Addressing Cryptococcal Infection in Africa: Better Diagnostic Opportunities Yield Results

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ASLM2014 Conference Activities Begin
Registration and Abstract Submission Now Open

In addition to the valuable partner features and ASLM programmatic updates within this ninth issue of Lab Culture, I wanted to take this opportunity to highlight ASLM’s upcoming second international biennial conference, ASLM2014.

Strengthening the laboratory profession throughout Africa remains a key priority of the ASLM2020 strategy. The relationships built, the ideas generated and the connections made among colleagues during our first international conference, ASLM2012, remain positive outcomes that strengthen and expand professional networks and opportunities.

Since ASLM2012, this network of action brought about changes and increased awareness of not only gaps in African laboratory networks but also the accomplishments and best practices presented to the more than 1,000 conference attendees. Additionally, recognition of laboratory successes through the biennial ASLM Awards Ceremony remains a highlight.

ASLM2014 – themed “Innovation and Integration of Laboratory and Clinical Services: Shaping the Future of HIV, TB, Malaria, Flu, Neglected Tropical Diseases and Emerging Pathogens in Africa” – will continue this discussion among health professionals, policy makers and the private sector in order to expand upon the latest developments and initiatives for strengthening national laboratory health systems, regional networks and diagnostics.

Early registration and abstract submission are now open, and I encourage our ASLM members to again become involved with making our international conference interactive, informative and a unique venue for expanding collaborations among global laboratory medicine professionals.

Please visit our conference website, www.ASLM2014.org, to learn more about abstract submissions, registration rates, exhibitions, keynote speakers, travel scholarships, partner airfare discounts and more! Your participation would be a tremendous honour.

Dr. Tsehaynesh Messele, CEO, ASLM
ASLM Holds First International Francophone Conference

ASLM’s first international francophone conference, ASLM2013, was held 1-4 October 2013 at the Université Félix Houphouët-Boigny - Cocody, Abidjan, Côte d’Ivoire. More than 300 participants gathered at the conference around the theme “HIV/AIDS and Antimicrobial Resistance in Africa: New Public Health Challenges”.

During four days of stimulating scientific programmes, seminars and presentations, many laboratory professionals, clinicians, programme managers, epidemiologists, researchers, students and policy makers addressed issues related to HIV/AIDS infections care and treatment, laboratory assessment and networking, laboratory infrastructure management and more.

The inaugural conference was focused on “new challenges concerning HIV/AIDS and viral hepatitis”, a topic presented by Professor Souleymane Mboup and “the evolution of the profile of African medical laboratories”. The latter was discussed by Professor Mireille Dosso, Scientific Committee Chair, who used the case of Cote d’Ivoire as an example.

Throughout the ASLM2013 scientific sessions, presenters discussed HIV/AIDS care and treatment, particularly treatment of adults and prevention of mother-to-child transmission of HIV. Additionally, they talked about the resistance to antiretroviral and antibiotics as well as the quality of laboratories in Africa. The speakers also examined existing national and international networks including the role they can play and the impacts they can have on the strengthening of the African laboratory system. ASLM2013 also encouraged a strong commitment from government authorities in the laboratory accreditation process to ensure that “by 2023, all laboratories are either on the path to accreditation or enrolled in a laboratory strengthening programme”.

The full ASLM2013 conference report will be published in the coming weeks on www.ASLM.org.
Le premier congrès francophone ASLM2013 était tenue à l’Université Félix Houphouët-Boigny – Cocody, Abidjan, Côte d’Ivoire du 1er au 4 Octobre 2013. Plus de 300 participants multidisciplinaires se sont réunis autour du thème “VIH SIDA et Résistances aux Anti-Infectieux en Afrique: Nouveaux Défis pour la Santé Publique”.

Durant quatre jours de programmes scientifiques, des cliniciens, microbiologistes, biologistes, professionnels de santé publique, et épidémiologistes, provenant particulièrement de pays africains francophones ont abordés des questions relatives à la situation du continent Africain concernant, entre autre, la prise en charge de l’infection à VIH SIDA, à l’évaluation et réseautage des laboratoires, et à la gestion des infrastructures de laboratoire.

La conférence inaugurale a porté sur les « nouveaux défis concernant le VIH-SIDA et les hépatites » présenté par le Professeur Souleymane Mboup et sur l’« évolution du profil des laboratoires médicaux en Afrique », un sujet abordé par Professeur Mireille Dosso qui a utilisé, comme exemple, le cas de la Cote d’Ivoire.

Au cours des autres séances de la conférence, la prise en charge de l’infection à VIH SIDA en particulier le traitement d’adulte et la prise en charge de l’enfant ; la résistance aux antiviraux, antituberculeux, antifongiques et antibiotiques et la qualité de laboratoires en Afrique ont été discutés. Les conférenciers ont également largement parlés de différents réseaux nationaux et internationaux, notamment le rôle qu’ils peuvent jouer et l’impact qu’ils peuvent avoir sur le système de laboratoire du continent Africain. ASLM2013 a aussi fait appel à un engagement fort de la partie des autorités gouvernementales dans le processus d’accréditation pour atteindre l’objectif d’avoir « tous les laboratoires dans un Programme d’Amélioration des Laboratoires ou sur le chemin de l’Accréditation d’ici 2023! ».

Le rapport complet de la conférence ASLM2013 sera publié sur notre site web www.ASLM.org dans les semaines qui suivent.

Writers:  Madeline DiLorenzo (ASLM), Daniel Sess (ASLM Ambassador); Contributors: Corey White (ASLM), Menyeshu Hailu (ASLM)
Implementing the pan-African programmatic objectives of the ASLM2020 strategic vision requires the successful engagement of local, national and regional advocates. Through an Ambassadors Programme, the African Society for Laboratory Medicine (ASLM) utilises such advocates to support the implementation of its vision: advancing the laboratory medicine services and networks needed to support preventative medicine, quality patient care and disease control in Africa. ASLM welcomes the addition of a new Ambassador to Senegal, Prof. Ndeye Coumba Toure Kane.

