

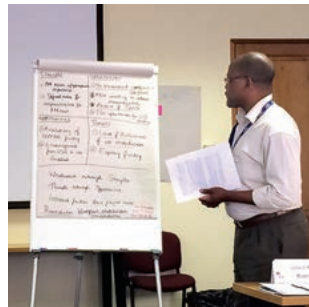
LABORATORY DEPARTMENT




LAB
VISION: An excellence in provision of diagnostic services.
MISSION: To provide quality diagnostic services to all Kenyans



SAVING LIVES, STRENGTHENING LABS
THE POWER OF THE APHL/CDC PEPFAR COOPERATIVE AGREEMENT





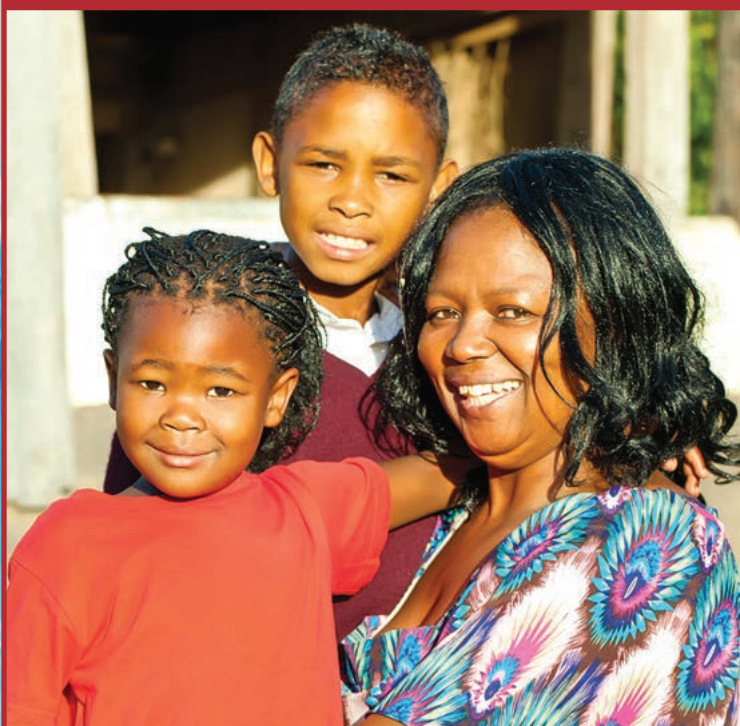
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**A HEALTHIER WORLD THROUGH
QUALITY LABORATORY SYSTEMS**

—APHL VISION STATEMENT



FOREWORD

A VISION, A LEGACY, A SUSTAINABLE REALITY

A *healthier world through quality laboratory systems.* This is the APHL vision, and our work with the US President's Emergency Plan for AIDS Relief (PEPFAR) has helped move it closer to reality.

Through the five-year Cooperative Agreement with PEPFAR and the US Centers for Disease Control and Prevention (CDC), APHL has been privileged to play a role in the most extraordinary global life-saving mission of our time. Since 2003 when PEPFAR was signed into law by President George W. Bush, more than 1 million babies have been born HIV-free to HIV-positive mothers. In fiscal 2014 alone, more than 32 million women were tested with PEPFAR support, and more than 5 million HIV-infected women and girls were placed on treatment.



APHL provides ongoing assistance to Guyana in implementing Laboratory Information Management Systems.



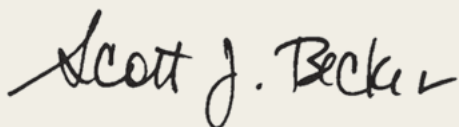
APHL Executive Director Scott Becker, second from left, visits a health facility in Ethiopia.

Laboratories, and public health laboratories in particular, are intricately tied into this process of prevention, testing, care and treatment of HIV/AIDS. Over the years, APHL has been an essential stakeholder in delivering services from quality assurance to strategic planning to training, working in-country, with respect for the expertise and diversity of all. Without quality laboratory work, the goal of ending HIV/AIDS cannot be reached.

Those in the public health laboratory field can both respond to immediate needs and think strategically about what will benefit generations to come. And these skills are some of the most valuable resources that public health laboratory professionals bring to this fight.

PEPFAR's mission has always been far-reaching, working to achieve an AIDS-free generation. Here, too, APHL's values align: Whether we're helping to implement early infant diagnosis for HIV, training leaders to continue advances in quality, or planning secure facilities to be prepared for any emerging infection or disease outbreak, we're looking ahead and around corners.

Every plan we contribute to and every action we help facilitate under the agreement also offers opportunities to improve laboratory systems and sustainably build capacity toward a healthier world. I'm proud to work with the people in this association and in all the PEPFAR-supported countries who share this vision and advance it every day.



Scott J. Becker, MS
Executive Director, APHL



Improved patient care is the ultimate outcome for Kenya's laboratory strategic planning effort.

INTRODUCTION



A CALL TO A LONGTIME PARTNER IN GLOBAL HEALTH ADVANCEMENT

The Association of Public Health Laboratories (APHL) was the first US laboratory partner called on by the Centers for Disease Control and Prevention (CDC) to support the implementation of the PEPFAR program. CDC recognized that APHL had the expertise and experience in laboratory setup, diagnostic methods and safety practices; APHL had been working around the world for more than a decade with multiple partners to strengthen laboratory systems.

APHL is a nonprofit, nongovernmental organization with more than 800 members representing US state and local public health, agricultural and environmental labs, health partners and interested individuals.

Working with 31 countries for over 20 years, APHL is unique in that it offers both expert specialization — the public health laboratory — and a strong grasp of the big picture. We bring the laboratory systems perspective and experience honed in a large US organization to support laboratories and public health internationally — assisting with strategic planning, design and interaction of laboratory and larger health systems.

APHL participated in significant global health projects as early as 1998, when we helped laboratory systems in the Caribbean respond to the destruction caused by hurricanes Mitch and Georges. From there, we expanded our global work to its present depth and breadth of capacities and capabilities, with funding first from CDC's Global AIDS Program and then, beginning in 2003, from CDC through PEPFAR.

With these resources, we have provided training, model practices, guidance documents and technical assistance. We help shape strategic plans and public health policy, champion the importance of laboratory systems and support sustainable laboratory strengthening initiatives.

In times of health crisis and in ordinary circumstances alike, APHL is a partner on which health organizations, ministries of health, public health professionals and laboratorians can depend.



