

INSIDE: ASLM ANNOUNCES VISION FOR YEAR 2020

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

LAB CULTURE

THE ASLM NEWSLETTER FOR
LABORATORY PROFESSIONALS
ACROSS AFRICA

February 2013, Issue 6



ASLM2012

And the Current
Diagnostic Pipeline
in Africa

Interview with Prof. Charles Mgone,
Executive Director of EDCTP: Page 13

ASLM2012 Sound Bites

The best quotations from ASLM's international conference and pre-conference symposia, 1-7 December 2012, Cape Town, South Africa.

"Since the launch of ASLM last year, we have witnessed significant achievements...in quality systems improvement, workforce development and regulation of diagnostics."

Hon. Dr. Seif Rashid, Deputy Minister for Health and Social Welfare, Tanzania

"Laboratories play a strategic role in the diagnosis and management of communicable diseases, such as HIV and TB, and non-communicable diseases that require routine testing, like diabetes."

Ms. Precious Matsoso, Director General, National Department of Health, South Africa

"We know that every lab test and every lab result is not just an inanimate, sterile test—it represents a person."

Hon. Dr. Aaron Motsoaledi, Minister of Health, South Africa

"ASLM's 2020 goals aim to strengthen diagnostics both in laboratories and at the point of care, to ensure that there are good diagnostics on the front line, better patient-clinician interaction, and that patients have confidence in the medical care being provided."

Dr. Tsehaynesh Messele, Chief Executive Officer, ASLM

"ASLM is an enormously exciting advancement for laboratory and medical science on the African continent... highlighting the pivotal role labs play in diagnostics. The success of this inaugural conference, with its considerable turnout from countries across Africa, bodes well for the future, encouraging and enabling collaboration and networking between institutions."

Prof. Barry Schoub, ASLM2012 Lifetime Achievement Award Winner and Acting Head of the Centre for Vaccines and Immunology, National Institute for Communicable Diseases, National Health Laboratory Service, South Africa

"[Healthcare services] in African countries will never be seen as complete until lab services are seen as part and parcel of health systems strengthening on the African continent."

Mr. Sagie Pillay, CEO, National Health Laboratory Service, South Africa

"I would like to deeply thank you [ASLM] for the great achievements to which you are conducting African countries...congratulations and many thanks again for giving me the opportunity to humbly contribute to this important achievement."

Dr. Vincent Habiambere, Programme on HIV/AIDS, World Health Organization

"I was truly impressed by the high quality of the presentations and the organisation of the event. The experience was truly inspirational."

Dr. Esther De Gourville, Centers for Disease Control and Prevention

"I thought the conference was excellent and I was very excited to be part of it. There was lots of energy and a wonderful sense of labs in Africa moving forward."

Prof. Lucille Blumberg, Deputy Director, National Institute for Communicable Diseases, National Health Laboratory Service, South Africa

LETTER FROM THE CEO

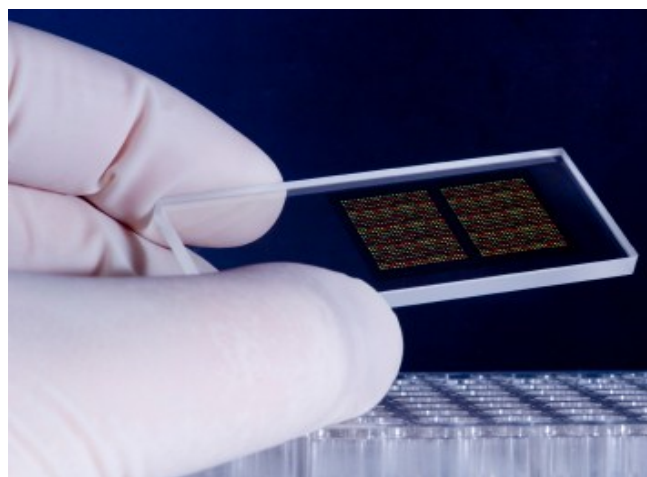
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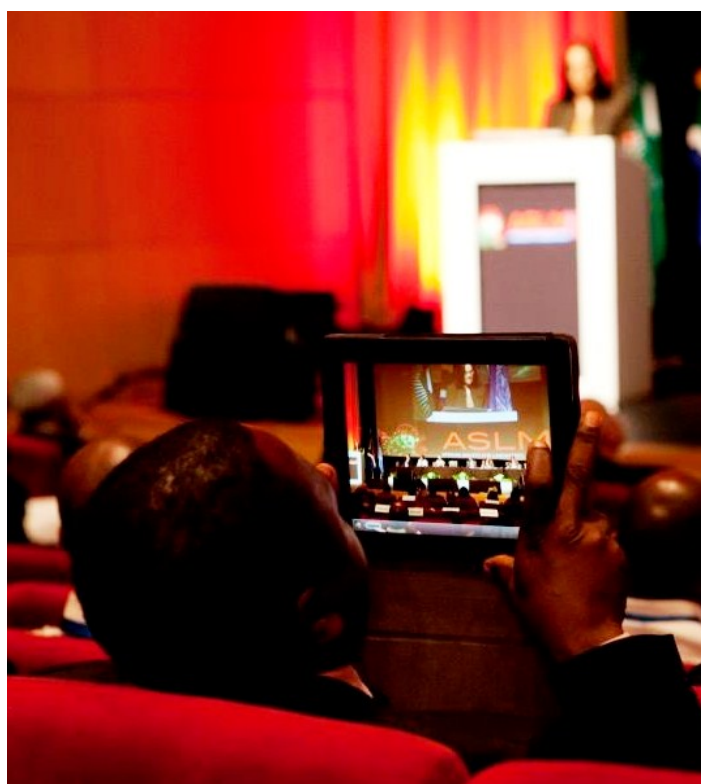
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ASLM2012 SETS THE STAGE FOR AN AMBITIOUS EIGHT-YEAR PROGRAMME



In 2012, our Society made great leaps forward, accomplishing more than I ever could have imagined. We launched our new website (aslm.org), published the first issue of the African Journal of Laboratory Medicine (ajlmonline.org), hosted and facilitated training workshops in grant- and abstract-writing, and trained professionals in laboratory auditing through SLIPTA (the Stepwise Laboratory Quality Improvement Process Towards Accreditation). We also opened the Botswana branch of ASLM, and launched our regional Ambassador Programme and Collaborating Centres Programme.