Prof. Toure Kane serves as a clinical researcher for the Bacteriology-Virology Laboratory at the University Hospital of Dakar, Senegal (Cheikh Anta Diop University). She is responsible for the Molecular Biology Unit, a World Health Organization-accredited laboratory serving as the National HIV Reference Laboratory for Senegal. Prof. Toure Kane has authored dozens of peer-reviewed publications in prominent scientific journals such as Vaccine, Journal of Acquired Immune Deficiency Syndromes (JAIDS), Journal of Clinical Microbiology and many others. With her extensive teaching and research experience, as well as multiple doctorate-level degrees, she provides Senegal and the broader region with vital laboratory medicine expertise.

ASLM Ambassadors promote the Society and its goals, as well as develop and sustain political engagement between local and national government officials, key institutions, laboratory professionals, and Society members to achieve measurable successes. They also work to identify and respond to the needs of the local laboratory medicine community.

Current Ambassadors include:

- Algeria: Prof. El-Hadj Belabbes
- Botswana: Dr. Madisa Mine
- Burkina Faso: Prof. Jean Sakandé
- Côte d’Ivoire: Prof. Daniel Sess
- Kenya: Dr. Matiku Mwau
- Kenya: Mr. Michael Wanga
- Ghana: Dr. William Ampofo
- Malawi: Mr. Reuben Mwenda
- Nigeria: Prof. Dennis Agbonlahor
- Senegal: Prof. Coumba Toure Kane
- Sudan: Dr. Adil Ismail
- Tanzania: Dr. Mohamed Ally Mohamed
- Uganda: Mr. Charles Kiyaga

Contact details and more information about the ASLM Ambassadors Programme can be found at www.ASLM.org/ambassadors. In the coming months, ASLM will launch an online application process for additional Ambassador positions.

*Writers: Corey White (ASLM); Coumba Toure Kane (ASLM Ambassador); Contributor: Michele Ostroski Merkel (ASLM)*
Cameroon Health Minister Mama Fouda: Leadership in Action

The huge task of instituting a well-functioning healthcare system in Africa requires taking stock of challenges and putting solutions forward. This cannot be realised without committed leaders and a shared vision for success with other government offices. Many people following Africa’s health sector growth agree that one of the names of leaders that come to mind in such calibre is the Republic of Cameroon’s Minister of Public Health Mama Fouda. Minister André Mama Fouda has served as Minister of Public Health of the Republic of Cameroon since 2007. Prior to his appointment as Minister, he served in several leadership positions within the Cameroon government both regionally and centrally. He has dedicated his career to public service and is widely credited for the reforms in the Ministry of Public Health that have led to increased access to quality healthcare services. He has been hailed for several accomplishments within the health sector in Cameroon, including the decline of HIV prevalence. The commitment and leadership of Minister Mama Fouda in the transformative landscape of laboratory medicine are amongst his numerous accomplishments.

It was in September 2008 that Minister Mama Fouda hosted the 58th session of the World Health Organization (WHO) Regional Office Committee of Member States. The Session adopted the resolution AFR/RC58/R2, on strengthening public health laboratories in the WHO African region (WHO AFRO) and emphasised the urgency to strengthen public health laboratories at all levels, as well as urging WHO to support member states to mobilise, access and sustain resources to strengthen laboratory services. The Resolution became a critical milestone for a continent in dire
need of quality laboratory medicine. A year later following this meeting, WHO AFRO, African health officials, the US Centers for Disease Control and Prevention, the US President’s Emergency Plan for AIDS Relief (PEPFAR), the Clinton Health Access Initiative, the American Society for Clinical Pathology and partners launched the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA). In April 2011, Minister Mama Fouda and eight other ministers participated at the launch of the first pan-African laboratory society, the African Society for Laboratory Medicine (ASLM) in Addis Ababa, Ethiopia. The Society was launched with the mission to advocate for quality laboratory medicine as well as competent laboratory professionals, bridging the gap between clinicians and laboratory professionals.

Minister Mama Fouda strongly believes that laboratory medicine leads to better patient management, disease surveillance, and innovations that improve healthcare delivery. At the first ASLM international conference in December 2012, in Cape Town, he was personally represented. With six of his colleagues from the continent, they issued a Ministerial Call for Action with ambitious targets and challenged delegates to support policies for enhanced and sustained quality laboratory services. Today ASLM has built on the strategic vision of AFR/RC58/R2 and the Ministerial Call for Action to advance and champion the case for laboratory medicine in the continent.

At home, Minister Mama Fouda is committed to implementing and rolling out SLMTA (Strengthening Laboratory Management toward Accreditation) and the WHO AFRO SLIPTA checklist for auditing laboratories. Furthermore, in April 2013, he reorganised the Cameroon Ministry of Public Health and established a sub-Directorate for Laboratory and Blood Safety. In line with his dedication and vision, and recognising the role of the laboratory in a nation’s healthcare system, he created the first Cameroon National Public Health Laboratory. His quest for quality and precision, forged by an engineering background, can equally be gleaned when he personally and steadfastly kept pace with the successful accreditation implementation programme in Cameroon leading to several laboratories being audited by ASLM using the WHO AFRO SLIPTA checklist. This was without doubt, a proud and historic moment for the Minister and his team.

The Minister’s dedication, leadership and knack for results since assuming office have led to the significant improvement of healthcare delivery in general and laboratory services in particular in Cameroon. Minister Mama Fouda was generous to spare a few minutes for an interview with Lab Culture.
Minister Fouda: Given the burden of infectious diseases in Cameroon and in Africa as a whole, I strongly believe we should dedicate our efforts towards strengthening quality laboratory facilities in Africa to improve the quality of healthcare services.

Minister Fouda: I believe that the laboratory structure in Cameroon has been one of the most evolving components of the health structure, and I would like to describe the current situation as being on the right side of the changing landscape in Africa. We have come from labs and lab staff with little or no knowledge of quality to implementation of basic quality systems in over 300 facilities. Our ministry of health laboratories had never known of or dreamt of becoming accredited, but today, we have 12 laboratories enrolled in the SLIPTA process. This alone gives you an idea of our current situation and I am proud of our achievements so far! At this pace, it is my fervent hope that five years down the line, we should have been able to strengthen the capacity of public health laboratories and blood banks. We also want to ensure that a functional national public health laboratory that will drive the implementation of laboratory policies and the national strategic plan for labs is in place. Establishing and ensuring the coordination of a national laboratory network also goes along with this. We are also aiming to have at least two internationally accredited ministry of health laboratories.

