From local decisions to global markets:

A symposium on key trends in HIV/AIDS supply chains

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management (GHSC-PSM)
Rapid Test Kits (GHSC-RTK)

USAID
FROM THE AMERICAN PEOPLE

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

Good morning!

Let's talk about

- Who we are
- Trends in HIV rapid test kits and self-testing
- Trends in ARVs
- Trends in viral load commodities and services
- Local action to support global strategy

Objectives of this satellite event

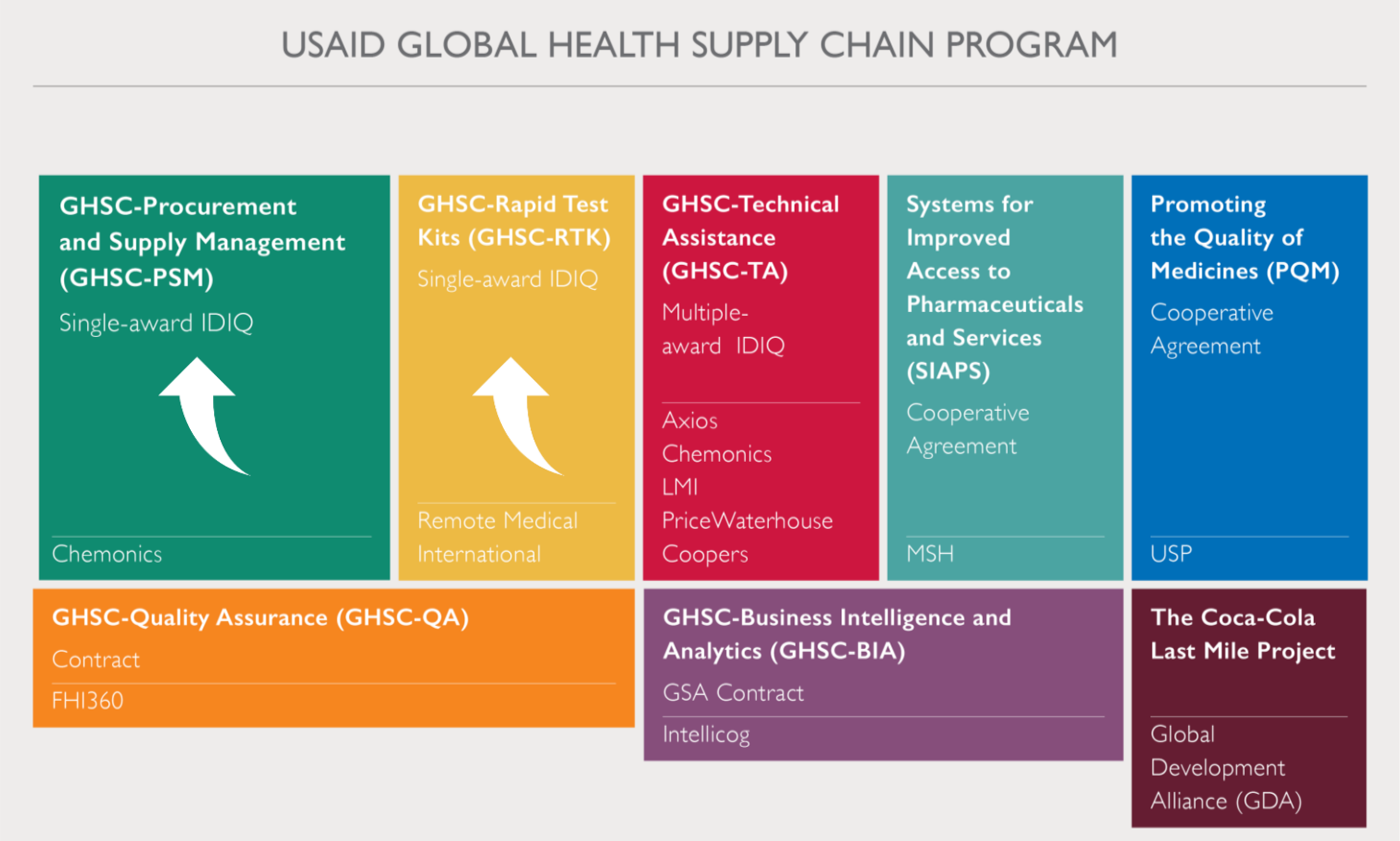
- Raise awareness of key trends for key HIV/AIDS commodities and USAIDS objectives for each
- Have participants understand how their local decisions may impact global markets

Which trends are you hearing about in the countries where you work?

How will what you're about to hear influence decisions you make?

Who are we?

THE USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM



GLOBAL HEALTH SUPPLY CHAIN – PROCUREMENT AND SUPPLY MANAGEMENT (GHSC-PSM)

- Jay Heavner, HIV/AIDS Global Collaboration Manager, GHSC-PSM

We support USAID's and PEPFAR's priorities in three ways

Global Supply Chain

Global Commodity Procurement and Logistics

Systems Strengthening

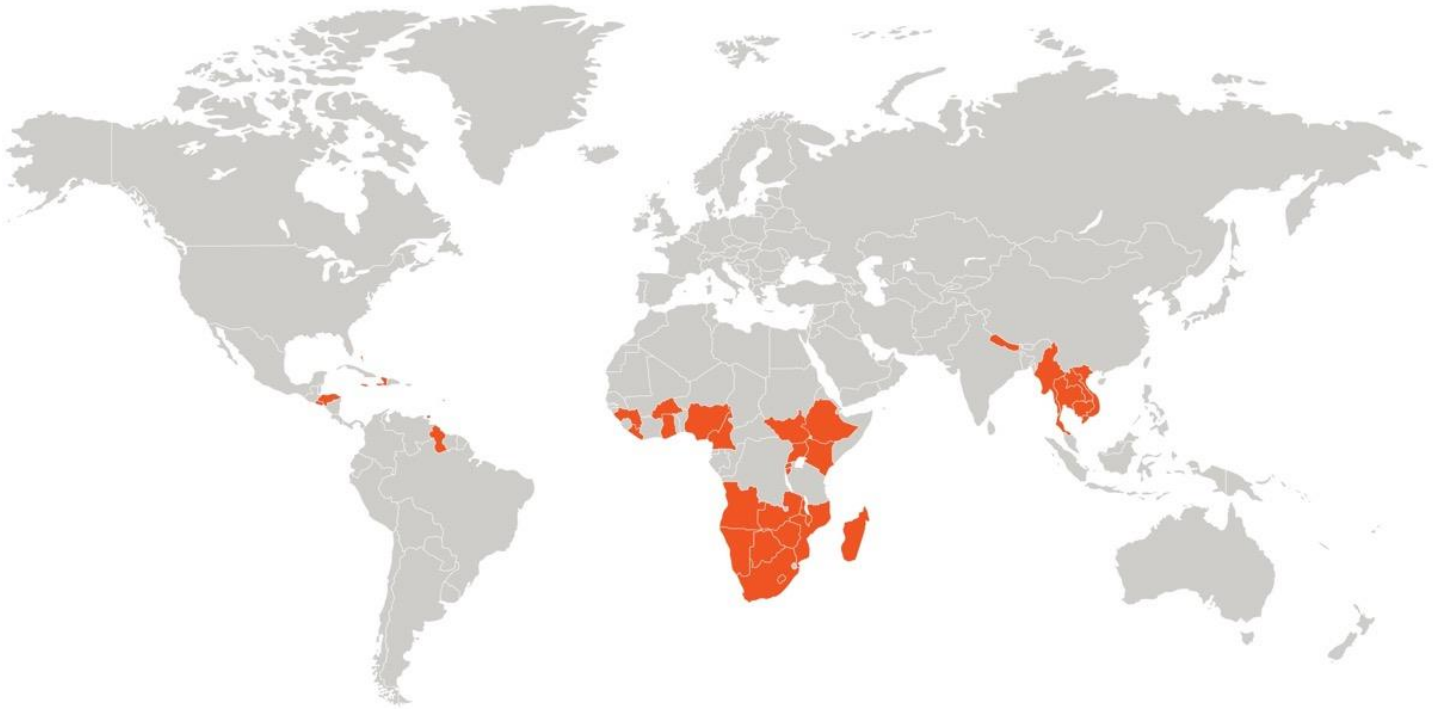
Country Supply Chain Systems Strengthening

Strategic Engagement

Global Collaboration, Market Dynamics, Knowledge Management, Communications, Advocacy

