

LAB CULTURE

THE ASLM NEWSLETTER FOR
LABORATORY PROFESSIONALS
ACROSS AFRICA

November 2011, Issue 1

WELCOME TO
YOUR
ASLM

Grace à moi, une grand-mère peut recevoir une
chirurgie salvatrice.
J'effectue des tests pour assurer une sécurité
transfusionnelle.

JE SUIS UN PROFESSIONNEL DE LABORATOIRE.
I AM A LABORATORY PROFESSIONAL.

IN THIS ISSUE:

An Interview with ASLM Board Chair, Dr. John Nkengasong

Kenya Takes Bold Steps to Increase Transparency in Lab Services

African Journal for Laboratory Medicine Launches New Website

Call for Papers!

The African Society for Laboratory Medicine is pleased to announce the inauguration of the African Journal of Laboratory Medicine (AJLM).

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

AJLM will be published quarterly, and will be available online for free. 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 their real-world application and effectiveness. Submissions accepted in French or English.

For more information on AJLM or to submit manuscripts, please visit www.afslm.org or contact ecl7@cdc.gov.

Do you qualify for an ASLM workshop? Applicants must meet the following requirements:

- Fluency in English (a future workshop for French speakers is being planned)
- Principal authorship of a manuscript currently in development
- Availability for participation throughout the entire 12-day workshop
- Commitment to having a manuscript ready for submission to AJLM
- Willingness to fund one's own travel and lodging expenses; a letter of financial support is required.

Applicants will be selected on the following criteria:

- Importance of research topic to the advancement of Laboratory Medicine
- Current status of manuscript, with preference given to those with a completed report/draft
- Quality of data and status of analysis

Contribute to Lab Culture

ASLM is currently accepting 150-650 word articles and photo submissions for its newsletter.

Newsletter topics include

- Member News: awards, promotions, articles relevant to membership
- Industry Focus: new diagnostics, supply chain solutions, IT systems to improve the lab
- Laboratory Standards: accreditation, new standards.
- Research, Education and Training: recent publications, new, updated or featured training programs/workshops.
- Clinical Medicine: Cross-training, impact of lab on clinical outcome/decision-making.
- Perspectives: editorials, opinion articles, letters to the Editor

Please contact newsletter@afslm.org for more details.

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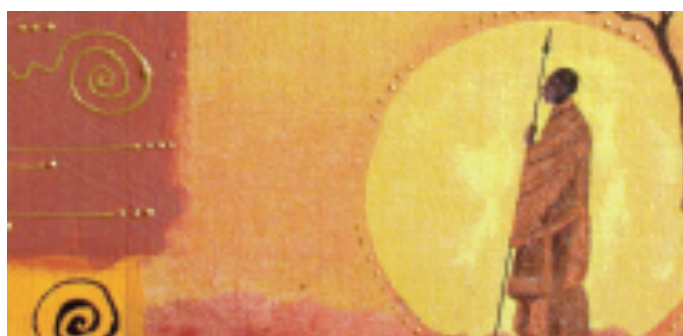
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LETTER FROM THE CEO



WELCOME TO LAB CULTURE

On behalf of the African Society for Laboratory Medicine (ASLM), I would like to welcome you to the first edition of *Lab Culture*. ASLM strives to establish and maintain regular communication among laboratory medicine professionals in Africa, and this newsletter is intended to provide a forum for communication among laboratory professionals. I wish to extend my personal thanks to those of you who contributed to this inaugural issue, and strongly encourage everyone to contribute to *Lab Culture* and to the *African Journal of Laboratory Medicine*.

As a young organization, ASLM faces both great opportunity and great responsibility. On the one hand, we have clear objectives, a strong sense of purpose and a vital mission. By concentrating our resources on public health laboratories across Africa, ASLM can make a profound and measurable difference in the development and welfare of the countries where we operate. On the other hand, we already have a full schedule of projects and need to address the various interests of medical laboratory professionals in a wide variety of regions and situations. ASLM is the first organization of its kind, and through a collaborative effort we will champion the advancement of laboratory medicine in Africa.

Things have been busy at ASLM. We recently opened our headquarters in Addis Ababa, Ethiopia; sponsored a SLIPTA training program in Dar es Salaam, Tanzania, in mid-September; and in mid-October co-sponsored a Grant and

Proposal Writing Workshop in Johannesburg, South Africa. We hope to build on the success of these projects as our organization continues to grow.

This edition of *Lab Culture* includes sections devoted to Member News, Industry Updates, Laboratory Standards, Research, Education and Training, Clinical Medicine and Perspectives, as well as two important Feature Articles. We chose these topics based on their relevance to you, the ASLM community.

I hope these articles will motivate you to participate in and take advantage of the many opportunities ASLM has to offer. I believe you will find a host of activities relevant to your professional development in this and in future issues. Thank you for reading.

Dr. Tsehaynesh Messele, CEO, ASLM

MEMBER NEWS

INTRODUCING THE ASLM SENIOR LEADERSHIP TEAM



Tsehaynesh Messele, Chief Executive Officer

Dr. Messele joined ASLM as CEO after serving as Director General of the Ethiopian Health and Nutrition Research Institute (EHNRI) from 2004 to March 2011. She recently worked as Senior Technical Advisor for the Federal HIV Prevention and Control Office. Messele also served as Ethiopian Laboratory Manager and later as a National Program Manager for the Ethio-Netherlands AIDS Research Project and led the development of the first national laboratory strategic plan in Ethiopia.



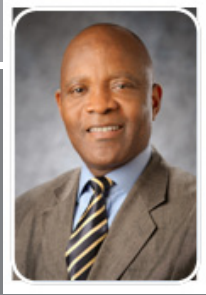
Giorgio Roscigno, Chief Operating Officer

Dr. Roscigno began as ASLM COO in September 2011. Prior to joining ASLM, Roscigno established the Foundation for Innovative New Diagnostics (FIND) where he served for eight years as CEO. He also served as Medical Director for Africa, Asia, and Europe; as European Clinical Research Director for Anti-infectives; and as International Medical Director for Anti-infectives with Aventis.



Etalem Engeda, Administrative Manager

Before joining ASLM Ms. Etalem Engeda served as Chief of Staff at EHNRI and held various posts of increasing professional and administrative responsibility within international and regional organizations. Ms. Engeda is a member of Executive Committee of the Ethiopian Economics Association (EEA), member of the Technical Advisory Committee for the Ethiopian Economic Policy Research Institute (EEPRI) and has taught at Addis Ababa University, Department of Economics extension program.



