

Beyond diagnostic network optimization: A network approach to strengthening and scaling up laboratory services

A multi-pronged network
approach improves the
quality of, availability of, and
access to laboratory testing



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Acronyms

3PL	third-party logistics service provider
ART	antiretroviral treatment
CDC	U.S. Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
DNO	diagnostics network optimization
EID	early infant diagnosis
FY	fiscal year
GHSC-PSM	Global Health Supply Chain-Procurement and Supply Management project
GIS	global information system
IP	implementing partner
KPIs	key performance indicators
LLP	lead logistics partner
LMIS	logistics management information system
MOH	Ministry of Health
NISRN	National Integrated Specimen Referral Network
PCR	polymerase chain reaction
PEPFAR	U.S. President's Emergency Program for AIDS Relief
POC	point of care
PSC	Cobas Plasma Separation Card
RFI	request for information
RFP	request for proposal
RRS	reagent rental scheme
RSL	remote sample login
RSS	reagent service scheme
SLA	service-level agreement
TB	tuberculosis
TWG	technical working group
USAID	U.S. Agency for International Development
VL	viral load
VMI	vendor-managed inventory
WHO	World Health Organization



Target audiences

The primary target audience for this guide is leadership in government — especially in ministries of health, laboratory services, and national laboratory technical working groups (TWGs) — who have supervisory, management, or operational responsibility over the diagnostic and molecular laboratory commodity supply chain functions, or whose primary responsibility depends on the availability of quality laboratory commodities to perform their day-to-day functions.

This includes **clinical and supply chain stakeholders** at the international, national, and subnational levels, since the primary focus of these interventions is to provide systemic and operational guidelines that improve the patient–clinician experience through the availability of timely laboratory test results. These audiences are responsible for developing national policies for laboratory services and managing operations of the laboratory network.

Additional target audiences are:

- **Donors**, including the Global Fund to Fight AIDS, Tuberculosis, and Malaria and the World Health Organization (WHO), which invest significant funding to increase testing capacity and support host-country governments in meeting national diagnostic testing needs
- **U.S. government donor agencies**, including the U.S. Agency for International Development (USAID) headquarters and missions, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), U.S. Centers for Disease Control and Prevention (CDC), and implementing partners (IPs) that support national and sub-national laboratory testing needs
- **Third-party logistics (3PL) providers** for transport of laboratory samples
- **In-country laboratory product distributors** and service providers
- **Private laboratories** that may offer diagnostic testing services required by national health systems

Objectives

The objectives of this guide are to:

- **Share lessons learned and benchmarks** from GHSC-PSM's experience in implementing different aspects of the network approach to laboratory services to achieve tangible and measurable improvements in addressing country diagnostic testing demand across multiple disease areas
- **Encourage adoption of the network approach** to laboratory services to improve public health supply chains
- **Encourage collaboration and coordination** across donors and implementing partners to inform laboratory network design, instrument placement, sample transport, procurement, and supply chain management
- **Help build the foundation for the next innovations** in diagnostic services
- **Demonstrate how diagnostic network optimization (DNO) can inform network design**, strategic sourcing, and new instrument placement to achieve improved service delivery



ADDITIONAL RESOURCES ON THE NETWORK APPROACH TO LABORATORY SERVICES

Jason Williams, Dianna Edgil, Matthew Wattleworth, Clement Ndongmo, and Joel Kuritsky. "[The network approach to laboratory procurement and supply chain management: Addressing the system issues to enhance HIV viral load scale-up.](#)" African Journal of Laboratory Medicine. August 2020.

Clement Ndongmo, Matthew Wattleworth, Paolo Maggiore, Maelle Barbancon, Dianna Edgil, and Jason Williams. "[Optimizing national laboratory networks for effective disease control.](#)" ASLM Lab Culture. July 2019.

WHO's "[Guidance for procurement of in vitro diagnostics and related laboratory items and equipment.](#)" 2017.

WHO's "[Technical Report Series, No. 961, 2201 I/Annex 9 - Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products.](#)" 2011

Global Laboratory Initiative's "[Guide to TB Specimen Referral Systems and Integrated Networks](#)"

01.

Executive Summary



PHOTO CREDIT: Mickael Breard

Executive summary

The network approach brings significant efficiencies to laboratory services, benefiting patients

Laboratory services are a key component of a comprehensive health system, providing essential diagnostic services so that patients receive appropriate medical care. Yet many countries have struggled to deliver adequate laboratory services.

USAID, PEPFAR, and their implementing partners have played a leading role in helping countries expand and transform their laboratory services to be more cost effective, efficient, and responsive to patient needs.

This document serves as a guide for implementing a network approach to strengthening and scaling up laboratory services. It describes the experience of countries, partners, and donors that are shifting to this network perspective and implementing the components of the network approach.

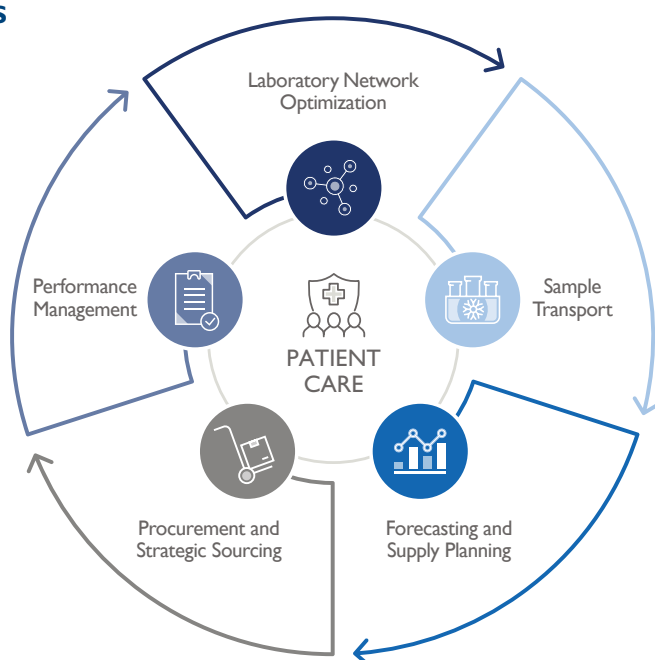
Components of the network approach are:

- Diagnostic network optimization (DNO)
- Optimizing transport of patient samples
- Forecasting and supply planning
- Procurement and strategic sourcing
- Performance management

The guide describes these components in detail, with practical examples from countries providing more information about the specific lessons learned, successes, and challenges of implementation.

The guide also examines progress by global HIV donors on negotiating national and global pricing agreements, as well as inclusive service agreements that ensure procurements of equipment and

COMPONENTS OF THE NETWORK APPROACH



commodities are tied to successful patient test results.

In the annex, readers will find a description of a sample pick-up and results return process flow.