Minister Fouda: I would love to see a strong collaboration between laboratory and clinical professionals defined by a well-structured lab-clinical interface aimed at providing the highest quality of care for the population. I am not a medical person, but to the best of my understanding since being in this office, these two professions are supposed to complement each other like white on snow!

Minister Fouda: I have been very keenly following up on the developments of ASLM since the launch and I’ve always been very supportive of ASLM’s mandate for laboratory system strengthening.
as a backbone for better healthcare in Africa. It has also given me a clearer understanding of my role as Minister of Health, in shaping the evolving landscape of laboratories in my country and in Africa. ASLM is really making a difference and the recent SLIPTA audit of four labs in Cameroon marked an important milestone for the laboratory structure in the country and speaks volumes for ASLM’s achievements this far. I was represented at ASLM2012… but I cannot wait to be part of ASLM2014 this December!

**ASLM:** You hosted what is now known as the Yaoundé resolution AFR/RC58/R2 (in 2008) which adopted strengthening public health laboratories in the WHO African region and emphasised the urgency to strengthen public health laboratories at all levels of the healthcare system. You were personally represented at the first ASLM conference in Cape Town last December 2012 in which you and your colleagues put out a Ministerial Call for Action. How are you translating the objectives of the Yaoundé Resolution and Cape Town Ministerial Call for Action in Cameroon?

**Minister Fouda:** Under the leadership of His Excellency Paul Biya, President of the Republic of Cameroon, we have created a sub-Directorate for Laboratories and Blood Safety at the Ministry of Public Health as well as a National Public Health Laboratory and a National Blood Transfusion Programme. We also recently created a National Public Health Laboratory that represents a landmark in laboratory systems strengthening and recognises the critical role played by the laboratory in the national health system. I also want to mention that we have appointed a local SLIPTA focal person in-country and we are proud to have 12 labs enrolled in the SLIPTA process towards accreditation.

**ASLM:** What is your secret to successful leadership and management?

**Minister Fouda:** I rely on collaborators to whom I assign specific tasks with objectives to attain. I always try to keep in mind that we need to work hard towards the improvement of the health of our people and that this can be best done through a collaborative effort and with the expertise and support of our partners.

*Writers:* Judith Chang (CDC-Cameroon), Minister Mama Fouda (Cameroon); *Contributors:* Corey White (ASLM), Yosef Tiruneh Demissie (ASLM)
**ASLM.org Web Portal Re-Launched**

As part of the African Society for Laboratory Medicine’s (ASLM) efforts to institute a comprehensive knowledge sharing platform for members and partners, a newly developed ASLM.org web portal has been launched. The new streamlined portal has now made laboratory news updates, resources and open-access library content more readily available to users. ASLM will continue its efforts to make the browsing experience easy and productive.

“ASLM aims to make open-access content readily available to laboratorians across Africa.”

Dr. Tsehaynes Messele, ASLM Chief Executive Officer

To quickly identify documents or news, users can use the targeted and refined search engine. The new site also allows users to register for ASLM membership more easily through a simple online form.

All ASLM publications can be easily downloaded from the redeveloped Resource Library and Press Room, including conference and meeting reports and quarterly issues of Lab Culture newsletter. Information about upcoming ASLM conferences and meetings is regularly updated, and partner links can be found within the Events Calendar.

The new site regularly hosts the most current information about African accreditation efforts via its SLIPTA programme page, as well as laboratory application documents for the SLIPTA programme – in English, French and Portuguese.

- Become a member (free!) through an easy-to-complete online form
- Read the latest laboratory-related news
• Read more about the ASLM2020 strategic vision and Ministerial Call for Action
• Download open-access documents from the Resource Library (free!) – including standard operating procedure (SOP) templates, guidelines and training materials
• Learn more about laboratory accreditation and the SLIPTA programme
• Register your credentials for potential consultancies
• View ASLM job vacancies
• Learn about opportunities to become a corporate sponsor or ASLM2014 conference sponsor
• Read Lab Culture newsletters
• Learn more about publishing in ASLM’s open-access scientific journal, the African Journal of Laboratory Medicine (AJLM)

Writers: Corey White (ASLM), Yosef Tiruneh Demissie (ASLM)
Getting the Most from Laboratory Medicine: The Case for Improved Service Delivery

The delivery of laboratory services is entering a new phase of development where laboratory medicine is no longer merely a support service, but is considered an integral part of the patient’s journey. For laboratory professionals, a potent mix is brewing, perhaps even a perfect storm, as the profession changes under the interlinking influences of political pressure, laboratory service reconfiguration, strategic workforce planning and increasing expectation for the delivery of service.

The last few years have set the new modern reality that laboratory medicine is expected to streamline and improve on quality and productivity while providing us with a unique opportunity to build on and accelerate the work institutions such as the African Society for Laboratory Medicine (ASLM). ASLM supports national laboratory services to embrace innovation, transform working practices and reduce waste and duplication.

The organisations involved in laboratory medicine, from professional bodies to governments, will have a challenge to provide strong far-sighted leadership, make difficult decisions and strike a delicate balance between competing and conflicting demands for trickier times to come. However, it is clear that in order to be part of the new modes of healthcare, laboratory professionals must work more closely with the clinician in developing and planning the patient journey.

The time has now arrived for laboratory medicine to integrate more with patient care through improved laboratory workforce, capacity building and collaborative research. Laboratory professionals must learn to become involved in a number of projects and initiatives such as laboratory weeks and tours, workforce groups and healthcare science workshops, all of which are key to helping governments and hospital administrators understand our role in healthcare; importantly, this ensures that laboratory medicine is not an easy target for budget cuts and that sustainable workforce planning will bring long-term benefit.