MEET THE BOARD MEMBER

Dr. John Nkengasong, Board Chair, Shares His Vision for ASLM

Editors: Jessica Fried, MPH and Jhosetta Goudelock (Editorial Team)

Why and how was ASLM started?

In developing countries, health systems are often inadequately resourced and the critical role of medical laboratories is frequently underappreciated. With the lack of capacity to provide the scope and quality of laboratory services required by the community, misdiagnoses and, consequently, inappropriate treatments are a reality. This presents significant economic and public health challenges locally, nationally, and internationally. Recognizing these challenges, the Ministries of Health in several African countries came together with the WHO, CDC, and other partners to form ASLM.

The origins of ASLM can be traced back to a conference held in Harare, Zimbabwe in February 2001. The idea was planted at the time, but wasn't developed until January 2008 with the Maputo Declaration, which called on national governments, donors, and partners in resource-limited settings to prioritize laboratory systems and develop strategic laboratory plans. The foundation for ASLM was then established and, two years later, the organization took form as a result of the Kampala Statement, which directly called for the creation of the African Society for Laboratory Medicine. The rapid formation of the society since June 2010 is a great accomplishment and underscores the continent's need for improved laboratory capacity.

How did your expectations for the launch meeting compare to the meeting outcome?

The outcome of the launch of ASLM greatly exceeded my expectations. Six ministers of health, two ambassadors, and over three hundred partners and participants attended. The objectives of the meeting were to engage stakeholders in the development of a strategic plan to advance the eight pillars of the

society (see Feature Article: Welcome to Your ASLM). We received valuable input and over 80% of participants signed up to be ASLM members. Receiving that type of support and feedback from our community was invaluable. We are still riding the positive waves of enthusiasm expressed during the launch.

What role do you play as Chairman of the Board of Directors of ASLM?

As Chairman of the Board I am charged with helping ASLM achieve its mission of advancing professional laboratory medicine practice, science, systems, and networks in Africa needed to support preventative medicine, quality care of patients, and disease control. In order to achieve this mission I am here to support the ASLM Leadership staff, provide mentorship when I am called upon, and work with the rest of the board to guide ASLM.

Who are the members of ASLM?

ASLM is very inclusive. Our services are targeted at laboratory scientists, scientific researchers, ministries of health, national institutes of health, public health laboratories, professional organizations, NGOs and private entities across the African continent.

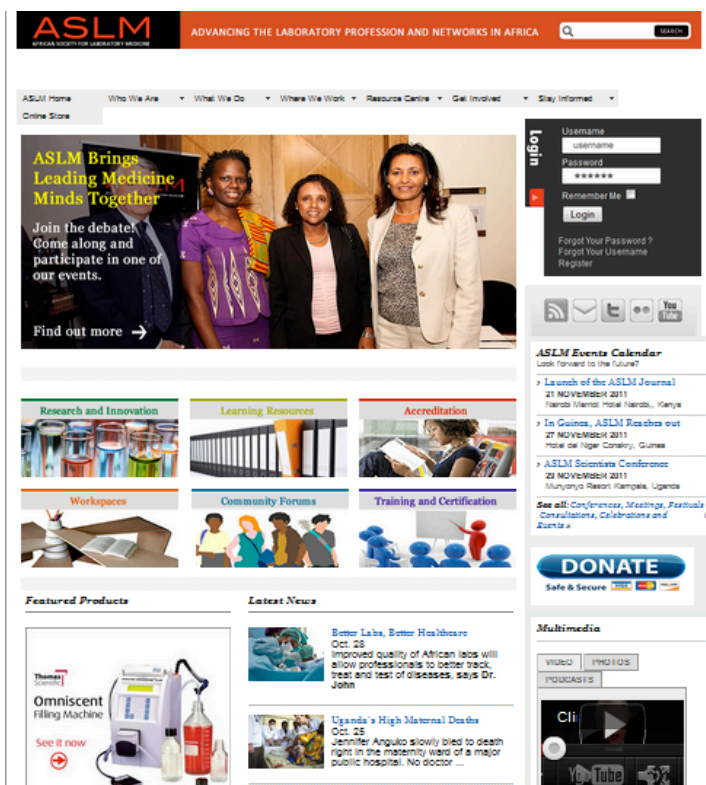
What can ASLM do for its members?

ASLM plans to help its members by providing a number of services, including tools to aid laboratory accreditation and the development of standards; online programs for science education and training; technical assistance for grant writing, publications, and presentations; and access to journals, essential documents, and forums to network and engage with the laboratory community.

Editors: Jessica Fried, MPH and Jhosetta Goudelock (Editorial Team)

MEMBER NEWS

ASLM WEB PORTAL IN DEVELOPMENT



“The portal will encourage networking, collaboration and knowledge-sharing among the ASLM community and serve as a resource for medical laboratory-related services and products. No such resource currently exists anywhere in the world.”

ASLM is developing an extensive web portal that will allow users to access its internet-based activities and a community of participating partners.

The portal will be organised into the following categories: Standards and Accreditation, Training and Certification, Technical Assistance, Research and Publication, and Networks and Community. It will incorporate resource libraries, forums, blogs, workspaces, directories and an online store.

The portal will encourage networking, collaboration and knowledge-sharing among the ASLM community and serve as a resource for medical laboratory-related services and products. No such resource currently exists anywhere in the world.

Through the portal, ASLM members and partners will be able to create and manage their own profiles, blogs and workspaces. The portal will also host the African Journal for Laboratory Medicine, employment listings and a calendar of events. Users will be able to search and upload text, images, audio and video.

The Technical Assistance section will include standard operating procedures, technical guidelines, laboratory safety tools and lab equipment manuals. Audit tools, online training courses and a database of laboratory education programs will be available in the Standards and Accreditation section. Training materials, event registrations and subscription information will be available through an ecommerce facility.

The web portal will have some capabilities up and running within the next three months. Member profiles, subscription information, and ASLM news will be the first resources available.

Writer: Rachel Crane (Editorial Team); Contributor: Paula Fernandes, MBA, PhD (Editorial Team)

PARTNER SPOTLIGHT



AFENET: Making Public Health and Laboratory Systems Count

In 2000, international governments committed themselves to the UN's Millennium Development Goals¹ to fight disease and save lives by building efficient health systems. To be effective, these systems must be supported by a skilled, competent and adequately resourced public health workforce. However, Africa's public health workforce is severely underdeveloped and constantly reduced by the flight of health professionals to developed countries. This, coupled with the increasing disease burden, is a recipe for public health disaster. Fortunately, several African governments, with support from international development partners, are committed to the development of home-grown solutions to public health crises in Africa.