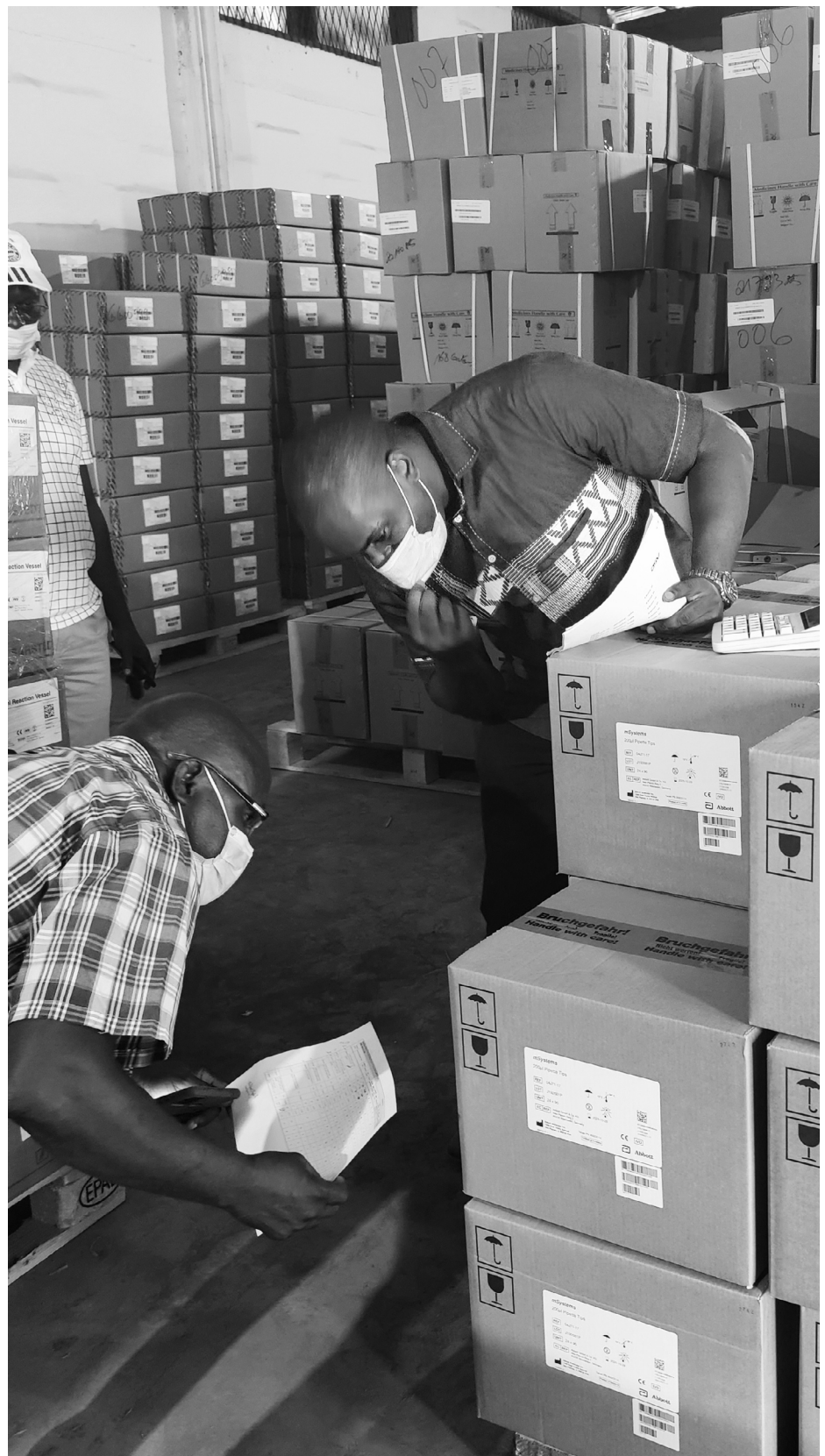
A data-driven, national-level approach continually improves the laboratory network

The network approach to laboratory services is holistic and data-driven. Each component provides a wealth of data that informs the other components on an ongoing basis. In essence, it is a continuous improvement approach grounded in data visibility and performance management.

While laboratory services in many countries previously operated in silos and faced frequent instrument breakdowns and reagent stockouts, the network approach brings the perspective to the national level and introduces significant efficiencies in instrument placement and maintenance, reagent pricing and stock management, and sample transport.

The ultimate impact of this laboratory network transformation is on the most important stakeholder: the patient. The network approach to strengthening and scaling up laboratory services results in uninterrupted access to high-quality laboratory services for patients, greatly reduced testing turnaround times, reliable results, and the ability of patients and their doctors to make timely and ongoing treatment decisions.

The ultimate impact of this laboratory network transformation is on the most important stakeholder: the patient



Verification of GHSC-PSM-procured viral load and EID consumables in Cameroon by GHSC-PSM staff and freight forwarding agent to confirm complete delivery of pallets and their contents.

PHOTO CREDIT: Elive Ngale, GHSC-PSM

02.

Background



PHOTO CREDIT: Glenn Gemuh | GHSC-PSM

Background

A shift in approach to meet the growing need for laboratory services

Inefficiencies in laboratory systems evolved over time

Until a few years ago, a country's laboratory network often evolved organically based on existing infrastructure and capabilities, with limited coordination among the government, local and international partners, and public health programs. Instruments to test for different diseases were procured according to individual ministry, donor, or IP requirements. They were then placed in either a standalone laboratory or at a point of care (POC), such as a hospital, to address testing access issues. **While this approach has significantly increased testing access, it has in many cases resulted in inefficiencies or suboptimal networks** that should be reviewed and analyzed to determine possible adjustments.

Countries have historically ended up with too many or too few of a certain type of laboratory instrument compared with the population's geographic distribution, disease landscape, and testing needs. This would lead to under- or over-utilization of laboratory instruments. The geographical placement of those machines was not

optimized according to epidemic data or need, and the way that patients or patient samples were referred to laboratory locations for testing was not coordinated, resulting in inefficient and parallel referral systems.

These inefficiencies often lowered patients' access to high-quality testing and caused long turnaround times for testing, hindering clinicians' access to the critical diagnostic information needed to make lifesaving treatment management decisions for patients. The inefficiencies also adversely impacted patients' ability to know their health status and ensure they were receiving appropriate treatment, while at the same time increasing the cost of providing laboratory services.

Procurement and supply chain management challenges also arose. The supply chain for reagents and other supplies required to run laboratory tests was often not coordinated or managed by trained supply chain personnel, and these commodities would therefore stock out or expire, leaving the machines idle. Also, maintenance and repair of the machines were not conducted routinely, leading to frequent breakdowns.

Further, the procurement of laboratory instruments was not coordinated or pooled across different partners and programs, which meant that more favorable pricing for the instruments and reagents could not be negotiated with manufacturers, nor could maintenance contracts be effectively established to keep the machines operational. In many cases, laboratory equipment was procured without an operational plan to ensure that instruments were used.

New global HIV and TB targets rapidly increased the need for laboratory services

In 2014, the global HIV community began to work toward achieving the UNAIDS 90-90-90 goals, which later became the 95-95-95 goals. This global strategy aims to end the HIV epidemic by 2030 by having 95 percent of all people living with HIV tested, 95 percent of those who tested HIV positive on treatment, and 95 percent of those on treatment virally suppressed. PEPFAR and USAID support these goals through their programs and funding.

Concurrently, the universal test-and-treat strategy — WHO's recommendation to initiate antiretroviral treatment (ART) for any patient testing positive rather than waiting until viral load (VL) reached a



Offloading of GHSC-PSM-procured viral load commodities at Cameroon's National Public Health Laboratory.
PHOTO CREDIT: Elive Ngale, GHSC-PSM

certain level — also scaled up globally to curb rising new HIV infection rates and has improved treatment outcomes. This VL scale-up included scale-up of molecular early infant diagnosis (EID).

Coupled with the scale-up of VL and EID was the scale-up of cervical cancer screening for women with HIV, as well as HPV testing, putting additional pressure on laboratory services.

Achieving the third “95” of the 95-95-95 goals depends on the scale-up of laboratory capacity with an effective sample transport network, which would allow patients to be routinely tested for their HIV VL and monitored for ART success or failure, and would ensure infants are diagnosed in a timely manner through EID. As such, donors have been investing to assist ministries of health in revising treatment policies, building laboratory capacity, and training and sensitizing clinicians and patients on testing.

However, as countries worked to take VL and EID testing to scale, challenges continued to surface that impacted the ability to increase testing and ensure quality services, including difficulty with procurement and sample transport and delays in the return of results.

Along with global efforts to end the HIV epidemic, **WHO and UNAIDS also set new targets to end tuberculosis (TB)**, which remains one of the leading causes of death from a single infectious agent, causing more deaths than HIV/AIDS. TB is also a serious co-infection for many patients with HIV or AIDS. WHO's post-2015 End TB strategy, adopted by the World Health Assembly in 2014, was incorporated in the UNAIDS Sustainable Development Goals, established in 2015 by the United Nations General Assembly and intended to be achieved by 2030.

In 2010, WHO endorsed the Cepheid GeneXpert MTB/RIF assay for TB diagnosis. This new technology reduced TB sample processing times from months to hours. Further global commitments by donors, particularly the Global Fund, to address TB case detection gaps significantly increased procurement and placement of these machines in countries to support the global strategies to end TB and test for multidrug-resistant TB. This, in turn, resulted in a proliferation of machine and reagent procurements to increase testing capacity at the national and subnational levels.

Beginning in 2020, the emergence of COVID-19 resulted in additional pressure

on existing machines — particularly GeneXpert machines — to conduct COVID-19 testing while maintaining VL, EID, and TB testing levels.

The paradigm shifts to a network approach to strengthen and scale up laboratory services

USAID and its Global Health Supply Chain-Procurement and Supply Management (GHSC-PSM) project responded to this need by working with countries to develop a network approach to laboratory services.

This approach is a holistic, data-driven strategy that:

- **Aligns instrument capacity with demand and utilization**, ensuring that the positioning of machines is based on need (geographic proximity to patients) and maximum output rather than political pressure with respect to equitable instrument distribution decisions, thereby ensuring that machines are appropriately placed according to need, are used, and no longer sit idle
- Promotes efficiency in the **procurement and placement of laboratory equipment** and develops **all-inclusive service delivery agreements**, preventing machines from breaking down and repairing or replacing them quickly when they do
- **Negotiates fair, consistent pricing** to ensure all health programs can access laboratory services based on total collective volumes across countries supported by PEPFAR
- Focuses on developing **efficient transport of patient samples** and return of results

Ultimately, these improvements increase patients' access to laboratory services, which helps ensure they will get the lifesaving treatment they need.