The essential role of public health laboratories in PEPFAR

In 2003, the world — particularly Africa — was facing the devastation of a rapidly growing HIV epidemic that had reached pandemic scale. In his State of the Union address, President George W. Bush presented the scope of the crisis: nearly 30 million people in Sub-Saharan Africa, including 3 million children, were infected with HIV. The US President’s Emergency Plan for AIDS Relief (PEPFAR) was passed soon afterward with bipartisan support.

Progress was as swift as the initiative was extraordinary. Public health labs in Mozambique, where APHL began engagement in 2004 and still works extensively, went from delays of several weeks to get an HIV test result to needing just a few hours.

Phase I of PEPFAR emphasized emergency response. Phase II, launched in 2008, emphasized engagement and sustainability. Phase III, or PEPFAR 3.0, began in 2013. The goal: sustainable control and, ultimately, an AIDS-free generation. From the start, the public health lab had an important role in accomplishing these aims.



The countries supported under PEPFAR, such as Ukraine, face diverse laboratory challenges and require unique solutions.

Some health crises demand specialized caregivers, a race to develop treatments or vaccines, more space in hospitals or a massive educational effort. HIV/AIDS demands all this and more: Controlling the disease requires an unprecedented degree and scope of laboratory skills and specialization. The long period without HIV symptoms makes accurate, early testing critical. Treatment to prevent mother-to-child transmission can grant a child a long and productive life, but

APHL Global Health Activities Overview

Countries	Laboratory Information Management Systems (LIMS)	Strategic plans & national laboratory policy	Surveillance & evaluation	Infrastructure	Accreditation	Training	Database development & management	Quality systems	Network & partnership building
Angola						●		●	
Botswana	●	●		●	●	●		●	●
DRC	●				●	●			
Ethiopia	●					●			●
Ghana	●	●							
Guyana	●	●							
Haiti		●	●			●	●	●	
Kenya	●		●		●	●	●	●	
Lesotho	●	●	●		●	●	●	●	
Mozambique	●	●	●	●	●	●	●	●	●
Namibia	●	●	●	●			●		
Nigeria		●	●		●	●		●	●
Rwanda	●				●			●	
Sierra Leone		●	●	●	●	●			
South Africa					●	●	●	●	
South Sudan		●		●	●	●		●	
Swaziland	●					●			
Tanzania	●			●		●	●	●	
Ukraine	●	●	●		●	●		●	
Vietnam	●		●		●	●		●	
Zambia	●	●		●	●	●			
Zimbabwe					●	●		●	

Activities recorded at any time over the full duration of the Cooperative Agreement



Access to quality, integrated laboratory services makes an enormous difference in the lives of mothers and babies — and can turn the tide toward improved health for generations.

requires precise testing and monitoring. Tracking viral loads, evaluating the effectiveness of treatments, maintaining treatment consistency, surveillance to discover whether some groups of people are going untested or untreated — none can be done effectively without a public health laboratory.

The World Health Organization/Regional Office for Africa, in its 2008 Maputo Declaration on Strengthening of Laboratory Systems, recognized as much, calling on governments to develop national laboratory policy and strategic laboratory plans.

Strategy: Prioritize areas of greatest benefit

In many PEPFAR-supported countries both in Africa and elsewhere, the public health

FROM EMERGENCY TO SUSTAINABILITY

APHL's work in Haiti parallels that of PEPFAR's vision: While it began as an emergency response — and we are there when needed in a crisis — the goal has grown to encompass sustainability and solutions.

We worked in Haiti in 1998 in the wake of Hurricane Mitch, before the Cooperative Agreement was established. After the Agreement, we assisted in crises such as the 2010 earthquake and cholera outbreak, helping to assess damage to laboratories and restore services, including sending a modular laboratory unit. To further strengthen the system toward sustainability, APHL collaborated with CDC to implement molecular testing at Haiti's national public health laboratory in 2012.

By 2014, APHL worked with a 23-member stakeholder representative team to formulate a national laboratory policy, covering responsibility for disease surveillance, quality assurance, management of a national laboratory network, training, evaluation, information systems and more.



Despite setbacks from natural disasters, Haiti's national public health laboratories continue to advance against HIV, with APHL offering training and implementation in viral load testing.

ABOUT THIS REPORT

The Centers for Disease Control and Prevention receives PEPFAR funds, some of which it then provides to APHL to work on PEPFAR goals. This report looks at the PEPFAR/CDC 5-Year Cooperative Agreement with APHL that ran from September 2009 to March 2015, noting seven significant areas of achievement among the accomplishments, placing these in the context of improved global health systems and highlighting some examples of extraordinary results.



laboratory system struggles. Some systems are damaged by war, such as in Sierra Leone. Others, such as laboratories in Nigeria, had expertise but had progressed so rapidly that systems were misaligned. Haiti had been beset by natural disasters; patients in Ukraine faced stigma and public misconceptions about safety.

To address these situations, APHL gave priority to helping to advance the seven areas of achievement in this report. Strategic plans, the importance of training and human resources, alignment with the larger health systems, meeting the challenges of rapidly advancing technologies and continual quality improvement — focusing on these seven areas brought results. The establishment of the African Society for

Laboratory Medicine, and its African Public Health Laboratory Network, with its attention to the role and needs of laboratories and particularly their advocacy of quality, has brought a strong partner to the effort.

Globally, there still are more than 40,000 new HIV infections every week. The rapid strengthening of public health laboratory systems in PEPFAR countries positions them to help detect cases and support treatment. And with a continued relationship with CDC and PEPFAR support, APHL is committed to success.



DEVELOPMENT OF AN AFRICAN PUBLIC HEALTH LABORATORY NETWORK

“APHL has been a critical partner in the design and framing of ASLM, as well as in building the political support. APHL continues to be a founding partner of APHLN and our strategic partner in the building of the network. APHL is important for strengthening laboratory medicine and access to diagnostics in Africa.”

— DR. TREVOR PETER
CHAIR OF THE BOARD, ASLM

It was the kind of rapid response worthy of laboratorians. Within four years, the laboratory system in Africa went from being referred to as the “Achilles’ heel” of the health services to a recognized capability with a continent-spanning professional organization, a professional journal and a foundational public health laboratory network.

APHL consultants and representatives joined more than 300 health leaders for the African Society for Laboratory Medicine (ASLM) launch in March 2011, in Addis Ababa. APHL helped develop and implement ASLM’s ambitious agenda: strengthening existing national laboratory professional associations and helping to create associations where needed; developing and implementing policies and guidelines from WHO and national health agencies; and guiding the certification of laboratory medicine training and continuing education.