The African Field Epidemiology Network (AFENET) is one of the results of this enterprise². Established in 2005, AFENET is a networking alliance for Field Epidemiology Training Programs (FETPs) and Field Epidemiology and Laboratory Training Programs (FELTPs) in Africa³. FELTPs offer Master's level training for public health professionals and focus largely on hands-on practice, giving trainees the opportunity to participate in the surveillance and detection of diseases and formulate winning strategies to combat them.

FELTPs as a Winning Strategy

The FELTP approach promotes academic pursuit and the subsequent incorporation of FELTP graduates into national public health systems. After their two-year training, FELTP graduates are equipped to develop dynamic, cost-effective interventions to address Africa's health problems. AFENET covers 21 African countries represented by 13 FELTPs. The success and achievements of these programs has attracted trainees from other countries and created a demand for public health specialists trained through the FELTP model. To date, the AFENET Network has over 400 graduates, the majority of whom are serving their home countries in Ministries of Health, Ministries of Agriculture, local government, central public health laboratories, academic institutions and non-governmental organisations.

Strengthening Laboratory Initiatives

In addition to the FELTP approach, AFENET is implementing the AFENET Lab Initiatives project, which supports public health laboratories in Africa by providing quality diagnoses through knowledge-sharing, quality laboratory management and laboratory-based disease detection and surveillance. On the accreditation front, AFENET also supports the training program Strengthening Laboratory Management Towards Accreditation (SLMTA), which facilitates the accreditation process. Other laboratory initiatives include the HIV External Quality Assurance Project to monitor and improve the quality of HIV testing and equipment.

Finally, AFENET is collaborating with the African Society for Laboratory Medicine (ASLM) to promote the appraisal of African laboratories and networks for a healthier Africa.

This year, AFENET will celebrate its 5th Anniversary as a leading network for public health training programs in Africa. The celebrations will take place during the 4th AFENET Scientific Conference from 11-16 December 2011 in Dar es Salaam, Tanzania. We welcome readers to visit our website www.afenet.net for more information.

Writer: Anita Tibasaaga (AFENET); Contributor: Stella Ekallam (AFENET); Editor: Rachel Crane (Editorial Team)



Participants of the HIV Quality Assurance Training in Uganda

1. <http://www.un.org/millenniumgoals/bkgd.shtml>

2. <http://www.afenet.net/>

3. Mukanga, D; Namusisi, O; Gitta, S; Pariyo, G; Tshimanga, M; Weaver, A; and Trostle, M. 2010. Field Epidemiology Training Programmes in Africa - Where are the Graduates? Human Resources for Health. 8:18.

A VENTILATED WORKSTATION FOR AFB SMEAR AND NUCLEIC ACID AMPLIFICATION TEST PREPARATION

Tuberculosis (TB) remains dangerously under-detected across Africa, with case-detection rates estimated to be fewer than 50% in low-income countries¹. Testing for drug resistance is even less common. Although new diagnostic technology like nucleic acid amplification, which identifies TB DNA directly from a sputum sample without culturing, has allowed laboratory staff to make rapid and accurate diagnoses in the developed world, the cost of such techniques remains prohibitive in most areas of the African continent. Nucleic acid amplification techniques however, require sputum sample manipulation that has low risk similar to preparing sputum smears for microscopy.

In low-income countries, especially in regions distant from city centers, the most common diagnostic method for TB remains acid-fast bacillus (AFB) smear microscopy, which is easy and inexpensive, and has the advantage of speed over culturing. However, in the laboratory, AFB smear microscopy mainly depends upon the quality of smears prepared. A good smear can be very effective in finding the TB cases and in determining the treatment outcome. Unfortunately, without proper technique, smear microscopy can give false negatives for up to half of TB patients; it also gives occasional false positives because the results do not differentiate between TB bacteria and other acid-fast bacilli. In many clinics, laboratories and hospitals, the advantages of AFB smears nevertheless outweigh the disadvantages.

During smear preparation, there is danger of generating infectious aerosols; therefore, the preparation of sputum smears in the laboratory carries a risk of infection. In a well-ventilated workspace under the care of diligent laboratory staff, the risk is small, but measures taken to prevent infection can compromise the test's reliability, as technicians are disinclined to manipulate the sample enough to obtain a good smear. In addition, inadequate ventilation in the laboratory is



a perennial problem in much of sub-Saharan Africa, where natural winds may be low with unpredictable direction and laboratory infrastructure (neither sufficient nor appropriately placed windows) can be a constraint. Laboratories performing culture and drug susceptibility testing must use biosafety cabinets (BSCs). This level of protection is not required for AFB smear microscopy or for molecular testing from sputum samples (e.g. GeneXpert) which carries very little risk of infection. In addition, the requirement for yearly maintenance of BSCs by qualified

professionals is often unaffordable and therefore out of reach to the majority of laboratories performing AFB smear microscopy. When maintenance is not performed or qualified professionals are unavailable, as is too often the case, BSCs may even increase the risk of infection by providing a false sense of security. The sub-Saharan climate is particularly taxing on BSCs, with dusty winds compromising the expensive filters.

What is needed is an affordable, easy-to-maintain ventilation system with which to perform AFB smears or molecular diagnostic tests directly from sputum specimens, ensuring both laboratory safety and diagnostic accuracy. Recognizing this urgent need, the Global Laboratory Initiative² and its partner organizations, Centers for Disease Control and Prevention (CDC), Atlanta, The Union, and Association for Public Health Laboratories (APHL) produced a document containing validated design guidelines to manufacture a Ventilated Workstation (VWS). The VWS is a partially-enclosed workstation that draws air inward and exhausts it outside the laboratory. The VWS does not use filters. A viewing window eliminates aerosol exposure from the samples and a duct system ensures that air moves continually inward and through the exhaust pipe, away from the user to remove any aerosols generated during the manipulation.

The VWS is far simpler and less expensive to produce and maintain than a BSC, and can be locally assembled. Manufacture and installation must, of course, be supervised and validated by a qualified professional, but the

system is not as vulnerable as a BSC and re-validation will only be necessary if the VWS is moved or repaired.

The VWS is extremely effective for sputum AFB smears and a valuable tool for rapid, on-site TB diagnostics (including molecular diagnostics) from sputum specimens, but should not be considered a replacement for a BSC in regards to more complex tests (e.g. manipulation of liquid and solid cultures). The VWS is not intended for procedures that generate aerosols, such as centrifugation, vortexing or manipulation of liquid cultures.