The resounding success of *ASLM2012*, Africa's first international meeting for laboratory professionals, was a fitting culmination to this eventful year for our Society. During this conference we unveiled *ASLM2020*, the Society's strategic vision for the coming eight years. *ASLM2012* provided laboratory professionals from across Africa opportunities to participate in interactive, hands-on training and workshops; and be a part of reaffirming the commitment of African governments and key stakeholders to laboratory medicine in Africa. The conference also provided opportunities for networking, collaboration, the exchange of new ideas and research, and the presentation of new diagnostic technologies. At the end of the conference, we hosted an awards ceremony at which we honoured individuals and laboratories for their excellence and commitment to the field of laboratory medicine.

This issue of *Lab Culture* covers the most important aspects of our first international conference, including the topics mentioned above. The Feature article, "The New Frontiers of Diagnostics", reviews the current diagnostic pipeline,

innovations in diagnostics, and continuing challenges to making accurate, affordable diagnostics available.

This year, ASLM strives to continue its remarkable growth, providing the medical laboratory community with ever more opportunities for collaboration, laboratory improvement and professional development. I wish you all a prosperous New Year, and look forward to our continued success. Thank you for reading.

Dr. Tsehaynesh Messele, CEO, ASLM

ASLM ANNOUNCES STRATEGIC VISION FOR 2020 AT PRESS CONFERENCE



Delegates of the ASLM Press Conference (seated, left to right: Ms. Julia Martin, Dr. Deborah Birx, Dr. Sheila Tlou, Dr. Seif Rashid, Dr. Tsehaynesh Messele, and Dr. Trevor Peter).

On 4 December 2012, at ASLM's first international conference in Cape Town, South Africa, the Society hosted a media event to discuss improved laboratory diagnostics, accreditation successes, and workforce development efforts, as well as to announce its new strategic vision, *ASLM2020*. Delegates included Ms. Julia Martin, Deputy US Global AIDS Coordinator for Programs; Dr. Deborah Birx, Director of the Center for Global Health Division of Global HIV/AIDS for the US Centers for Disease Control and Prevention; Dr. Sheila Tlou, Director, UNAIDS Regional Support Team for East/South Africa; the Hon. Dr. Seif Rashid, Deputy Minister for Health and Social Welfare, Tanzania; Dr. Tsehaynesh Messele, Chief Executive Officer of ASLM; Dr. Trevor Peter, Scientific Director for Laboratory Services at the Clinton Health Access Initiative and Chair of the ASLM Board of Directors; as well as representatives from the World Health Organization (WHO).

According to Dr. Messele, ASLM's goals for the next eight years are "to strengthen diagnostics both in laboratories and at the point of care, to ensure that there are good diagnostics on the front line, better patient-clinician interaction, and that patients have confidence in the medical care being provided."¹

ASLM2020 encompasses a component central to the Society's mission: increasing capacity and standardisation in laboratories to improve healthcare delivery in Africa. By 2020, ASLM targets include certifying at least 30,000 laboratory staff; attaining international accreditation for 250 laboratories; harmonising regulation of diagnostics throughout the region; and strengthening an African network of national public health reference laboratories in 30 countries in Africa's five economic regions.

In order to achieve these goals over the next eight years, ASLM plans to strengthen relationships with a variety of public and private stakeholders, especially local governments, which play a crucial role in developing and integrating policy changes and, in some cases, providing financial support for national laboratories.

"It's one thing looking at the technical side of healthcare — the science and its implementation — but all efforts come to nothing without an enabling environment," said Dr. Peter. "We can do all the planning and approval of curricula for the implementation of large initiatives to train people in service, but unless governments and their ministries of health are politically behind the drive, it can all be for nothing."² The initial support for *ASLM2020* by government stakeholders is a significant and promising step, demonstrating an active interest in improving diagnostics in Africa to positively impact healthcare delivery throughout the continent.

By: Jessica Fried, MPH (Editorial Team)



ASLM CEO Dr. Tsehaynesh Messele and ASLM Board Chair Dr. Trevor Peter.

¹ Rising to healthcare action | Special Reports. (2012, December 14). Mail & Guardian. Retrieved January 23, 2013, from <http://mg.co.za/article/2012-12-14-rising-to-healthcare-action>.

² Rising to healthcare action | Special Reports. (2012, December 14). Mail & Guardian. Retrieved January 23, 2013, from <http://mg.co.za/article/2012-12-14-rising-to-healthcare-action>.

ASLM COLLABORATING CENTRES CONVENE AT ASLM2012

In a closed session at *ASLM2012* on 1 December, representatives from ASLM and member institutions discussed the Society's new Collaborating Centres Programme, which aims to build and strengthen laboratory networks in Africa and standardise their services.

The Programme focuses on developing a platform for efficient laboratory networking to support disease prevention; evaluating new technologies and addressing gaps in quality practices; and coordinating with public health laboratories to adopt high-efficiency operating models to improve cost-effectiveness, quality, and capacity for diagnostic testing. These activities are implemented by ASLM's Collaborating Centres, which serve as formal mechanisms of cooperation.

The Centres, which currently include partners in Ethiopia, Kenya, Nigeria, Senegal, South Africa and Tanzania,¹ "play an important, functional role in policy and regulatory issues, and a role in defining strategies and programmes," said Dr. Trevor Peter, ASLM Board Chair and Scientific Director for Laboratory Services at the Clinton Health Access

Initiative.

Through the Collaborating Centres Programme, ASLM will expand its reach to encourage pan-African networking, knowledge-sharing, and laboratory quality improvement through collaboration.

To be eligible for the ASLM Collaborating Centres Programme, institutions must have strong infrastructure, systems, and leadership, as well as trained staff and adequate resources. Centres must also have extensive experience in training and capacity-building, and have established working relationships with institutions at regional, inter-country, and international levels. For more information about the ASLM Collaborating Centres Programme, please contact the Director of Programmes at communication@aslm.org.

By: Jessica Fried, MPH (Editorial Team) and Rachel Crane (Editorial Team)

¹ Ethiopian Health and Nutritional Research Institute, Ethiopia; Kenya Medical Research Institute / US Centers for Disease Control and Prevention, Kenya; Institute of Human Virology, Nigeria; West African Network Against AIDS, TB and Malaria, Senegal; National Health Laboratory Service, South Africa; National Public Health Laboratory, Tanzania; .

ASLM EXPANDS AMBASSADOR PROGRAMME

ASLM is pleased to announce the addition of two Ambassadors to the Society's regional Ambassador Programme. Prof. Jean Sakandé of Burkina Faso and Dr. Mohamed Ally Mohamed of Tanzania join current ASLM Ambassadors Prof. El-Hadj Belabbès (Algeria), Prof. Daniel Sess (Côte d'Ivoire), Dr. William Ampofo (Ghana), Prof. Dennis Agbonlahor (Nigeria) and Dr. Adil Ismail (Sudan). Serving as liaisons between the Society and its members in various African countries, Ambassadors strive to promote ASLM goals and programmes within the countries they serve, collaborating with health authorities and public health organisations to identify and address regional training needs.



