

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA



Laboratory Professionals Across Africa

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Proficiency Testing: Diagnosing Threats to Quality

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Letter from the ASLM CEO



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Letter from the ASLM CEO

Advocacy, Education and Collaboration: Bolstering Laboratory Medicine on All Fronts

Here at the ASLM headquarters, we have been busy reinforcing our commitment to increasing the visibility and prospects of African medical laboratory professionals through advocacy, training, and collaborative activities with stakeholders. In February and March, ASLM co-coordinated



training workshops for two laboratory professionals-an auditor certification training in the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), and a Strengthening Laboratory Management Toward Accreditation (SLMTA) Training of Trainers course. On 28 March, in Johannesburg, South Africa, ASLM co-hosted the first of a series of successive diagnostics industry forums with the intention of creating stronger, more cooperative relationships between the diagnostics industry and policy makers. In April, at the 16th International Congress on Infectious Diseases in Cape Town, South Africa, ASLM Board Chair Dr. Trevor Peter presented on the importance of laboratory capacity building for disease control and health systems strengthening.

In addition to our advocacy, training and partnership-building activities, we have been mobilising for the ASLM2014 international conference (ASLM2014.org), finalising abstract submissions, registering sponsors and exhibitors, and promoting ASLM2014 activities including early-bird registration and the Travel Scholarship Programme. The conference, which is expected to convene 2,000 professionals around the theme "Innovation and Integration of Laboratory and Clinical Systems", will serve as a platform to share best clinical and laboratory practices, acquire and exchange knowledge, and discuss ground-breaking novel approaches to tackling Africa's major public health challenges.

As well as preparing for the ASLM2014 conference, our team has been committed to disseminating Society news via our ASLM e-news communications, website updates, social media pages, and this newsletter. Not only does this edition of Lab Culture elaborate on the activities mentioned above, but it also provides relevant and interesting stories on laboratory strengthening through accreditation, recent developments in the fight against drug-resistant malaria, and the current activities of ASLM's partners. The Feature article, "Proficiency Testing: Diagnosing Threats to Quality," available on page 11, covers the role and importance of proficiency testing in assuring quality laboratory services. I hope you enjoy issue 10 of Lab Culture, and thank you for reading.

Dr. Tsehaynesh Messele, CEO, ASLM

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ASLM Board Chair Champions Laboratory Medicine at Infectious Diseases Conference

The prominent 16th International Congress on Infectious Diseases was held from 2-5 April 2014 in Cape Town, South Africa, where notable experts in the field came together to discuss current interventions aimed at curbing the toll of infectious diseases, neglected tropical diseases and nosocomial infections. Over 2,000 clinical and laboratory professionals and practitioners convened to examine solutions to these problems in Africa and elsewhere.

Recognising the unique role that ASLM plays in supporting quality healthcare services, Dr. Trevor Peter, Chair of the ASLM Board of Directors, participated in the conference to advocate for the strengthening of laboratory services and recognise the vital role laboratories play in infectious disease surveillance, screening and diagnosis.

Many of the topics that were discussed during the conference – including HIV, Ebola, malaria and other challenging diseases – require systems-level approaches for effective disease control. Dr. Peter addressed attendees about the importance of using a cross-cutting systems approach to improve African laboratory systems. He outlined four specific goals that ASLM aims to achieve by 2020, through collaboration with governments, organisations and the private sector.



Components of the ASLM2020 Strategic Vision.

Goal #1: Train 30,000 laboratory professionals

There is less than one laboratory professional per 10,000 people in Africa, Dr. Peter noted. Developing professional councils and upholding quality standards for training and certification can aid in recruiting and retaining qualified clinical and laboratory workforce.

¹ Sapa. (2014 April). SA has 90% of Africa's internationally accredited laboratories: expert. Accessed 17 April 2014 at: http://www.timeslive.co.za/scitech/2014/04/03/ sa-has-90-of-africa-s-internationally-accredited-laboratories-expert

Goal #2: Increase the number of accredited laboratories in Africa

This is an urgent issue: fewer than 500 African laboratories are currently accredited to international standards.¹ (View current accreditation statistics: www.aslm.org/SLIPTA) Dr. Peter advocated for widespread use of the World Health Organization, Regional Office for Africa's (WHO-AFRO) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) to foster laboratory accreditation.

Goal #3: Harmonise regulatory standards for diagnostics in Africa

Dr. Peter emphasised the importance of government leadership in diagnostics and stressed the benefits that greater commonality among standards could bring, including expedited access to quality diagnostics.

Goal #4: Establish a network of Public Health National Reference Laboratories

ASLM will help establish a laboratory network with at least 30 member countries, building on best practices and sharing challenges can benefit all members involved. Dr. Peter's presentation underscored the importance of strengthening the capacity of laboratory systems through continent-wide collaboration.

The conference also addressed important and pressing challenges that are affecting public health systems in the region. Many participants called for West African governments to make rigorous, collaborative efforts to keep the current Ebola outbreak contained. In other sessions, scientists from the International Pneumococcal Vaccine Project highlighted the progress of potential vaccines against pneumonia.² During a plenary lecture, Dr. Salim Abdool Karim, MD, PhD, director of the Centre for the AIDS Program of Research in South Africa (CAPRISA) and ASLM2014 conference plenary speaker, spoke of the tremendous successes in increasing the number of clients living with HIV due to the increased availability of antiretroviral therapy (ART). Many HIV-related deaths are partly due to initiation of ART at low CD4 count, low ART adherence, and drug resistance.³

The International Congress on Infectious Diseases is an annual conference of the International Society for Infectious Diseases, hosted in partnership with the Federation of Infectious Diseases Societies of Southern Africa.