The USAID approach to transforming HIV/AIDS laboratory services. GHSC-PSM is now supporting expansion of the approach to more countries and health areas.

FROM	→	TO
<ul style="list-style-type: none"> • Fragmented networks with some low-utilization machines/sites 		<ul style="list-style-type: none"> • Optimized networks that maximize equipment utilization
<ul style="list-style-type: none"> • Low data visibility for both testing and service performance 		<ul style="list-style-type: none"> • Service levels defined, measured via KPIs, and consistently met • Testing data captured and reported
<ul style="list-style-type: none"> • Aging or last-gen technology 		<ul style="list-style-type: none"> • Latest technology deployed to the field
<ul style="list-style-type: none"> • Pace of volume growth variable country-to-country 		<ul style="list-style-type: none"> • Grow volume more aggressively in a more structured manner
<ul style="list-style-type: none"> • New machines purchased and owned by ministries 		<ul style="list-style-type: none"> • All countries transitioned to an all-inclusive pricing/contracting model
<ul style="list-style-type: none"> • Highly variable pricing above best-in-class; limited transparency 		<ul style="list-style-type: none"> • Optimize procurement, with increased volumes at lower price, with transparency and consistency across all price components

This network approach to laboratory services also supports a new way of operating at the country level to ensure sustainable improvements in laboratory services, by:

- Leveraging robust data collection on an ongoing basis to **inform laboratory-related decision-making** at the national level, national **laboratory policy**, and **vendor management** of machines and commodities
- Enabling **ongoing collaboration** among donors, partners, and countries on strategic planning and management of laboratory services
- Building **country capacity and ownership** of laboratory services to ensure sustainability

In addition to USAID and GHSC-PSM, **other global and domestic stakeholders and donors** — such as the Global Fund, CDC, PEPFAR, and HIV IPs working in country, such as the Clinton Health Access Initiative (CHAI) — have also been collaborating with USAID on this effort, as well as conducting their own initiatives to improve laboratory networks. FIND, the global alliance for diagnostics,

These networks will be more resilient. They will be poised to test for multiple diseases, improve overall national disease surveillance, and support effective responses to disease outbreaks and other chronic diseases.

has been providing technical assistance to countries in optimizing diagnostic networks and recently published a stepwise guide to DNO.

Investments in the network approach are enabling countries to strengthen laboratory systems and ready them for current and future laboratory needs. These networks will be more resilient. They will be poised to test for multiple diseases, improve overall national disease surveillance, and support effective responses to disease outbreaks and other chronic diseases. This improved performance and resilience will better serve patients with HIV, TB, COVID-19, and other infectious diseases, ensuring they can access routine high-quality testing, receive timely results, and obtain the right treatment.

GHSC-PSM's network approach to laboratory services includes five key components

GHSC-PSM — the primary global mechanism for procurement and supply chain management of PEPFAR's HIV VL and EID testing commodities — is working with countries to optimize their supply chains to meet their VL, EID, and TB scale-up needs so that programs can meet patients' testing and treatment needs. The project supports countries in implementing a network approach to laboratory services that applies best practices for procurement and supply chain management to drive efficiencies and ensure ongoing patient access to laboratory services.

The approach is multipronged, consisting of five key components:



1. Diagnostic network optimization (DNO).

DNO fully engages stakeholders in collecting and visualizing data to enable countries to optimize laboratory network design, equipment placement, and sample referral networks for current needs and to accommodate future demands. Efforts typically include global information system (GIS) modeling scenarios and operational planning.



2. Optimizing transport of patient samples.

Optimizing sample transport can further complement DNO. Like DNO, it entails GIS modeling, in this case of transport routes. But an added consideration is whether country ownership of large vehicle fleets and management of transport can be efficient and cost effective or whether to outsource transport to 3PLs for better performance and cost savings.



3. Forecasting and supply planning.

Stakeholders develop accurate national forecasts for testing needs and develop 18-month supply plans. This component of the network approach is informed by data from the DNO analysis and implementation. Forecasting and supply planning ensure the ongoing availability of quality data for procurement and supply management decision-making.



4. Procurement and strategic sourcing.

Using information from DNO and demand planning, stakeholders can implement a global approach for procurement and strategic sourcing of instruments and supplies. Countries can then access all-inclusive pricing that encompasses equipment placement, maintenance, and replacement; provision of reagents and consumables; and testing results

transmission and reporting solutions supported by the internet connectivity capability of laboratory machines.



5. Performance management.

Central to program implementation success is the creation of a performance monitoring and management system. At this stage, key performance indicators (KPIs) are established to measure service and maintenance, error rates, reporting, and supply chain management. KPIs also hold vendors accountable — both local suppliers of instruments and reagents and 3PLs providing transport services.

The third and fourth components — forecasting and supply planning, and procurement and strategic sourcing — are ongoing activities that countries were conducting before DNO implementation began through donor support. DNO strengthens these processes by helping them become more data based and less reliant on estimates.

In fact, **the network approach to laboratory services is an ongoing,**

cyclical process, with synergies among the components. Each component of the approach provides data that informs the other components, enabling continual improvement across all aspects of laboratory services.

True transformation of the laboratory network is possible only through embracing all components in a coordinated approach, with each pillar in the cycle continuing to inform the others. This approach focuses on managing and supporting all diagnostic services and needs at the national level to build resiliency and responsiveness not possible in prior paradigms.

The sections below will describe each component in detail, as well as examine progress made in countries toward implementing a network approach to laboratory services, and will discuss the results of donors' efforts to secure global pricing and maintenance service agreements for country laboratory networks through global requests for proposal (RFPs).



Viral Load Equipment Installation at Anaka Hospital, Uganda.
PHOTO CREDIT: GHSC-PSM

03.

A Network Approach



PHOTO CREDIT: Andi Gultom

A network approach to laboratory services

The five components and practical country-based examples



COMPONENT I.

Diagnostic network optimization

First, laying the groundwork for DNO and the network approach: Advocacy and initial buy-in

In 2018, PEPFAR included conducting and implementing DNO in its country operational planning, a significant development in encouraging PEPFAR-supported countries to begin using data analytically to optimize their laboratory networks to meet growing demand for testing services.

This enabled USAID and GHSC-PSM to begin implementing DNO in PEPFAR-supported countries that also receive support from GHSC-PSM.

The fundamental key to success in all countries where DNO assessments have been conducted, with implementation based on findings, is strong and early broad stakeholder engagement, visibility, and political will throughout the entire process. DNO has been and should continue to be a collaborative exercise, led by ministries

of health and supported by domestic and international partners. USAID, GHSC-PSM, the Global Fund, PEPFAR, the CDC, CHAI, the Elizabeth Glaser Pediatric AIDS Foundation, FIND, and Coupa (which provides OptiDx and Supply Chain Guru software to model, optimize, and simulate supply chain operations) have facilitated and provided technical assistance to countries in support of government DNO efforts.

All stakeholders work together to define and refine the scope of the optimization, data collection, and validation to map the existing laboratory network and sample referral system (see also next section on sample referral and transport) using GIS-based tools, then develop future-state programmatic and cost-based scenarios that ensure laboratory instruments are placed and used appropriately to meet national needs. This can include cost comparisons between different instrument types (e.g., instruments set up at conventional laboratory sites versus at points of care) and number of locations.

As part of DNO, stakeholders collectively develop an operational plan for moving

from the current state to the future optimized state. The operational plan will also support the four complementary components of the laboratory network approach — sample transport optimization; laboratory forecasting and supply planning; strategic sourcing of laboratory supplies; and performance management of laboratory equipment.

The DNO analysis and operational plan — as well as the strategic plans developed in the four complementary components of the network approach to laboratory services — must be translated into policy and operational plans at the country level. All stakeholders will need to embrace DNO and the full cycle of the network approach to scale up diagnostic services in support of programs, such as HIV and TB, and to strengthen the laboratory network as a whole. This will not only address more immediate challenges, but also prepare countries for future laboratory needs and disease outbreaks.

Next, collecting data and assessing the current laboratory network

Once initial stakeholder buy-in is achieved, especially from the Ministry of Health (MOH), **all tiers of the existing laboratory network are assessed** — laboratories at community sites, health

centers, and district or provincial hospitals, as well as regional and national reference laboratories.

The **following data and information** are considered in this assessment:

- National public health demographics
- Current and projected national testing volumes, testing capacity, and equipment utilization rates
- National distribution of patients
- Laboratory infrastructure
- Funding commitments
- Supply chain operations

This information is then compared against the capacity needed for national laboratory coverage and the sample referral and transportation network (see also next section) required to support a rational flow of samples and results between collection and testing sites, in terms of instruments, sample types, infrastructure, human resources, and referral routes.