You can download a copy of the VWS Manual from the APHL website:

http://www.aphl.org/aphlprograms/global/Documents/GH_2011July_VentilatedWorkstationGuidance.pdf

Writer: Aaron Krol (Editorial Team); Contributor: Pawan Angra, PhD (CDC).

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Back cover	\$4,550	\$4,277	\$4,020	\$3,779

1. World Health Organization. Global tuberculosis control: WHO report 2011. Geneva : World Health Organization, 2010. WHO/HTM/TB/2011

2. <http://www.stoptb.org/wg/gli/>

FEATURE ARTICLE

WELCOME TO YOUR ASLM

A Unique Resource for African Laboratory Professionals

Clinical laboratory scientists are the unsung heroes of modern medicine, providing diagnostic testing which results in more targeted treatments, the development of public health policies and, ultimately, improved quality of life. With the exception of South Africa, only 8.2% of laboratories in sub-Saharan Africa are internationally accredited. In most countries, government-run laboratories conduct a majority of diagnostic testing; however, fewer than 10% of accredited labs are in the public sector¹, posing a significant public health challenge, as laboratory data informs 60-70% of clinical decisions and diagnoses².

The African Society for Laboratory Medicine (ASLM), a Pan-African professional body working with countries to advocate for the critical role and needs of laboratory medicine, recognizes the indisputably significant role laboratory scientists play, contributing to the global fight against disease and poverty.

ASLM developed as a result of recent interest in and increased funding for laboratory medicine. In February 2001, at the first World Health Organization (WHO)/CDC Global AIDS Program (GAP) network conference in Harare, Zimbabwe, attendees discussed laboratory capacity in Africa, sparking conversations that would continue for years. This initial spark, ignited in 2001, was further fuelled by three landmark agreements in 2008: the Maputo Declaration, the Lyon statement, and the Yaounde resolution, all targeting the improvement of the quality of laboratory medicine and health systems in Africa. In Kigali, Rwanda in 2009, representatives from several African countries, donor organizations, and the WHO

met to delineate the mission of what has become the African Society for Laboratory Medicine. With greater exposure of unmet needs in this field, an increased understanding of the importance of laboratory medicine, and the fiery conviction of its creators and supporters, ASLM was born.

*"...The opportunity has presented itself for the international community to act now, act collectively, but act differently to ensure sustainability of global health efforts to enhance laboratory networks and systems."*³



ASLM was officially launched in Addis Ababa, Ethiopia in March 2011 during a meeting of 300 participants from 36 countries. Speaking to the attendees via video, former US President Bill Clinton endorsed and applauded ASLM, saying, "As health professionals, you all know the challenges of improving health services, but you also know the potential that exists to serve your countries. The creation of the African Society for Laboratory Medicine is one step in realizing that potential, which we all strive for every day."

"As health professionals, you all know the challenges of improving health services, but you also know the potential that exists to serve your countries. The creation of the African Society for Laboratory Medicine is one step in realizing that potential, which we all strive for every day."

Former US President William J. Clinton

in steering the organization is COO Dr. Giorgio Roscigno, who comes to ASLM after significant accomplishments during his tenure as CEO of the Foundation for Innovative New Diagnostics (FIND), overseeing its remarkable

At the helm of this pioneering organization are three prominent and committed individuals. With extensive experience as Director General of the Ethiopian Health and Nutrition Research Institute and Ethiopian Laboratory Manager for Ethiopian-Netherlands AIDS Research Project, Dr. Tsehaynesh Messele was a clear choice for CEO of ASLM. Aiding her

1. Gershby-Damet et al. 2010. WHO-AFRO Laboratory Accreditation Process, American Journal of Clinical Pathology, 134:393-400.
2. The Lewin Group. 2009. The value of laboratory screening and diagnostic tests for prevention and health care improvement. Prepared for: American Clinical Laboratory Association and Advanced Medical Technology Association.
3. Nkengasong, J. (2010). Strengthening Laboratory Health Systems American Journal of Clinical Pathology, 134:359-360.



ASLM Board of Directors (from back left to right) Dr. Giorgio Roscigno, Dr. David Mukanga, Dr. Jane Carter, Celestin Hakiruwizera Krista Thompson, Prof. Wendy Stevens, Dr. Deborah Bix, Dr. Trevor Peter, Dr. Thomas Shinnick; (from front left to right) Dr. Jean-Bosco Ndiokubwayo, Dr. Tsehaynesh Messele, Prof. Souleymane Mboup, Dr. Fausta Mosh, Prof. Anthony Emeribe, Dr. John Nkengasong, Prof. Alash'le Abimiku, Ralph Timperi.

growth since its launch in 2003. Also bringing a range of experience and expertise is the newly-appointed Administrative Manager, Etalem Engeda, who served as Chief of Staff at the Ethiopian Health and Nutrition Research Institute and will play an essential role in building and supporting the ASLM team.

ASLM "is a critical institution that will play a norm-defining role for the continent," said Ambassador Eric Goosby, US Global AIDS Coordinator, at the launch of the Society.

ASLM is working to improve the quality of patient care through its advocacy and core activities to strengthen laboratory infrastructure. The eight "pillars" supporting the Society's activities are: Laboratory-Clinical Interface; Laboratory Network Strategy; Laboratory Accreditation; Laboratory Workforce Development; Research Capacity and Publication; Technical Assistance; Laboratory Policy Development; and Advocacy. With these precepts as guidance, ASLM promotes collaborations and is working to establish a peer-reviewed journal, providing a platform for networking, sharing best practices and experiences, and improving capacity for research.

In the first few months since its launch, ASLM has established its headquarters in Addis Ababa and, along with the central leadership is in the process of appointing country and regional ambassadors, tasked

with communicating and responding to the needs of local laboratory professionals, promoting ASLM membership and activities, and building and maintaining relationships with key institutions and businesses.

With the aim of expanding the WHO-AFRO "Laboratory Progress Towards Accreditation" program across Africa, ASLM sponsored a Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) workshop in Tanzania in September. To further increase capacity, ASLM, in collaboration with CDC, sponsored a grant and proposal-writing workshop in South Africa in October. The Society plans to mark its first year with an annual meeting late 2012 in Johannesburg, South Africa. ASLM headquarters in Addis Ababa will host the Annual Meeting of the ASLM Independent Advisory Committee 24th and 25th November. The Annual Meeting of the ASLM Research Direction Committee will follow shortly thereafter.