Prof. Jean Sakandé

Prof. Sakandé joins ASLM as the Ambassador to the Republic of Burkina Faso. He is as a Professor of Biochemistry at the University of Ouagadougou and the National Director of Laboratories for the Burkina Faso Ministry of Health. He earned a PhD in Biological Sciences from the University of Ouagadougou and a Doctorate in Pharmaceutical Sciences from the University of Abidjan-Cocody. Prof. Sakandé has produced more than 30 publications and participates in several local, regional and international scientific societies.



Dr. Mohamed Ally Mohamed

Dr. Mohamed Ally Mohamed joins ASLM as the Ambassador to the United Republic of Tanzania. Mohamed serves as the Director of Health Quality Assurance for the Tanzania Ministry of Health and Social Welfare, as well as the Principal Investigator for its Stepwise Certification Towards Accreditation Project. Dr. Mohamed earned a Doctorate of Medicine from Muhimbili University, College of Health Sciences. He has published several papers and has extensive research experience, with a particular emphasis on comprehensive disease investigation and evaluation in Tanzania.

MINISTERIAL CALL FOR ACTION RAISES PROFILE OF LABORATORY SERVICES IN AFRICA

ASLM2012 was a key indicator of the swiftness with which the African public health community has turned its attention to the continent's ailing laboratory systems. Just over a year since ASLM was formally launched as a membership organisation and advocacy group for African laboratory professionals, the Society gathered hundreds of students, medical professionals, policy makers and non-governmental organisation (NGO) representatives from around the world for a wide-ranging conversation on the state of diagnostic science in Africa and the urgent need for its improvement. Only a few years ago, laboratory services were nearly invisible in the shadows of pharmaceuticals and health care delivery; now, there is a growing recognition that medical laboratory services in Africa can no longer be side-lined.

The most notable display of African governments' renewed commitments to laboratory services was a Ministerial Call for Action delivered at the conference during a Ministerial and Experts Roundtable on 5 December. The co-chairs of the Roundtable, the Hon. Dr. Aaron Motsoaledi, Minister of Health of South Africa, and the Hon. Prof. Peter Anyang' Nyong'o, Minister of Medical Services in Kenya, unveiled



Signatories of the Ministerial Call for Action.

the Call for Action after a discussion about the present situation of African laboratory services; goals for the future; and the role of ASLM, governments, and other organisations in meeting those goals.

Among the commitments outlined in the Call for Action are the creation of a harmonised set of regulations for diagnostic products and equipment across borders; the investment of resources toward training laboratory staff and maintaining their expertise; and prioritising the international accreditation of hundreds of laboratories across Africa, through the use of SLIPTA (the Stepwise Laboratory Quality Improvement Process Towards Accreditation), to ensure quality. The Call for Action also requests that, at a future session of the African Union, ASLM report on the progress of implementing these measures. The document's specificity provides an accessible model that can be replicated by ministries across the continent and outlines tangible steps that can be taken to improve laboratory systems on every level.

While the Ministerial Call for Action has no formal authority over ministries of health, the profile of its signatories¹ sends a clear message that public health officials at the highest level understand the critical importance of strengthening laboratory systems in Africa and have common governmental priorities in this mission.

The full Call for Action is available at aslm2012.org.

By: Aaron Krol (Editorial Team); Editor: Jessica Fried, MPH (Editorial Team)

¹ The signatories of the Ministerial Call for Action are: the Hon. Andre Mama Fouda, Minister of Health, Cameroon; the Hon. Prof. Antoine Amonkou Akpo, Director of the Cabinet of the Ministry of Health, Côte d'Ivoire; the Hon. Dr. Samwel Kazungu, Deputy Minister of Medical Services, Kenya; the Hon. Dr. Nazirra Abdula, Deputy Minister of Health, Mozambique; the Hon. Prof. C.O. Onyebuchi Chukwu, Minister of Health, Nigeria; the Hon. Dr. Aaron Motsoaledi, Minister of Health of South Africa; the Hon. Dr. Seif Rashid, Deputy Minister of Health and Social Welfare, Tanzania.

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ASLM2012 AWARDS CEREMONY HONOURS LABORATORIES AND CLINICIANS



ASLM2012 Award Recipients and Benefactors, 6 December 2012.

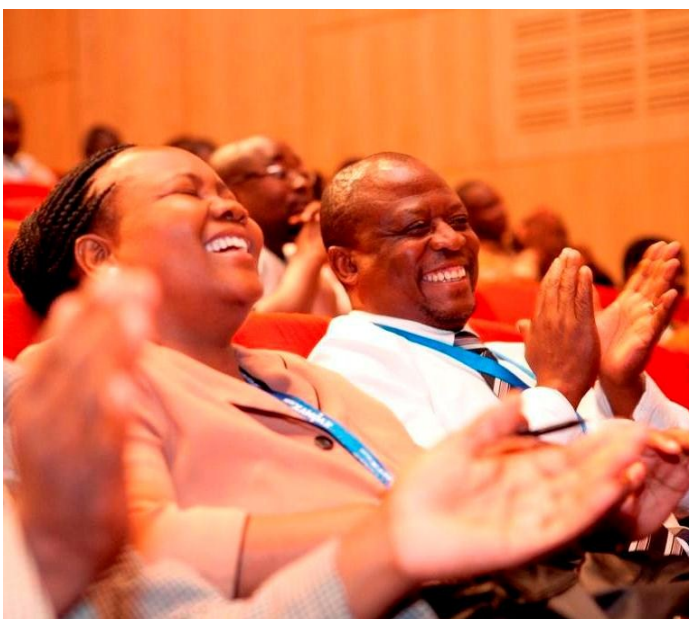
While ASLM works hard to provide practical tools to laboratory workers in Africa—building information-sharing networks, helping laboratories achieve accreditation, recommending effective laboratory management and supply chain policy—the organisation also takes seriously its role as an advocate for laboratory science as a whole. Diagnostic work has often been treated as a lesser priority in Africa, with technicians working behind the scenes and receiving too little notice from their governments, the public, or donor organisations.