Each of our consortium partners plays a key role

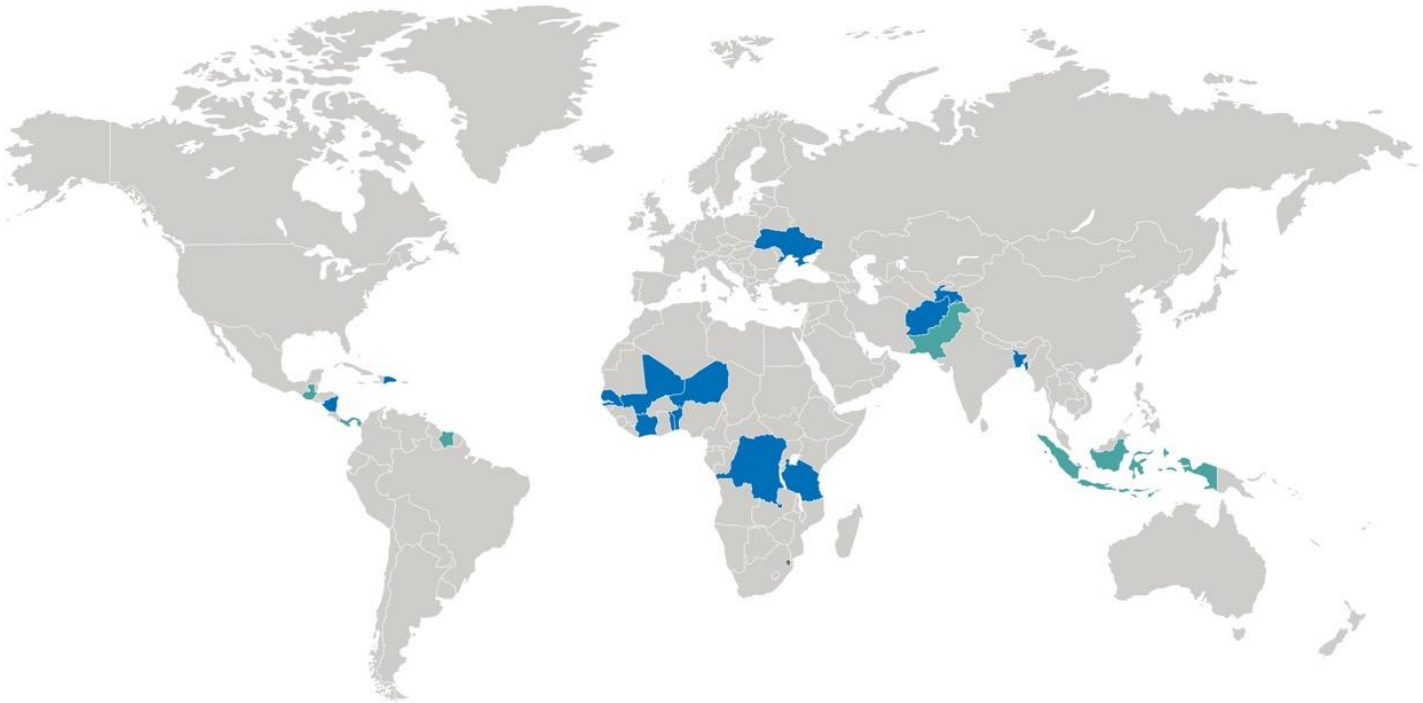
Many countries receive both technical assistance and deliveries of public health commodities



Technical assistance and Deliveries

Angola	Burundi	Guinea	Laos	Namibia	Trinidad & Tobago
Bahamas	Cambodia	Guyana	Liberia	Nepal	Uganda
Barbados	Cameroon	Haiti	Lesotho	Nigeria	Vietnam
Botswana	Ethiopia	Honduras	Madagascar	Rwanda	Zambia
Burkina Faso	El Salvador	Jamaica	Malawi	South Sudan	Zimbabwe
Burma	Ghana	Kenya	Mozambique	Thailand	

We also deliver commodities to many more countries, and a few countries receive technical assistance only



Deliveries only

Afghanistan
Bangladesh
Benin
Cote d'Ivoire
Democratic Republic of the Congo
Dominican Republic
Mali
Nicaragua
Niger
Senegal
Swaziland
Tajikistan
Tanzania
Togo
Ukraine

Technical assistance only

Guatemala
Indonesia
Panama
Pakistan
Suriname

Based on March 10, 2017 reporting.

GLOBAL HEALTH SUPPLY CHAIN – RAPID TEST KIT (GHSC-RTK)

The first 90

- Joshua Pinedo, Procurement and Logistics Manager, USAID Global Health Supply Chain Program – Rapid Test Kit (GHSC-RTK)

Reaching the first 90 – the USAID award for HIV rapid test kits (RTKs)

- On February 27, 2015, RMI together with Tetra Tech was awarded a $95 million contract from USAID to provide HIV rapid test kits to USAID partner programs throughout sub-Saharan Africa
- Worked closely with the incumbent to ensure a smooth and quick transition without stock interruptions
- On September 2017, RMI received an extension of their initial 3 year Task order through February 26, 2020.

Delivering quality assured HIV rapid test kits

USAID FROM THE AMERICAN PEOPLE

World Health Organization

No.	Product Description	Manufacturer
1	Determine HIV 1/2	Alere International, Ltd.
2	Alere HIV 1/2 Ag/AB Combo Set	
3	Stat-Pak HIV-1/2	Chembio Diagnostic Systems, Inc.
4	Stat-Pak HIV-1/2 Dipstick	
5	SURE CHECK HIV® HIV 1/2 Assay	
6	Uni-Gold HIV-1/2	Trinity Biotech Plc
7	SD Bioline HIV-1/2 3.0	Standard Diagnostics, Inc.
8	VIKIA HIV-1/2	bioMérieux S.A.
9	First Response HIV 1-2-0 Card	Premier Medical Corporation
10	Oraquick HIV-1/2 Rapid (Professional use)	OraSure Technologies
11	Oraquick HIV -1/2 Rapid Antibody Self-Test	
12	Rapid Test HIV (Colloidal Gold Device)	Beijing Wantai Biological Pharmacy Enterprise Co. Ltd.

Where GHSC-RTK Delivers

- Haiti

- Angola
- Botswana
- Burundi
- Cameroon
- Côte d'Ivoire
- Democratic Republic of the Congo
- Ethiopia
- Malawi
- Mozambique
- Namibia
- Nigeria
- Rwanda
- South Africa
- South Sudan
- Swaziland
- Tanzania
- Uganda
- Zambia
- Zimbabwe

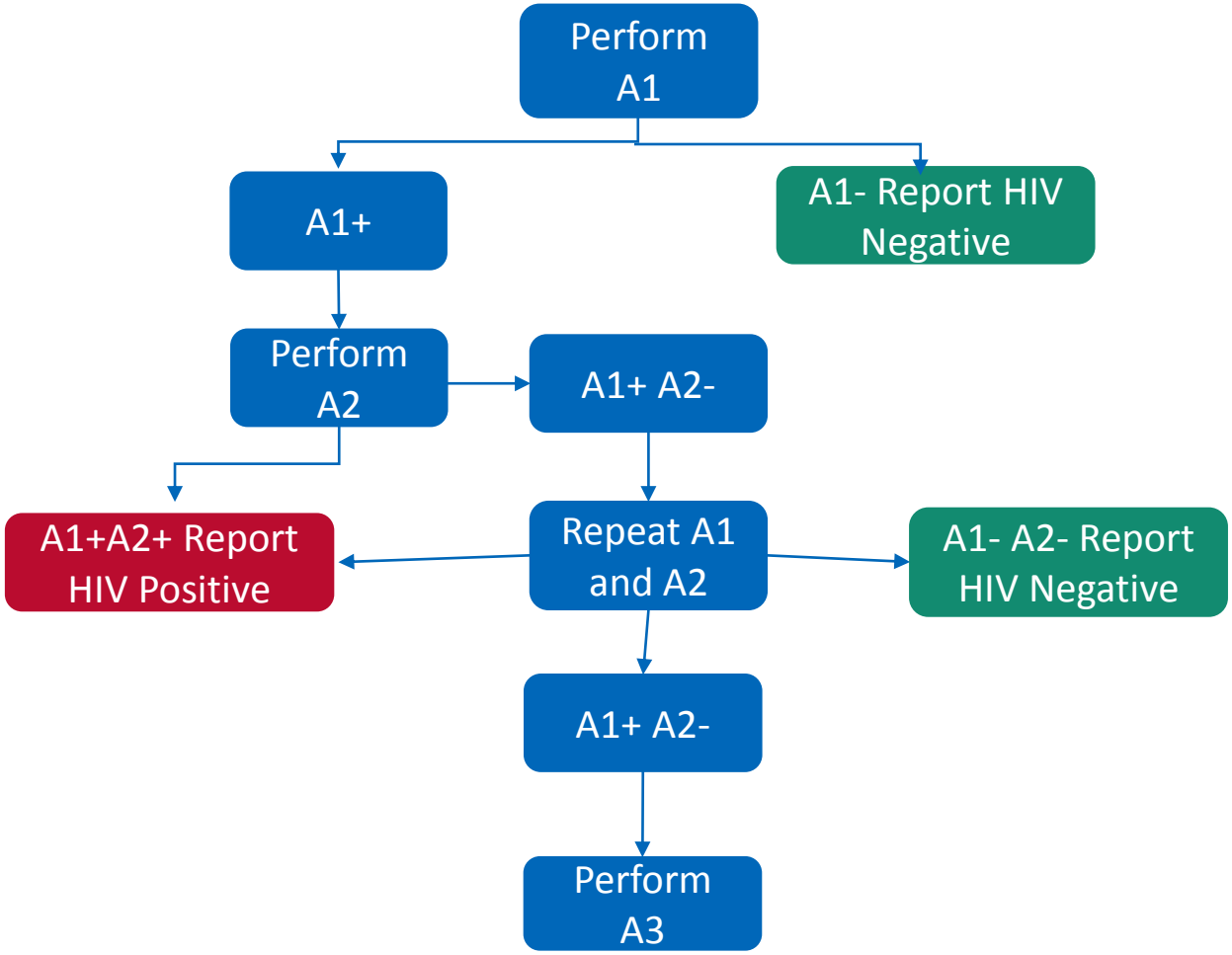
HIV rapid test kits (RTKs)