A profession is as good as its practitioners, and we are fortunate to have a good number of African scientists who are active and undertaking so many roles within the continent of Africa and beyond. Whatever successes can be achieved by working together as a continent must be complimented by professional networking at local, national and regional levels. By sharing knowledge we will be able to learn what works from others’ practice and experience. Through partnerships, laboratory services can develop supportive networks that enable good practices to be shared and solutions to be found in order to meet national needs and challenges. However, the key message is that as a
profession, we must believe in and adhere to principles as well as learn to improve our individual and collective practices. Professional standards must be maintained, patient safety must not be compromised and fully accessible professional and career development must be made available for all professionals working in pathology laboratories – no matter at what level.

With these measures put in place, the future of African laboratory medicine looks bright and exciting.

ASLM Member Feature Writer: Aliyu Samuel Abdulmumuni

AJLM – Call for Papers
The African Journal of Laboratory Medicine is currently accepting submissions.

AJLM serves as a forum for perspectives on the role of laboratories in public health and clinical care. It also fosters communication among laboratory staff, clinicians, scientists, the medical community, public health officials and policy makers.

AJLM is published on a rolling basis, and is available for free online. Article topics of particular interest include:

♦ the conversion of laboratory expertise, procedures and technology into clinical care,
♦ the intersection of laboratory and medical science, laboratory-based epidemiology, and laboratory investigations, and
♦ the real-world application and effectiveness of laboratory science.

For more information on AJLM or to submit manuscripts, please visit www.ajlmonline.org or contact editor@ajlmonline.org.
Over the past decade, the global community has made significant progress in scaling-up HIV treatment and averting mortality in developing countries. Since 2005, there has been a 30% reduction in AIDS-related deaths worldwide. However, despite this progress, the 2012 UNAIDS Global Report suggests that 1.7 million individuals still die every year from AIDS-related illnesses. Some of these illnesses – such as tuberculosis (TB) – are acknowledged as major threats to public health and form a pillar of the global response to HIV. Others, such as cryptococcal meningitis, exact a significant toll on people living with HIV but are severely neglected and underfunded.
The Opportunistic Fungus

Cryptococcal meningitis is an opportunistic infection caused by the fungus Cryptococcus neoformans and is responsible for 20 to 25% of HIV-related deaths in developing countries annually, particularly among those with a CD4 count <100 cells/μL. Cryptococcus neoformans is found in soil throughout the world and is easily acquired through the inhalation of fungal spores. If patients with latent cryptococcal infection become immuno-compromised, they may develop a clinical illness that often manifests as meningitis, the most common presentation of cryptococcal infection in those with HIV/AIDS. Despite global efforts to increase antiretroviral therapy (ART) coverage, cryptococcal disease burden remains high due to delayed presentation of advanced disease and poor access to adequate diagnostics and antifungal treatments. Much of this mortality is preventable with timely diagnosis and treatment. At present, however, diagnosis happens too late, or not at all, and treatment is often sub-standard using therapies that are known to have limited efficacy. Asymptomatic patients with sub-clinical disease can be successfully treated with fluconazole monotherapy (single-drug treatment), but symptomatic patients with cryptococcal meningitis require combination treatment using amphotericin B, flucytosine (5-FC) and fluconazole. All of these drugs are off-patent.

World Health Organization Guidelines

In 2011, the World Health Organization (WHO) released Rapid Advice Guidelines for the diagnosis, prevention and treatment of cryptococcal disease. The guidelines include best practices for diagnosis and treatment and highlight the importance of cryptococcal meningitis prevention through screening and pre-emptive treatment. Historically, lack of access to reliable rapid diagnostics has been a major barrier to early diagnosis of cryptococcal disease. Fortunately, a new rapid lateral flow assay (LFA) has been developed by a US-based manufacturer to detect the cryptococcal antigen (CrAg). The CrAg LFA was approved by the US Food and Drug Administration (FDA) in 2011 and is a highly sensitive dipstick test that can be stored at room temperature and provide results in 10 minutes. The LFA has been cleared by the US FDA for serum and cerebrospinal fluid (CSF), and CE-marked for serum, plasma and CSF specimens. Urine and whole blood specimens are currently undergoing validation studies.

South African Successes

Dr. Nelesh Govender, a pathologist at the National Institute for Communicable Diseases (NICD), explains that South Africa is one of the first African countries to initiate a CrAg screening programme.

Govender and the NICD have collected national patient data beginning in 2002 on the incidence of cryptococcal disease in South Africa. Even though one in three patients with the disease still die despite receiving amphotericin B treatment, 2011 data shows a marked decline in the disease’s incidence given rising ART coverage.

The need to address this high mortality (paired with the issuance of the 2011 WHO Rapid Advice Guidelines on cryptococcal disease) has catalysed new initiatives in South Africa dedicated to improving the timely screening and treatment of cryptococcal disease. Part of South Africa’s success in expanding access to the CrAg screening through the new rapid LFA test lies in South Africa’s capitalisation of pre-existing, well-functioning laboratory infrastructure. The LFA test has been designed as a reflexive test for adults with a CD4 count <100 cells/
Therefore, South Africa has first decided to direct its scale-up activities to the 60 public-sector National Health Laboratory Service (NHLS) sites that already have the capacity and resources to perform CD4 tests. Since 2012, when the CrAg screening became incorporated into the country’s National Strategic Plan, over 10,000 patients have been screened for CrAg in over 100 different health facilities in Gauteng Province, 4% of whom screened positive.

Despite these successes in improving CrAg screening through a reflexive test model, Govender identifies several challenges to the implementation processes that must be addressed in order to improve early screening and diagnosis of the disease and reduce mortality rates. For one, Govender explains national scale-up has been slowed in some South African provinces simply because clinical guidelines and WHO recommendations have not been internalised or adopted as formal policy. “We’ve continued to engage the government to address this,” Govender says. Secondly, since the test has been designed to be performed reflexively in conjunction with a CD4 test, ensuring that healthcare workers understand the programme’s rationale and are adequately trained on standard treatment algorithms has been an important task for NHLS, NICD and international partners. Govender identifies healthcare workforce development as a key issue for laboratory specialists considering initiating a CrAg screening programme in their countries. Lastly, although the LFA test has been used reflexively to test patients at NHLS facilties with CD4 counts <100 cells/µL, the test is at best a point-of-care (POC), low-throughput technology, ill-suited for workflows at high-throughput, automated CD4 testing sites. As the screening programme expands beyond Gauteng Province, NHLS may consider “a tiered testing model to reduce costs and improve turn-around times,” Govender says. Pursuing a “tiered” approach would mean scaling-up the LFA test at laboratories with low-volume testing and the enzyme immunoassay (EIA) test at laboratories with medium to high volume testing.