At its first international conference in December 2012, ASLM chose to highlight recent progress in African laboratory science with an awards ceremony, honouring a number of laboratories and individuals across the continent that have advanced the cause of laboratory medicine. The awards included Best Practice in Laboratory Medicine, given to the Uganda National Tuberculosis Reference Laboratory for its great strides in delivering swift, efficient and accurate TB testing through training programmes, an effective quality control system, and the implementation of new diagnostic tools; Best Laboratory Champion Clinician, awarded to the Hon. Prof. C. O. Onyebuchi Chukwu of the Federal Ministry of Health in Nigeria, for his tireless striving to deliver quality laboratory services to the hardest-to-reach regions of his country; and the ASLM Lifetime Achievement Award, given to Prof. Barry David Schoub of the National Institute for Communicable Diseases in South Africa, for his pioneering work in making his country a regional hub for original research in virology and epidemiology. The awards ceremony also individually recognised 31 laboratories from Botswana, Ethiopia, Kenya, Mali, Nigeria and South Africa for receiving international accreditation between October 2010 and October 2012.

ASLM hopes to draw international attention to the field of laboratory science by publicly recognising the outstanding service of its honourees, and to encourage others to seek international accreditation for their laboratories and continually push themselves to excel in providing their communities with accurate and timely diagnostics. For their indispensable role in an efficient and effective medical system, laboratories deserve prominent attention whenever public health is considered.

The full list of awards and honourees can be found online at <http://www.aslm2012.org/images/docs/ASLM2012-awardees.pdf>.

By: Aaron Krol (Editorial Team)



ASLM2012 Award Ceremony Participants, 6 December 2012.

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“LAB DEVELOPMENT TAKES A VILLAGE” ROCHE AND US PEPFAR TO COLLABORATE ON LABORATORY STRENGTHENING IN AFRICA

On 4 December 2012, the US President's Emergency Plan for AIDS Relief (PEPFAR) and Roche Diagnostics, the world's largest biotech company, announced their new public-private partnership. During a press conference at *ASLM2012* in Cape Town, South Africa, the two groups discussed their five-year, US \$12 million collaboration to improve medical laboratory training and laboratory medicine in African countries acutely affected by HIV/AIDS. The primary intent of the partnership is to bolster the laboratory workforce in Africa and build its capacity through targeted, intensive trainings that focus on *in vitro* diagnostics.

Dr. Deborah Birx, Director of the Center for Global Health Division of Global HIV/AIDS for the US Centers for Disease Control and Prevention (CDC), and Mr. Knut Seifert, Country Manager for Roche Diagnostics South Africa, outlined the four key objectives of the new partnership: to develop competency and certification for Laboratory Human Resources for Health; to develop pre-service training curricula; to improve quality for laboratory services and provide certification courses for pathologists, molecular diagnostics and quality management; and to collaborate with ASLM to strengthen local capacity and ensure the sustainability of the partnership's programmes.¹ The CDC will implement PEPFAR's contributions.

PEPFAR has had a considerable impact on HIV/AIDS diagnoses and management in Africa, through its provision of antiretroviral therapy, support of public health campaigns, and investment in large-scale interventions.² Roche, too, has played a role in the war against HIV/AIDS in Africa; through its AmpliCare programme, it works with governments and private programmes to provide diagnostic and viral monitoring tests at the lowest possible price to low-income countries in sub-Saharan Africa.³

Both Roche and PEPFAR recognise the importance of work-



Mr. Knut Seifert (Roche Diagnostics, South Africa) and Dr. Deborah Birx (CDC, Center for Global Health, Division of Global HIV/AIDS).

ing with the public sector and encouraging community engagement. “Working from the ground up and the top down will be very effective,” said Birx. Dr. Michael Heuer, Head of Europe, Middle East and Latin America for Roche Diagnostics, added that the collaboration “demonstrates the unique impact that public-private partnerships can have on addressing health challenges in the developing world. We are confident that this partnership will make a meaningful difference in people's lives.”⁴

By: Jessica Fried, MPH (Editorial Team)

“We are confident that this partnership will make a meaningful difference in people's lives.”

¹ Media Release - Roche and the US President's Emergency Plan for AIDS Relief (PEPFAR) partner to strengthen laboratories medicine training and knowledge on the African continent. (2012, December 4). Roche. Retrieved January 23, 2013, from http://www.roche.com/media/media_releases/med-cor-2012-12-04.htm.

² Eighth Annual Report to Congress. (n.d.). The US President's Emergency Plan for AIDS Relief. Retrieved January 23, 2013, from <http://www.pepfar.gov/reports/progress/187803.htm>.

³ Roche - AmpliCare. (2012, November 14). Roche. Retrieved January 23, 2013, from http://www.roche.com/responsibility/access_to_healthcare/developing_countries/amplicare.htm.

⁴ Basel. (2012, December 6). Roche, US PEPFAR partner to strengthen lab medicine training on African continent. Pharmabiz. Retrieved January 23, 2013, from <http://pharmabiz.com/NewsDetails.aspx?aid=72504&sid=2>.

H3AFRICA ANNOUNCES GRANTS TO AFRICAN RESEARCHERS

On 8 October 2012, the inaugural grants for the Human Heredity and Health in Africa (H3Africa) initiative were announced by the two funding agencies, the US National Institutes of Health (NIH) and the Wellcome Trust, a charity based in the United Kingdom. The grants will fund projects undertaken in Africa by local researchers and will focus on hereditary factors of various diseases, their impact on African healthcare systems, and building the infrastructure for future genomic research in Africa.

As Dr. Charles Rotimi, Director of the Trans-NIH Center for Research on Genomics and Global Health, said, "H3Africa is certain to have profound and lasting effects on the landscape of genomics research in Africa...[It] will enable African researchers to study African populations, to solve African problems and to train the next generation of African scientists."¹

The H3Africa initiative was launched in June 2010 to encourage research into the role genetics and the environment play in predisposing populations to disease. With its commitment to fostering projects in African countries rather than overseas, H3Africa

will benefit Africa as well as the global scientific community. In Africa, the funds will help to build a network of researchers and strengthen laboratory infrastructure to close the gap in genomic research between resource-poor and resource-

rich countries. The research conducted in Africa will also have an international impact, as the population in Africa is the most genetically varied in the world and offers unique insights into disease and heredity.²

In 2012, nine projects were awarded grants under the H3Africa initiative. The NIH and Wellcome Trust pledged a combined US \$38 million over five years. Grants were given for research into the role human genetics plays in diseases as varied as type 2 diabetes, rheumatic heart disease, trypanosomiasis (sleeping sickness), and tuberculosis.³

¹ NIH News. "First recipients of research grants to support genomic studies in Africa announced." <http://www.genome.gov/27550933>.

² NIH News. "First recipients of research grants to support genomic studies in Africa announced." <http://www.genome.gov/27550933>.

³ IHVN H3Africa Biorepository Initiative Report. h3africa.org/docs/2012_inaugural.../Session4_04_Abimiku.pdf

⁴ NIH News. "First recipients of research grants to support genomic studies in Africa announced." <http://www.genome.gov/27550933>.