USAID GHSC-RTK Policy for the Procurement of HIV Diagnostic Test Kits

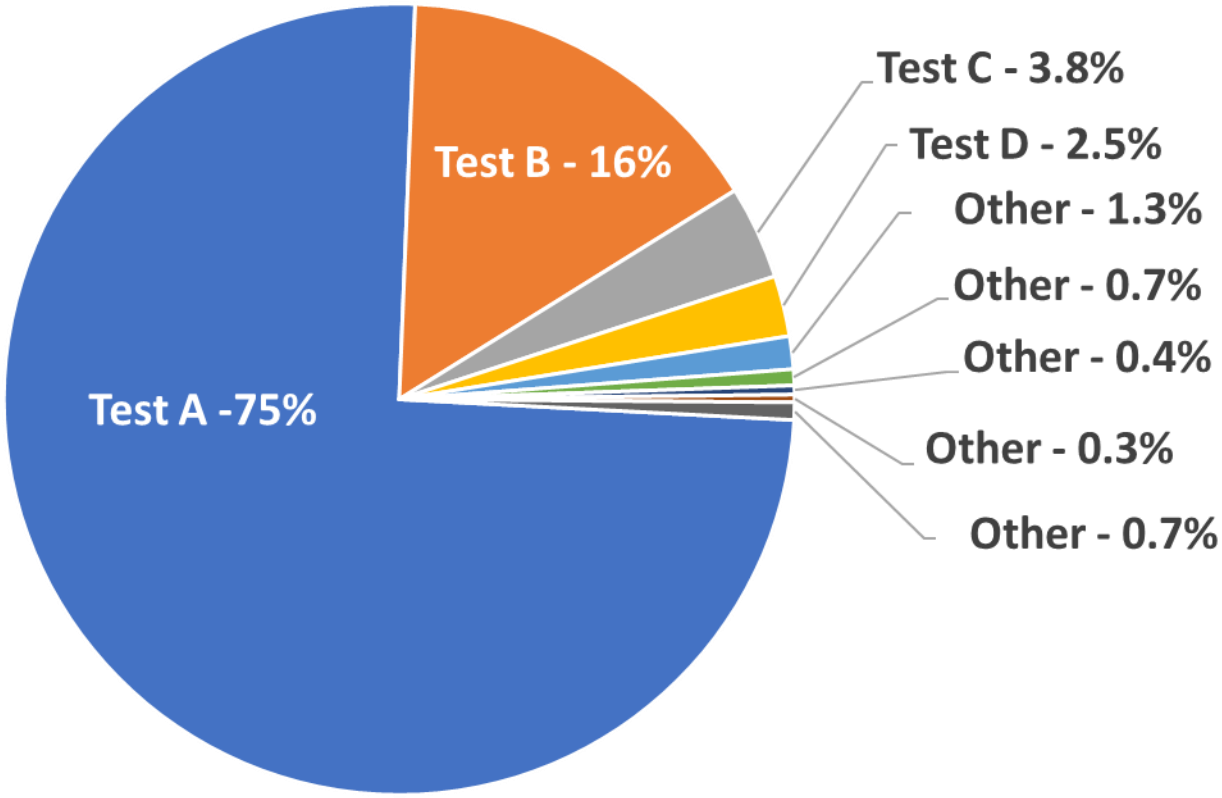
Procurement Requirements	Quality Assurance Requirements
WHO Prequalified List of Approved in vitro diagnostic products	200 samples (tests) per lot must be collected by GHSC-QA Sampling agent prior to release
USAID List of Approved HIV Rapid Test kits	Concurrent shipping – samples must be successfully collected in order to be released for shipment
Included In the Country's validated National HIV Testing Algorithm	Every lot (no matter the size) of the order is sampled and tested for quality assurance acceptability and must pass FHI360's QA protocol

Delivering quality assured HIV rapid test kits

Recommended Testing Strategies for HIV Diagnosis



One brand dominates the market



What are the risks of a rigid algorithm? How is the market affected?

- Too much reliance on one test
  - quality assurance recall
  - manufacturing issue or delay
  - service disruptions
- Market becomes stagnant
- No competition among manufacturers
- No incentive to lower prices
- Higher risk of stock out due to one or few brands
- Strict algorithms don't allow room for growth for new manufacturers and new pre-qualified products

What are the advantages of a flexible HIV testing algorithm?

- Competitive Pricing
- Potential stock outs can be avoided
- Introduction of newly WHO pre qualified products at lower prices
- Switching between two screening tests could gradually ease health care worker introduction
- If two different screening tests are in stock then it would allow for the 'Repeat A1 and A2' to be performed according to developed WHO Guidelines

Would a flexible algorithm work?

- Do countries have the capacity to forecast and provide supply plans for two different screening assays?
- Will countries be able to provide training and ensure ongoing support and supervision for new testing procedures?
- Would this added layer of responsibility put too much pressure on already demanding workloads and stressful environments for health care workers?

In order to reach the first 90 donors need to ensure that they're purchasing efficiently and maximizing the number of tests procured with the available budget. Countries need to continue forecasting so there is no risk of stock out and also no risk of wasted product. Reviewing National HIV testing algorithms are essential to a healthy testing strategy to avoid misdiagnosis and make each test count

HIV self-tests (HIVSTs)

OraSure Technologies and The Bill & Melinda Gates Foundation

On June 27, 2017 OraSure Technologies entered into an agreement with the Bill & Melinda Gates Foundation to offer it's OraQuick HIV Self Test for $2.00 per test. Previously, the OraQuick Self test was upwards of $5.00 a test.

HIV Self-Testing is ramping up very quickly

- Placing a bulk order with the manufacturer
- Rotating stock to fulfill orders quickly
- Gathering as much consumption data as possible
- Hard to develop a supply plan for self-testing – is flooding the market the answer?
- Focus on getting HIVST to Key Populations

Destination	Quantity (Individual tests)
Burundi	3,000
DRC	3,500
Kenya	27,075
Malawi	8,000
Malawi	3,388
Namibia	800
Namibia	5,000
Namibia	20,000
Rwanda	20,250
South Africa	3,000
Swaziland	1,977
Bulk	400,000
Zambia	5,500
Zambia	80,000
Zambia	320,000
Zambia	400,000
Zimbabwe	33,500
Zimbabwe	33,250
Zimbabwe	33,500
Zimbabwe	24,250
Zimbabwe	4,000
Grand Total	**1,429,990**

Maintaining a healthy emerging self-testing market

Key considerations

Did the buy down negatively affect the market?

Will new products be able to compete with $2.00 a test?

Procurement Consideration: Since Self-Tests are not part of a testing algorithm (not a diagnosis) can agents like GHSC-RTK contractually purchase self-tests on a single source basis?

If there is more than one oral fluid based test on the market – then YES, a healthy market could be established.

Competitive bidding at high volumes could lead to greater access for forgotten individuals

Will HIV self-testing help us cross the finish line?

- Allows people to know their status privately
- Convenient and discreet testing will allow more people to feel comfortable testing
- People who have difficulty accessing existing testing services.
- Remember that HIVST is NOT a diagnosis – confirmation is still needed
- Reaching Key populations is important and should not be forgotten
- Increasing availability and flooding the market with self tests may be the key to reaching the first 90
- May be the first step in normalizing HIV testing and relieving the stigma
- Gateway to treatment – second 90

ARV: Pediatric Lopinavir/ritonavir (LPV/r)

Second 90: treatment

- Anita Deshpande, Acting Manager for Market Dynamics, USAID Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM)

Adult and pediatric 1st line ART guidelines vary, but they face similar market challenges during new product introductions

A successful transition requires…

1. **Successful supply and demand planning and coordination**
   Planned demand should match planned supply; visibility established across stakeholders to enable coordinated action
2. **Successful global supply management**
   Actual supply to match planned supply; bottlenecks to supply identified early and resolved
3. **Successful in-country demand management**
   Actual demand to match planned demand; bottlenecks to supply identified early and resolved