As Dr. John Nkengasong, the Chairman of the Board of Directors for ASLM, noted, laboratory medicine has for too long been "a field without a face and a profession without a voice." ASLM will change this by increasing the capacity and elevating the profile of laboratory scientists, giving them a unified voice and recognition for work which directly impacts patient care and public health throughout Africa.

Writer: Jessica Fried, MPH

FEATURE ARTICLE



From front left: Dr. Moses Njue and Dr. Michael A. Wanga walk with Honourable Minister, Professor Anyang Nyong'o

INCREASING LAB SUPPLY CHAIN TRANSPARENCY, KENYA TAKES BOLD STEPS

For many years, health ministries and international aid organizations have worked to strictly regulate the quality and supply of medical drugs provided in low-income countries, understanding that substandard drugs pose threats not only to individual patients, but also on a societal level by cultivating drug-resistance. However, equal attention has rarely been given to reforming the medical diagnostics industry, where many of the same dangers are regularly encountered. Low-quality diagnostics that yield false negatives may cause hospital or laboratory staff to miss early signs of an outbreak, while false positives can result in wastage of valuable medications. In addition, misdiagnoses can lead doctors to overmedicate or undermedicate patients, reducing the quality of care and creating a breeding ground for drug resistance.

The diagnostics industry suffers from many of the same faults as the more closely monitored drug industry. Manufacturers and suppliers operating in low-income countries are not always required to adhere to international standards, with governmental authorities imposing insufficient quality control. Even when adequate standards are theoretically required, ministries

of health may lack the financial or legal resources to thoroughly implement these standards; in addition, interconnections between the industry, procurement agency and quality control boards may provide incentives that result in poor quality diagnostics reaching the market. A general shortage of diagnostic equipment also creates demand for unscrupulous back-alley vendors, who peddle low-quality diagnostics with no oversight. Individual consumers and laboratories alike may be forced to choose between under-regulated companies and completely unregulated black market sources.

Diagnostics also face a unique hurdle once equipment reaches the laboratories. Because diagnostics require professional training for effective use, even high-quality equipment can be rendered ineffective if laboratory staff is unprepared to operate it. Many regions distant from city centers suffer chronic shortages of qualified professionals to train laboratory technicians in the use of new diagnostic methods and equipment. Tragically, the increasing availability of more advanced medical technology can compound this problem, as laboratories, clinics and hospitals receive the latest diagnostics but no guidance in their operation.

In Kenya, fortunately, the Ministry of Health is setting a sterling example of a systematic approach to addressing the challenges that disrupt the field of diagnostics. Under the leadership of the Hon. Minister for Medical Services, Prof. Anyang Nyongó, the Ministry has launched an aggressive campaign to implement and enforce international standards for the industry, providing careful oversight on both a national and local level. The key element of Prof. Nyongó's initiative is increasing transparency in the health care industry. As Dr. Michael Wanga, Chief of Staff of the Ministry for Medical Services, told the African Society for Laboratory Medicine in an interview, "Lack of transparency means compromising standards through bribery, dubious registration of personnel, shortcut ways of licensing institutions and lack of a score card or checklist to inspect the laboratories."

In pursuit of higher standards of transparency, Prof. Nyongó has recently taken two bold measures to reform the practice of diagnostic regulation in Kenya. First, he dissolved the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), under the suspicion of inappropriate ties to manufacturers and suppliers. He invited the Efficient Monetary Unit to investigate the Board's activities, and after six months, incorporating the Unit's recommendations, created a new Board to be the sole laboratory regulatory body in Kenya. Prof. Nyongó has extended partnerships with the new KMLTTB to several international donor agencies.

Second, Prof. Nyongó has introduced legislation that empowers the KMLTTB to more tightly regulate universities and laboratories, providing oversight on the consumer level. This legislation prohibits the employment of unregistered personnel and criminalizes the failure to provide all staff with relevant medical training, under penalty of fines and even jail time. This ensures that laboratory and university staff is qualified to correctly administer and interpret diagnostic tests.

Specific diagnostics that have been shown to be unreliable have faced immediate clampdowns. Prof. Nyongó banned the use of Widal testing kits for typhoid after studies demonstrated they were leading doctors to regularly over or under-medicate patients. "It's giving false information about patients' health status and endangering lives by giving wrong prescriptions," said the Minister in a recent press briefing.

At the same time, the Ministry of Health has aggressively redoubled its efforts in maintaining the stricter standards introduced under Prof. Nyongó. The Ministry has trained 100 new inspectors and auditors and re-inspected all organizations that train laboratory staff, closing several substandard institutions. The Ministry has also formed partnerships with local media houses and police units to alert the public to the activities of unscrupulous vendors and labs that use faulty products. Prof. Nyongó directly addressed the problem of black market suppliers and the laboratories that deal with them in his press briefing, saying, "We don't want anybody importing all kinds of equipment claiming that it's lab equipment before it is properly certified."

With these determined reforms underway, Kenya is setting a new standard for quality control of diagnostics and industry transparency. The ASLM will continue not only to support Prof. Nyongó's work in Kenya, but also to form partnerships with health ministries in other African countries to assist in implementing similar measures. A functional diagnostic service is the first step to addressing national and international health crises, and the Kenyan model is a powerful blueprint for a sound approach to quality control in this essential industry.

Writer: Aaron Krol (Editorial Team); Contributors: Michael Wanga MLT, LLB (Kenya Ministry of Medical Services), Jessica Fried, MPH and Rachel Crane (Editorial Team)



LABORATORY STANDARDS AND ACCREDITATION



The staff of PLASVIREC: (back row, left to right) Grace Amos, Nenbam Daniel, Lilian Amunum, Azeezat, Kaneng Dalyop, Fatima, Salome Ishaku, Tecla Ngo-Ndomb, Timzing Miri-Dashe, Hamdalat Adiamoh, Sophia Osawe, Suhaila, Magdalene Yager, (front row, left to right) Petronilla Jean Ozumba, Ille Mamman, Dr. Helen Omuh, Dr. Pam Datong, Othniel Luka, David Daniel Yanta.

REACHING FOR THE STARS: PLATEAU STATE HUMAN VIROLOGY RESEARCH CENTRE SHARES SLMTA EXPERIENCE

The Plateau State Human Virology Research Centre (PLASVIREC) in Jos, Nigeria, went from earning one star on the WHO stepwise SLMTA accreditation checklist to earning four stars. Once PLASVIREC achieves the maximum rating of five stars, the lab will be ready to seek and attain international accreditation. The lab and its staff have come a long way; others can learn from them.