In 2012, ASLM held its first international meeting, welcoming more than 1,400 attendees from 36 countries to Cape Town, where it put forward a historic Ministerial Call to Action, signed by one-third of African countries. Also that year, the PEPFAR Blueprint recognized the importance of the ASLM. By the time of the 2014 meeting, APHL was holding training sessions for participants on topics including LIMS implementation and Ebola response strategies.

The laboratory needs of HIV/AIDS spurred an important project within the ASLM: creation in 2014 of the African Public Health Laboratory Network (APHLN), which APHL assisted in developing. The landmark, pan-African network of 28 countries will look to models such as the US Laboratory Response Network, which APHL was instrumental in creating. The APHLN brings increased coordination and collaboration among national reference laboratories, capacity to perform joint training activities and the ability to better disseminate best practices to assure laboratory service quality. ASLM considers the network to be among its most important achievements.

MINISTRIES OF HEALTH: ESSENTIAL COLLABORATORS

Communicating to ministries of health and similar governing bodies the importance of public health laboratories — and making it clear what these laboratories need to operate effectively — has been a priority. APHL has extensive experience in coordinating multiple levels and types of stakeholders in the United States — states, regions and various groups of first responders — which was vital to our work with laboratories in PEPFAR-supported countries. We provided tools and resources to help present the importance of strategic planning, worked on procurement issues for equipment and infrastructure and outlined the need for reference laboratories and international networking.



Namibia's Integrated Public Health Laboratory Committee workgroups tackle challenges from strategic planning to outbreak response. From left: Harold Kaura, general manager, NIP; Rob Wilkinson, director, National Blood Services; Dr. Jack Nyamongo, APHL consultant; Professor Sylvester Moyo, dean, School of Health and Applied Sciences, Polytechnic of Namibia; Souleymane Sawadogo, laboratory chief, CDC/DGHA-Namibia.



THE CALL TO STRENGTHEN LABORATORY SYSTEMS

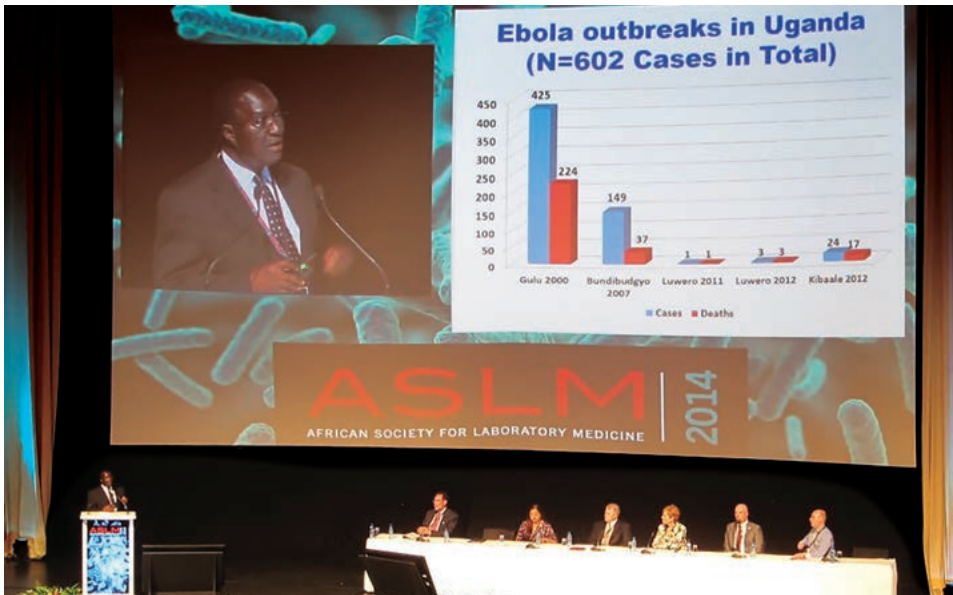
“**RECOGNIZE** the need to expand and further develop quality-assured laboratory services as part of a greater framework of health system strengthening within resource-limited settings. ...

“**CALL ON** national governments to support laboratory systems as a priority by developing a national laboratory policy within the national health development plan that will guide the implementation of a national strategic laboratory plan. Governments should establish a department of laboratory systems within the Ministry of Health. ...

“**CALL ON** countries and all partners to urgently address the broader laboratory human resources agenda for laboratory strengthening including training, recruitment and retention of laboratory workers and their adequate financing. ...

“**CALL ON** donors and development partners to commit to work collaboratively with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated national laboratory network. These laboratory strengthening efforts should seek to build public private partnerships.”

— WHO-AFRO
MAPUTO DECLARATION ON
STRENGTHENING OF LABORATORY
SYSTEMS, 2008



The African Society for Laboratory Medicine's second international meeting, in Cape Town, addressed a crisis that highlighted the need for the African Public Health Laboratory Network.

And the new network was forged just in time — the Ebola virus outbreak hit several nations in 2014, making the need for APHLN to support surge capacity and share laboratory services highly visible. An email group links many of the continent's national public health laboratory directors for the first time, making it easier for them to share information and best practices.

APHLN's boosting and streamlining of data sharing will also be beneficial to activities under PEPFAR 3.0, where transparency, accountability and using data to tackle the biggest challenges first are the goals.



DEVELOPMENT OF NATIONAL LABORATORY POLICY AND NATIONAL STRATEGIC PLANS

Strategic plans are the backbone for establishing and strengthening national laboratory systems in developing countries. The strategic plan is a living document that guides a country's laboratory function and action and is also an essential component of the overall health system. First-line response, prevention, treatment, surveillance and outbreak investigations all rest on a national laboratory system and a strategic plan. Plans and policy also are critical to satisfying the United Nations' Millennium Development Goals, including reversing the incidence of major diseases and achieving universal access to HIV/AIDS treatment.

In January 2008, an Africa-wide consensus called for governments to develop national laboratory systems, issuing the Maputo Declaration on Strengthening of Laboratory Systems. This agreement has guided the development of strategic plans ever since.

Since strategic planning weaves in everything from training and research to infrastructure and accreditation, it enables nations to:

- Establish standards across labs, with preparedness that cuts across disease areas
- Promote the best use of local and national resources
- Build capacity to respond
- Position the public health system for a sustainable future

Changing from an approach of isolated emergency responses to one of a laboratory system requires a new knowledge base. In collaboration with CDC, WHO and other stakeholders, APHL developed "Guidance for Development of National Laboratory Strategic Plans," a dynamic document assisting health systems worldwide to understand every stage of strategic planning.