Optimizing the laboratory and sample referral network is critical to ensuring all platforms in the country are accounted for and are placed appropriately for optimal patient coverage and use.

GHSC-PSM shares the assessment with the MOH and stakeholders and works with them to identify priorities and begin to collect and refine key laboratory network data (e.g., the facility list, level, type, and GIS location) and patient demand data.

Then, modeling and mapping the laboratory network and sample transport network

These data on the laboratory network and patient demand are then input into a GIS-based software application. **OptiDx — an open-source DNO tool** developed by GHSC-PSM and FIND in collaboration with USAID, Gates Foundation, and supply chain software firm Llamasoft (recently

purchased by Coupa) — is a leading tool to develop initial mapping of instrument placement and the sample referral network. OptiDx was designed specifically for low- and middle-income countries and uses country-specific data to run a series of customizable scenarios aimed at improving access and cost efficiency of laboratory services for HIV, TB, and other diseases.

Supply Chain Modeler™, another former Llamasoft tool now owned by Coupa, is another leading tool used to model network scenarios, informing the integration of POC technologies and assisting in prioritization and instrument rebalancing to address over-burdened or under-burdened testing demands.

Virtual modeling before laboratory instrument placement, or as part of formalizing an overall shift in testing strategies, is a critical component in informing the approaches to DNO. Supply Chain Guru and LabEQIP (predecessor tool to OptiDx) have been used in Cameroon, Eswatini, Nigeria, Rwanda, Zambia, and Zimbabwe, with support from PEPFAR, the Global Fund, CHAI, and GHSC-PSM, to develop virtual strategies to integrate HIV and TB sample transport, reduce instrument footprints to improve operational costs, and place instruments to determine the impact on laboratory testing demands and instrument capacity requirements.

In the DNO process led by government counterparts — modeled by GHSC-PSM and other stakeholders — the **iterative modeling often includes:**

- **Basic GIS mapping** of laboratories (capacity), health facilities, and patient numbers (demand); may also include mapping of test type (VL, EID, TB, COVID-19, etc.) and sample type (dried blood spot, etc.)
- Mapping of the **current specimen transport network**

- **Network modeling** using epidemiological data and systems capacity analysis; when key data are absent, models are based on defined variables and assumptions developed with the MOH and stakeholders
- Development of **optimized specimen referral and equipment location** scenarios and maps
- **Costing and modeling** of budget constraints, commodity pricing, operational costs, and cost per kilometer

These models are updated regularly as new data are collected and added to the dataset.

Use of OptiDx and Supply Chain Guru allows trained key stakeholders — usually staff from the MOH, the national laboratory program, or donors — to undertake advanced mapping, overlay cost modeling, and optimize larger networks (more than 1,000 national sites).

Throughout this process, GHSC-PSM collaborates with stakeholders, including Coupa, to refine the modeling and optimization scope.

More information on OptiDx

To learn more about OptiDx, watch this [five-minute video](#) on YouTube.

Finally, conducting a DNO policy workshop to socialize stakeholders, ensure full buy-in, and establish country ownership

During the DNO process, the project continuously engages government stakeholders to ensure their buy-in to the process and outcomes and to collaboratively develop efficient national policies that support the emerging national laboratory network. Several stakeholder meetings are typically held at the beginning, middle, and end of DNO analysis and implementation. Standalone

workshops may also be held on, for example, monitoring and evaluation, policy documents, or guidance documents for sample transport. Outcomes of these workshops are presented and implemented by the national laboratory TWG.

During the workshop held at the end of the DNO process, stakeholders develop an operational plan to move to the future state and optimized network. The project works with stakeholders to determine the workshop participants.

Activities during the workshop include:

- Providing information to participants on the **principles of DNO**
- Presenting the **current state** of the laboratory network

- **Modeling and refining scenarios** using OptiDx and Supply Chain Guru based on capacity, cost, location, and country-specific issues
- **Narrowing the list of modeled scenarios** based on national testing targets, specific country objectives, and budgetary constraints
- Developing an **operational plan** to implement the new network

The plan may include an optimal sample transport network design that can be refined by developing specific routing and scheduling modeling. Stakeholders can use this logistics information to inform operational planning for the optimized network or to develop sourcing events to support outsourcing of sample transport services to private-sector 3PLs (see next

section on considerations for outsourcing sample transport).

The operational plan is a collaborative document that is developed and reviewed by all stakeholders and provides the work plan for moving from the current state to the future optimized state. This document should provide timelines, activities, persons responsible, and linkage to the DNO outcomes.

By providing training and tools for countries to implement the network approach to laboratory services to improve supply chain management, GHSC-PSM assists countries in supporting efficiencies and cost savings in laboratory network scale-up. With the project's support, several countries in Africa have implemented this first step of the network



COUNTRY CASE STUDY

Rwanda: One of the first countries to implement DNO and see the impact

Rwanda's referral network was inefficient and not optimized. The National Reference Laboratory was overburdened by participating referral sites.

In 2017, GHSC-PSM led Rwanda's first training and comprehensive DNO exercise, using LabEQIP (the predecessor to current DNO tool OptiDx) to support VL scale-up.

Stakeholders in Rwanda collected data on patient numbers per site, equipment quantities, distances between sites, test types, health facility categories, and referral linkages. Partners aggregated, cleaned, and validated the data.

Participants then learned how to upload the data into LabEQIP. They learned how to create, run, and compare multiple scenarios based on different platforms, which led to their understanding the concept of optimization.

Participants ran **various scenarios** to reflect:

- Location of all sample collection sites
- Basic equipment characteristics of each machine for each test type
- Current and future planned sites
- Patient numbers by site location

Based on the scenarios, **LabEQIP revealed several opportunities to gain efficiencies.**

Participants also ran a scenario to project lab equipment usage and network impact based on an 8 percent increase in patients from 2017 to 2018.

As a result, some test sites were reassigned based on laboratory testing capacity, human resources, and distance to optimize the existing network. The ultimate outcome of the optimization was to reassign service delivery sites to testing laboratories to achieve an efficient laboratory network.

Efficiencies gained from the optimization included:

- A decrease of 16 percent in distance traveled by patient blood samples or results
- A decrease of average travel time for blood samples and results from 44 minutes to 37 minutes
- An increase of average equipment utilization of 5.6 percent
- A reduction in workload at the national laboratory of 6 percent
- An increase in national network coverage from 98.61 percent to 100 percent
- A finding that existing equipment in the national network was sufficient for the projected 8 percent increase in VL patients in 2018



COUNTRY CASE STUDY

Mozambique: Moving forward with DNO despite a complex advocacy process

Mozambique was the first country to conduct a DNO mapping exercise and begin DNO implementation. In 2016, the country worked with GHSC-PSM to begin data collection, mapping, and modeling using LabEQIP (OptiDx's predecessor) and Supply Chain Guru. Then, CDC requested that Llamasoft conduct a study to assess the costs of DNO, and Llamasoft developed recommendations for optimization based on that study.

Subsequently, in 2019, GHSC-PSM worked with the MOH, USAID, CDC, and stakeholders to conduct another DNO exercise using LabEQIP and Supply Chain Guru, and developed recommendations for DNO implementation based on this exercise.

Since then, some of the recommendations have been approved by the MOH and implemented. The MOH approved the allocation plan of 2021 for six Cobas 6800, four Alinity m, and two Panther machines. Approval of the placement plan for 2022 is ongoing, and consolidation of laboratories from 16 to 9 by the end of 2022 is in progress.

Four high-throughput instruments (two Cobas 6800 and two Alinity m) were procured and installed and are now being used to increase testing capacity and speed.

Importantly, these instruments are conducting tests for multiple disease areas.

Additional key recommendations from the Llamasoft study and GHSC-PSM DNO exercise include:

- Where to place laboratory instruments now and in the future to respond effectively and efficiently to current and future demand for laboratory testing
- What mix of instrument types to procure — the approved plan includes Hologic, Abbott, and Roche high-throughput instruments and prevents mixing platforms at laboratories
- How the national laboratory network could be consolidated from six laboratory sites down to two sites (the sites where the high-throughput instruments are currently installed) to create efficiencies and cost savings

Since 2019, GHSC-PSM and stakeholders have been working to gain MOH approval to implement all DNO recommendations. CDC has a lead role in supporting laboratory operations in

Mozambique and therefore has priorities it is working with the country to achieve as well. Also, some of the laboratory sites that are part of GHSC-PSM's consolidation recommendation are not managed by the MOH but rather by other government ministries, which adds time and effort to the approval process.