⁵ IHVN. H3Africa Biorepository Initiative Report. h3africa.org/docs/2012_inaugural.../Session4_04_Abimiku.pdf

⁶ IHVN. "Dr. Alash'le Abimiku receives grant to develop H3 Africa bio repository at IHVN." <http://ihvnigeria.org/ihvnweb/webnew/index.php/ihvn-news/42-ihvnstories/448-dr-alashle-abimiku-receives-grant-to-develop-h3-africa-bio-repository-at-ihvn.html>

Three grants were also devoted to the creation of bioinformatics networks and biorepositories, laying the necessary groundwork for expanded genomic research in Africa. All H3Africa grants enable African scientists to remain on the continent and perform research of direct relevance to African healthcare systems.

ASLM wishes to extend particular congratulations to H3Africa grant recipient Dr. Alash'le G. Abimiku, a member of the ASLM Board of Directors, Director of the Institute of Human Virology Nigeria (IHVN), and an Associate Professor at the University of Maryland School of Medicine, USA. Dr. Abimiku and her team at IHV-N aim to build three biorepositories in Abuja, Jos, and Zaria for use in future research as part of the IHVN Biorepository Initiative.⁴ The H3Africa grant provides funds for the central biorepository in Abuja.⁵

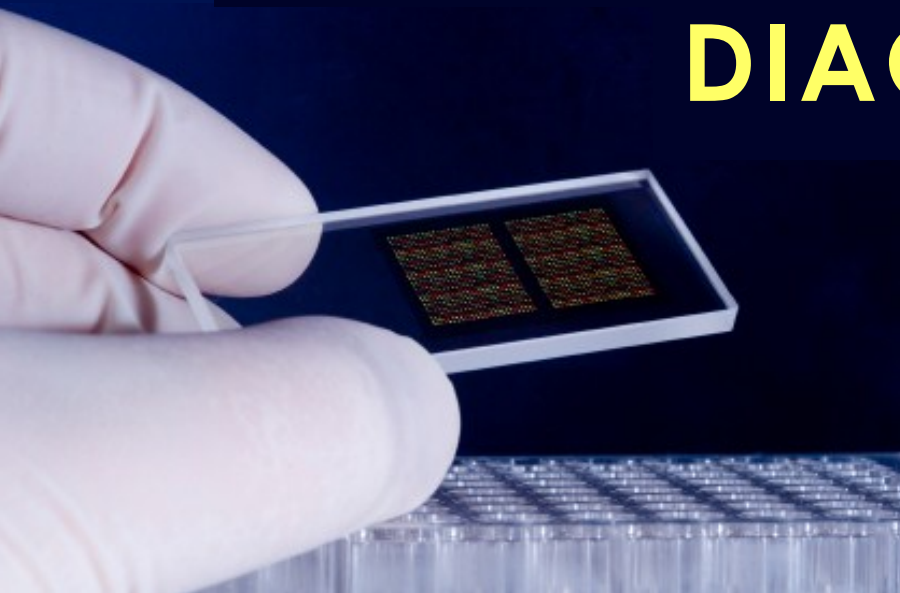
By: By: Aaron Krol (Editorial Team); Editor: Jessica Fried, MPH (Editorial Team)

"H3Africa is certain to have profound and lasting effects on the landscape of genomics research in Africa."



THE NEW FRONTIERS OF

DIAGNOSTICS



In rural Africa, it can be a daunting task to bring the patient to the laboratory.

Can modern technology bring the laboratory to the patient?

“What is the value of an accurate diagnosis—to the patient and to the healthcare system?” This question, asked by Zachary Katz of the Clinton Health Access Initiative (CHAI), is key to the diagnostics market. To patients, the value is huge. To treat patients effectively, a doctor must know what is making them sick; when diagnostics are inaccurate or slow, care is administered inappropriately or with long delays. According to Maurine Murtagh, a consultant in the field of diagnostics, “accurate, high-quality diagnostic technologies exist for the major infectious diseases affecting Africa; however, most of these technologies are only available at central laboratories and are not available at or near the point of patient care.” Fortunately, the next big advance is underway, making accurate diagnostic tests available where patients first present themselves to be diagnosed and treated.

It is important to ensure the quality of new diagnostics as they are adopted; poor-quality diagnostics do a disservice to patients, doctors, and public health. The history of testing for active pulmonary tuberculosis (TB) over the last 10 years is a good example of this. The gold-standard diagnostic for TB is culture of *M. tuberculosis* from patient sputum samples; however, this requires time and extensive

laboratory infrastructure. As a result, smear microscopy for acid-fast bacilli is often used instead. But it is not very sensitive, and even an expert technician is able to detect only highly infectious active pulmonary TB, missing as many as half¹ of true infections. Thus, when antibody-based blood tests for TB came onto the market, they were met with great excitement. However, quality testing by third parties has revealed that these tests have unacceptably high false-positive and false-negative rates. Dr. Mario Raviglione of the World Health Organization (WHO) Stop TB Department severely criticised the tests, saying that their “results are inconsistent, imprecise and put patients’ lives at risk.”² Therefore, in 2011, the WHO recommended their use be halted. Setbacks such as this lead to clinicians’ mistrust of new diagnostics. In TB, the unfortunate result has been that “less than five percent of individuals infected with HIV are screened for TB, despite the fact that TB is the leading killer of people living with the disease.”³

A similar lack of diagnostic testing tends to occur with malaria. CPT Elizabeth Wanja, director of the US Army Medical Research Unit Malaria Diagnostic Center in Kenya, writes that “lack of a robust and reliable diagnostic system...[has] led to loss of trust in the laboratory result by clinicians with increased reliance on clinical acumen for the diagnosis and treatment of malaria.”⁴ However, obser-

¹ “Blood tests for active TB not accurate or cost-effective.” Johns Hopkins School of Public Health press release, August 2011 <http://www.jhsph.edu/news/news-releases/2011/dowdy-tb-blood-tests.html>.

² “WHO warns against the use of inaccurate blood tests for active tuberculosis.” WHO press release, July 2011. http://www.who.int/mediacentre/news/releases/2011/tb_20110720/en/index.html.

³ “Access to Medicines: Laboratory Services Team.” (CHAI) <http://www.clintonhealthaccess.org/program-areas/access-to-medicines/labs>.

⁴ “Malaria Diagnostics- issues and progress toward achieving functional diagnostic system and framework.” Elizabeth Wanja, ASLM2012 abstract book.

