

Laboratory medicine in Africa since 2008: then, now, and the future



John N Nkengasong, Francois-Xavier Mbopi-Keou, Rosanna W Peeling, Katy Yao, Clement E Zeh, Miriam Schneidman, Renuka Gadde, Alash'le Abimiku, Philip Onyebujoh, Deborah Birx, Shannon Hader

The Maputo Declaration of 2008 advocated for commitment from global stakeholders and national governments to prioritise support and harmonisation of laboratory systems through development of comprehensive national laboratory strategies and policies in sub-Saharan Africa. As a result, HIV laboratory medicine in Africa has undergone a transformation, and substantial improvements have been made in diagnostic services, networks, and institutions, including the development of a competent workforce, introduction of point-of-care diagnostics, and innovative quality improvement programmes that saw more than 1100 laboratories enrolled and 44 accredited to international standards. These improved HIV laboratories can now be used to combat emerging continental and global health threats in the decades to come. For instance, the unprecedented Ebola virus disease outbreak in west Africa exposed the severe weaknesses in the overall national health systems in affected countries. It is now possible to build robust health-care systems in Africa and to combat emerging continental and global health threats in the future. In this Personal View, we aim to describe the remarkable transformation that has occurred in laboratory medicine to combat HIV/AIDS and improve global health in sub-Saharan Africa since 2008.

Introduction

The unprecedented Ebola virus disease outbreak that occurred in west Africa exposed severe weaknesses in national health systems, including laboratory networks and infrastructure of the affected countries.¹ Long neglected and under-resourced laboratory networks, systems, and services quickly became the Achilles' heel to an effective response in Guinea, Liberia, and Sierra Leone. Globally, investment in health since 2008 has been unprecedented, with funding attaining an unparalleled US\$28.2 billion per year.¹ Most of this funding was contributions to combat HIV/AIDS by several bilateral and multilateral donors including the US President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to fight AIDS, Tuberculosis and Malaria, the World Bank, the Bill & Melinda Gates Foundation, and others.² Although most of the funding focused on disease-specific programmes such as those targeting HIV, tuberculosis, and malaria, substantial improvements were observed across several other areas in national health laboratory systems. In 2013, the Institute of Medicine reviewed the PEPFAR programme and noted that advancement in laboratory medicine had substantially improved non-HIV laboratory service capacity in Africa, and that laboratory infrastructure and capacity can be used to strengthen national health-care systems overall.^{3,4} The report further states that improvements of laboratories under PEPFAR support and guidance have been a signature achievement of the programme, a theme emphasised with near universality among committee members.^{3,4} In this report, we describe the transformation that has occurred in laboratory medicine and in laboratory networks in sub-Saharan Africa over the past decade and discuss ways to sustain these gains.

HIV laboratory medicine before 2008

In 2006, Petti and colleagues⁵ conducted a comprehensive review in which they concluded that laboratory medicine

in Africa was a barrier to effective health care. In 2003 and 2004, major initiatives to fight HIV/AIDS, tuberculosis, and malaria were launched. However, it was obvious that inadequate laboratory systems and services would be the Achilles' heel to meeting programme goals.^{6–11} Laboratory services and systems did not have the capacity to reliably and accurately diagnose and monitor patients to achieve PEPFAR's HIV/AIDS programme targets of treating 2 million HIV-infected patients, preventing 7 million infections, reducing the rate of mother-to-child transmission by 20% by 2005, and providing care to 10 million affected people.¹² Some of the major challenges were paucity of national laboratory policies or strategic plans, inadequate laboratory workforce to do basic and complex diagnostic testing, non-existent supply chain management systems, insufficient laboratory facilities to do PCR assays for diagnosis of HIV in infants, dilapidated laboratory infrastructures, poor equipment maintenance, weak specimen referral systems and results return (particularly in remote and rural areas where transportation was difficult), and paucity of highly trained staff and absence of quality management systems.