Our work extends this guidance through collaborating with ministries of health throughout Africa and convening key stakeholders to develop strategic plans. In Kenya, for instance, APHL contributed to development of the National Policy Guidelines for Medical Laboratory Services, the blueprint for the country's national laboratory system, now approved by the Ministry of Health and in implementation. APHL also assists with existing strategic plans, such as in Sierra Leone, where we led a SWOT analysis for implementing the National Laboratory Strategic Plan and Policy.

PEPFAR countries' progress toward strategic plan development and implementation

Country Engaged in Discussion	Coordinating and Technical Committees Formed	Strategic Plan Developed	Strategic Plan Implemented	Plan Reviewed & Evaluated	
Mali	Cameroon DR Congo South Africa	Antigua St. Kitts & Nevis St. Vincent Grenada Dominica St. Lucia Suriname Bahamas Jamaica	Haiti Mozambique Nigeria Sudan Zambia Trinidad & Tobago Barbados Angola Ghana	Nambia Côte d'Ivoire Sierra Leone Vietnam Swaziland Malawi Botswana	Guyana Rwanda Tanzania Uganda Zimbabwe Cambodia Lesotho
				Kenya Ethiopia	

Countries under the PEPFAR agreement have made significant steps in developing national strategic plans for their laboratory systems. APHL has assisted the countries highlighted in red in advancing strategic plans.



A strategic plan for laboratories maps out an integrated course for resources ranging from equipment to curricula to communication.

“The Medical Laboratory ... needs to be elevated from its present status to a height comparable to other counterpart laboratories worldwide. To ensure the realization of this vision, it is imperative that a strategic plan be put in place to chart the course.”

— FOREWORD TO NIGERIA'S MEDICAL LABORATORY STRATEGIC PLAN
PROFESSOR C.O. ONYEBUCHI CHUKWU,
HONOURABLE MINISTER OF HEALTH,
NIGERIA

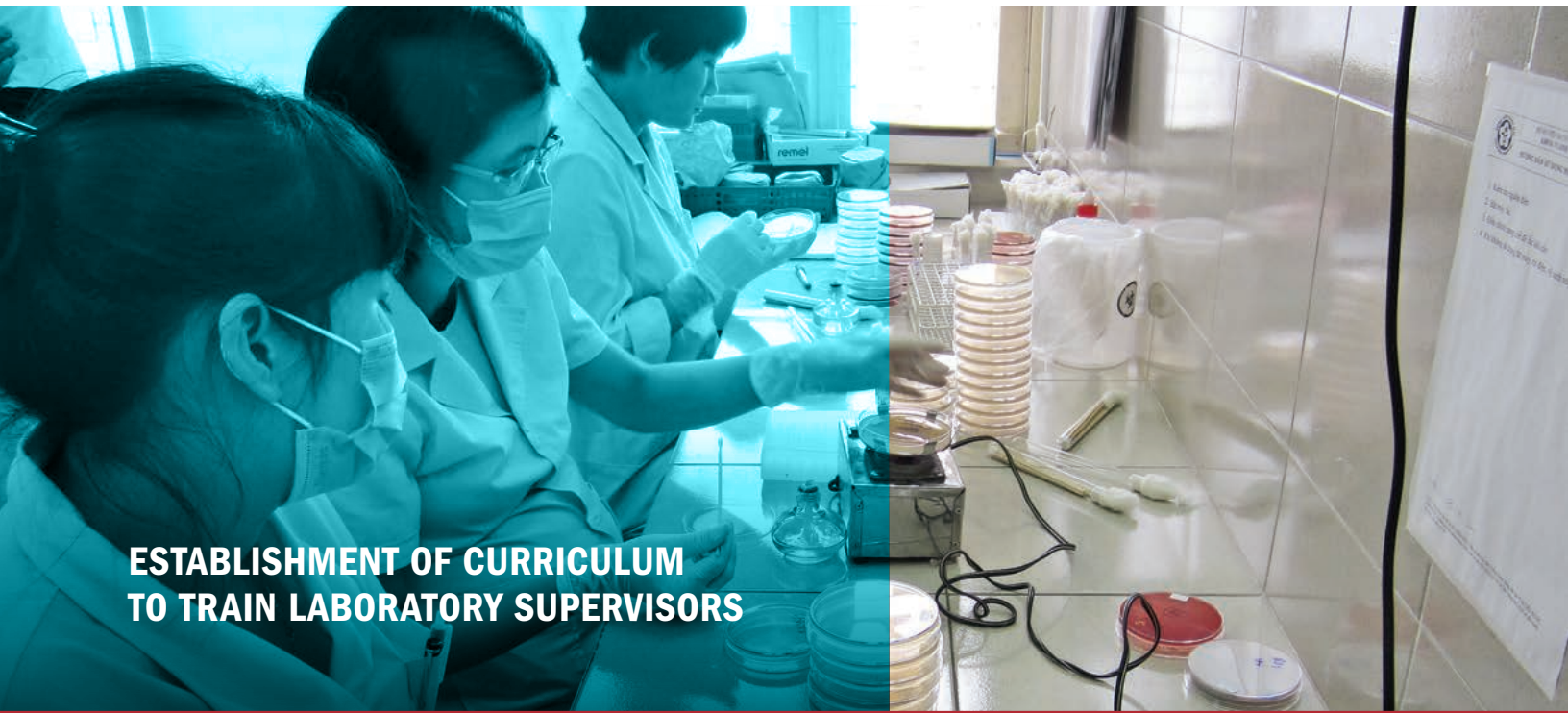
Living document, improving health

Nigeria is the most heavily populated country in Africa: 174 million people live in 36 states with 774 local governments. How can all of these governments work in unison to bridge gaps in lab standards and ensure communication across the health system?

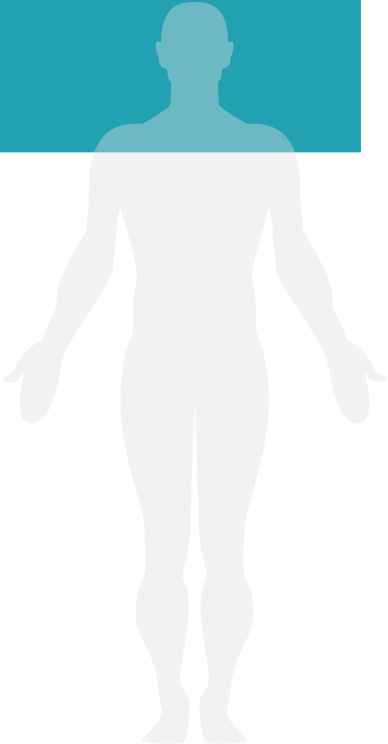
The key is a common frame of reference to guide the labs across the country and improve the public health system. That's the crucial role played by the Nigeria Medical Laboratory Strategic Plan 2015–2019: A broad range of stakeholders

worked together toward a common goal of providing appropriate, cost-effective and high-quality lab services to all Nigerians, and the plan links to national policy to achieve that goal.