**Sustainable Implementation in Mozambique**

Motivated by similar concerns about the high burden of cryptococcal disease and high AIDS-related mortality rates, Mozambique has also recently worked to fill gaps in the cryptococcal testing space. Mozambique has initiated processes for a national CrAg screening programme using the LFA and, like South Africa, will focus its initial efforts on patients with CD4 counts <100 cells/µL.

Although products (or test kits) have not yet been procured in Mozambique, Dr. Eduardo Samo Gudo, Head of Reference Laboratory Services, Mozambique National Institute of Health, cites key successes and accomplishments in preparing for the programme’s launch. The Mozambican Ministry of Health (MoH) has been engaged in the early implementation phases of the CrAg screening programme, a tell-tale sign of country ownership that is crucial for long-term project sustainability. Specifically, the MoH has been instrumental in developing and publishing standardised implementation guidelines for CrAg screening, conducting assessment studies on health facilities eligible for test scale-up and formulating a strategic selection plan for where to target scale-up. A gradual phase-in approach will be followed, in which a select number of facilities will produce patient data and evidence that demonstrates the effectiveness of CrAg screening and builds consensus for a larger, nationwide rollout.

Mozambique’s screening programme, much like in South Africa, has great potential to save lives through pre-emptive treatment and meningitis prevention. Inevitably, however, several challenges in programme implementation, identified by
Gudo, must be addressed. There are, Gudo says, “training needs for clinicians on proper diagnosis and management of cryptococcal infections.” In addition to trainings and workforce development initiatives, the effectiveness of the programme will also depend upon the abilities of laboratories to ensure effective patient flow. Indeed, since the LFA test will be performed reflexively after patients have been tested for a CD4 count <100 cells/µL, there is a critical need to have decreased turn-around times for CD4 tests to avoid high rates of loss to follow up between the CD4 test and the CrAg screening. Lastly, Gudo identifies supply chain management as a key area requiring close consideration. There must be engagement with the private sector and suppliers to ensure the regular and timely access to tests and treatment for symptomatic and asymptomatic patients, especially in rural, hard-to-reach areas.

Addressing such challenges is critical to the further reduction of AIDS-related illnesses, such as cryptococcal disease. The sustainable implementation of programmes for diagnosing, preventing and treating cryptococcal disease would support the progress achieved in scaling-up HIV treatment programmes and decreasing mortality rates in developing countries.

Writers: Sean Regan (CHAI), Madeline DiLorenzo (ASLM), Nick Baer (CHAI), Corey White (ASLM)
Contributors: Michele Ostroski Merkel (ASLM), Yosef Tiruneh Demissie (ASLM), Aliyu Samuel Abdulmumuni (ASLM), Hishe Hailu Teklehaimanot (ASLM)

Lab Culture | Call for Submissions

ASLM is accepting submissions to Lab Culture, our quarterly newsletter. We invite you to submit articles (200-500 words) on the following topics:

- Standards & Accreditation
- Research
- Education & Training
- Clinical Medicine

If you are interested in contributing an article or photo, or in advertising with Lab Culture, please email us at newsletter@asl.org.
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\(^1\) WHO (2013)
The use of antiretroviral drugs for treating and preventing HIV infection.

\(^2\) WHO (2011)
Fluorescent light-emitting diode (LED) microscopy for diagnosis of tuberculosis policy.

\(^3\) WHO (2010)
Community-based reduction of malaria transmission.
Advancing the quality of laboratory medicine across Africa is an initiative that cannot be realised without strong collaboration among the leading institutions in the field. The experience in other sectors of development in the continent also provides testament to the importance of building partnerships towards a common goal. Based on that principle, ASLM has successfully collaborated with six centres of excellence across the continent to build local capacity, improve service quality, bring about high standards of care and improve outcomes for Africans. These centres are well recognised in their research, policy, technology assessment and implementation, and training in laboratory medicine. One of ASLM’s reputable collaborating centres championing the goal of providing high standard of laboratory medicine is the Institute of Human Virology Nigeria (IHVN).

**Partnership to Improve Outcomes**

Since 2004, IHVN (www.ihvnigeria.org) has worked to actively strengthen Nigeria’s laboratory capacity to mitigate HIV, tuberculosis and other infectious diseases. As a local organisation and one of Nigeria’s largest implementing partners of the US President’s Emergency Plan for AIDS Relief
(PEPFAR) and The Global Fund to Fight AIDS, Tuberculosis and Malaria, the Institute is providing laboratory support to over 70 facilities in the country.

This support is in the form of provision of equipment and infrastructure to carry out high throughput blood screening tests (hemogram) clinical chemistry, CD4 monitoring, HIV-1 RNA (viral load) testing for adults and children, early infant diagnosis (EID), tuberculosis (TB) culture, and first and second line drug susceptibility testing for TB, amongst others. IHVN also supports the roll out of optical TB smear microscopy with fluorescent microscopes, reagents, supplies and technical supervision. Technical assistance is also provided to the Federal Government of Nigeria in developing policy documents for laboratories at the national level.

**IHVN Expertise**

With its laboratory and clinical expertise, IHVN has built upon an ongoing collaboration with the National TB and Leprosy Training Centre (NTBLTC). This collaboration focuses on strengthening the integration of high quality TB and HIV care delivery in support of the National TB Control Strategy.

At all points of service directly supported by IHVN, all newly presenting HIV positive patients or existing care and support patients are screened for TB and linked to on-site DOTS (directly observed treatment, short course) centres for treatment if necessary. NTBLTC has several laboratories including HIV diagnostics, CD4 testing, haematological tests, hepatitis, chemistry analysis, microscopy, GeneXpert and BSL-2 (biosafety laboratory) section for TB diagnosis using solid culture. It also has a containerised BSL-3 laboratory with its own mechanical room. It is the main facility for supporting surveillance for drug resistant TB in Nigeria.