-vation is fallible; when artemisinin therapy is prescribed based only on clinical observation of fever, misdiagnosis is more likely. In cases of misdiagnosis, the true cause of fever goes untreated, while malaria drug resistance is likely to rise.⁵ Therefore the WHO now recommends that “every suspected malaria case be confirmed by microscopy or a rapid diagnostic test (RDT) prior to treatment.”⁶

To bridge the gap between the requirement for certainty in diagnosis and widespread lack of confidence around new diagnostic tests, the WHO has issued what it calls ASSURED criteria for new diagnostics: they should be affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable.⁷ Often, these requirements are best met by RDTs, which bridge the gap between clinical and laboratory-based diagnoses. Designed to be administered in a clinical setting and analysed while a patient waits, these rapid, relatively simple tests improve a patient’s chances of receiving appropriate care by making follow-up available at the time of a patient’s first visit. Such tests, which are available at the point of patient care (POC), require less training than laboratory-based tests, which means that doctors, nurses or community health workers can administer them; they also require fewer consumables and require no cold-chain reagents, making them more practical for rural and peri-urban settings, which may lack a ready supply of consumables or a reliable cold-chain supply line. In addition, RDTs are generally inexpensive, with many lateral flow tests (in strip or cassette form) for diagnosis of malaria and HIV available at US \$1 or less per test.

However, given the limitations of current diagnostic technology, not all testing can be done using RDTs, which are generally only qualitative tests, giving a simple “yes” or “no” result for a given disease. For quantitative molecular testing, like nucleic acid amplification (NAAT) assays, RDTs are not yet a possibility, but testing can still be done at or near the POC (at a health centre, for instance) using small, easy-to-use devices that do not require full laboratory in-

The WHO has issued what it calls ASSURED criteria for new diagnostics: they should be affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable.

frastructure. For example, the Cepheid GeneXpert MTB/RIF test, a self-contained cartridge for DNA-based TB diagnosis and rifampin resistance typing (US \$10 per test in many developing and high-risk countries),⁸ has been endorsed by the WHO and rolled out successfully in a number of countries. Although not suitable for use at the lowest levels of the healthcare system, it can be somewhat decentralised and offers distinct advantages over both culture and smear microscopy. A satellite session at *ASLM2012*, hosted by South Africa’s National Health Laboratory Service, discussed the success of this tool in South Africa to date and trained attendees in its use.⁹

At present, the continuum of testing for an HIV/AIDS patient generally requires a mix of rapid POC testing for an initial diagnosis and laboratory-based testing for staging and monitoring the patient both before and after initiation onto antiretroviral therapy (ART). However, a few POC platforms are now available for CD4 testing and have already been shown to save lives by improving patient access to treatment.¹⁰ Although viral load testing and early infant diagnosis are still laboratory-based tests, several companies are developing technology to make these tests available at the POC with the introduction of some of these platforms expected in 2013. In cases where POC diagnostics are still unavailable, some strategies, such as using short message service (SMS) or cellular technology to send test results directly from central laboratories to the clinic, have been used to reduce the turnaround time for tests and improve patient access to care.

For certain other infections, reliable POC diagnostics are not yet available, although existing platforms, especially NAAT-based systems, could likely be expanded to diagnose these infections as well. For example, POC tests for dengue, rubella and measles, among others, are in late stages of development, but not yet endorsed by the WHO or other international health authorities.^{11,12} POC tests have not been developed for trypanosomiasis and other parasitic

⁵ “Role of rapid diagnostic tests in managing malaria.” Bisoffi et al PLoS Medicine. 2009.

⁶ “Scaling up diagnostic testing, treatment and surveillance for malaria.” WHO Test/treat/track brochure.

⁷ “Rapid tests for sexually transmitted infections (STIs): the way forward.” Peeling et al. Sex Transm Infect. 2006.

⁸ Negotiated prices for Xpert® MTB/RIF and FIND country list. (n.d.). FIND - Foundation for Innovative New Diagnostics. Retrieved February 13, 2013, from http://www.finddiagnostics.org/about/what_we_do/successes/find-negotiated-prices/xpert_mtb_rif.html

⁹ “GeneXpert technology workshop: Xpert MTB/RIF for the diagnosis of tuberculosis: the How and Wow of new developments.” South Africa’s National Health Laboratory Service, ASLM2012 abstract.

¹⁰ CHAI website. <http://www.clintonhealthaccess.org/program-areas/access-to-medicines/labs>.

¹¹ Clemens, J. “Evaluating diagnostics: Dengue.” Nature Reviews Microbiology. 2010.

¹² Warren et al. “A point-of-care test for measles diagnosis: detection of measles-specific IgM antibodies and viral nucleic acid.” Bulletin of the World Health Organization, Sept 2011.

diseases, nor for yellow fever and various other neglected diseases, restricting tests for these diseases to the laboratory.

Limitations to the diagnostic development pipeline may be financial as well as scientific. According to Dr. Bernhard Weigl, who helps to develop POC diagnostics at the US-based non-profit PATH, while it is easy to find sponsors for potential diagnostics for which the road to profitability is clear, others are harder to finance. He adds that, on a technical level, "It is very hard to make a consistently good (sensitive, specific, durable, etc.) diagnostic test for less than [US] \$1, which is a frequent requirement. It is much easier to make a very sensitive and specific test if the per-test cost can be higher."

This returns to the question of how diagnostics are valued. Mr. Katz points out that in different settings at different times, the answer changes. For example, HIV resistance typing is not widely used at present, but will likely become more prevalent as countries move patients to more expensive second-line drugs. As the rate of use increases and the size of the market for a possible POC resistance test grows, developing such a test will become more appealing to diagnostic manufacturers. CHAI works to support resource-limited countries in expanding access to diagnostics, which often involves price negotiations with companies based on the use of detailed market information. As Mr. Katz puts it, CHAI "[tries] to make a good business case" for companies to reduce prices, with the philosophy that improved diagnostic access benefits both sides.

Price aside, in the regulation process, health departments in many countries face the dilemma of needing to ensure the quality of diagnostics that they approve, without discouraging manufacturers with an overly long and costly in-country evaluation and registration process. While it is crucial to avoid qualifying substandard diagnostics, it is best not to block reliable ones from the market. According to Ms. Murtagh, "suppliers often have to submit new diagnostic products to evaluation in every country in which they wish to register their product," and each of these approval processes is internally complex, costing considerable time and money. At a satellite conference on regulation of POC diagnostics at *ASLM2012*, Dr. Giorgio Roscigno pointed out that an expensive, time-consuming regulatory structure results "in the cost of registration being passed on to the end customer."¹³

One promising solution to this barrier to access is greater harmonisation of regulatory structures across countries.