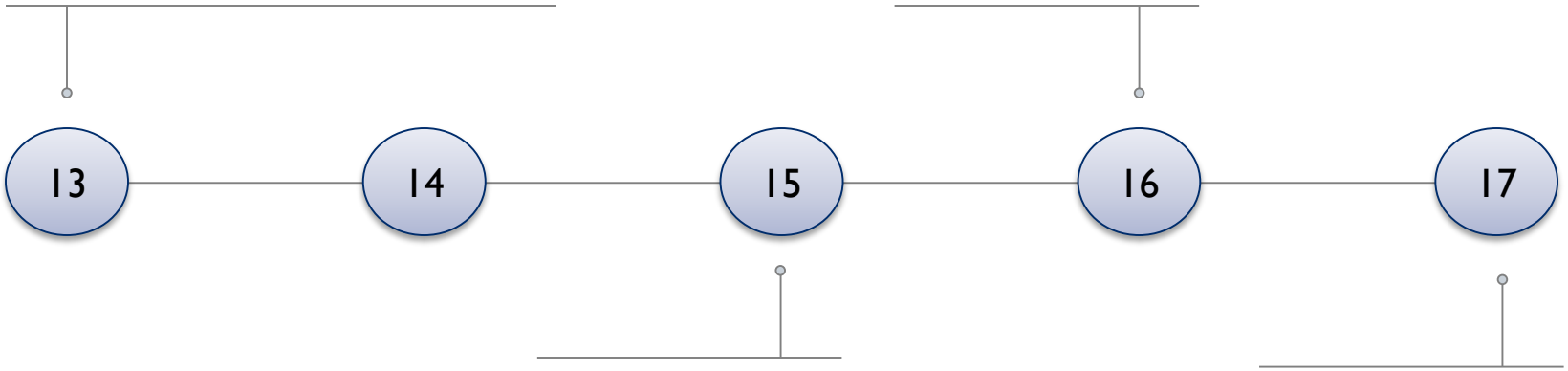
GHSC-PSM objectives:

- Identify risks that may hinder a successful transition
- Assess best practices and lessons learned from similar, past transitions
- Prioritize critical risks and develop actions to overcome and mitigate risks

Trend: Pediatric Lopinavir/ritonavir (LPV/r)is critical to first-line antiretroviral therapy

Ritonavir-boosted lopinavir (LPV/r)-based antiretroviral therapy (ART) recommended by the **WHO** as a preferred first-line for all children under 3 years of age

H/S oral pellets were approved by the US Food and Drug Administration (FDA) in May 2015 and became available for country procurement



Heat-stable (H/S) lopinavir/ritonavir oral pellets approved by US Food and Drug Administration (**FDA**)

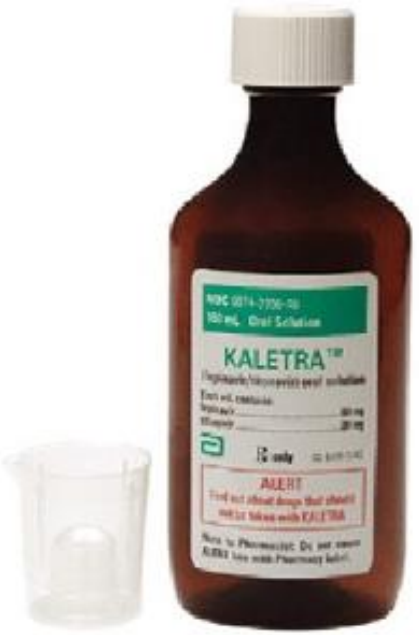
Global procurers continue to coordinate supply planning for pediatric LPV/r

Trend: Industry is developing appropriate products for ART to improve adherence and improve health outcomes

Clinical significance of pellets v other formulations

LPV/r Oral Solution 80mg/20mg/mL

- ✗ 42% alcohol; 15% propylene glycol
- ✗ Strong flavor (most people do not like the flavor)
- ✗ Requires cold chain storage at 2-8°C until expiration date



LPV/r Oral Tablets 100mg/25mg/tablet

- ✗ Oral tablets must be swallowed whole
- ✗ Not suitable for infants and children <3yo

LPV/r Oral Pellets 40mg/10 mg/capsule

- ✓ No cold chain requirement
- ✓ 8 pellets vs. 3 tablets per dose for wt band 30-34.9 kg
- ✓ Indicated for treatment in infants and children ≥ 14 days of age and ≥ 5
- ✗ MUST be swallowed whole, at room temperature (not hot)
- ✗ MUST NOT be broken, crushed, chewed, or dissolved

Key trend: The current market for LPV/r oral pellets is unstable due to an imbalance of supply and demand

Demand-side perspective

- ✓ Coordination amongst global partners was well done and supported by the development of job aides and tools that were clear and explanatory
- ✓ Demand for LPV/r oral pellets is now growing as country programs plan to adopt and roll-out LPV/r oral pellets and more effectively implement their adopted preferred 1st line pediatric regimen.
- ✓✗ **Clinicians have found the pellets useful, unexpectedly, with stable NNRTI patients and older children who are unable to swallow pills**
- ✓ Multiple large orders have already been placed and delivered to programs.

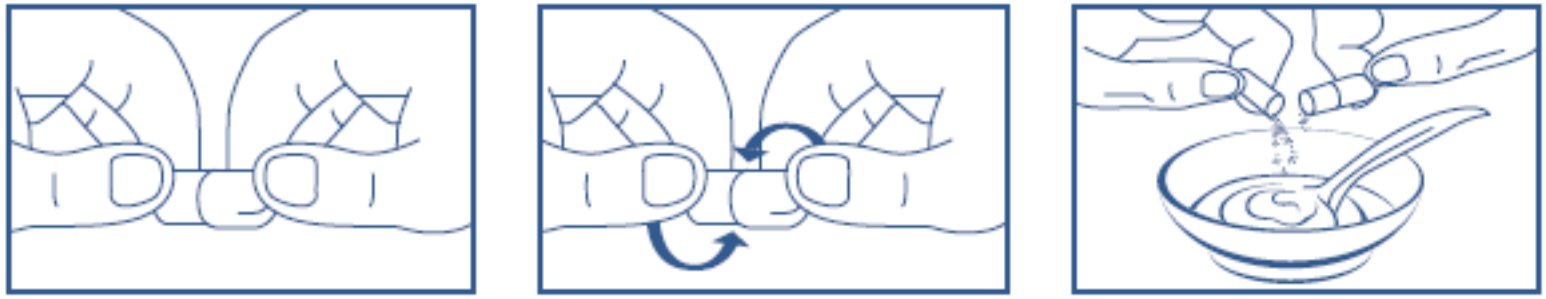
Currently forecasted demand for LPV/r oral pellets may exceed the production capacity

Key trend: The current market for LPV/r oral pellets is unstable due to an imbalance of supply and demand

Supply-side perspective

- ✗ Supply-side lacked the visibility into how popular the product would be upon roll-out and globally the market size was underestimated for this new and novel product
- ✓ Manufacturers are responding to the demand by working toward increasing their production capacity for quality assured pellets
- ✓ Additional manufacturers are developing new formulations to fill this niche such as granules and FDC granules

Adapted from Cipla package insert approved by USFDA



Local action …

- When forecasting for new and novel products, discuss the forecast clinical protocols with prescribing clinicians to better plan uptake potential.

- Specifically for pediatric LPV/r, plan a slower roll-out of h/s pellets and encourage continued use of the liquid and tablet until more global supply is available to fill this niche.

ARV: Dolutegravir

Three APIs are poised to replace existing major first line adult ARV APIs over the next 5 years

First line ARV FDCs are composed of 2 NRTIs and 1 NNRTI or INSTI

	Current APIs	New API	Description	Estimated FDC approval
NRTI #1	▪ TDF	▪ **TAF**	▪ Prodrug replacement of TDF with better clinical outcome and lower dose	▪ TAF 2018
⊕				
NRTI #2	▪ 3TC ▪ **FTC**	▪ N/A	▪ N/A	▪ N/A
⊕				
NNRTI/INSTI	▪ EFV	▪ **DTG**	▪ DTG is replacement for EFV with better clinical outcomes though still awaiting approval for certain patient segments	▪ N/A

SOURCE: Gupta A et al. (2016) PLOS ONE 11(10): e0164619; WHO/UNAIDS Meeting documents and presentations | 8-9 March 2016 | Geneva, Switzerland; supplier interview

Key Trend: TLD has high potential as a new HIV treatment to replace Efavirenz (EFV) based ARV combinations

- ✓ DTG-based combinations show superior efficacy and fewer adverse effects for one-pill, once-daily dose*.
- ✓ DTG is cheaper to manufacture than EFV(on a per-dose basis – 50mg v 600mg) and has entered the market at $75 pppy
- ✓ Demand-side country interest is strong with Nigeria, Kenya, and several other countries planning to move to TLD as a preferred first-line for new patients in 2018
- ✓ Supplier interest in DTG is strong with two manufacturers already USFDA approved and several more preparing to file for regulatory approvals in early 2018

Likelihood and impact of supply chain risks are dependent on target transition population and speed of transition