Nigeria's next step is an operational plan for the next five years, but the value of its strategic plan will live far into the future: it serves as a “living document” that will assist in an environment of calm or crisis, because it sets the ground rules for how to adapt and thrive.



ESTABLISHMENT OF CURRICULUM TO TRAIN LABORATORY SUPERVISORS



Teaching and training at a foundational level serves as a valid response to the health crises that face our global community. But building sustainable teaching capacity carries benefits beyond the crises. APHL has focused not only on establishing training foundations, but also on assisting in broader teaching capacity, in areas ranging from equipment maintenance to designing practical and efficient labs.

But countries noted significant gaps in leadership and management training that needed to be filled. APHL responded by developing a five-day workshop covering lab essentials such as communication, organizational structure, leadership, problem solving and financial management.

The program debuted in Zimbabwe in 2004 with overwhelming success. We used a follow-up course in Kenya and evaluations to streamline content and evolved the complete training package, *Foundations of Laboratory Leadership and Management* (FLLM). It includes in-class exercises, student document tools and an instructor's manual, has been offered in more than a dozen African countries and is translated into Portuguese and French.

In keeping with the PEPFAR sustainability mission, several countries have used APHL's train-the-trainer version of the course, a two-week extension that combines the core curriculum with extra sessions focusing on training others. Ethiopia and Mozambique are among the countries that have put FLLM into practice with their own facilitators. Furthering the value, Nigeria's Ambrose Ali University in Edo has offered the course to its university professors.



Mozambique boosted its lab leadership capacity through participation in several programs, including learning the FLLM curriculum. Top right: Kenya lab leaders receive training on LIMS implementation.

Starting with universities

Improving laboratory training for university students can benefit not just individual students but generations in a health system. APHL was tapped to collaborate with the Institute of Human Virology-Nigeria on a survey of medical lab science training programs at Nigerian universities and colleges of technology.

The survey collected information evaluating the programs on degree and

certificate programs offered, capabilities of hospital posting, curriculum content, lab and classroom facilities, class size and more. APHL supported the project with technical assistance and survey review. Results will be applied to improve the effectiveness of pre-service training and enrich knowledge and skills of medical laboratory professionals entering the workforce — and ultimately, medical laboratory science training in Nigeria.



TRAINING FOR CHANGE

With the HIV/AIDS crisis came radical changes in testing practices: point-of-care testing has become routine. Moving testing from the laboratory to the patient is often cheaper, involving fewer skilled staff and less infrastructure.

But increased point-of-care testing brings increased demand for assurance of quality. APHL assisted in creating a framework of best practices, through the PEPFAR Laboratory Technical Working Group, at the “Innovative Strategies to Ensure Quality of HIV-related POCT” consultation. Along with more than 100 representatives from CDC, ASLM, WHO and other groups, we helped determine ways to ensure quality in diverse settings and how to strengthen partnerships.



ADVANCED MANAGEMENT TRAINING OF SENIOR LABORATORY LEADERS

Even in countries where scientific training has kept pace with health crises, people in health systems point out serious gaps in other types of training for leaders and managers. APHL recognizes this need from its work helping to fill such gaps in the United States — and adapts what it has learned in working with leaders and potential leaders of widely varying experience and needs. We offer leadership forums, one-on-one mentorship and paradigm-altering pilot programs that concentrate as much on the human factors of leadership as the technical ones.

To run a public health laboratory, skills needed can range from a PhD in microbiology, to knowledge of testing techniques, to an understanding of realities such as having to wash and reuse scarce exam gloves.



Left, laboratorians in Ukraine get leadership training. Through its partnership with The George Washington University, APHL helps advance senior lab leadership training in several countries including Tanzania, above.

NEW LEADERS STEP UP

Between July 2014 and March 2015, 10 laboratory scientists participated in a unique PEPFAR-funded Emerging Leadership Program. The interactive pilot program was designed to advance leadership skills among current laboratory staff with specific emphasis on generating new solutions to the critical challenges facing the medical, clinical and public health laboratories in Lesotho.

To address these challenges, APHL extended a model that had yielded success for US leaders, one that relies heavily on one-on-one mentoring from program graduates. The pilot's success makes the program a good candidate for extension to other countries.

Two of its projects have already shown national impact. The first addressed the essential (and previously inconsistent) procurement and inventory management process of laboratory commodities. The second advocated for specialized human resources to meet a ministry of health's strategic plan.

The technical working groups identified bottlenecks, discovered gaps and made recommendations. APHL faculty also led workshops in topics such as:

- Strategic planning
- Team building
- Managing diverse working styles
- Accountability

- Change management
- Active listening
- Analytical skills
- Building trust in relationships
- Conducting leadership interviews
- Effective communication
- Project planning and management



Lab leaders bring their best practices and ideas to the table at a laboratory management training in Dar es Salaam.

Institute delivers training ROI

APHL and The George Washington University Milken Institute School of Public Health established the Institute for Public Health Laboratory Management in 2006. Its mission: Meet the pressing need for strengthening the capability of national public health laboratory networks to provide quality services for surveillance and emergency response and reliable, timely information to guide public health treatment and prevention actions and long-term planning.

The Institute offers several learning areas, including:

- Basic medical science applied in public health

- Clinical medicine applied in public health
- Evaluation related to programs, research and other areas of practice
- Epidemiology
- Implementation of health education strategies, interventions and programs

Since 2007, its two-week seminar has trained more than 195 public health leaders from 33 countries. The seminar has been offered in Washington, DC, as well as in Tanzania (in partnership with the University of Dar es Salaam), in Namibia (in partnership with the Polytechnic Institute of Namibia) and in South Africa (in partnership with Stellenbosch University).

“A strong public health laboratory system is critical to addressing international health challenges. Our goal is to help participants effectively apply the information learned when they return to their home countries.”

— RALPH TIMPERI, MPH
SENIOR ADVISOR OF LAB PRACTICE &
MANAGEMENT, APHL



IMPLEMENTATION OF ELECTRONIC LABORATORY INFORMATION SYSTEMS



Availability of test kits, numbers of mothers tested, viral loads, presence of trained lab technicians in a region — data are powerful forces in the fight against HIV/AIDS. A robust Laboratory Information Management System (LIMS, also called LIS) allows public health laboratories to gather, appropriately share and use these forces. It is essential for handling the massive data load involved in HIV/AIDS testing, surveillance and treatment.