ASLM's Call for Action, presented at the end of *ASLM2012*, states this as a priority of the organisation, and one of its goals for 2020. By working with ministries of health and laboratory leaders across the continent, together with other organisations, ASLM can be a leader in moving countries towards regulatory harmonisation. By facilitating the evaluation of new products at accredited central laboratories, the organisation can minimise redundant tests of quality, and help make promising new diagnostics accessible to more patients in a shorter period of time and at lower cost.

According to Ms. Murtagh, ASLM and other organisations can also improve access to diagnostics by providing:

- ◇ Clear, objective, published tables or summaries/recommendations of existing and new technologies, listing the pros and cons and making known good and bad performance.
- ◇ Technical guidance on the selection and evaluation of new technologies, simplifying the methodology so that evaluations can be done more quickly
- ◇ Targeted technical assistance on the adoption of new technology, focusing on selection and strategic implementation/deployment planning, procurement planning and budgeting, setting tender specifications and coordination of partners around a national budget and implementation plan.
- ◇ A strong, coordinated effort by laboratory partners to encourage regional evaluations of new platforms to serve as guides to good quality technology.

It is an exciting time in the world of diagnostics, with new technologies poised to change the way care is provided. ASLM will be a key force in bringing accurate diagnoses to patients across the African continent.

Written by: Laurel Oldach (Editorial Team); Contributors: Zachary Katz (Director of Diagnostic Services, CHAI), Maurine Murtagh (CEO, The Murtagh Group), Bernhard Weigl (Principal Investigator in Global Health Diagnostics, PATH)

¹³ Giorgio Roscigno. "ASLM role in regulating POC diagnostics." *ASLM2012*.

SLMTA GAINS GROUND AT ASLM2012



Participants of the ASLM2012 SLMTA Symposium.

Programme Thrives Four Years Following Launch

From 2-3 December 2012, a Strengthening Laboratory Management Toward Accreditation (SLMTA) satellite symposium took place at *ASLM2012*. The workshop, hosted by representatives from the US Centers for Disease Control and Prevention (CDC), the Clinton Health Access Initiative (CHAI), and the African Field Epidemiology Network (AFENET), convened SLMTA implementers and key stakeholders to share lessons learned and exchange success stories.

SLMTA is a structured laboratory quality improvement framework that aims to teach laboratory professionals practical steps for improving work areas, inventory and procedures. SLMTA supports the World Health Organization Regional Office for Africa (WHO/AFRO) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), which helps medical laboratories in develop-

ing countries take incremental steps toward achieving international accreditation.

“SLMTA training is activity-based, task-oriented and very prescriptive,”¹ says Dr. Katy Yao of CDC, one of the founders of SLMTA. “Before SLMTA, laboratorians were trained on the theory of quality improvement, but had no guidance on the practical approach. SLMTA teaches exactly that.”²

The two-day symposium included discussions on sustainable improvements in laboratory management and on achieving a broader, long-lasting impact on laboratory quality through SLMTA. Participants discussed the strengthening of the “SLMTA network” and South-to-South collaboration.

The SLMTA symposium was a popular feature at *ASLM2012*, as attendees had the opportunity to share challenges, innovations and best practices in implementing SLMTA. The symposium emphasised the importance of

“SLMTA training is activity-based, task-oriented and very prescriptive.”

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¹ Quality labs mean better testing . (2012, December 14). Mail & Guardian. Retrieved February 21, 2013, from <http://mg.co.za/article/2012-12-14-quality-labs-mean-better-testing>.

² Quality labs mean better testing . (2012, December 14). Mail & Guardian. Retrieved February 21, 2013, from <http://mg.co.za/article/2012-12-14-quality-labs-mean-better-testing>.

AN INTERVIEW WITH PROF. CHARLES MGONE, ASLM2012 PLENARY SPEAKER AND EXECUTIVE DIRECTOR OF EDCTP

Prof. Mgone of the European and Developing Countries Clinical Trials Partnership (EDCTP) speaks about his organisation's growing scope and changes in the environment for African research.

Can you provide a brief overview of the mission and vision of EDCTP?

EDCTP seeks to accelerate the development of new or improved interventions and products for HIV, TB and malaria, with a focus on clinical trials. Drugs, vaccines, microbicides and diagnostics cannot be developed without the capacity to ensure good practice, so we support capacity building by equipping laboratories, improving infrastructure, promoting strong regulatory frameworks and helping ethical committees to become independent bodies.

We will expand our scope in 2014 under the Horizon 2020 programme of the European Union (EU), and will include neglected tropical diseases and all phases of clinical trials.

What influenced EDCTP's decision to expand its scope?

Given where EDCTP stands now with a well-established platform, it makes sense to expand our focus and add value by including other neglected diseases. We held internal and external reviews, involving stakeholders, and ultimately agreed that we have the structure we need to expand. We will, however, remain focused on HIV, TB and

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Prof. Charles Mgone. Photo reproduced with the kind permission of EDCTP.

SLMTA GAINS GROUND AT ASLM2012

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mentorship, method validation and data use in programme implementation.

Anna Murphy, a co-creator of SLMTA, says, "One of the beauties of SLMTA is that it doesn't dictate — it asks people at the front lines what they need and what they can do. Each lab defines how SLMTA will be achievable for them."

Developed in 2009 by the CDC in partnership with the American Society for Clinical Pathology and CHAI, SLMTA has been adopted in 36 countries so far, including 20 in Africa.³

SLMTA has helped laboratories improve their systems despite resource limitations, through the implementation and maintenance of quality management procedures, standard operating procedures and records. By keeping cohorts engaged in the journey towards accreditation through monitoring and the efficient use of data and guidelines, SLMTA is making continuous improvement a reality for laboratories on the African continent. This, in turn, strengthens healthcare systems, helping laboratory professionals better contribute to quality patient care.

"This particular lab programme has changed the face of the laboratory in more ways than you can ever imagine," says Christa Siyem, SLMTA symposium participant from the Bamenda Regional Hospital Laboratory in Cameroon. "It has changed the lives of many workers like myself, and most of all has provided patients with better diagnoses that have gone a long way to save lives."

SLMTA Governance Board Holds Inaugural Meeting

On 1 December 2012, the SLMTA Governance Board was formed and held its inaugural meeting at the ASLM2012 conference in Cape Town, South Africa. The board will strive to ensure that the SLMTA programme achieves broader coverage, deeper impact and sustainable gains.

ASLM2012 SLMTA oral presentations are available at aslm2012.org.

By: Rachel Crane (Editorial Team); Contributors: Katy Yao, PhD (CDC) and Anna Murphy, MLS(ASCP)CM

³ Quality labs mean better testing . (2012, December 14). Mail & Guardian. Retrieved February 21, 2013, from <http://mg.co.za/article/2012-12-14-quality-labs-mean-better-testing>.