HIV laboratory medicine since 2008

HIV laboratory medicine in Africa has evolved greatly since 2008 in diagnostic services, systems, networks, and institutions. Systems and services to support HIV diagnosis using rapid testing have been scaled up in most countries, with an estimated 150 million individuals tested in 2014.¹³ The use of dried blood spot-based PCR testing for early infant diagnosis (EID) has increased from a few laboratories in three countries in 2005 to more than 150 laboratories in over 35 countries, resulting in the diagnosis of more than 1.5 million babies and the identification of about 400 000 HIV-infected infants needing treatment.³ The past decade also witnessed the introduction, with great effect, of point-of-care

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Division of Global HIV/TB, Centres for Global Health, US Centers for Disease Control and Prevention, Atlanta, GA, USA (J N Nkengasong PhD, K Yao PhD, C E Zeh PhD, S Hader MD); Faculty of Medicine and Biomedical Sciences, University of Yaounde 1, Yaounde, Cameroon

(Prof F-X Mbopi-Keou PhD); London School of Hygiene and Tropical Medicine, London, UK (Prof R W Peeling PhD, M Schneidmann MPH); World Bank, Washington, DC, USA (M Schneidmann); Becton, Dickinson and Company, Franklin Lakes, NJ, USA (R Gadde MBA); University of Maryland, Institute of Human Virology, Baltimore, MD, USA (A Abimiku PhD); World Health Organization Regional Office for Africa, Brazzaville, Congo (P Onyebujoh PhD); and Office of the Global AIDS Coordinator, Washington, DC, USA (D Birx MD)

Correspondence to:
Dr John N Nkengasong, Division of Global HIV/TB, Centres for Global Health, Centers for Disease Control and Prevention, Atlanta, GA 30333, USA
jen5@cdc.gov

diagnostics, including assays for CD4 cell count testing such as the Alere PIMA CD4, Muse Auto CD4/CD4% system, the BD FACSPresto, the Gene Xpert for diagnosing tuberculosis, and the Alere and GeneXpert technologies for EID. The use of point-of-care EID in Malawi has resulted in 100% of infants receiving timely results within the study, with the time from HIV diagnosis to antiretroviral therapy (ART) initiation reduced from a mean of 31.5 days using conventional laboratory-based testing to a mean of 9.0 days with point-of-care CD4 testing.¹⁴ During the first phase of PEPFAR, the number of individuals trained in the provision of laboratory-related activities increased from 3131 in fiscal year 2004, to 60 037 in fiscal year 2009.³

In January, 2008, global stakeholders from 33 countries, WHO, PEPFAR, US Centers for Disease Control and Prevention (CDC), the Clinton Health Access Initiative, the Global Fund, and other implementing partners, issued the landmark Maputo Declaration on Strengthening of Laboratory Systems. The Declaration called on national governments to prioritise support for laboratory systems through the development of a national laboratory policy, a national laboratory strategic plan, and establishment of a laboratory services department within the Ministry of Health to tackle the challenges that prohibit the scale-up of services for tuberculosis, malaria, and HIV diagnosis and care. The declaration also called on donors and partners to support these national efforts by coordinating and collaborating with each other to support the strengthening of laboratory systems including efforts aimed at building public-private partnerships.¹⁵ At that time, only two countries in Africa (Kenya and Ethiopia)^{9,16} had developed and were implementing a national laboratory strategic plan (NLSP). However, as of 2015, over 35 countries were at different stages of developing and implementing their integrated NLSPs, with support from various donors and partners. The plans also allowed all donors and partners to better coordinate and align their efforts to increase efficiencies in the use of human and infrastructural resources. Furthermore, in 2008, the Regional Committee of the WHO Regional Office for Africa (WHO AFRO) issued a resolution calling on all countries to strengthen laboratory systems as an integral part of disease control.¹⁷ This resolution further enhanced the Maputo Declaration and was encouraging in placing the need for laboratory services and systems at the centre of effective disease control, management, and prevention.

In the spirit of the Maputo Declaration, PEPFAR and Becton Dickinson established a 5-year public-private partnership to strengthen laboratory systems and services in Ethiopia, Kenya, Mozambique, South Africa, and Uganda.^{18,19} This partnership resulted in great improvement of laboratory systems in these countries. For instance, in Ethiopia, using geographical information systems, specimen referral systems were strengthened by use of the shortest distance for specimen transport irrespective of geographical boundaries, greatly reducing

turnaround time and transportation cost. In Uganda, a ten-times increase in referrals of patients with presumptive multidrug-resistant *Mycobacterium tuberculosis* was observed.^{20,21}

There has also been substantial progress from diagnosis to monitoring of patients receiving ART. The number of laboratories that do CD4 cell count testing, which monitors biochemical and haematological variables, and the availability of molecular diagnostic platforms for EID, viral load, and HIV-1 genotypic drug resistance testing (both as individual patients and in population-based surveillance), have increased from zero in some countries to almost full capacity.