This more complex advocacy process is a reality in some countries. DNO is often an ongoing, evolving process, regardless of how quickly the recommendations are approved and implemented. But the work in **Mozambique illustrates how results can still be achieved on the path to DNO optimization, no matter how long the advocacy and approval process take.**

In Mozambique, the first-of-its-kind DNO mapping and modeling for this large country, **the mapping and modeling of an optimized sample referral network, and the recommendations that emerged from the DNO exercises continue to facilitate ongoing conversations** with the MOH and partners. Importantly, these conversations are starting from a place of viewing the country's laboratories as a national network rather than separate networks operating in silos. The decisions discussed are based on high-quality data on laboratory locations, disease prevalence, and current and future patient demand. And the conversations are led by the MOH and involve all stakeholders and disease areas. Laboratory consolidation and procurement of new, more reliable, and efficient instruments are still very much part of the discussion, as are decisions on the right balance of machines and the target audiences for samples to be tested at traditional laboratories versus POC locations, where throughput is lower and reagent costs are higher.

And through these conversations, the first decision was made — approving the request for introducing new technology through procurement and installation of the four high-throughput machines.

Recommendations to consolidate the number of laboratories, in particular, can create resistance among a country's laboratory stakeholders related to ownership and budgets. But GHSC-PSM's transparent DNO process, the gathering of robust data and development of visualizations, and the inclusion of every stakeholder in the decision-making process strengthens the advocacy approach and potential results.



COUNTRY CASE STUDY

Lesotho: Successful DNO implementation despite COVID-19 challenges

In 2019, although Lesotho had five VL laboratories, its goal of universal VL monitoring was hindered by barriers and delays. In the third quarter of 2019, more than one of every four people living with HIV/AIDS still lacked access to VL testing services.

Aiming to provide coverage to all HIV/AIDS clients — and with the support of the MOH, USAID, and CDC — implementing partners banded together to implement an ambitious DNO program.

The program began with a workshop in September 2019 at which participants mapped an optimized diagnostic network for HIV VL testing, EID, and TB diagnosis. The network was comprised of a mix of large and small laboratory sites around the country, including 13 minilabs.

The MOH's head of infectious disease control and the laboratory director joined forces to form a task force to lead implementation, leveraging each participating organization's expertise to define clear roles.

The task force **prioritized POC VL testing for pregnant and breastfeeding women to provide faster identification and**

access to care for preventing mother-to-child transmission.

A pilot program launched in February 2020 at five central “hub” sites, with eventual full rollout of the program in March 2021 to additional “spoke” sites.

Despite challenges related to COVID-19, which forced some training programs to happen virtually, more than 400 health facility staff were trained in the skills needed to implement DNO.

As a result of DNO, the **time required from laboratory sample collection to delivery of results at facilities dropped from a range of 13 to 43 days to less than 24 hours.** Health care providers reported a marked increase in patient satisfaction, including among pregnant and breastfeeding women.

The work in Lesotho continues, with partners preparing to carry out training to the remaining sites for inclusion of infants and children, ongoing supervision and mentorship for support of trained personnel, and training of more personnel to minimize gaps during rotations. Next steps also include plans to reach patients with unsuppressed VL and with advanced HIV disease.

approach — DNO — while others are in progress.

Once stakeholders adopt a refined network through DNO, they must coordinate planning and procurement to avert the addition of more instrumentation that may not be included in the planned diagnostic network, and to ensure the constant supply of reagents and consumables and the proper maintenance of instruments. Planning and procurement are covered in sections below.



COMPONENT 2.

Optimizing transport of patient samples

To provide access to diagnostics within a tiered laboratory network, a referral network must be in place to refer patients

or patient specimens to laboratories for testing.

Within one country, or even just within disease programs such as HIV or TB, multiple referral mechanisms often exist depending on the tier, region, funding available, transportation options, and such, leading to a fragmented referral network. Programs are often not aware of the different referral systems.

To gain understanding of current referral networks and other disease networks, an effective approach is to form an integrated sample referral and transport TWG to conduct a landscape assessment and clearly map out each referral network across all disease types. This exercise gathers information on current equipment placement, testing capacity, referral systems, transportation services (and/or third-party service providers), and the national testing algorithm.

Then, using the OptiDx and Supply Chain Guru platforms, the TWG designs a coordinated and optimal referral of specimens from collection points to first-line diagnostics and any further specialized referral testing. The TWG can model different scenarios based on geographic location, budget, and other criteria.

In designing this optimized referral and transport network, TWGs should consider:

- **Integrating disease programs** for efficiency and cost savings
- Moving to **electronic or mobile delivery of priority results**, alongside paper results for lower-priority testing
- Assessing and improving the **biosafety and quality provided by the packaging and transport equipment** and processes

- Ensuring **built-in responsiveness** of the system in the event of outbreaks
- Designating staff to manage and **continually monitor and improve** the system

Once an optimal scenario is chosen, pilot testing is conducted. Based on results, the referral system can be adjusted accordingly and scaled up, with ongoing monitoring and evaluation in place to ensure continuous improvement.

As part of scale-up, clinicians will need sensitization on available testing in the new referral system, and laboratories should be prepared for any resulting increases in throughput.

Considerations for outsourcing transportation of laboratory samples to private-sector service providers

Some public health systems contract with third-party logistics service providers (known as 3PLs) to provide broader logistics services, which may include freight forwarding, storage, distribution planning, and transportation. For countries that have not yet outsourced much or any of their health supply chain and logistics operations to 3PLs but see a potential need or benefit to doing so, transportation is often

the most logical place to start, including transportation of laboratory specimens.

Contracting for transportation of specimens can be done to achieve a few main results — for example, to:

- Improve **patient access** to laboratory services and timely results
- Improve **transportation performance** (e.g., speed, capabilities, accuracy)
- Bring about **cost savings** compared to the current costs for transportation
- Allow a country to focus on the **core business of ensuring positive health outcomes** rather than supply chain management
- Reduce a country's **operational management burden**

Contracting for specimen transportation services should help strengthen the laboratory network's overall performance and cost effectiveness while retaining a country government's oversight and stewardship of the network, thereby building country ownership and sustainability.

The first step in deciding whether outsourcing specimen transport is an

option is for a country to determine current transport costs and performance and then compare these data to the cost and performance of 3PLs through a market analysis or request for information (RFI).

If outsourcing would be beneficial for costs and/or performance, the next step would be to determine expectations for 3PL costs and performance and set KPIs accordingly. KPIs could include metrics for on-time delivery of specimens, transport routing and associated costs, and the safety and security of specimens.

Once KPIs are determined, the country can decide on what contracting approach to use, incorporate the KPIs into the contract, and then conduct a RFP process or other 3PL sourcing method.

For detailed information on contracting for transportation services, please see GHSC-PSM's guide "[Contracting for Transportation of Public Health Commodities to the Private Sector](#)."

For detailed information on costing aspects of public health supply chains, please see GHSC-PSM's guide "[Implementing Activity-based Costing \(ABC\) and Activity-based Management \(ABM\) in Warehousing and Distribution](#)."

Reporting and monitoring of KPIs aims to reduce downtime, improve instrument utilization and ensure supplier accountability to address issues.



GHSC-PSM resources on contracting and costing

For comprehensive information on contracting for transportation services and a listing of additional resources, please see GHSC-PSM's guide "[Contracting for Transportation of Public Health Commodities to the Private Sector](#)."

For comprehensive information on costing aspects of public health supply chains and a listing of additional resources, please see GHSC-PSM's guide "[Implementing Activity-based Costing \(ABC\) and Activity-based Management \(ABM\) in Warehousing and Distribution](#)."



COMPONENT 3. Forecasting and supply planning

To prevent stockouts of laboratory reagents and other supplies, programs need consistent and reliable data on commodity stock levels and consumption to be reported from testing sites to the central warehouse. These data are usually tracked and reported through a logistics management information system (LMIS) or a laboratory information management system. The data enable accurate forecasting for laboratory commodities, timely procurements, and improved visibility that allows manufacturers to assist with

manufacturing lead times for large order quantities.

In the initial phase of laboratory network scale-up, programs often use demographic or target-based forecasts. A demographic forecast multiplies the number of patients on ART by the number of VL tests per patient; a target-based forecast does the same but uses the national or program annual treatment numbers.

Both types of forecast invariably overestimate commodity demand, as they do not account for unreliable laboratory or logistics information systems, poor reporting, poor site-level stock management practices, uncoordinated instruments, or instrument failure. Further,



COUNTRY CASE STUDY

Nigeria outsources transport in its National Integrated Specimen Referral Network

Nigeria's experience with outsourcing laboratory specimen transport within a coordinated national specimen referral network offers a good example of how effective this approach can be.