Preparing for Accreditation

The Strengthening Laboratory Management Towards Accreditation (SLMTA) program was developed to foster laboratory quality improvement and accelerate the World Health Organization, Africa Regional Office (WHO AFRO) accreditation process. It serves as a stepping stone towards achieving international accreditation schemes such as ISO 15189.

The PLASVIREC laboratory undertook extensive preparations for the WHO AFRO stepwise assessments. To improve accreditation scores after the baseline assessment, the lab team incorporated a schedule involving every staff member. The schedule included mentorship, weekly meetings, quizzes and exercises designed by

senior laboratory staff. Quality indicator monitoring, individual contributions to standard operating procedure development and repeated internal laboratory audit using the WHO AFRO accreditation checklist contributed greatly to the quality improvement process.

The Challenges of Implementation

Implementing standards necessary for accreditation can be challenging, as they are difficult to interpret and it is often unclear how they translate to processes within the laboratory. Working towards and maintaining accreditation also appears to place an added work load on laboratory staff. However, it is important to note that the implementation of WHO AFRO standards improves the quality of testing and clinical outcome for the patient. There are additional benefits that are often misunderstood such as better organization in the laboratory, improved management of supplies, fewer equipment breakdowns, more efficient testing and an overall increase in staff pride. SLMTA makes the process of quality improvement easier as it breaks down quality improvement tasks into manageable pieces. Despite the benefits of quality improvement and the simplicity of the SLMTA approach, personnel do not adjust to changes

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overnight. Additional time, motivation and support are needed to facilitate staff adaptation. It can also be difficult to adhere to assessment schedules and integrate the SLMTA process into everyday laboratory work.

Results and Lessons Learned

From a baseline assessment score of 1 star, the PLASVIREC lab achieved a 4-star score. The lab made major improvements in all areas, including safety and documentation. The lab team learned that regular internal audits could help them address critical issues.

Dr. Pam Datong, Facility Director of PLASVIREC, notes that “years back, the lab was just one room; but now, through the collaboration of the state and international donors, a state of the art facility has been put in place that serves the city, state and the country.”

PLASVIREC has taken on new research to support studies and clinical trials. The lab provides training to students and other laboratory personnel and maintains high standards. Accreditation has placed

PLASVIREC at an international level, so it can now participate in high-level research and support clinical trials. The state has largely benefited from the superb work demonstrated by PLASVIREC.

Key Recommendations

There are two major requirements to fulfill before embarking upon the accreditation process. Commitment from senior management is the first; engagement of every laboratory staff member is the second. Laboratories should ensure that their personnel remain well-informed by establishing and maintaining training, refresher courses and mentorships for new and senior staff. By hosting interactive meetings about laboratory issues and future objectives, laboratory staff can communicate more effectively and remain on course. Conducting frequent audits using the WHO AFRO checklist can also ease the accreditation process.

*Writers: Rachel Crane and Paula Fernandes, MBA PhD (Editorial Team);
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LABORATORY STANDARDS AND ACCREDITATION

FHI 360 SUPPORTS WORLD ACCREDITATION DAY



On June 9th, the global development organization FHI 360 hosted a World Accreditation Day event in Nairobi, Kenya, in collaboration with the Kenya Medical Laboratory Technician and Technologist Board. This occasion served to increase awareness of the importance of laboratory quality and accreditation and encourage laboratory professionals, stakeholders and ministries to support laboratory accreditation and capacity-building activities.

As a contributor to this event, FHI 360 invited interested groups and stakeholders to sign a petition detailing the importance of quality laboratory service delivery. Over 300 groups from 21 countries across Africa, Asia, Europe and the U.S. signed the petition; over 75% of the signatories were African groups. People at all levels of laboratory management and

administration signed the petition, including government agencies, which contributed over 30% of all signatures. The strong and crucial participation of government officials in the petition testifies to the high level of support for quality laboratory service delivery.

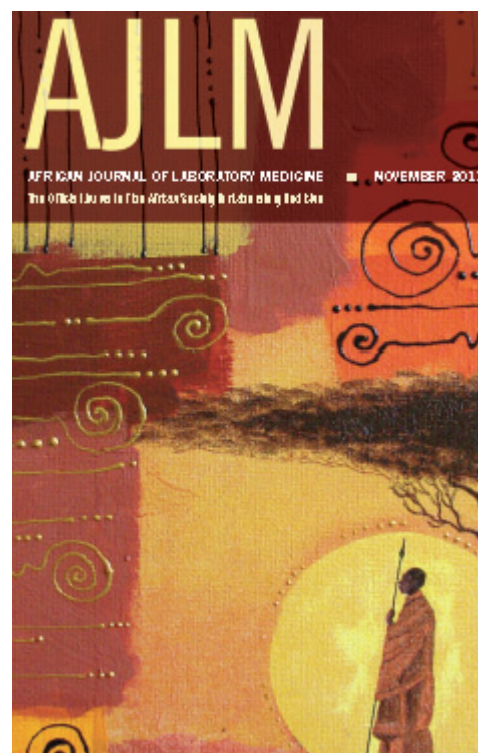
The celebrations for World Accreditation Day were attended by the Minister of Medical Services, Professor Nyongó. The event began with a procession that was flagged by the Permanent Secretary of the Ministry of Public Health and Sanitation, Ms. Mary Ngare. Over 500 people joined the procession, which marched from the AFYA House to the Kenya International Conference Centre, where celebrations and speeches continued.

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AFRICAN JOURNAL FOR LABORATORY MEDICINE REDESIGNS WEBSITE

In early November, the African Journal for Laboratory Medicine (AJLM) released its redesigned website, www.ajlmonline.org. The AJLM website is an online platform for AJLM publications as well as a publishing venue for independent writers. Its content includes original articles, reviews, editorials, opinion papers, scientific letters and case studies. The site provides free access to AJLM publications and belongs to the Directory of Open Access Journals. Articles appear in PDF, HTML, ePub and XML formats.

The AJLM website is designed to provide a convenient and accessible forum for health professionals to access the most up-to-date research, communicate with one another about trends, programs and opportunities for growth, and engage in direct peer review. Though the AJLM website is in English, users can translate articles into over 50 languages with a Google Translation plug-in. Users can also search online journal content by chronology or subject, or search for content related to a given article.



Those who register with the site will create their own profiles to which they can receive site notifications. Through these profiles, users can contact authors, submit content and forward articles to third parties, lending greater facility to the process of peer review. Publication-ready articles are added to the table of contents of the current AJLM issue as soon as they are submitted, allowing the site to remain continuously up-to-date.

*Writers: Rachel Crane and Aaron Krol (Editorial Team);
Contributor: Trudie Retief (AOSIS)*

Volunteers Needed!