With APHL training and tools, countries under PEPFAR have been empowered to use LIMS data as input for policy and strategy, to improve turnaround time and revenues, to guide supply-chain management and to evaluate quality.

Using best practices established through years of work in LIMS implementation, APHL begins by strengthening what is there — including paper and legacy systems. APHL integrates training, equipment purchasing decisions, responses to requests for proposals and long-term support.

Over the five years of the Cooperative Agreement, we've participated in numerous LIMS success stories, including development of open source LIMS in 20 laboratories in Vietnam. We have assisted in implementing countrywide LIMS in locations such as Lesotho.

Training and tools make LIMS sustainable for the long term, so we concentrate resources there, including training multiple super-users. In addition, we've produced a set of resources used by lab leaders to make decisions ranging from selecting a software provider to meeting information system standards to managing and staffing a LIMS implementation.

***APHL has assisted with
LIMS implementation
in more than 60 locations
in 12 countries.***



Lesotho's LIMS implementation provided a strong coordinating tool against the challenge of HIV/AIDS. Left, National LIMS officer Mokenyakenya Matoko guides Lesotho's Minister of Health, the Hon. Pinkie Manamolela and US Ambassador Matthew Harrington through a look at the system, in use at right.



INFORMATION INDEPENDENCE FOR LESOTHO

In November 2014, US Ambassador Matthew Harrington led a ceremony to hand over a completed LIMS to Lesotho — the result of years of work at the country's Health Ministry, in partnership with APHL and CDC, with PEPFAR support. "We care deeply about the struggle of the Basotho in their fight against HIV/AIDS and other diseases," Harrington said. "We stand firmly beside you in confronting this threat." With the capacity to manage the high volume of data generated by the increase in treatment and prevention of HIV/AIDS, Lesotho can improve quality and timeliness of testing, ultimately saving lives. The LIMS is now in all 19 laboratories throughout the country, at national and district levels.

LIMS serves as lab-to-physician lifeline

Cutting the average turnaround time for lab results by more than half saves resources and can contribute toward saving lives. Implementing a new LIMS system made the difference in Kenya.

In providing this kind of assistance, APHL starts with the strategic plan: What does this country need, and what resources does it have? Sometimes, more than one solution is called for. In Kenya, 12 labs implemented the commercial LabWare LIMS; two others used the open source Basic Laboratory Information System (BLIS).



The Kenya LIMS project involved training, help finding vendors and visits by APHL to labs and healthcare facilities including the Migori Level IV District Hospital.

Different patient information systems installed in Kenyan hospitals posed a barrier to connectivity between clinicians and their needed laboratory services. APHL IT expertise solved this dilemma and developed reliable two-way connectivity between the LIMS installed in seven hospital laboratories that had three different patient information systems. Clinician test requests are immediately sent to the lab and quality assured results returned electronically the moment they are ready. Delays are eliminated, errors are reduced, patients receive proper treatment sooner and health outcomes are improved.

In addition, analysis showed the hospital/lab connection in Kenya to be a link that could be strengthened through system integration. The result was not only a faster turnaround time but also an immediate uptick of 50 percent for lab revenue.

"With an effective LIMS to link data to a central database, health officials can look at laboratory data at the national level to discern trends over time. They can tell quickly when they have a spike over usual disease levels. If we had something like that in Sierra Leone, we would have known that Ebola was brewing far sooner."

— LUCY MARYOGO-ROBINSON
DIRECTOR, APHL GLOBAL HEALTH



DEVELOPMENT OF MODEL DESIGN PLANS FOR LABORATORIES

Laboratory infrastructure improvements are the most tangible expression of our work. The value of a new laboratory or piece of equipment is easy for leaders, lab technicians and patients alike to grasp.

But the immediate practical benefits are just a starting point. A quality design model can be applied across labs and regions, thereby saving resources; infrastructure offers opportunities to build local and regional capacity in multiple industries and fields, thereby sparking innovation.

For such work, APHL teams with a diverse range of partners: large, global engineering and architecture partners such as HDR; philanthropic arms of international corporations, such as the Abbott Fund; and numerous laboratory equipment manufacturers.

APHL has helped position numerous PEPFAR countries to advance their own infrastructure into the future:

- Renovation of Sierra Leone's Central Public Health Reference Laboratory after civil war damage
- Team planning and implementing standardization and renovation of 23 labs in Tanzania, with Abbott Fund
- Development of equipment maintenance curriculum in Ethiopia for use throughout Africa



The vision of a new public health laboratory in Namibia emerges in architectural renderings. Local, regional and international partners joined to share knowledge and needs for the new lab.



Modeling the design process in Namibia

Namibia's first-ever National Public Health Laboratory is projected to open its doors in 2017, but it has already opened doors of opportunity locally, nationwide and for other countries.

APHL, working with architects and engineers from global partner HDR, assisted in the ground-up planning and implementation process, starting with the big picture: design. How could legacy resources best be used, and how could new resources be identified and put to work most cost-effectively? What level of biosecurity would serve this country's needs? Airflow, building security, power and water sources — in a quality lab, every element must align. Could autoclaves and benchtops be built into the design? The team explored the use of sustainable solar power sources, modeled optimum people and work-station flow and evaluated cost estimates.

Local and regional firms and experts brought knowledge and leadership in resources, logistics and architecture. Yet while they had experience building resorts, offices and residences, this process-driven project with its multitude of specific needs was a new challenge.

APHL took care to help guide the process so it could influence capacity building not only in health services but also in other fields. We facilitated a visit by colleagues in Namibia to the United States to tour public health labs in Virginia and the District of Columbia and to tap resources in the APHL offices in Maryland. The next step is construction, but other countries can analyze the process thus far for best practices for their own new and remodeled laboratories.





ESTABLISHING QUALITY MANAGEMENT SYSTEMS

Established laboratory standards save lives and resources. APHL helps to define and maintain quality, through multifaceted processes involving cooperation, customization and communication — in both directions — with all stakeholders.

Our work includes in-country consultations and training, set-up of testing services including instrument selection and validation, software, and the development and implementation of internal and external quality-management programs.