Nigeria did not have a unified, standardized, and adequately coordinated system for clinical specimen referral. Specimen transport initiatives were independent of each other and not coordinated nationally, resulting in capacity under-utilization of laboratory equipment; increased costs because of duplication of efforts; backlogged tests, leading to long turnaround time for test results; and lack of visibility.

In 2017, the Nigeria MOH, with support from PEPFAR and the Global Fund, conducted a complete DNO and began implementing the optimized **National Integrated Specimen Referral Network (NISRN) as a solution to the specimen referral challenges**. As NISRN improved access to laboratory services, demand grew for reliable specimen transport services to move samples between the laboratories and points of care where patients were treated.

So in 2018, **GHSC-PSM sought out a private-sector partnership for NISRN to meet this demand**. With Nigeria having the world's third-largest population with HIV or AIDS, the use of 3PLs was vital to ramp up sample transport and support national efforts to achieve the UNAIDS 95-95-95 goals. The

efficient transport of specimens from collection centers to testing laboratories, and the transport of results back to the requesting facilities, allow for more patient testing, an increase in accurate and timely laboratory analysis, and improved VL monitoring — all of which moves the nation closer to reaching the third 95 goal, where 95 percent of all people on ART have achieved viral suppression.

While we often use 3PLs for in-country supply chain distribution services, transporting clinical samples is different from transporting other health commodities, so GHSC-PSM provided contracted 3PLs with specialized training and equipment to perform this new function.

Working with the 3PLs has yielded positive results. By using 3PLs instead of health facility staff, specimens were moved from facilities with backlogs to laboratories with capacity to analyze specimens quickly through the enhanced laboratory network. As a result, **the number of samples tested increased by 38 percent, reagent use increased by 21 percent, and the number of facilities receiving testing services increased by 83 percent**. This demonstrates how the use of 3PLs led to an expansion of laboratory services and a robust optimized sample referral network that can respond more readily to public health emergencies.

Additional supply chain factors that limit scale-up of viral load testing

While working to scale up VL testing, stakeholders may have to address concurrently commodity stockouts and other factors that impede improvements in reagent availability.

As programs scale up, limitations in **site-level storage space** can become a challenge, causing laboratory staff to store reagents across various locations, including hallways and other inappropriate storage space. Dispersed storage can make difficult routine stock management tasks and reduce reporting frequency and accuracy.

As programs scale up, supply chain managers may need to increase reagent distribution frequency — for example, from quarterly to monthly — while reducing quantities delivered to lower the storage burden. Consistent and reliable stock status visibility supports a shift to more frequent deliveries.

Early visibility and coordination for new VL instrument introduction is also important to ensure availability of necessary reagents and other commodities.

during a period of rapid scale-up, historical consumption and procurement are not reliable indicators of future consumption.

To conduct more accurate national laboratory forecasting as part of the network approach to laboratory services, GHSC-PSM uses the data gathered through DNO implementation to inform forecasting, as well as a tool called ForLab+, which was developed by USAID and CHAI and is managed by software company Opian Health.

A “mixed-methodology approach” means that ForLab+ uses demographic and morbidity data, service statistics, and logistics data on commodity consumption as a way to triangulate multiple forecasting methods to derive a best-fit laboratory procurement plan. Stakeholders can use this plan to establish realistic budgets and conduct supply planning activities.

As a data-driven tool, ForLab+ works well when data are available and are of high quality. In this case, it can precisely predict need. However, poor site-level reporting can reduce its forecasting accuracy.

ForLab+ has been used in more than 20 countries since its launch in 2013.



COMPONENT 4. Procurement and strategic sourcing

Procurement and strategic sourcing at the national level

Coordination between partners and governments to ensure the distribution of laboratory resources according to program needs has been challenging, frequently resulting in the over-procurement or under-procurement of instruments and reagents that do not meet the testing needs of programs.

Further, pricing variability across different stakeholders, donors, and disease programs in a country leads to a barrier scale-up because it creates challenges with budgeting. Many countries with budget limitations have historically paid more per test due to lower testing volumes, which may also be compounded by more difficult infrastructural challenges to overcome as part of service delivery.

A solution to this is to conduct procurement nationally, which allows countries and their partners to aggregate volumes and donor

investments as leverage to negotiate with manufacturers and vendors in establishing volume prices for tests performed nationally. This creates consistency and transparency in pricing and allows all stakeholders to access the same price.

National pricing schemes usually include shifting to an all-inclusive reagent rental scheme (RRS) or reagent service scheme (RSS) that serves all existing and new instruments in a country, no matter the stakeholder, donor, or disease. A vendor-specific instrument contract is put in place that contains terms and conditions that are informed collectively by all stakeholders.

Negotiated agreements with manufacturers and vendors should go beyond pricing for reagents and consumables and bundle in additional service offerings. Revised pricing schemes could potentially include a:

- **National cost and contract structure that allows for volume growth and instrument expansion** within a complete network, regardless of the disease type or program area, and that can be accessed by all stakeholders
- **Cost structure translated into an all-inclusive per-test cost** spread across all instruments of the same manufacturer brands within the network

This all-inclusive per-test cost could include:

- **Network expansion through leasing.** As part of network expansion, cost options are developed that would account for existing legacy instruments and the development of new contract models (e.g., leasing and rentals) that facilitate the supplier's provision of new instruments under standardized pricing schemes. PEPFAR no longer supports capital procurement of laboratory instruments, and as such, countries and partners are moving toward paying only for reagents and all-inclusive service agreements — in other words, paying for performance.

Once machines are past their useful life, suppliers replace them.

- **Service and maintenance.** Ongoing service and maintenance are included in the cost.
- **Data solutions and internet connectivity.** Electronically connected data solutions would include patient result transmission, as well as remote instrument and user performance monitoring.
- **Training.** Laboratory network staff receive training to ensure consistency.
- **Technology support.** Additional technology support is provided that could assist in site-level efficiencies (e.g., barcode use, sample processing, and workflow evaluations).
- **Contractually required data sharing.** Contracts require sharing data on downtime, testing protocols, specimen types, and such to facilitate real-time management of the network and improve vendor accountability.
- **Commodity management.** Enhanced commodity management strategies ensure reagent availability, including shifting the responsibility for commodity management from countries and their partners to

vendors, known as vendor managed inventory (VMI).

- **Instrumentation risk management.** The longer-term management and mitigation of risks associated with instrumentation is shared with manufacturers and local vendors by amortizing instrument costs into reagent costs to lower start-up costs associated with scale-up; or by assigning the risk to them by providing no-cost options for instrument replacements due to high failure rates, capacity issues (need for upgrade), or outdated technology.

The robust data gleaned from DNO implementation and from forecasting and supply planning will inform national procurement and strategic sourcing, enabling countries to negotiate and develop pricing and service-level agreements based on a strong understanding of their current and future laboratory testing needs.

In a network approach to laboratory services, it is important to **look beyond lowest price per test and focus on the total cost of ownership.** Initially, per-test costs could be higher; but the longer-term strategy will benefit the network with greater efficiencies, improved performance, and lower costs.

Data and connectivity solutions inform performance management, supply planning, and strategic priorities. Suppliers must be held accountable to keep their machines connected.



Performance Management

- How instrument suppliers perform against their key operational metrics
- Where errors and anomalies occur so that technical assistance can be provided



Supply Chain Management

- How ordering cadence and amounts be changed to reduce wastage and stockouts
- How supply plans can adjust to reflect actual testing needs and platform performance



Network Approach

- How capacity can be shared to support multiple-healthcare diagnostics
- Where to scale up capacity based on the referral network and testing activities



COUNTRY CASE STUDY

Nigeria awards reagent rental and all-inclusive service package tender following successful optimization of the laboratory network

In Nigeria, the laboratory network had grown to 27 laboratories, resulting in higher operational costs for government ministries and suppliers.

To reduce this footprint and accelerate progress toward the 95-95-95 goals, the conversation for network optimization peaked in February 2017 from the ground up through demand analysis, technology assessment, and detailed performance management analysis. **This DNO enabled a reduction from 27 to 16 laboratories.**

Next in 2017, the country issued a **reagent rental and all-inclusive service package tender for six high-volume laboratories**, representing 72 percent of national demand. Two suppliers were awarded agreements.

The outcome of this effort was improved market health through diversification of the instrument fleet and significantly enhanced laboratory network performance for the cost. Viral load testing has increased from 150,000 tests in Fiscal Year (FY) 2016 (end September 2016) to more than 1.3 million in FY 2021.