Publication Mentors:

Experienced researchers, epidemiologists and statisticians to help with research methods/analysis, scientific communication skills, manuscript preparation/submission and peer review. Mentors will offer guidance for papers recommended for advisement. Subject matter expertise not necessary. Volunteer time commitment depends on mentee needs.

Writing Workshop Mentors:

Researchers, statisticians and epidemiologists with extensive publication experience. Help with daily lectures and discussions and work with a small group of participants on manuscript development. Mentors will provide guidance on research methods, analysis, laboratory or epidemiology subject matter within their expertise, manuscript preparation, scientific interpretation, and communication skills. The time commitment is a two-week workshop.

Manuscript Submission:

Laboratory Medicine-related manuscripts. Of particular interest: the role of labs in clinical care and public health; the translation of laboratory knowledge; the juncture of laboratory and medical science; lab-based epidemiology; laboratory investigations. Submissions accepted in French or English.

Peer Reviewers:

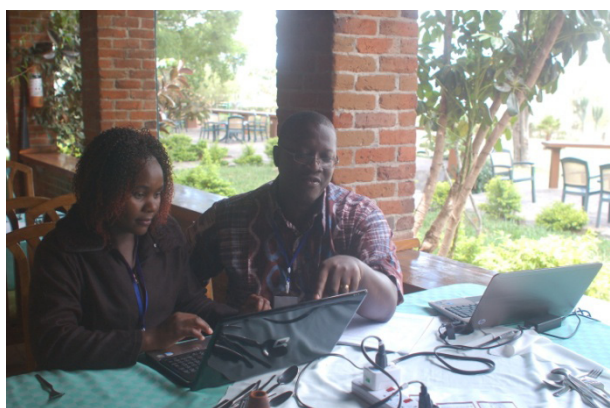
Objective reviewers with high level of expertise to evaluate the quality of manuscripts. Reviewers will offer detailed comments and suggestions, and make recommendations to accept, accept with revisions, reconsider with major revisions, or reject submissions. Reviewers will be contacted before being forwarded manuscript. A 2-3 week turnaround is expected.

For more information or to volunteer, please contact: ecl7@cdc.gov.

RESEARCH

FIRST ASLM WORKSHOP NURTURES SCIENTIFIC WRITING

On April 19, 10 participants arrived at the first ASLM manuscript-writing workshop in Naivasha, Kenya. Over the course of two weeks they undertook an intensive program to produce high-quality, peer-reviewed manuscripts for publication in the African Journal of Laboratory Medicine (AJLM). Five experts in laboratory medicine and epidemiology mentored the participants, providing guidance and structure to the journal-writing process. Participants spent the majority of the workshop working one-on-one to revise papers, while mentors presented short daily lectures on the writing and submission process. The participants also reviewed



Writing workshop student Stella Kiambi discusses with her mentor, Dr. William Ampofo, about how to present the results of her study. Photo courtesy of Dr. Elizabeth Luman.

study topics, which ranged from disease prevalence and risk factors to strengthening laboratory systems.

Anyone who has developed a manuscript for publication knows how daunting the writing process can be. A good manuscript needs to be relevant, organized, and easily understood — a feat difficult to achieve from the writer's close perspective. Peer review is an important quality control system that provides writers with feedback and the opportunity to view their work from an outsider's vantage. By creating manuscript-writing workshops, ASLM is providing African scientists with a forum for advancement and the exchange of ideas. On April 28, the final night of the workshop, attendees received their certificates of completion and held

a graduation party. Participants celebrated with a slideshow of the weeks' events and enjoyed traditional dancing and singing by the local Masai people. "The fear to write a paper is waning," said one participant. "I have learned that a paper gets much improved with co-authors and mentors."

Workshop attendees came from Kenya, Ethiopia, Ghana, Nigeria, South Africa, the U.S. and Uganda. Five of the mentees were graduates of the Field Epidemiology and Laboratory Training Program (FELTP), a two-year applied epidemiology program offered by the Centers for Disease Control and Prevention (CDC), Atlanta. Participants applied for the workshop in February-March 2011 and were selected from over 30 applicants. ASLM sponsored the workshop tuition and mentor expenses, but participants were required to obtain sponsorship or self-sponsor their travel and accommodation costs.

The ASLM is planning to host future writing workshops—both in English and in French—to foster further manuscripts and grant applications.



ASLM Writing Workshop participants proudly display their certificates of completion. Photo courtesy of Dr. Elizabeth Luman.

Please watch the ASLM website www.afslm.org for more information. Society members will also receive email updates for all ASLM events.

Writer: Rachel Crane (Editorial Team); Contributor: Elizabeth Luman, PhD (CDC)

ENABLING PROGRESS TOWARDS ACCREDITATION

What is SLIPTA?

The WHO-AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) is a laboratory training program that has emerged to confront the challenges facing public health systems in Africa today. As a multi-party initiative from the World Health Organization, Africa Regional Office (WHO AFRO), Centers for Disease Control and Prevention (CDC) Atlanta and ASLM, SLIPTA helps countries improve their medical laboratory services and maintain the latest methods of disease prevention and control. It provides successive levels of performance recognition to spur laboratories to fulfil the ISO 15189 standard, which describes the Quality Management System requisites specific to medical laboratories.

Background

In Sub-Saharan Africa, public health systems have long suffered from a lack of resources, outmoded laboratory infrastructure and limited laboratory management capacity. The region is increasingly burdened by diseases like HIV/AIDS, malaria and tuberculosis, which place enormous strain on the already overextended public health systems. In this environment, it is critical to implement an effective program to modernize laboratories on a local level and encourage all laboratories to meet international standards.

Why SLIPTA?

SLIPTA not only fosters quality improvement in individual laboratories, but seeks to integrate its goals into national plans, stressing the importance of accreditation to industry professionals. SLIPTA promotes the use of Quality Management Systems (QMS), which enable laboratories to produce more precise and timely results. Laboratories that participate in the SLIPTA program will take progressive steps to conform to the WHO-AFRO standard and will eventually be prepared to apply for accreditation on a regional, national or international level.



Recent Activities

A SLIPTA auditor training program took place on September 23, 2011, in Dar es Salaam, Tanzania. The five-day program trained 16 participants to assess medical laboratories in participating countries to ensure progress towards the achievement of accreditation and implementation of international standards. The program participants were experienced laboratory professionals from Tanzania, Kenya, Uganda, Lesotho, Rwanda, Botswana and Zimbabwe. The SLIPTA program also received backing from the World Bank-supported East African Public Health Laboratory Network, Ministries of Health in East Africa, and the Southern African Development Community Accreditation Services (SADCAS).