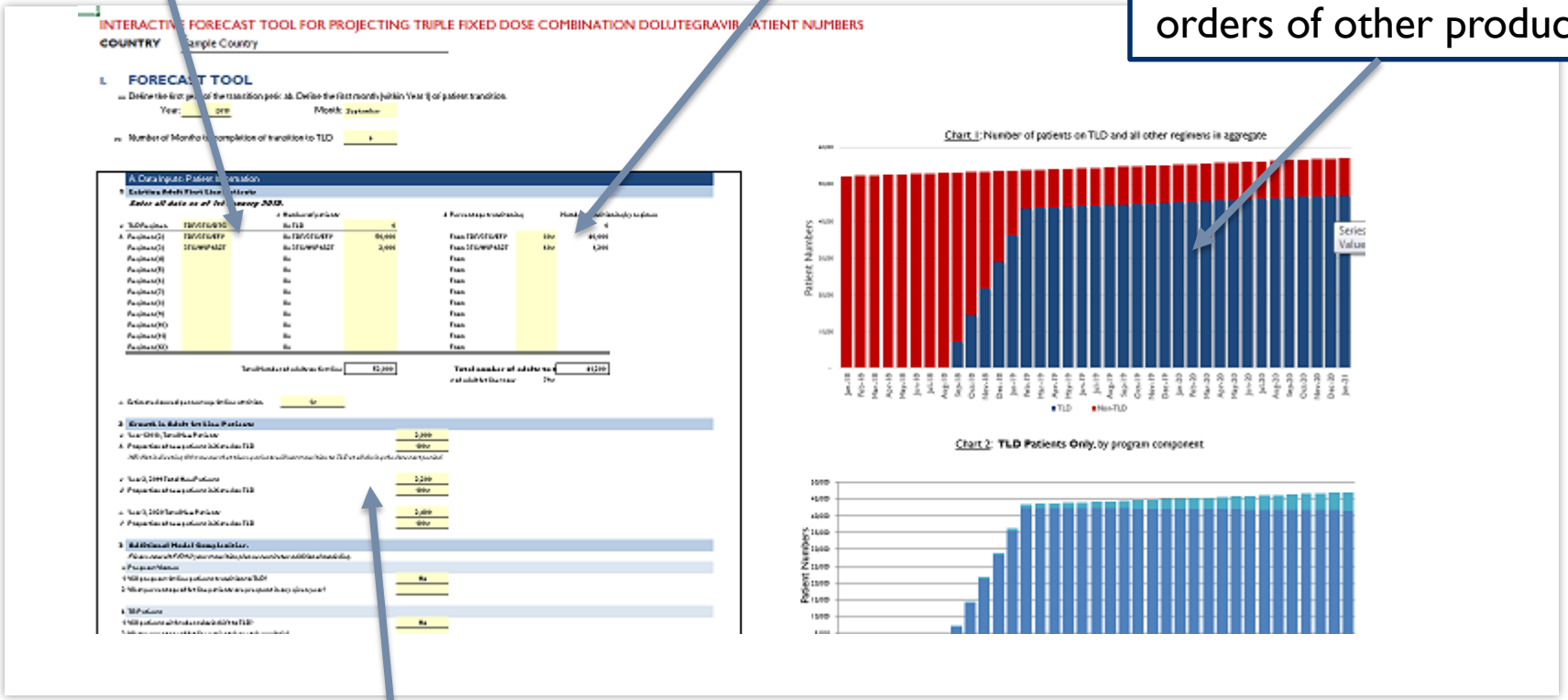
Initial transition population	Speed of single country transition: Rapid (e.g., single-date)	Speed of single country transition: Phased (e.g., by region)
All patients	**Advantages:** ✓ Easier to forecast and manage TLD demand ✓ Easier to communicate timeline with in-country stakeholders (e.g., physicians, patients) ✓ Easier to coordinate run-down of existing stock ✓ Lower risk of leakage to non-target populations / regions **Supply-chain challenges:** × Higher risk of global supply shortages if demand forecasts were too conservative × Higher risk of current inventory wastage × Lower-priority countries may need to wait longer to get TLD based on global supply capacity	**Advantages:** ✓ Lower risk of global-supply shortages ✓ Lower risk expiry for current inventory ✓ Potential to pilot in a portion of country to test physician and patient reactions **Supply-chain challenges:** × Additional demand management, forecasting, and transition plan communication complexity with two treatments simultaneously in country
New and / or resistant patients only	**Advantages:** ✓ Lower risk of global-supply shortages ✓ Lower risk expiry for current inventory **Supply-chain challenges:** × Additional demand management, forecasting, and transition plan communication complexity with two treatments simultaneously in country	**Advantages:** ✓ Lower risk of global-supply shortages ✓ Lower risk expiry for current inventory ✓ Potential to pilot in a portion of country to test physician and patient reactions **Supply-chain challenges:** × Additional demand management, forecasting, and transition plan communication complexity with two treatments simultaneously in country

GHSC-PSM's TLD Transition, Demand Planning Tool

Input existing ART patient figures

Estimate treatment switches by regimen (%)

Estimate how much TLD is required by month and how to scale down orders of other products



Estimate new patients and special population TLD needs

A robust TLD transition plan contains several critical components

	Component	Key questions to address
Strategy definition	**Transition strategy**	▪ What is the target TLD transition population (e.g., all first line patients, new patients)? Will the transition be phased? ▪ What is the high-level timeline for the TLD transition? ▪ When will TLE 600 procurement cease? ▪ Who is paying for and procuring the new TLD product (e.g., % mix of GFATM, PEPFAR)? ▪ How much TLD needs to be procured over the transition period each quarter? ▪ Will there be out-of-pocket charges for the consumer?
Detailed implementation plan	**Supply chain adjustments**	▪ How will existing TLE 600 or TLE 400 inventory be run down? What is the tolerance for inventory wastage? ▪ How much TLD inventory needs to be stored at the state level, district level, and local stores by quarter to maximize product mobility and minimize wastage? ▪ How will TLD product be distributed from port to storage sites and clinics? ▪ How will and what is the timeline for data management processes be changed to include TLD? ▪ What metrics will be used to manage and track the progress of the above supply chain adjustments?
	Field communication and training	▪ How will country guideline changes be communicated to physicians, patients, the private sector, and civil society groups (e.g., National Association of Pharmacists)? ▪ What are the key timelines and milestones associated successful field communication and training? ▪ Who is funding the various portions of the communication strategy (e.g., flyers, trainings)? What is the total funding available? How will budget be allocated? ▪ What metrics will be used to manage and track the progress of field communication and training milestones?
	Stakeholder collaboration	▪ What is the communication / coordination strategy with national regulatory agencies (including timeline for national approval)? ▪ What is the communication and coordination strategy with donors and procurement partners (e.g., GHSC-PSM, PEPFAR)?
	Governance mechanisms	▪ Which stakeholders will be on the coordinating team responsible for tracking implementation? ▪ What authority does the coordinating team have to enforce the implementation roadmap?

Local action to impact local and global markets

1. **Supply and demand planning and coordination**
   Planned TLD demand should match planned supply; visibility established across stakeholders to enable coordinated action

2. **Global supply management**
   Actual TLD supply to match planned supply; bottlenecks to supply identified early and resolved

3. **In-country demand management**
   Actual TLD demand to match planned demand; bottlenecks to supply identified early and resolved

4. **Smooth importation**
   Registration in each country with NDRAs, potential shelf-life waivers, appropriate blanket waiver for import duties

5. **Management of legacy ARVs**
   Draw down of TLE and other ARVs to avoid cost of expiry and overstock

Viral load scale up:

- Market dynamics & challenges
- Lab network optimization strategies
- Strategic sourcing

Third 90: viral load

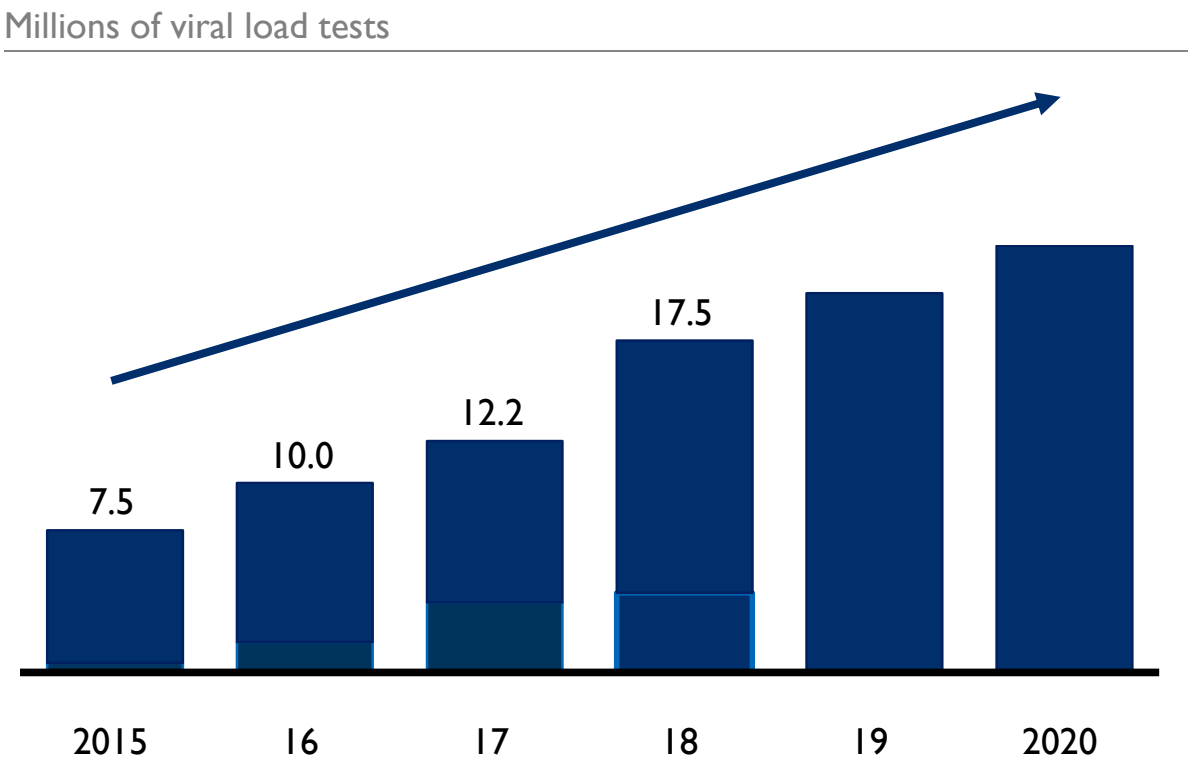
- Dr. Clement Ndongmo, Senior Technical Laboratory and VMMC Advisor, GHSC-PSM