COUNTRY CASE STUDY

Mozambique's reagent rental and all-inclusive service agreement builds reliability and resilience into the laboratory network

In Mozambique, VL instruments suffered many breakdowns, and the local vendor holding the maintenance contract had insufficient technical capacity and incentive to provide adequate service. The reagents were purchased separately from instruments, and lead times did not allow for flexibility in machine downtime.

Building flexibility into the reagent supply chain required a reagent rental agreement. Using all-inclusive pricing in a contract with a local vendor, the country aligned supplier and public health incentives to achieve uninterrupted VL testing.

The country no longer buys instruments; it now buys reagents, and the reagent price includes maintenance and distribution. The vendor's incentive is that it makes money by making sure the instruments are working.

This model allows for responsiveness to demand. After the 2019 cyclones, samples and reagents were rerouted to other laboratories, and the vendor had responsibility for repairing damaged instruments. The model also simplifies scale-up: the vendor manages instruments awaiting any delays in the building of laboratories, and the vendor ensures reagents are available once the instruments are installed.

Performance is managed through KPIs that measure weekly breakdowns, monthly stock levels, and equipment utilization and contribution.

Using this approach, **Mozambique achieved a 26-fold increase in VL testing over three years and never experienced an interruption in testing due to reagent stockouts.**

Following this experience, the MOH adopted the same approach for laboratory procurements.

Procurement and strategic sourcing at the global level through PEPFAR's global service-level agreement

In 2018, the global HIV community began to advocate for aggregating procurement of laboratory instruments and reagents at the global level. USAID and GHSC-PSM conducted a summit between global HIV program partners (the Global Fund, CDC, and PEPFAR) and seven manufacturers of VL testing instruments to discuss establishing and joining a global service-level agreement (SLA) developed by PEPFAR. This proposed global SLA would benefit all stakeholders — not only the donors, manufacturers, and country governments that would join the SLA, but ultimately **the most important stakeholders: the patients served by more efficient and cost-effective laboratory services globally.**

During this summit, USAID and GHSC-PSM first presented the network approach to laboratory services and discussed the pillars of this approach. With implementation of the network approach to laboratory services underway in various countries, GHSC-PSM's sourcing and procurement of laboratory instruments and reagents has been conducted more strategically on a national level in each of these countries, achieving volume discounts and maintenance service agreements.

The global SLA would streamline the relationship between donors and manufacturers and take this procurement strategy to the next level for potentially even better pricing and service outcomes. It would potentially further reduce reagent pricing by scaling procurement up to the global

level and significantly increasing the volume and regularity of procurements. In return for agreeing to lower reagent prices, manufacturers of VL testing instruments would be given volume commitments by HIV donors and would gain a greater share of the global market through the global SLA.

The global summit aimed to engage all stakeholders in this global perspective of laboratory services and enable them to see how the global SLA would benefit their differing program needs and business targets.

Following the summit, PEPFAR developed the SLA based on stakeholder input and subsequently developed and issued an RFP, so that manufacturers could submit their proposed pricing and requirements. As a result of the RFP process, PEPFAR reached agreement and established contracts with three laboratory instrument manufacturers — Abbott, Roche, and Hologic — that had the required technical strength and business strategy to supply instruments and reagents and provide maintenance service agreements.

All countries that receive PEPFAR funding can now access global pricing for instruments and reagents through these three manufacturers by joining the global SLA. Also, countries can choose to join the global SLA to access maintenance service agreements with the three manufacturers.

Implementation of the global SLA is a parallel activity to the DNO implementation underway in different countries. While GHSC-PSM continues work with countries to implement DNO, the project is simultaneously working with manufacturers to convey the aggregate information learned through DNO — country testing needs, quality and performance management needs, data and connectivity needs, and total cost of ownership — to guide the ongoing development and full use of the global SLA. Countries do not have to have completed DNO implementation to access global SLA pricing or service agreements; once

Illustrative KPIs to monitor vendor service and instrument performance through all-inclusive service contracts

CATEGORY	INDICATOR	STANDARD TARGET
Maintenance, insurance, and ongoing end user training	1. Percentage of machines that are serviced with 2 preventative maintenance visits per contract year	100%
	2. Mean time to response for equipment breakdown: time lapsed from time issue first reported to the time a follow-up plan is communicated to the customer	48 hours
	3. Mean time to repair: average # of calendar days lapsed from time issue first reported to job completion	≤5 days
	4. Percent of instruments that experience ≤2 outages which occur less than 3 months after any scheduled / unscheduled maintenance work, per year	100%
	5. Percentage of machines that are operational >85% of days each quarter	100%
	6. Average percentage of failed tests due to machine or human error	<5%
Connectivity/ reporting	7. Percentage of Quarterly Reports submitted on-time per the terms of the subcontract	100%
	8. Average percentage “uptime” of automated reporting system	>95%
Commodity supply chain management	9. Of batches with committed goods available date (C.GAD) in the month, percentage of batches that comply with the shelf life terms in the Basic Ordering Agreement (BOA)	100%
	10. Percentage of line items delivered in full and on time. In-full is measured against agreed ordered quantities. On-time is defined based on incoterm as either 7 days prior/3 days after or 14 days prior/7 days after the current committed goods available date	>90%

DNO is completed, terms of the SLA can be adjusted as needed.

To join the global SLA to access the maintenance service agreements, countries must gain agreement of their PEPFAR-led laboratory TWG. Patient impact is also a factor in prioritizing countries to join the SLA for service agreements, meaning that larger countries with more patients are prioritized.

USAID and GHSC-PSM continue to advocate for full use of the global SLA. Currently, USAID and the project are examining how building information technology (IT) management into the global contracts can reduce laboratory network costs further.



COMPONENT 5. Performance management

When developing RRS or RSS contracts, all stakeholders must define expectations.

They should negotiate these contracts collaboratively and develop a **harmonized set of KPIs**, which should include:

- Minimum response times for instrument repairs
- Training
- Logistics
- Instrument performance
- End-user performance

Stakeholders should establish clear thresholds for instrument failure frequencies, and service providers should be held accountable for responding to site-level failures that go beyond these established thresholds.

Contracts should dictate a standardized monthly and quarterly reporting format to assist in addressing site-specific or instrument-specific challenges, as well as vendor service delivery issues. The contract should also define at least quarterly

meetings with the supplier to review performance and work collaboratively to solve problems and address any performance issues. Contracts should also clearly delineate lists of parts to be made available in-country for high-failure parts, minimum service technician requirements, and possible data solutions for patient result transmission.

In **Mozambique**, as mentioned in the section above, vendor performance is managed through KPIs that measure weekly breakdowns, monthly stock levels, and equipment use and contribution. Monthly meetings are held with the vendor to review breakdowns.

USAID and GHSC-PSM continue to advocate for full use of the global SLA.

04.

Progress by Donors



PHOTO CREDIT: Anthony Abu | GHSC-PSM

Progress by Donors

National and global pricing and inclusive service agreements for diagnostic networks

In addition to the global SLA that PEPFAR is currently implementing, all donors and partners in the HIV community are working to achieve improved pricing and service agreements for country laboratory networks.

The Global Fund

The Global Fund has negotiated global access pricing for low- and middle-income countries with the two most commonly used molecular brands for VL testing and infant virological testing—Roche Molecular Diagnostics and Abbott Molecular Inc.

For Roche, commodity-related prices include reagents and consumables, with ex-works terms (goods are available at the seller's or manufacturer's site and must be transported by the buyer).

Abbott's pricing is based on volumes and duration commitments, which resulted in pricing variability across countries. Yet based on volumes and multi-year commitments, as well as national negotiating influence, some countries have further reduced these prices.

Recent coordination with the Global Fund has also resulted in price transparency in Haiti, the Democratic Republic of Congo, and Cameroon, with initial reagent price reductions and then further reductions. Efforts are still in process to promote further reductions as scale-up continues in these countries, as well as to provide more comprehensive packages that include service, maintenance, and data management, as well as standardized reporting requirements informed by agreed-to KPIs as part of a price-per-test scheme.

PEPFAR

PEPFAR has **renegotiated all its existing VL and EID procurement contracts to significantly lower all-inclusive pricing schemes**. PEPFAR has also engaged the Global Fund to push further transparent pricing reductions, with additional itemized system-costing options, including all-inclusive reagent rental, instrument service and maintenance, and data management systems, as well as possible vendor-managed inventory.

PEPFAR is committed to all future instrument investments and reagent

procurement strategies using **RRS for new instruments, as well as inclusive RSS for existing instrumentation**.

PEPFAR's current COP technical guidance emphasizes the use of RRS for instrument expansion, **driving countries toward a more systems-focused approach**.

Currently, Kenya, South Africa, and Uganda, and, more recently, Haiti, Mozambique, and Nigeria, are taking advantage of RRS or a combination of RRS and RSS.