NTBLTC also houses a polymerase chain reaction (PCR) suite for TB and multi drug resistant TB (MDR-TB) diagnoses by Hain using Line Probe Assay (LPA) method. The genotype tests include MTBDRplus, MTBDRsl, and common mycobacteria (CM) and additional species (AS) molecular assays.

The BSL-3 has also provided a platform for training on TB culture, first line, second line drug susceptibility testing and Hain assay for upcoming zonal TB laboratories. NTBLTC demonstrated the superiority of the iLED fluorescent scope over Ziehl–Neelsen (ZN) staining within the Nigerian setting, and supported a national survey of MDR-TB by analysis of sputum samples from selected sites from the northern part of the country. It also analysed 1,319 sputum samples from clients demonstrating the prevalence (%) of MDR-TB in Nigeria while 3,139 samples were analysed for the National TB Prevalence Survey.

**IHVN and ASLM**

It was back in December 2012 that the African Society for Laboratory Medicine (ASLM) made two of the Institute’s supported laboratories collaborating centres. These centres are the Asokoro
Laboratory Training Centre in Asokoro District Hospital, Abuja, and the Plateau State Human Virology Research Centre in Jos. The Asokoro Laboratory Training Centre (ALTC) serves as the central PEPFAR training laboratory for the Institute.

**The Asokoro Laboratory Training Centre**

The laboratory is set up as a model clinical laboratory that has separate training areas for haematology, clinical chemistry, enhanced smear microscopy, fungal cryptococcal antigen, serology for Hepatitis B and C, and syphilis and rapid HIV testing and all instrument platforms employed at sites. ALTC also houses specialised services including PCR for early infant diagnosis test training and genetic analysers for HIV drug resistance testing.

The main laboratory holds equipment for sample separation, processing and storage. Facilities available there include a 10 m² virology laboratory and a state-of-the-art 55 m² laboratory equipped for comprehensive serologic testing with equipment such as centrifuges, refrigerators, standard equipment/commodities necessary for good laboratory practice, ELISA plate washer, Vitros 350 clinical chemistry analyser, Sysmex hemogram counter, FACS Count flow-cytometry, -80 freezer, hood, thermocycler for Roche Amplicor PCR, ABI 3130xl and 3500xl automated sequencers and clean isolation facility for PCR.

**The GeneXpert Partnership**

IHVN is the only ASLM collaborating partner in the GeneXpert roll out project in West and Central Africa. The Institute has over ten GeneXpert machines deployed to its supported facilities with many patients to increase TB detection among people living with HIV across the country. GeneXpert is an automated diagnostic test that can rapidly identify TB and resistance to the treatment drug rifampicin (RIF).

**Training and Accreditation**

The partnership between ASLM and IHVN has also resulted in the training of 50 laboratory scientists on laboratory quality management systems under the SHaRING project, a laboratory pre- and in-service collaborative agreement funded by the US Centers for Disease Control and Prevention (CDC)/PEPFAR. Steps are also being taken to ensure national accreditation for 30 laboratories and international accreditation for eight laboratories supported by IHVN.

The collaborative work that ASLM undertakes with IHVN is just one of the many partnerships that are established to bring about visible improvements in laboratory medicine and care in Africa. ASLM is currently working with some of the high performing laboratories for international ISO-based accreditation.

**Writers:** Blessing Ukpabi (IHVN), Yosef Tiruneh Demissie (ASLM), Corey White (ASLM)
A comprehensive approach to strengthening laboratory systems in Africa requires reinforcing and supporting the capacity of the broader laboratory workforce. In resource-limited settings, medical laboratory training programmes can many times be deficient as a result of insufficient funding, limited political commitment or poor understanding of the laboratory’s role in the overall health system. Building a sustainable laboratory workforce is one of the strategic goals of the ASLM2020 vision. To achieve such, ASLM recently partnered with local organisations in Cameroon and South Sudan to support the review and enhancement of curricula used in national laboratory training programmes. In each country, ASLM worked in concert with local stakeholder partners and health officials to perform gap analyses of training curricula, develop recommendations and plan intervention strategies to address the identified gaps.

Over a two-week period in Cameroon, ASLM met with Ministry of Public Health officials and implementing partners including the directors of five training facilities in Bamenda, Buea, Douala, Shisong (Kumbo) and Yaoundé to review training curricula, tour facilities and interview faculty and staff. The regional Global Health Systems Solutions (GHSS) personnel assisted with onsite assessments. Findings were presented at the Le Centre Pasteur du Cameroun, Yaoundé, in a final stakeholders meeting which included government officials as well as representatives from both the French and English-speaking laboratory professional organisations, the Association of Laboratory Technicians of Cameroon and Cameroon Association for Medical Laboratory Science,
respectively. While reinforcing sustainable accomplishments, they also discussed the importance of working cooperatively with the Ministry of Public Health and the Ministry of Higher Education to improve training programmes by addressing the gaps identified and developing strategic initiatives for advancing the laboratory profession.

Similarly, ASLM undertook a week-long mission in South Sudan to meet with officials from the Ministry of Health and local partners in order to review medical sciences education and laboratory services in the country. After working to identify gaps in existing curricula and its implementation across South Sudanese health training institutions, ASLM worked collaboratively with local officials to outline next steps in revising the curricula where necessary as well as to develop plans to conduct review and sensitisation workshops.

As with many resource-limited health systems, ASLM and its partners identified the need to strengthen course curricula and corresponding clinical attachments in both locations. Additionally, staff shortages, professional development and financial constraints need to be addressed in order to achieve sustainable laboratory training programmes. These challenges are not unique to Cameroon or South Sudan; instead, the findings reinforce what is already well-known. To address these challenges and to develop best practices for adoption elsewhere, ASLM will return to both Cameroon and South Sudan in 2014 to continue its partnerships via the delivery of targeted workshops and to further assist in improving the education of laboratory medicine professionals.

