Thank you.







GHSC-PSM Conference Hub

The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership. For more information, visit ghsupplychain.org.

The views expressed in this presentation do not necessarily reflect the views of USAID or the U.S. government.

Thank you!

If you have any questions, please reach out to GHSC-PSM Strategy team at GSCStrategy-Lab-HQ@ghsc-psm.org

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