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malaria in sub-Saharan Africa, as it is at the epicentre of the storm.

As Executive Director of EDCTP, what initiatives have you undertaken to strengthen and integrate existing national European and African health research programmes?

Our whole concept is to coordinate the European effort, to ensure that countries involved in the partnership pool their funding and collaborate on activities rather than function individually. In terms of the work done in Africa, decisions are made jointly, with the involvement of African policy makers and the health research community. We need to prioritise clinical trials through a genuine, inclusive partnership and the commitment of African governments.

In Africa, how has the capacity for conducting medical research changed over the past decade? Are there more institutional review boards and ethics review committees to define and enforce guidelines?

The capacity for medical research is improving significantly, though there is still much more that needs to be done. The capacity belongs to the people themselves, and to sustain it we must have the support and the commitment of policymakers and African governments. We develop capacity using clinical trials as our core function, and strengthen the capacity around this. This includes the training of personnel and the improvement of the infrastructure of clinical laboratories, data management services, clinical trial field sites and other required capacities. For instance, we train people who are working on clinical trials currently in progress, allowing them to learn by doing while ensuring the work is done using best practices. EDCTP has trained more than 500 people at all levels and it strives to ensure skills are being used and retained.

There is also the question of the environment for regulatory functions and ethics committees. Today, most countries are using ethical standards following accepted international guidelines. In the past, ethics committees did not function according to the highest standards and their members were not as well-trained. In recent years, we have been able to engage individuals of various backgrounds, such as civic leaders and scientists, who have been trained in ethics and who have an independent office and the infrastructure necessary to perform high-quality ethical and regulatory work. There are many more regulatory and ethics committees than there used to be, and they are more independent. At the same time, current advancements are not enough. We need further commitment from African governments for infrastructure, regulations, and personnel.

EDCTP strives to ensure that clinical trials are conducted using strict international standards. What steps can laboratories take to achieve these standards?

In order to conduct good clinical trials, laboratories must have good clinical laboratory practice, must be well-equipped, and must have staff trained in quality assurance. This is the work ASLM is doing, helping laboratories achieve such standards. Currently, EDCTP provides funding for 24 laboratories in Africa to help them achieve international standards for accreditation. By doing this, we can ensure that samples are analysed in Africa, not sent abroad.

Your plenary speech at ASLM2012 was entitled, "Preparing Africa for High Level Research and Clinical Trials". What kind of capacity is required to execute clinical trials in Africa, and what are the major barriers to initiating clinical trials on the continent?

To carry out a clinical trial, you need to have the capacity for everything—international standards, good clinical laboratory practice (GCLP), GCLP-trained personnel, harmonisation, equipment, and ethical standards that adhere to the Declaration of Helsinki. Trained staff need to know how to operate equipment, follow standard operating procedures, and develop and use systems for quality assurance and quality control.

One obstacle we have found in initiating clinical trials is that laboratories need to have international accreditation. With this certification, everything they do and produce will be accepted throughout the world. I am very happy to say that we are assisting in tackling this issue by working in collaboration with ASLM to help laboratories attain accreditation.

Were you happy with the representation of clinical research interests at ASLM2012? What could ASLM do to enhance your experience at its next international conference in 2014?

Yes, I was pleased with the quality of the event. Participants included both clinical researchers and healthcare providers, so representation was balanced.

By the next meeting, I would like ASLM to perform a self-evaluation. At that point, the Society will be a few years old and will be able to assess the outcome of its work, describe its successes, and demonstrate the impact of its work.

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"We need to prioritise clinical trials through a genuine, inclusive partnership and the commitment of African governments."

ASLM FACILITATES SLIPTA AUDITOR TRAINING IN SOUTH AFRICA



SLIPTA course trainers and participants, Kopanong Hotel and Conference Centre, South Africa (December 13, 2012).

The National Health Laboratory Service, South Africa (NHLS-SA) hosted a Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) auditor training course from 10-14 December 2012 in Johannesburg, South Africa. The course, facilitated and certified by ASLM, convened 17 prospective auditors from NHLS-SA and two from the Clinton Health Access Initiative (CHAI) with the purpose of promoting the implementation of SLIPTA in South Africa. Course trainers included representatives from ASLM, CHAI and the African Field Epidemiology Network.

During the training, participants learned to use the SLIPTA Checklist to audit laboratories for gaps in their preparation for accreditation; support laboratory personnel in developing quality improvement plans; and contribute to the improvement of diagnostic services. Participants visited three laboratories during a mock audit session and were tested on their auditing skills. All 19 participants successfully completed the training.

Supporting the SLIPTA framework through auditor trainings, NHLS-SA, ASLM, and other participating organisations provide African laboratories with the opportunity to move towards international accreditation in feasible stages, using an accreditation checklist and a five-tiered laboratory ranking system. The NHLS provides laboratory and related public health services to over 80% of South Africa's population through a national network of laboratories, making SLIPTA training and accreditation a major priority. With international accreditation, laboratories in South Africa and throughout the continent will be able to demonstrate the ability to produce reliable results, maintaining quality standards that are critical to patients, healthcare providers, researchers and policy makers.

By: Rachel Crane (Editorial Team) and Jessica Fried, MPH (Editorial Team); Contributor: Teferi Mekonen, MSc, MPH (ASLM)

INTERVIEW WITH PROF. CHARLES MGONE

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As a partnership consisting of member states from sub-Saharan Africa and the European Union (EU), from where does EDCTP get most of its funding?

Most funding comes from the European Union, from EU member states, and from African governments. The EU has provided seed funding that is then matched by European member states. Funding from African countries is contributed to specific activities by paying for utilities and services as well as staff salaries to execute the trial. EDCTP is also working with product development partnerships and pharmaceutical companies to increase and diversify funding.

What advice do you have for ASLM members interested in applying for an EDCTP grant ?

They should apply. The grants are given based on merit and we usually put calls out every four to six months. Organisations that apply must have good clinical practice and must be equipped and have well-trained staff. If individuals are applying for the first time and don't have a strong application, they can always team up with a more experienced institution.

Do you have anything else to add?

This programme was established to respond to the "big three" diseases—HIV, TB, and malaria—and will now address neglected infectious diseases as well. We aim to address health-related Millennium Development Goals and coordinate EU member activities in partnership with their sub-Saharan counterparts. We strive to ensure that the products we develop attain international standards, and strive to improve capacity holistically, at all levels.

Editors: Rachel Crane (Editorial Team) and Jessica Fried, MPH (Editorial Team)

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 advertising in *Lab Culture* or providing a photo or article contribution, please email us at newsletter@aslm.org.



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.

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