Writers: Corey White (ASLM); Independent Consultant Contributors: Ellen Hope Kearns, Marguerite Neita, Bryan Nyary, Erica Rosser
The Institute of Human Virology Nigeria (IHVN) and African Society for Laboratory Medicine (ASLM) have recently trained over 20 scientists on writing biomedical research manuscripts for publication.

The eight day workshop, which was held at the IHVN training hall in Abuja, mentored health researchers on the process of writing, data analysis and revising it for submission to international journals. Other topics covered at the workshop included methods, literature review, results, discussion, authorship and peer-review.

Former Director-General of the Nigerian Institute of Medical Research (NIMR), Prof. Oni Emmanuel Idigbe, a workshop facilitator, said that the workshop would enable researchers to share important findings with the public. “It is a common practice by most organisations to shelf relevant generated data which ought to be made public for the scientific and academic community for possible contribution towards improving strategies, policies and healthcare generally,” he said.

Participants at the workshop, Dr. Bashir Zubairu and Dr. Oluwakemi Akagwu, said it has simplified the scientific writing process and helped them to sharpen their writing skills in preparation for research publications.

IHVN Director of Laboratory Research, Dr. Nicaise Ndemb, and ASLM Senior Communications Officer, Mr. Corey White, facilitators of the training, said the workshop is also a way to expand the capacity of both IHVN and ASLM as collaborating partners. Dr. Ndemb added that the Institute has data generated from past research work that needs to be put out there in the public domain. He added that the participants who were chosen on the basis of authorship, possession of a complete draft manuscript and quality of data, are now better equipped for dissemination of quality scientific research abstracts in both national and international meetings.

Writers: Blessing Ukpabi (IHVN); Contributor: Corey White (ASLM)
Pan-African Partners Aim to Harmonise the Regulation of Medical Devices and Diagnostic

Harmonisation of the policies and regulations governing medical devices and diagnostics remains a critical gap in the effort to strengthen African healthcare systems. For example, a new generation of point-of-care (POC) diagnostic tests are under development that could save lives and halt the spread of infectious diseases. Access to new tests in Africa can be delayed, however, sometimes for years, due to complex and costly requirements for regulatory approval in some countries. Costs incurred by the test manufacturers are subsequently passed on to patients – increasing the price of the goods and ultimately limiting access to life-saving tests. Regulatory harmonisation ensures quality-assured, safe medical devices and diagnostics are available and accessible to patients without delay.

The recently launched Pan-African Harmonization Working Party (PAHWP) studies and recommends ways to harmonise regulations related to medical devices and diagnostics throughout Africa. PAHWP is a voluntary body conceived in 2012, and formally announced at ASLM2012, ASLM’s inaugural international
conference in Cape Town, South Africa. It undertakes pilot projects throughout Africa, and it is housed within the African Union-New Partnership for Africa’s Development (AU-NEPAD) Planning and Coordinating Agency, under the auspices of the African Regulatory Harmonization Advisory Committee for Medicines, Medical Devices and Diagnostics. Founding members of PAHWP include:

- **East African Community Health Secretariat (EAC)** and the **EAC Partner States** of **Burundi, Kenya, Rwanda, Tanzania** and **Uganda**
- **Ethiopia**: Food, Medicine and Health Care Administration and Control Agency (FMHACA)
- **Nigeria**: National Agency for Food and Drug Administration and Control (NAFDAC)
- **South Africa**: National Health Laboratory Service (NHLS)

PAHWP partners include ASLM, the Asian Harmonization Working Party (AHWP), the German Society for International Cooperation (EAC-GIZ), the Latin America IVD Association (ALADDIV), the London School of Hygiene and Tropical Medicine (LSHTM), and the World Health Organization Regional Office for Africa (WHO AFRO). PAHWP is facilitated by the London School of Hygiene & Tropical Medicine (LSHTM), with grant funding from Grand Challenges Canada (GCC).

PAHWP activities are focused on five harmonisation areas: a) developing a common registry for in vitro diagnostic (IVD) medical devices; b) reducing repetition, costs and delays associated with regulatory audits of manufacturers’ quality management systems; c) minimizing duplication of clinical trials for regulatory approval in African countries; d) providing safe, reliable diagnostic products across Africa through post-market surveillance and e) creating standard classifications for IVDs based on their risk to individual and public health.

Notable PAHWP achievements to date include:

- A baseline survey of regulation of medical devices and medical diagnostics in East African Community (EAC) Partner States was undertaken in October 2012.
- The EAC Regional Task Force on Regulation of Medical Devices and Diagnostics meeting was held in April 2013 in Dar es Salaam, Tanzania. At this meeting, the proposed structure of PAHWP was approved.
- The 1st African Regulatory Forum on Medical Diagnostics was convened on 24-26 July 2013, Nairobi, Kenya. At the Forum, the approved PAHWP structure was formally presented to meeting participants. Over 90 laboratory medicine professionals from 21 countries - including stakeholders from national regulatory authorities, IVD manufacturers, laboratory-based organisations, NGOs and international organisations - were in attendance.

The 2nd African Regulatory Forum on Medical Diagnostics was conducted 22-23 January 2014 in Cape Town, South Africa. Representatives from the Southern African Development Community (SADC) participated in the second forum; updates are forthcoming in future Lab Culture issues.

Additionally, to reaffirm its commitment to the objectives of PAHWP, the EAC recently convened a workshop in Entebbe, Uganda, from 14-19 October 2013, in order to draft a funding proposal to further strengthen and harmonise the regulation of medical devices and diagnostics within the
region. At the workshop, representatives from the five EAC member states were joined by ASLM and WHO. The regional proposal was adopted and technical working groups (TWGs) were established in order to follow-up on and implement the proposal.

Visit the PAHWP web portal for resources and more information: www.PAHWP.org.

Information is also available at www.ASLM.org/PAHWP.

Content provided by: the Pan-African Harmonization Working Group (PAHWP)
Writers: Ndlou Nqobile (ASLM), Corey White (ASLM); Contributor: Madeline DiLorenzo (ASLM)
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Director, Centre for the AIDS Programme of Research in South Africa

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Senior Advisor and Team Leader, Country Programme Scale-up UNICEF

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Why attend?