Several public-sector laboratories have been built or upgraded their infrastructure to align with increasing demand and to accommodate the uptake of new tools. For example, PEPFAR has supported the establishment of state of the art laboratories in Botswana, Cameroon, Côte d'Ivoire, Ethiopia, Kenya, Mozambique, Tanzania, and Uganda. In Ethiopia, PEPFAR helped to establish the National Public Health Laboratory in Addis Ababa and six regional laboratories around the country. The Ethiopian Regional Referral Laboratory in Hawassa has mechanical ventilation, a backup generator, wear-resistant floor covering, a wide and clean corridor, and walk-in freezer. The referral laboratory will serve millions of people in southern Ethiopia and neighbouring Oromia regions and will provide external quality assurance services for the entire region's hospitals and health centre laboratories. The Uganda National Laboratory Services are expected to address crucial gaps in new emerging diseases such as Ebola virus disease, Marburg virus disease, Crimean-Congo haemorrhagic fever, and swine flu among others. The laboratory will give priority to viral load monitoring capacity, EID, quality assurance, and other aspects of laboratory services coordination. The new building will also accommodate a laboratory screening for sickle cell diseases, hepatitis B, meningitis, and cholera among others. In Tanzania, with the support of the Abbott Fund, 23 regional laboratories were strengthened.^{18,22} The partnership with the Abbott fund has resulted in an estimated \$200 million investment in laboratory strengthening.

In 2009, after the WHO resolution and the Maputo Declaration, and as part of implementation of the NLSPs, WHO AFRO and partners launched two innovative initiatives in implementing quality management systems: Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA, a benchmarking framework used to measure a laboratory's compliance with ISO 15189 through a graded system of zero to five stars),^{23,24} and Strengthening Laboratory Management Toward Accreditation (SLMTA, a 12–18 month long training and mentoring programme designed to bring about immediate and measurable laboratory improvement in quality management systems).²⁵ To assess the progress, a laboratory's compliance with the requirements is measured

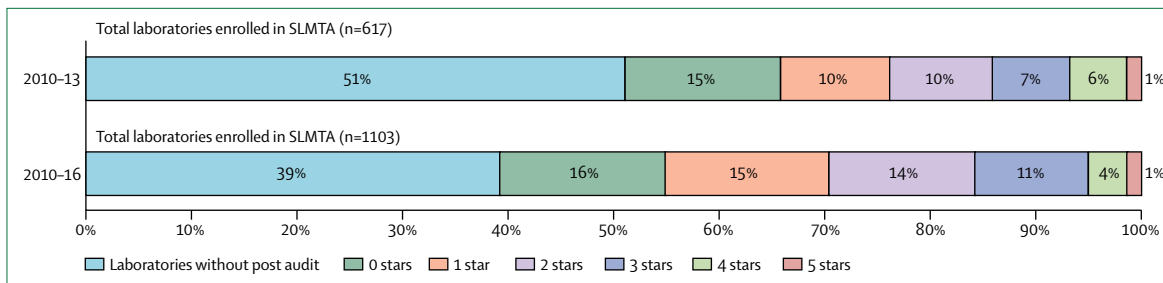


Figure: Star ratings from audits after completing the SLMTA accreditation programme, 2010–13 vs 2010–16
Results based on the Stepwise Laboratory Quality Improvement Process Towards Accreditation checklist. SLMTA=Strengthening Laboratory Management Toward Accreditation.

before the start of SLMTA (baseline audit) and at the end of the programme (exit audit) using the SLIPTA checklist.²⁶ SLMTA defines gaps, improves them, and measures the effect of continuous quality improvement of the laboratories.

Between 2010 and 2013, 617 laboratories from 47 countries, mainly in Africa, implemented SLMTA with noteworthy results.²⁷ At baseline, 84% of the 617 laboratories scored zero stars on the SLIPTA rating scale. However, of the 302 laboratories that completed the SLMTA programme, 70% achieved at least one star after an average of 16-month implementation period with a mean score of 64%.

Progress has been maintained 8 years after the launch (figure), when comparing the exit audit performance from the first 4 years (2009–13, 302 laboratories) with that of the first 8 years (2009–16, 680 laboratories) in terms of the percentages of laboratories rated at zero to five stars. By 2018, SLMTA had been used to guide more than 1100 laboratories toward meeting the ISO requirements.