The UNAIDS has set ambitious Fast-Track treatment targets known as the 90-90-90 targets to help end the AIDS epidemic

http://www.avert.org/professionals/hiv-around-world/global-response/targets

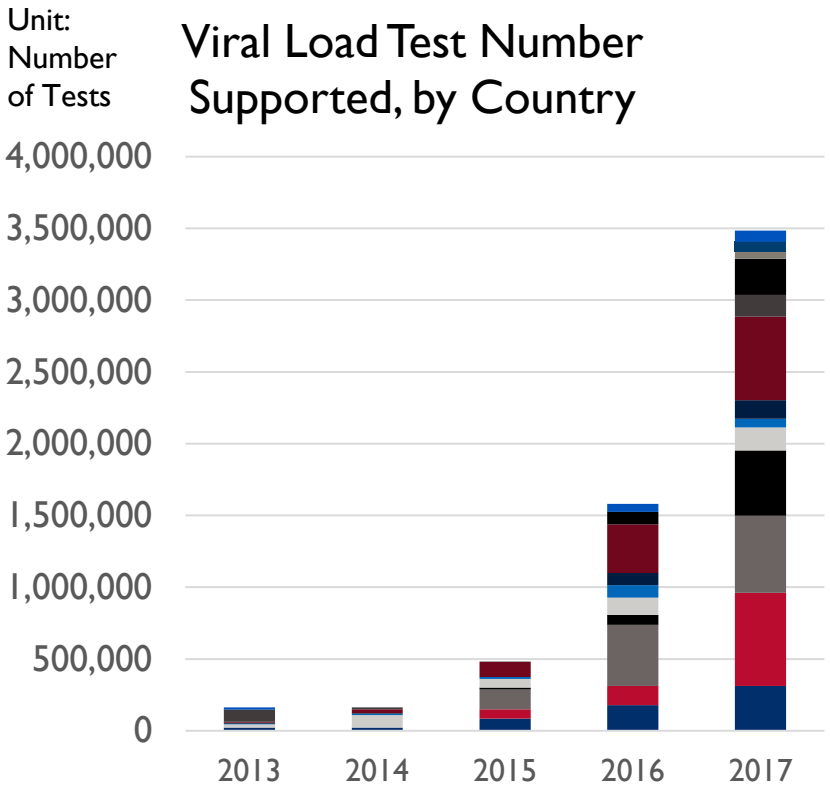
Global demand for viral load tests will more than double over the next 5 years; we are scaling up our procurement substantially

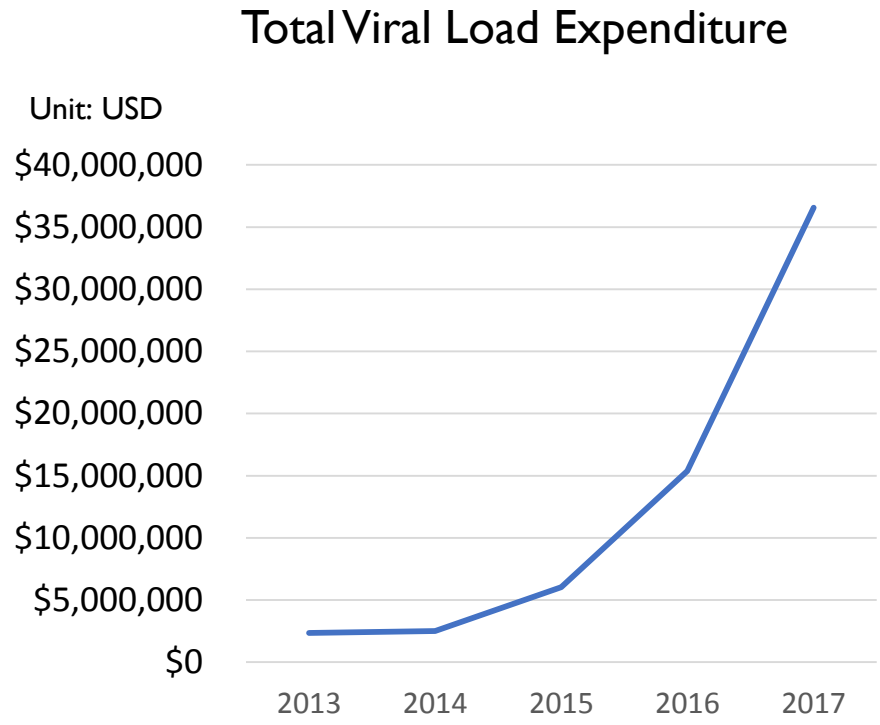
Forecasted demand for viral load tests in broader public sector within low and middle-income countries



SOURCE: WHO 2016 Annual Meeting with Manufacturers and Stakeholders Global Forecasts of Diagnostic Demand for 2015-2020, CHAI's 2015 HIV Diagnostics Market Forecasts Global Supplier Meeting

Many countries have performed significantly increasing numbers of VL tests and expenditure over the last few years





Data from over 12 GHSC-PSM supported countries

(Ethiopia, Zambia, Nigeria, Mozambique, Rwanda, Haiti, Cote d'Ivoire, Uganda, Zimbabwe, Tanzania, Cameroon, Congo DRC, others)

Scaling up VL testing to reach the 3rd 90 requires multiple elements (including laboratory infrastructure, HR, supply chain, and quality systems) that all have to be in place

Viral load testing cascade

ILB, HCTB and MCHB collaboration

Outcomes

- Maximizing durability of first-line regimens
- Better patient management and adherence

Pre-test | **Post-test**

Demand creation for testing

- National policies
- Medical professionals and patients as stakeholders
- HIV DR surveys

Specimen collection & processing

Sample transport

- Implementing series of tools
- Sample referral
- Quantification & forecasting
- Costing model
- Clinicians and laboratorians

Laboratory testing

- Technology and method evaluations (protocols)
- Quality assurance

Result reporting & interpretation by clinician

- Develop LIS
- Clinical algorithms
- Job aids

Patient management

- SOPs for timely switching of regimens
- Client tracking
- Adherence counseling

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Pre-test | **Post-test**

Demand creation for testing	Specimen collection & processing	Sample transport	Laboratory testing	Result reporting & interpretation by clinician	Patient management
• National policies • Medical professionals and patients as stakeholders • HIV DR surveys		• Implementing series of tools • Sample referral • Quantification & forecasting • Costing model • Clinicians and laboratorians	• Technology and method evaluations (protocols) • Quality assurance	• Develop LIS • Clinical algorithms • Job aids	• SOPs for timely switching of regimens • Client tracking • Adherence counseling

Countries are using 2 main laboratory network approaches to provide viral load (and EID) testing services: Centralized vs. Decentralized

	Advantages	Disadvantages
Decentralized	• Patients' timely access to diagnostics and results • Current focus on decentralization • No limits for growth	• Complexity of quality systems • Complexity of instrument service and support • Infrastructure Challenges
Centralized	• Quality is maintained though less complicated means • High throughput, low cost instrumentation is utilized	• Limits for growth • Specimen or patient transport • Ineffective information systems

Countries are facing a number of challenges with VL testing scale up implementation

- **Placement of equipment (infrastructure, disease burden)**
- **Frequent breakdown of test instruments**
- **Lack or delays with technical support (servicing, maintenance)**
- **Reagents and supplies stock outs and expiration**
- **Break in cold chain during reagent delivery**
- **Changes in technologies**
- Lack of private companies for liquid waste management
- HR issues
- Backlog of work
- Long turnaround time to results

Some approaches being taken with countries to address VL scale up challenges include…