- Learn about the most recent laboratory advances and innovations
- Connect with colleagues from across Africa
- Gain continuing education credits
- Help shape collaborations between laboratories and clinicians

www.ASLM2014.org
African Partners Release Consensus Recommendations on HIV Viral Load Testing

To date, over seven million HIV patients in Africa have received antiretroviral therapy (ART). Although a significant achievement, this is less than 50% of all treatment-eligible patients on the continent according to criteria set by the new 2013 Consolidated ART Guidelines from the World Health Organization (WHO). Today, Ministries of Health face a dual challenge – first, to continue to expand access to ART for the millions of patients still in need and, second, to sustain effective treatment for patients already on ART.

Routine viral load monitoring of patients on ART is a powerful tool to achieve the second goal – improving the long-term success of therapy – and is now strongly recommended by the WHO. Viral load tests detect treatment failure earlier than CD4 tests and with adherence support help patients remain virologically suppressed. This improves patient outcomes, preserves the efficacy of drug regimens, limits drug resistance and lowers the risk of HIV transmission.

Currently, it is estimated that less than 20% of ART patients in Africa receive routine viral load testing. The cost-effective and sustainable scale-up of viral load monitoring faces many challenges, including financial, policy, clinical, operational and technical barriers.

“Ensuring that people living with HIV have access to safe and accurate monitoring of the virus is a basic human right,” said Michel Sidibé, Executive Director of UNAIDS. “Testing needs to be simpler, quicker, more cost effective and more widely available, only then will the full benefits of antiretroviral therapy be realised.”


The African Society for Laboratory Medicine (ASLM), in partnership with the WHO Regional Office for Africa (WHO AFRO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Society for AIDS in Africa and the Southern African HIV Clinicians Society, recently convened over 100 international clinical, laboratory and policy experts including representatives from 20 African Ministries of Health to discuss these challenges and highlight priorities for Ministries of Health considering expanded access to HIV viral load testing. The priority, consensus recommendations have been released.

Coordinated efforts based on best practice are essential for building effective testing programmes. Successful scale-up of viral load testing will yield significant benefits for millions of patients without access to this test and will substantially improve the effectiveness of HIV treatment and prevention services. The partners recommend that Ministries of Health, with the support of implementing partners, take steps to scale-up viral load testing and to consider the consensus priorities as they seek to successfully expand access to this important test.

The recommendations and priorities are available for download at: www.ASLM.org/viralload
Research Feature: The Global Health Network

As the African Society for Laboratory Medicine (ASLM) continues to push for advances in research capacity throughout Africa, it is closely partnering with The Global Health Network to expand access to scientific content and best practices. The Global Health Network (www.theglobalhealthnetwork.org) is an open-access digital hub for researchers to share their knowledge and methods through a wide range of free online seminars and courses; eLearning modules; downloadable training kits; and country-specific regulatory advice, articles, discussions, news, templates and tools.

The Global Health Network is a collection of individual online web spaces that create subject-specific online communities of researchers who can build collaborations, develop documents, share resources and exchange information. Each member area is a separate entity with specialised goals and objectives. Many Global Health Network communities also have closed workspaces that members can set up to facilitate development of grant applications, project plans, research documents and protocols.

One such Global Health Network community is SiteFinder (www.site-finder.org), a free and open-access online portal which enables health facilities in developing countries to take part in diverse research opportunities. Often research sites have been involved in externally sponsored trials in one disease area and it is difficult to find further studies in which they can participate or to gain the confidence and skills to run their own independent studies. SiteFinder allows sites to make themselves known within their region and globally so they have access to diverse research opportunities.

Researchers and research sites can register to connect with product development organisations, colleagues and funding agencies across the world to further develop their experience and study diversity.

Research groups planning studies can let others know about their ideas, plans and request research partners. Organisations who are sponsoring trials can also conduct highly detailed and informative searches for trial sites tailored to their specific needs. Using technology adapted from dating websites, SiteFinder automatically suggests suitable collaborations and informs sites of new studies which are relevant to them.

Following a six-month pilot study, SiteFinder launched in July 2013. Over 60 research sites have already registered, with many making use of the ability to add photos and documentation such as training certificates.
Research sites and studies are already contacting one another, with several new budding partnerships, and fantastic feedback from all parties. Excitingly, research sites are also using SiteFinder as a means of building relationships with one another for local collaborations; for example, sites in Cameroon are discussing linking together to share training and resources.

Technical support for SiteFinder is always on hand to help with any questions, and live help sessions are offered every weekday between 11 am-1 pm GMT on Skype Instant Messenger: simply add “site-finder” on Skype. You may also email site-finder@theglobalhealthnetwork.org.

The Global Health Network is led by a founding steering committee and managed by a central operational team. It is funded by the Bill and Melinda Gates Foundation and the Oxford Tropical Network. Each member website has its own governance structure and details are found on each site. The Interim Founding Steering Committee is comprised of Jeremy Farrar (Oxford University Clinical Research Unit, Vietnam), Trudie Lang (University of Oxford), Kevin Marsh (KEMRI-Wellcome Programme, Kenya) and Rosanna Peeling (London School of Hygiene and Tropical Medicine).

To add your research site or study to SiteFinder:
- Register for free at www.Site-Finder.org
- Select “research sites” or “studies seeking sites”
- Select add a site or study
- Complete the form; add photos, videos or docs
- Editable anytime

Writers: Tamzin Furtado (TGHN), Corey White (ASLM)
The World Health Organization (WHO AFRO) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) programme measures and evaluates the progress of laboratory systems towards international accreditation standards and awards certificates of recognition based on 0-5 star ratings.

**Figure 1. SLIPTA Tiers of Recognition**

**Figure 2. Charting the Spread of SLIPTA**
Since SLIPTA’s inception, a total of 169 participants have attended SLIPTA auditor trainings. 153 of these trainees successfully completed this initial course. Of the 153 trainees, 29 have become certified SLIPTA auditors. The remaining trainees will complete the final requirements of their certification during upcoming SLIPTA audits.
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