Before SLMTA and SLIPTA were launched, only 28 accredited laboratories existed in sub-Saharan Africa outside of South Africa.²³ Within 8 years, SLMTA had helped 65 laboratories to achieve accreditation, and 41 of them in sub-Saharan Africa outside of South Africa. SLMTA has transformed the laboratory landscape in Africa and has the potential to make a substantial and sustainable effect on quality of laboratory testing and patient care, and the overall health systems.²⁷

Emergence of regional laboratory networks

The decade also witnessed remarkable progress in the establishment of several regional laboratory networks to support programme scale-up and disease surveillance.

In 2010, the East Africa Public Health Laboratory Network was established with support from the World Bank. In total, five East African Community member states (Burundi, Kenya, Rwanda, Tanzania, and Uganda) received \$128.7 million to establish a network of efficient, high quality, accessible public health laboratories. Most facilities were located in cross-border areas, to bring services closer to poor and vulnerable groups, and to

contain the spread of diseases. The network promotes specialisation in service delivery, supports regional quality standards, and serves as a platform for learning, training, and research. The 32 laboratories in the network serve as centres of excellence, and have benefited from state-of-the-art investments, capacity building, and mentorship.²⁸ Recognising serious human resources constraints in the laboratory workforce, over 10 000 experts have been trained, expanding the pool of qualified laboratory professionals, assessors, and managers.²⁹ All facilities were enrolled in the SLIPTA and SLMTA programme with 90% reaching at least two stars by 2016, by comparison with 23% in 2011, and with three attaining ISO accreditation. Several countries used the concept of performance-based financing incentives linked to progress on the SLIPTA scores.³⁰ A unique peer review mechanism was developed for the network, with east African experts assessing each other's laboratories annually, which has proven to be an effective way to promote peer-to-peer learning and build regional capacity. The Uganda Tuberculosis Reference Laboratory is now part of the prestigious WHO Supranational Reference Laboratory network, providing specialised services and technical assistance to 20 African countries, highlighting the importance of strong regional institutions, and the power of networking. Since 2010, the 32 networked facilities have served over 4 million beneficiaries. The laboratories have rolled out new molecular technologies, which have reduced turnaround time; supported disease outbreak investigations with greater involvement in Ebola virus, Marburg virus, and cholera outbreaks; and engaged in operational research.³¹ With an extension provided by the World Bank, the number of facilities has risen from 32 to 39 and new areas have been introduced, such as cancer diagnosis.

In 2005, Fondation Mérieux, with the support of the European Commission, launched a national laboratory network initiative in Mali called Action BIOMALI. In 4 years, the network grew to cover more than 80 public and private laboratories. In 2009, in response to official demands from the ministries of health of two neighbouring countries, Burkina Faso and Senegal, and with the support of the French Development Agency and Fondation

Panel: Key lessons learned

- Effective partnerships are crucial. None of the achievements could have been made without partnerships. A country-owned strategic plan was crucial for coordinating multiple partners' efforts in a given country. The private sector also plays a notable role in strengthening laboratory medicine in Africa as shown by the Becton Dickinson and Abbott partnerships. However, there was a strong need to explicitly define the roles and responsibilities of each of the partners, and communication between partners were a key to the success of the public-private partnerships.
- Host country leadership matters. The role of the host government in directing and guiding multiple partners' efforts within the country's strategic plan is crucial.
- Sustained advocacy is fundamental to advancing laboratory medicine in Africa. The advocacy role of the Maputo Declaration and the WHO Regional Office for Africa Resolution were key determinants in mobilising resources and focusing the laboratory medicine strengthening agenda.
- A set of clear monitoring and assessment metrics, such as the Stepwise Laboratory Quality Improvement Process Towards Accreditation, to measure improvements in the laboratory efforts was fundamental.
- Commitment of funding by donors was a key driver in sustaining the gains made in improving the approach to strengthening laboratory services in Africa.