1. Laboratory network optimization

2. Strategic sourcing
   - Commodity long-term agreement (LTA)
   - Reagent rental agreement

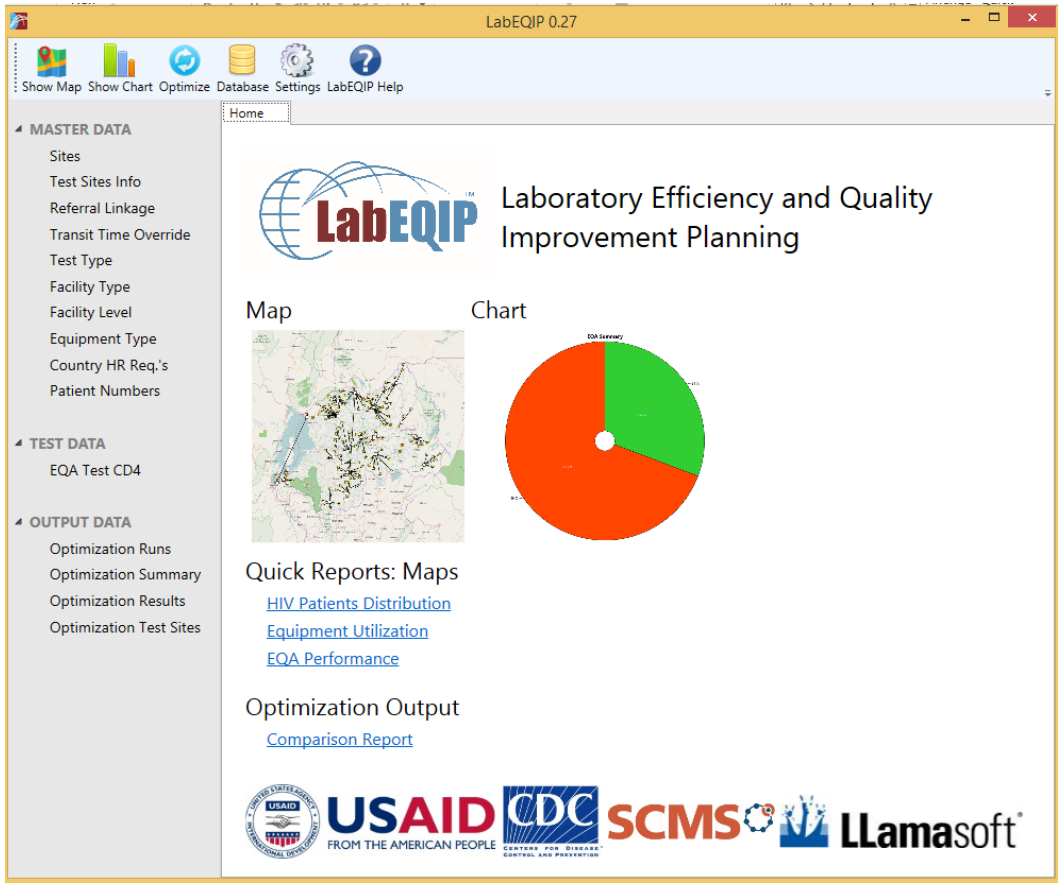
1- GHSC-PSM is providing technical assistance to countries to optimize their existing laboratory testing network

- A dynamic understanding of the functionality of the national laboratory network and supportive systems (diagnostic of disease type or program area),
- Site selection & equipment placement
  - Disease burden geographic distribution
- Understanding current equipment utilization rates.
- Identification of functional instruments,
- POCT extension of the existing conventional laboratory network & integrated into existing resources and systems

Laboratory network optimization requires:

- Mapping and assessing the existing network
- Ensuring laboratory instruments are placed and used appropriately
- Making informed decisions for efficient and cost-effective program growth and instrument expansion.

To aid strategic equipment placement and laboratory network optimization, GHSC-PSM is using a software tool called LabEQIP



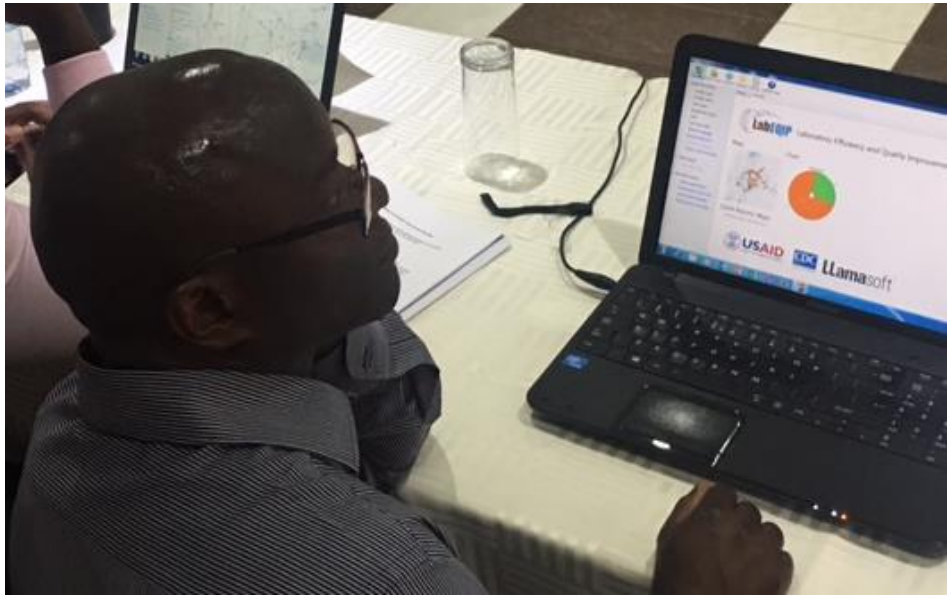
Desktop Application

- Open source tool (data repository for information relevant to the laboratory network performance)
- Links relevant data (visuals)
- Provides visibility into performance and resources over time to assess the effect of various interventions
- Provide optimal referral assignments and equipment (re)placement/scale-up plans

Using LabEQIP for current instrument location mapping provides for a better **understanding** of the existing laboratory network

What we've done so far:

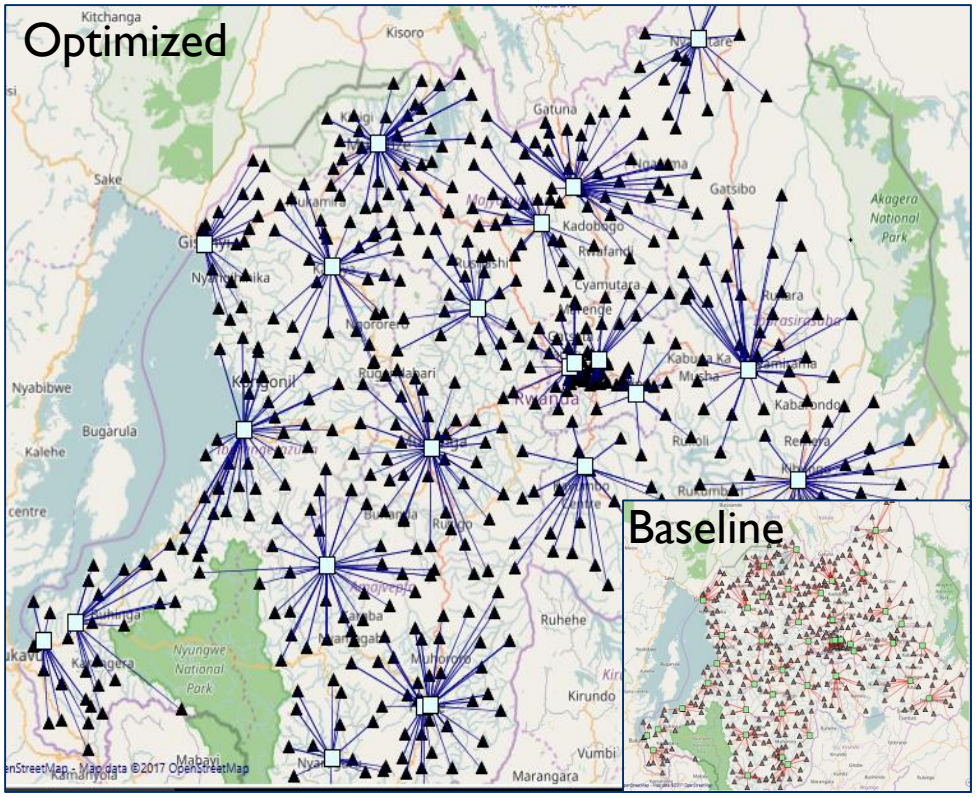
- Nigeria modeling
- Rwanda modeling
- Mozambique training
- Zimbabwe (initiated)
- Cote D'Ivoire (initiated)



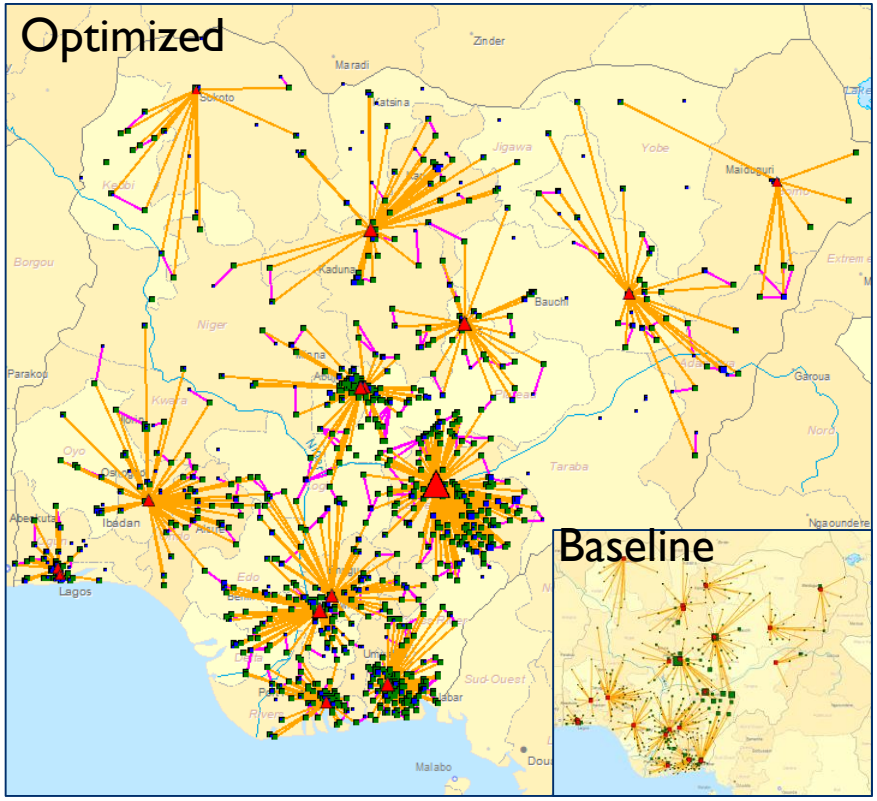
LabEQIP Regional workshop – October 30 to November 4, 2017: Kenya, Cameroon, Uganda, Tanzania, Swaziland, Malawi, Zambia

Understanding the existing 'network' to design a new network can lead to many benefits

CD4 Equipment Footprint Reduction (Rwanda)



HIV/TB Sample Integration Referral Network (Nigeria)



2- GHSC-PSM is using a strategic sourcing approach to ensure cost-efficient laboratory equipment and commodities procurement

- Planning and procurement coordination among agencies / donors in country
- Development of and adherence to commodity supply plans.
  - (National quantification / forecast)
- Instrument data reporting is key to asset management.
  - (downtime /protocols / specimen type / etc.)