Participants and trainers at the SLIPTA auditor training program in September

Future Activities

In 2012, ASLM will organize additional English-speaking trainings in West Africa as well as trainings in French-speaking and Portuguese-speaking countries.

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THE LABORATORY-CLINICAL INTERFACE IN QUALITY DIAGNOSTIC SERVICES DELIVERY

Laboratory services are essential for clinical management and disease control, and are now provided at most levels of national health systems in African countries. However, despite the increasing availability of essential equipment, reagents and test kits, and refresher training of clinical and laboratory staff, the limitations of laboratory services remain a major constraint to infectious disease control and patient management in African communities, including the management of malaria, tuberculosis and HIV/AIDS. Because the laboratory provides vital information to guide clinical decision-making, effective communication between clinicians and laboratory staff is of critical importance.

Current Levels of Communication at the Interface and Barriers to Effective Communication

Communication between clinicians and laboratory staff is typically most effective at university and tertiary hospital levels, where pathologists head laboratories and advise clinicians on diagnostic requirements and test results. However, most laboratories in Africa are staffed by laboratory technicians, who are less likely to advise clinicians on the use and interpretation of test results; clinicians in turn assume the laboratory has the capacity to perform requested tests and produce useful, timely results. The perception of unequal authority between clinicians and laboratory technicians hinders open and direct communication, and mutual distrust develops when each side fails to live up to the other's expectations. Due to critically low human resource levels, staff work under conditions of heavy workloads and extreme pressure, cut corners in clinical assessment and laboratory processes, and have little time to review laboratory issues with their colleagues. Long laboratory turn-around times and unanticipated results lead

to clinically-based management, which frustrates clinicians and demotivates laboratory staff.

Influence of Technological Advances

In recent years, there have been huge technological advances in laboratory practice. Computerization and automation have minimized analytical and clerical errors, allowed greater test output and quicker access to results. Widespread "point-of-care" (POC) testing has brought the laboratory closer to clinicians and patients. Technological advances have also strengthened pre-service training and provided wide access to continuing education, through increasing accessibility to e-learning. However, these advances have been slow to reach laboratories at peripheral levels in rural areas, many of which still use outdated equipment and techniques. In these regions, mobile phone use is typically limited, and many hospitals have no intranet services; this lack of up-to-date communication technology means that recent advances have not adequately influenced communication at the laboratory-clinical interface.

How to Improve Trust and Communication

An important action that can be taken to facilitate communication between laboratory staff and clinicians is the exposure of both cadres to the tasks and challenges facing their counterparts. Pre-service training for clinicians should include practical training in laboratory methods, and laboratory staff should be provided with a detailed orientation on the clinical importance of tests to better understand clinicians' expectations. All staff need to be regularly updated about clinical and laboratory methods through reference books, manuals, guidelines and the Internet. Publications outlining laboratory principles and use are available and specifically targeted to clinicians.¹

Joint in-service training of clinicians and laboratory staff² would aid mutual understanding of diagnostic processes. Clinicians must be aware of test availability, routine and emergency turnaround times, and laboratory charges. Laboratory staff should be included in clinical decision-making, and clinicians and laboratory staff encouraged to attend health facility and professional meetings. Finally, greater oversight is essential to ensure the adherence of all medical staff to reasonable standards of knowledge and practice. Regular support supervision and performance audits should be conducted for both clinicians and laboratory staff. Participation in external quality assessment schemes (EQAS) promotes trust in the laboratory; some EQAS include clinical components.³

Laboratory accreditation also provides an important ongoing measure of laboratory quality and reliability.



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1. Jane Y. Carter and Joseph M. N. ole Kiu. Clinicians Guide to Quality Outpatient Diagnosis. A manual for eastern Africa. AMREF Publication. 2008.
2. Ministry of Health, Kenya. National Curricula for Refresher Training in Good Diagnostic Practices for Clinicians and Laboratory Staff. 2006.
3. East African Regional External Quality Assessment Scheme (EA-REQAS).

How ASLM Can Help

As an advocate for laboratory medicine in Africa, ASLM can and will play a major role in the improvement of the laboratory-clinical interface. ASLM will promote communication and trust by establishing standards of pre-service and in-service training for laboratory staff and clinicians. It will also promote the development and availability of in-service training courses, especially distance learning and e-learning. ASLM will also support relevant External Quality Control Systems, and the publication and distribution of appropriate guidelines and reference materials. By promoting supportive supervision, mentoring, auditing and accreditation, ASLM will bolster laboratory credibility and trust between clinicians and laboratory professionals.

PARTNERSHIPS ARE KEY TO THE SUCCESSFUL STRENGTHENING OF LABORATORIES IN AFRICA

Over the past few years, a growing awareness of the importance of laboratory services to a functional public health system has led many African countries, with support from Laboratory Development Partners, to intensify their efforts to strengthen laboratory services. The result has been a patchwork of initiatives targeting specific diseases, such as HIV/AIDS, tuberculosis, STIs and malaria, implemented at local, national and international levels. While these programs have achieved some important successes in their specific fields, the connection between different laboratory initiatives has not been strong, and the focus has been more on short-term results than on long-term capacity-building. The formation of the African Society for Laboratory Medicine (ASLM) is a promising step toward correcting this imbalance.

Given the increasing reliance of African countries on laboratory science, evidence-based medicine and modern public health programs, it is imperative that laboratories be empowered to provide input in making informed decisions about the national welfare. This level of influence cannot be promoted through disconnected, narrowly-focused initiatives. All parties involved in supporting laboratory services need to coordinate efforts and give priority to the laboratory workforce to address such challenges as the inadequate number of laboratory professionals, insufficient training and supervision programs, low retention of staff, and a lack of career structure and opportunities. Only through a collective and concerted strategy that places laboratory professionals at the forefront can partners overcome these obstacles and implement quality laboratory services with long-term sustainability.

The establishment of ASLM can place the focus of the African medical community squarely on this approach. By forming partnerships with Ministries of Health and Laboratory Development Partners with wide experience in the continent, such as the Institute of Human Virology Global Laboratory Program (IHV GLP), ASLM

can level existing laboratory partners on the development of a collective strategy that will address policy and technical issues, rather than working piecemeal on individual laboratories or crises. ASLM has a vital role to play in bringing together medical professionals throughout the continent and drawing on the experience of leaders with different areas of expertise in the laboratory arena already operating in Africa.

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