Mérieux, the Mali network was expanded into four other countries: Benin, Guinea, Niger, and Togo. The network has done more than 350 supervised external quality assessments to assess the quality of diagnostics being used and identify necessary corrective measures. Because of the network, Burkina Faso and Senegal have established a national laboratory department under the Ministry of Health, consistent with the WHO AFRO resolution and the Maputo Declaration. Technicians trained by the RESAOLAB had a crucial role in the control of a cholera outbreak that affected nine health districts in Mopti and Timbuktu, Mali, in 2011. Skillsets developed through the network to facilitate the detection of epidemic-prone diseases in the laboratory and the collection and analysis of surveillance data were applied in containing the outbreak.³²

In 2007, member states of the Southern African Development Community (SADC) developed a protocol on health that addressed communicable diseases including HIV/AIDS, malaria, and tuberculosis. With funding from the African Development Bank, member states established a network of regional reference laboratories. The goal was to develop and strengthen a network of reference laboratories to become centres of excellences across several disease disciplines that could be used for the reduction, elimination, and eradication of communicable diseases where possible.³³ Since then, and

under the guidance and technical support from WHO and the Stop TB Partnership's Global Laboratory Initiative, supranational reference laboratories have been established in South Africa for tuberculosis, and through separate technical support for HIV/AIDS, two Regional Centres of Excellence for Quality Assurance have been established in South Africa and Zimbabwe. All the facilities are accredited and fulfil the SADC minimum standards for supranational reference laboratories and regional centres of excellence.

Institutions

The African Centre for Integrated Laboratory Training (ACILT) was created in 2008, under a partnership between the South African National Health Laboratory Services and CDC/PEPFAR, to accelerate the training of African laboratory scientists on complex diagnostics techniques as part of south-to-south capacity development.³⁴ ACILT has so far trained over 2000 individuals from 35 African countries on several specialised laboratory techniques such as culture of tuberculosis, tuberculosis drug resistance susceptibility testing, implementation of biosafety and biosecurity protocols, DNA PCR testing for infant HIV diagnosis, HIV viral load, HIV drug resistance testing, quality assurance, and laboratory management.

In 2010, representatives from several countries in Africa, partners, and donors issued a statement in Kampala that called for the establishment of a professional body in the continent that will help to guide efforts to strengthen laboratory medicine in Africa. In 2011, eight ministers of health launched the African Society for Laboratory Medicine (ASLM) in Addis Ababa, Ethiopia. ASLM's mission is to support African countries in advancement of laboratory medicine and networks for better patient care and disease management. ASLM has since become instrumental in supporting countries to scale up the implementation of quality management systems, including training laboratory auditors and certifying more than 200 laboratories.

Looking to the future

Despite achievements in strengthening laboratory medicine and its associated services in Africa, challenges remain. In many countries, capacity is still low and the process of transporting specimens to laboratories and results back to the sites creates delays between testing and result reporting with negative effect on treatment outcomes. Other major challenges include equipment maintenance, procurement and supply chain management of laboratory commodities, human resource development, and bridging the diagnostic-clinician gap. Studies have shown that even when diagnostic test results are available, they are not optimally used in managing patient care.³⁵ As efforts continue to strengthen laboratory medicine in Africa, emphasis should be placed on bridging the diagnostic-treatment

chasm.³⁶ State-of-the-art laboratories that have been established across Africa should form the basis on which to establish national public health institutes that will be fundamental in strengthening the capacity of African countries to prepare, detect, and respond to disease occurrences. The Global Health Security Agenda is an opportunity to use resources and further the laboratory strengthening agenda on the continent for patient care and to meet the International Health Regulation requirements. The establishment of the Africa Centres for Disease Control and Prevention (Africa CDC)³⁷ is opportune as it provides a new public health architecture to further strengthen laboratory systems in the context of its Regional Integrated Surveillance and Laboratory Networks (RISLNET). RISLNET is a crucial platform to build robust health-care systems and networks in Africa as integral parts of national public health institutes, using all the public health assets in the regions to combat emerging continental and global health threats in the decades to come. The development and anticipated implementation of advanced surveillance systems for detecting, monitoring, and reporting on diseases with pandemic potential will enable African governments to establish programmes that will improve data analytics and model outbreak data to enhance response capabilities in Africa.

In 2008, weak laboratories were seen as the Achilles' heel of global health and a barrier to effective care. Remarkable progress has been made thanks to the contributions of governments, donors, implementing partners, and industries (panel). With these gains, it is now possible to turn the tide by scaling up the best practices across the continent with sustained advocacy from the Africa CDC and WHO.

Contributors

JNN, FM, CEZ, and RWP developed the concept and drafted the text. KY, MS, and RG conceptualised and produced the figure and panel. AA, PO, DB, and SH critically reviewed and edited the manuscript. All authors critically reviewed the final manuscript.

Declaration of interests

We declare no competing interests.

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