PROTECTING QUALITY, PRESERVING HEALTH

QUALITY ASSURANCE continuously improves the reliability and efficiency of laboratory services

QUALITY CONTROL maintains lab controls operation, including everything from instrument maintenance to checking staining solutions

EXTERNAL QUALITY ASSESSMENT (EQA) ensures that participating laboratories assess and compare results via on-site evaluation, panel testing and blinded rechecking

Results in Rwanda

Success in external quality assurance hinges on a number of factors. In Rwanda in particular, a well-organized supply chain was as essential as adequate training, centralized oversight and outstanding communication. With partners both in the United States and in-country, APHL helped to implement a cost-effective commercial program with a Canadian-based vendor to provide four different proficiency tests to the 49 participating labs of the Rwandan hospital laboratory network, with strong results:

- Continued improvement was noted in the quality of results.
- Between the first and fourth test event, participating labs scored 15% and 5% improvements in chemistry and hematology results respectively — with the fourth test showing results of 76% and 82% within acceptable ranges.
- Lymphocyte immunophenotyping results alone exhibited a 17% increase in acceptable results from the first to the third test event — topping out at an impressive 92%. Indeed, these results were nearly 30% above the African continent average.

Lab quality snapshots

ETHIOPIA: In one pilot EQA program, participating treatment sites and laboratories:

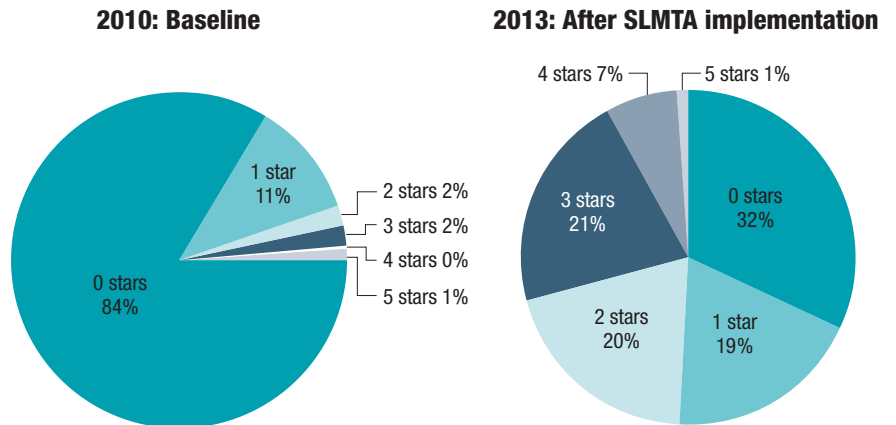
- Provided flow cytometry and chemistry testing
- Performed hematology testing via automated instrumentation
- Assigned trained laboratory personnel
- Maintained an adequate supply of testing kits and reagents
- Selected rapid HIV antibody testing and counseling sites across various Ethiopian health regions

This comprehensive plan was shared with, and approved by, not only the Ministry of Health and public health agency director, but also the national laboratory technical working group, national laboratory heads, regional laboratory heads and antiretroviral lab managers.

SOUTH SUDAN: Having seceded from Sudan in 2011, the country suffers one of the highest mortality rates in the world — and is among the top 25 in terms of HIV prevalence. APHL has been on site, working closely with Ministry of Health and local health officials, focusing on implementation of quality management systems to strengthen and further develop the laboratories in Juba and improve patient care overall.

ZIMBABWE: Here, APHL works with the National Microbiology Reference Laboratory to implement new methods for quality assurance of point-of-care tests for HIV and CD4.

SLMTA-Driven Improvement



APHL has been part of the effort to implement and guide the Strengthening Laboratory Management Toward Accreditation (SLMTA) program to improve quality of laboratory services. A 2014 study in the *African Journal of Laboratory Medicine*, the official journal of the African Society for Laboratory Medicine, looked at star-rating improvements for labs in 47 countries in Africa, the Caribbean, Latin America and Southeast Asia and called the results “remarkable,” concluding that “SLMTA has transformed the laboratory landscape in resource-limited countries worldwide and has the potential to make a substantial and sustainable impact on the quality of laboratory testing and patient care.”

SLMTA: THE KEY TO QUALITY

From one small room to a fully functional, high-performing lab in three years: The Makoanyane Military Hospital Laboratory in Lesotho demonstrates the power of a commitment to quality. The lab won its four-out-of-five-star quality assessment rating in 2012 with the help of Strengthening Laboratory Management Toward Accreditation (SLMTA) training.

Pursuing international accreditation is the direct path to quality labs, and SLMTA training develops the capacity to walk that path to excellence. It covers everything from when to perform an HIV Rapid Test to waste disposal to placement of fire extinguishers.

APHL's goal was to fully transfer training capability and responsibility to local partners, creating a self-sustaining method of constant improvement. With the efforts of labs such as Makoanyane, and the Lesotho Ministry of Health, which set up a training team, Lesotho now has that foundation.

By providing training as well as train-the-trainer sessions, APHL helped each of the country's 19 laboratories upgrade quality and enhance systems. In a country where HIV prevalence is 28.9%, a lab that consistently delivers accurate and timely results is a lifesaving resource.



FOR FUTURE GENERATIONS

In 2013, PEPFAR launched its third phase: PEPFAR 3.0, the strategy guiding work today. APHL's approach parallels the advancements in this unprecedented and successful program, and we are continuing to assist public health laboratories in the PEPFAR countries with developing capacity.

The aim is clear: meet the Joint United Nations Programme on HIV/AIDS global treatment targets, known as 90-90-90, such that 90 percent of people living with HIV are diagnosed, 90 percent of the diagnosed are under treatment and 90 percent of those in treatment are virally suppressed. In short, as PEPFAR puts it, we have to “go where the virus is.”

And APHL is there. Once again, reaching these goals is inextricably tied to laboratory access, quality and the strong information systems and networks that can track action and results. “Our work will be data-driven from the national level down to the most granular site level to best guide programmatic decision-making and solidify sustainability and quality,” states the PEPFAR 3.0 guidance.

The single task of getting an accurate read on a viral load depends on a laboratory system of multiple functions working reliably and well: a strategic plan to help ensure placement of resources, partnerships for reagents and supplies, lab leaders who are themselves ready to guide future leaders into place, training for LIMS super-users and more.

“Going where the virus is” to strengthen public health laboratories will empower countries not only to reach PEPFAR goals but also to meet other needs: screening of newborns for genetic disorders, identifying drug-resistant TB, even meeting goals of the Global Health Security Agenda for prevention, detection and response in infectious disease threats.



The work done so far in public health laboratory sustainability is only the first step; APHL has always worked toward the goal of self-sufficiency for every country. Nations have closed in on that target remarkably quickly. The rapid standup of the ASLM's African Public Health Laboratory Network, for example, will benefit the continent and the world through transparent and secure data exchange. In Mozambique, APHL's decade of collaboration shows results that include a LIMS system for HIV/AIDS treatment support and a strengthened National Reference Laboratory.