USAID and GHSC-PSM

USAID and GHSC-PSM worked with Haiti, Kenya, Mozambique, Nigeria, Tanzania, Uganda, and Zambia, and are working with other countries, to put in place **more dynamic RRS agreements**, which is now the norm for any USAID-supported VL or EID conventional platform. By moving to an RRS or a RSS approach, countries can amortize their initial capital investment for the scale-up and servicing of VL-testing instruments within their reagent pricing scheme, offsetting initial scale-up costs and expanding instrument coverage, as well as ensuring complete service contract availability.

To assist countries in this approach, USAID developed a **12-question approach** (see Annex 1 of WHO's "[Guidance for procurement of in vitro diagnostics and](#)

[related laboratory items and equipment](#)”) designed to help countries think through the use, placement, and servicing of laboratory instruments before initiating procurement or RRS or RSS arrangements.

GHSC-PSM has also made significant gains toward **improving service and maintenance of VL, EID, and TB laboratory diagnostic networks in Nigeria**. The project worked with a primary POC provider, USAID, CDC, the Global Fund, and the MOH to develop the first all-inclusive reagent and consumables model in Nigeria and to pool volumes to generate the most value for the program. Working with the POC provider of VL, EID, and multi-drug-resistant TB reagents and cartridges, GHSC-PSM and partners negotiated an SLA to bring visibility and accountability to servicing and maintaining the provider’s network in Nigeria. This network includes 407 sites and will serve more than 500,000 patients with products funded by PEPFAR and the Global Fund, and up to an additional 400,000 patients with products funded by the MOH and other donors.

This was the **first time that the global community negotiated a surcharge deal with KPI accountability and enhanced service terms that make spare parts available in country**.

Other international donors, partners, and the provider are using the GHSC-PSM contract to pursue this innovative surcharge model in other countries.

In Haiti, GHSC-PSM worked with USAID, CDC, and national VL sites to address equipment breakdowns and service interruption. The working group identified spare parts for the equipment that breaks down most often. GHSC-PSM worked with the key equipment supplier and the in-country distributor to establish a new depot for standard in-country inventory of high-failure-rate parts. This new spare parts depot will increase instrument uptime and



In Zambia, a demonstration on how to use a high-volume viral load testing machine.
PHOTO CREDIT: GHSC-PSM

reduce repair time for the most commonly affected Abbott m2000 parts.

Preliminary data show that in 2020, GHSC-PSM procured approximately 10 million VL patient tests and **generated around \$20.5 million in savings from lower prices negotiated with the three suppliers under the global RFP**. The project worked with USAID, CDC, and the laboratory TWGs in the first wave of countries that participated in the RFP to renew annual global and country-level volume commitments with the VL suppliers for FY 2021. Establishing higher commitment levels can enable GHSC-PSM to negotiate even lower prices per patient test in FY 2021.

VL and EID suppliers have continued submitting their quarterly and monthly KPI reports on instrument servicing, uptime, test failure rates, and supply chain indicators. To conduct the KPI reports

and procurement activities with greater continuity and efficiency, GHSC-PSM and USAID worked to equip the first wave of PEPFAR countries that participated in the global RFP for VL and EID with **instrument internet connectivity, laboratory information management system integration, and remote monitoring capabilities**. With the FY 2020 deployment of networking equipment in most first-wave countries, GHSC-PSM and partners will prioritize FY 2021 activities to develop and drive adoption of software applications that help reduce waste, avoid stockouts, and assist overall VL contract management.

Data-sharing agreements were signed by the ministries of health of Mozambique and Nigeria, which set a tangible precedent of health data sharing among USAID, CDC, and Department of Defense-supported HIV programs and beneficiary countries.

05.

Conclusion



PHOTO CREDIT: Elive Ngale | GHSC-PSM

Conclusion

Continuing collaboration to drive further improvements

USAID and GHSC-PSM's support to countries in implementing the network approach to laboratory services has resulted in significant improvements in performance, resilience, cost savings, and ultimately the ability for patients to access lifesaving care and treatment.

In particular, the global HIV community has made great strides in governance, optimized placement and transport, pricing, service, and performance management through KPIs. We have leveraged the private sector to improve commodity security, eliminate stockouts and machine breakdowns, and professionalize the transport network.

Looking forward, the global community will be working to make new or further gains in:

- **Ensuring reliable internet connectivity of instruments.**

Since laboratory commodities have shorter shelf lives, they are more at risk of stockout, which is why real-time reporting of consumption is so

important for laboratory services. If data reporting is lagging, it may be too late for decision-makers to properly manage stock and avoid stockout. In global SLAs, PEPFAR is requiring that reliable internet connectivity is installed in all machines so they can automatically report performance and consumption data directly into country and supplier systems.

- **Extending SLAs.** USAID and GHSC-PSM will be extending this methodology to other Wave 2 countries, negotiating fixed prices for other countries, and expanding beyond VL into other areas (e.g., TB and COVID-19)

- **Further improving sample transport.**

Driving further visibility into turnaround times and implementing electronic tracking systems are the next steps.

- **Increasing VMI.** Donors and partners are shifting further toward suppliers being accountable for managing reagent inventories, ensuring stock is replenished in a timely manner and maintained at appropriate levels. Country programs will still be responsible for proper storage of commodities. VMI adds flexibility and resilience in the laboratory system to manage the ebbs and flows in demand, respond to emergencies, increase instrument use, and reduce testing turnaround times. Internet connectivity will provide real-time monitoring of reagent consumption, enabling this shift to VMI.

Leveraging the private sector can improve commodity security, reduce stockouts and machine downtime, and professionalize the transport network.

06.

Annex



PHOTO CREDIT: Andi Gultom

Annex

Nigeria's routine sample pick-up and results return process flow

Sample pick-up from health facility

1. Rider calls health facility to confirm availability of samples for pick-up on scheduled pick-up day.
2. If samples are not available for pick-up, Rider documents the unavailability and reasons.
3. If samples are available for pick-up, Rider confirms by telephone call the actual time for pick-up.
4. Rider proceeds to the facility and records/documents date and time of arrival.
5. On arrival, Rider confirms that samples are available and ready for pick-up.
6. If samples are available but not ready for pick-up, Rider documents the date/time of arrival.
7. If samples are ready for pick-up, the Lab point of contact and Rider conduct spot checks to verify documents (NISRN transportation manifest, requisition forms) against samples.
8. Rider signs the NISRN transportation manifest (four copies) and leaves a duplicate copy for the facility, packages sample for transport, and records the temperature.
9. The health facility focal person and Rider document date and departure time at facility on the facility attendance sheet. The facility point of contact and 3PL sign off.
10. Rider transports samples to hub/**polymerase chain reaction (PCR)** testing laboratory within 24 hours.

Sample delivery and pick-up of results from PCR laboratories

1. On arrival, the PCR laboratory point of contact (or dedicated laboratory staff assigned to the 3PL) verifies and documents temperature of log-in. The PCR laboratory point of contact documents date/time of arrival and confirms samples against documents

(NISRN transportation forms or remote sample login (RSL) manifest, requisition forms).

2. If samples are not accepted at the PCR/testing laboratory, the PCR laboratory point of contact documents the affected client information on rejection register and releases the form to 3PLs.

Riders communicate to the originating facility/3PL coordinator/GHSC-PSM lead logistics partner (LLP)/partner point of contact within 24 hours and documents time and date of communication.

Rider returns rejected forms to the facility by next visit.

3. If samples meet all criteria and are accepted at the PCR/testing laboratory, the testing laboratory signs three copies of the NISRN transportation forms or RSL manifest and retains a copy. The 3PL keeps a copy and returns the last copy to the referring facility.

4. If results are ready for pick-up at the PCR/testing laboratory, the laboratory focal person informs the IP focal person so they can download results from the LIMS or RSL handles, and

Rider then calls the 3PL/state coordinator and awaits feedback within 20 minutes.

If samples are not ready, Rider departs and documents time of departure.

- notifies the 3PL/LLP for pick-up of hard copies for non-RSL.
5. Rider uses the NISRN transport manifest (proof of delivery) to check off results picked and indicate date of pick-up.
 6. Results arrive at the originating facility.
 7. The health facility point of contact documents date/time of result arrival in the facility. The health facility point of contact/3PL signs off on three copies of the NISRN result transport manifest and returns two copies to the 3PL. The 3PL returns a copy to the testing laboratory (this process will continue until all results are returned).
 8. Rider appends signature on attendance sheet and indicates date and time. The health facility countersigns the attendance sheet. (The entire process of sample log-in, verification, result dispatch, and signing of documents should take a maximum of three hours, and attendance to 3PLs from outside the state of PCR mega laboratory should be prioritized.)