Commodity LTA

For existing equipment footprint

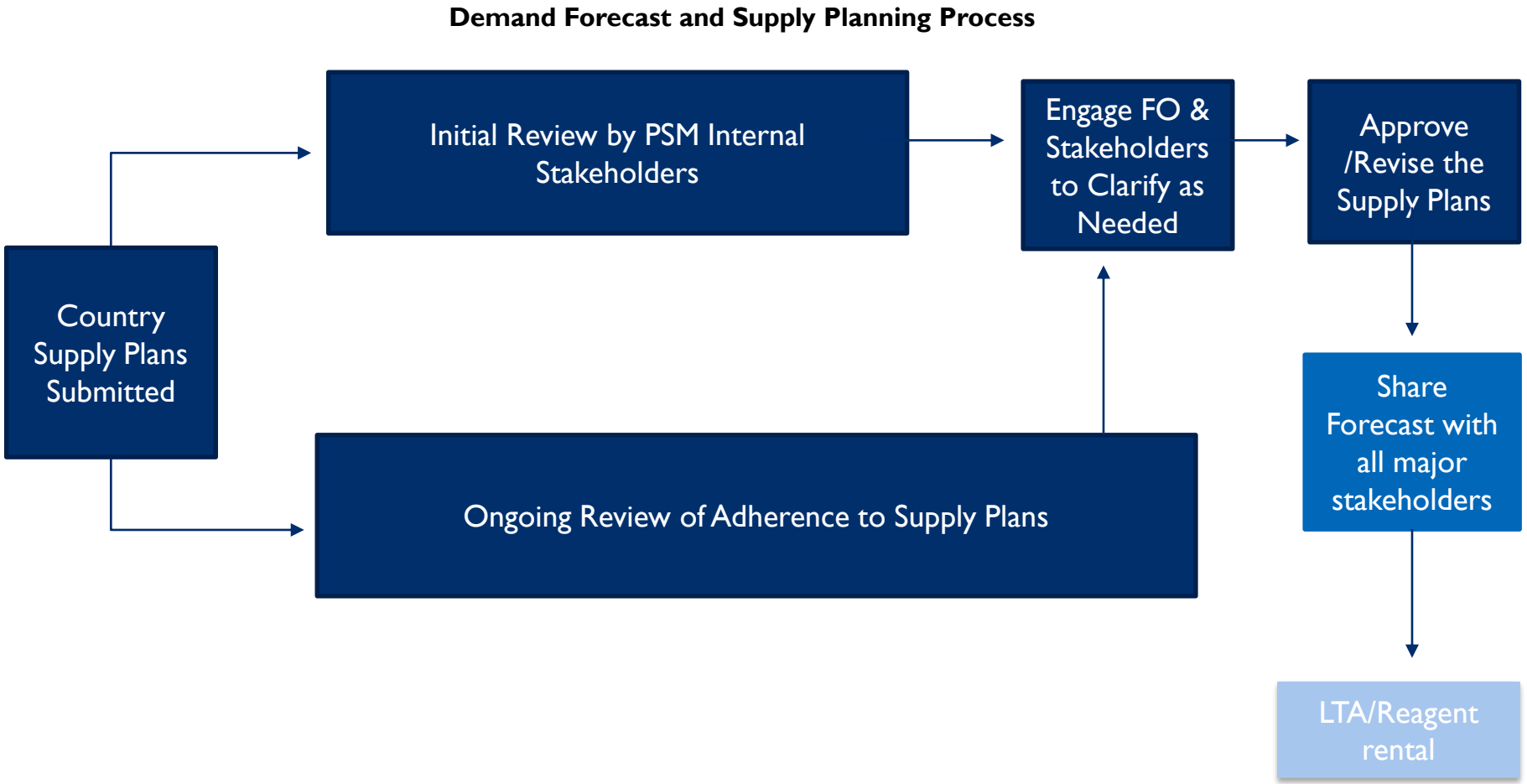
- Using demand forecast analysis
- Mutually-agreeable approach to obtain pricing for next 12 months

Reagent rental

For new equipment expansion

- Bundling of services (including connectivity) into contracting
- Development of and adherence to criteria for placement of additional machines or higher throughput platforms

Supply plans: Leveraging the intelligence from PSM FOs to create demand forecasting sharable with suppliers and major stakeholders



2-a) Commodity LTA: increase efficiency and ensure compliance in commodity procurement

- Primary goal is to supply equipment fleet, improve on-time delivery, and manage landed cost of reagent and consumables
- Better manage risks and increase compliance in delivery, quality, warranty, and other critical terms and conditions
- Reduce the administrative time spent on placing orders

Note: we are making progress on suppliers who will cover 90% of PSM procurement volume

2- b) Reagent rental: one major objective of GHSC-PSM strategic sourcing is to ensure that contracts are well developed and executed in supported countries

- An all-inclusive per test cost structure spread across all instruments of the same brand within the network and available to all stakeholders to include:
- Cost options that account for existing instruments along with new contract models (i.e. Leasing and rentals) that facilitate network expansion
- Service and maintenance
- Data solutions for patient result transmission, instrument / user performance
- Network staff training and consistency
- Additional technology support (barcoding, sample processing, and workflow)

Note: There are FO-led, HQ-led initiatives, and 3rd party-led reagent rental negotiation

2- b) Reagent rental sourcing involves multiple key steps, deliverables and stakeholders

Legend: Process Owner
FO &Country Stakeholders
HQ-FO Joint Activity

Key Steps

Scale-up, Capacity, Budget Planning → Technology /Supply Market Analysis → Develop Lab Sourcing Strategy → Conduct RFP & Negotiation → Plan Implement -ation → Execute Contract &Manage Performance

Key Deliverables

- Purpose of procurement clarified
- National Instrument capacity& utilization understood
- Instrument inventory collected
- Site-level burden and technical specification documented
- Future expansion plan considered
- Budget established for reagents, services, other lifecycle costs

- Nationally-approved instruments identified
- Maintenance & warranty needs understood
- Local support identified
- Existing service agreements considered

- 12 Questions reviewed
- Sourcing objectives created
- Ensure sourcing objectives aligned with network optimization
- Short-list of participating suppliers
- RFP Project Plan created

- RFP Package created
- Evaluation scorecard created
- Supplier responses received
- Evaluation completed
- Negotiation strategized and conducted
- Leadership approval received
- Reagent rental Agreement awarded

- Deployment plan drafted
- Site-level infrastructure &peripheral prepared
- Deployment plan (final) co-created with supplier
- Procure-to-pay process formalized

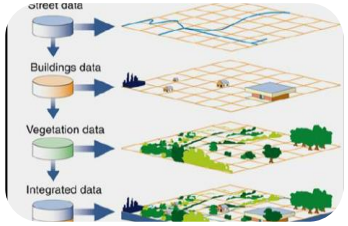
- Risk /contingency management procedures in place
- Contract executed by vendor and managed by country stakeholders
- Performance report created and submitted to PSM HQ
- Corrective actions taken as needed

Conclusions:

GHSC-PSM is working with countries to address VL scale up challenges through informed decision-making laboratory network optimization and strategic procurement approaches

Demographic

Diagnostic capacity



Geospatial

Laboratory network development

National Supply plans

Effective and efficient supply chains by having products positioned appropriately within the national tiered laboratory system.

Conclusions

1-Laboratory network optimization

2-Strategic sourcing

a) Commodity long term agreement

b) Reagent rental agreement

- Optimized laboratory network
- Higher utilization of VL machines
- Reduce equipment down-time
- Managing/sharing risk with suppliers
- Healthier competitive supplier market
- Cost efficiencies

3rd 90 goals

- More patients accessing VL testing
- Improved patient management

Let's talk about local actions to support global strategies

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- Provides an on-line forum where members can network, exchange ideas, and improve professional skills.
- Membership is **free** at iaphl.org

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Thanks for coming! For more information…

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