But we must go where the virus is — to South Sudan, for instance. A devastating civil war has left this country trailing globally in controlling HIV/AIDS. In some areas, in fact, it's at the same level other countries were in 2003, when PEPFAR was launched. Speaking as a public health laboratory champion, I know we have the expertise to change this. Speaking as someone who has gone with APHL to South Sudan and has seen the public health challenges there, I am committed to getting the resources to do so.

And this is only one such country that can benefit from a strengthened public health laboratory system. There are many more to work with, into the future. APHL is proud to be a PEPFAR partner with CDC at every phase, and we look forward to celebrating together the results of our collaboration: an AIDS-free generation.

— Lucy Maryogo-Robinson, MPH
Director, APHL Global Health

“Al-Sabah is the only children’s hospital in South Sudan... so little could go so far here in saving the lives of these infants. APHL belongs here. The laboratory staff we support soak in all they can from APHL trainings and, amidst the struggles of their tough lives, they look to APHL as a beacon of hope.”

— LUCY MARYOGO-ROBINSON, MPH
DIRECTOR, APHL GLOBAL HEALTH

ACKNOWLEDGEMENTS

The Association of Public Health Laboratories works to strengthen laboratories serving the public's health in the United States and globally. A national nonprofit, the organization represents state and local governmental health laboratories in the United States. Its members, known as "public health laboratories," monitor and detect health threats to protect health and safety. Founded over 50 years ago as a forum for state public health laboratory directors, APHL has expanded to encompass governmental health laboratories and staff from multiple disciplines, including public health, environmental, agricultural and food safety laboratories.

APHL collaborates with laboratory and public health partners to assure effective surveillance, detection and response to health threats. It works closely with US federal agencies, including the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Food and Drug Administration and the Environmental Protection Agency, to develop and execute national health initiatives. During public health emergencies, APHL operates as a coordinating center for laboratory response.

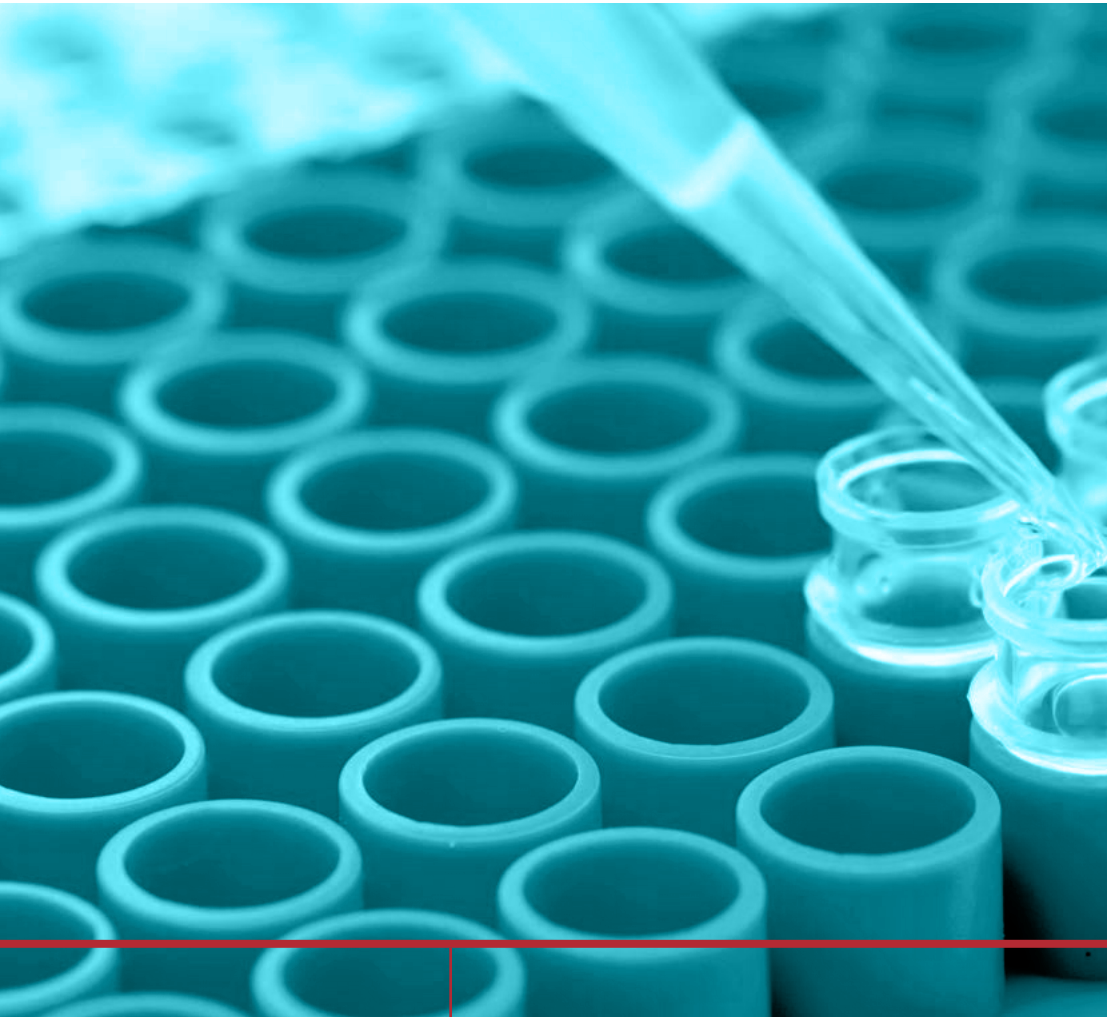
APHL works internationally as well as nationally to develop effective national laboratory systems and expand access to quality diagnostic testing services. With over 20 years' experience in 31 countries on five continents, it is recognized internationally as a leader in laboratory science and practice.

This report was created through a series of interviews with laboratory leaders and review of formal reports and APHL and ASLM publications and presentations. APHL wishes to thank those with CDC and in laboratories in all the PEPFAR countries, who generously share their experiences and insights with us, with students and colleagues, and with partner organizations. Special thanks go to the dedicated APHL Global Health staff and our members and their staff who volunteer with APHL Global Health.



“APHL was central in developing guidance and frameworks for national strategic plans, together with CDC, WHO and others, and was equally instrumental in guiding countries to make remarkable progress in implementing the plans.”

— JOHN N. NKENGASONG, PHD
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