For more information on ASLM's 2020 vision, please visit: http://www.aslm.org/2020

By: Michele Merkel, MS (Editorial Team)

² Farber T. (2014 April). Vaccine hope against pneumonia. Accessed 17 April 2014 at: http://www.iol.co.za/scitech/science/news/vaccine-hope-against-pneumonia-1.1671424#.UIEwQ1dTbAs

³ Sapa. (2014 April). Momentum against Aids at 'tipping point'. Accessed 17 April 2014 at: http://www.iol.co.za/news/south-africa/western-cape/momentum-against-aids-at-tipping-point-1.1670706#.U1Es4VdTbAs



MEMBER SPOTLIGHT

Professor Anthony Emeribe,

ASLM Board Member, recently spoke with us about his career, the landscape of laboratory services in Nigeria, and the future of ASLM.

What first interested you in a career in laboratory medicine?

I was driven by a desire to serve humanity and to save lives. Clinical laboratories play a large role in this; results obtained in the laboratory can impact public health outcomes and can guide patient management. I was struck by the notion that from within a small corner in a laboratory, one can play a critical part in bringing about positive change in public health. I also appreciate the qualities required for being an effective medical laboratory scientist; practitioners must be meticulous and exhibit thorough attention to detail when investigating illnesses.

Could you tell us a little about your professional background and current projects?

My undergraduate and postgraduate training in laboratory medicine were at the Universities of Ibadan and Calabar in Nigeria and the University of Birmingham in the UK. I am a tenured Professor of

Laboratory Haematology and Blood Transfusion Science at the University of Calabar, and I also served as the Head of Haematology at the University of Calabar and Teaching Hospital from 1996-2005. I was awarded grants from the World Health Organization and other agencies to conduct research on tropical diseases.

I have also been a consultant for various organisations. With the Global HIV/AIDS in Nigeria (GHAIN) group, I played a key role in enhancing quality improvement and standardisation of laboratory services. As consultant to the Axios Foundation, I provided technical advice and guidance for the External Quality Assessment Programme for PEPFAR (the US President's Emergency Plan for AIDS Relief) supported laboratories in Nigeria, which was funded by the US Centers for Disease Control and Prevention.

Within a small corner in a laboratory, one can play a critical part in bringing about positive change in public health.

My current role is in the public service sector, where I am the Registrar/CEO of the Medical Laboratory Science Council of Nigeria. This national regulatory authority for medical laboratory services

aims to improve laboratory systems in the country by leveraging judicial and administrative systems in Nigeria. After this national assignment, I hope to return to my primary assignment at the university where my duties include teaching, supervising, mentoring, managing workforce and resources, conducting operational research in tropical diseases, monitoring and evaluating projects and community service.



Professor Anthony Emeribe

Image reproduced with the kind permission of Prof. Emeribe and the Medical Laboratory Science Council of Nigeria.

Member News

What do you enjoy most about your work? What are some of the challenges you face in your profession?

In my current assignment, we aim to transform the entire medical laboratory service sector by working with a number of broad-ranging sectors. I enjoy the dynamic nature of this role; every day there are new people to meet and new problems to overcome. This demanding role requires flexibility and the strategic use of administrative and technical skills to make change.

In terms of challenges, there are many. However, this does not mean that the wheel of progress is not rolling forward. A uniform challenge, throughout various sectors of the economy, is insufficient funding. As you know, there is always competition from a wide variety of agencies for federal government support. We still aim to make the best use of the limited financial support from the government as we can, in order to achieve our shared vision of good health for our citizens. The second major challenge is poor compliance to regulations by various stakeholders. For example, in Nigeria, the quality of laboratory and clinical services ranges quite greatly. Also, there is a lack of harmonisation throughout the health sector regarding the import and use of in-vitro diagnostic products.

In Nigeria, how have the quality and capacity of laboratory services evolved since you began working in the medical laboratory field? How do you expect laboratory services to evolve in Africa within the next decade?

The quality and capacity of laboratory services have gradually improved over time due to advances in technologies, improvement in professional training and laboratory workforce development, and enhanced regulatory framework. There is a need to meet diagnostic requirements for emerging and re-emerging infections.

In Nigeria, and other African countries, the PEPFAR programme revitalised medical laboratory services. The programme provided the opportunity for health laboratory system strengthening through capacity building, infrastructure upgrade and increased laboratory accreditation. It also provided a uniform and standardised template for quality improvement programmes for laboratories across Africa, including QMS (quality management systems), SLMTA (Strengthening Laboratory Management Towards Accreditation) and SLIPTA (Stepwise Laboratory Quality Improvement Process Towards Accreditation). While some of these initiatives were pilot-tested in PEPFAR supported laboratories, the concepts have been used in non-PEPFAR supported laboratories. The gradual increase in participation in these initiatives has greatly improved uptake of quality assurance programmes such as site assessments, proficiency testing, internal quality control and equipment calibration services. In the next couple of years, I imagine that the quality of services across Africa will compete favourably with services offered in developed countries' laboratories.

What are your responsibilities as a member of the ASLM Board of Directors?

As a pioneer member of the board, my responsibilities include participation in the development of ASLM's Strategic Plan, which consists of expanding their goals, objectives and code of ethics. I also

help assess organisational performance and forge new partnerships with various governments and NGOs.

In your opinion, what do laboratory professionals have to gain from ASLM membership?

It is in the interest of all laboratory practitioners to identify with ASLM because it offers such a huge platform for practitioners across the continent to network, improve the quality of their functions, build capacity and generally keep well-informed with latest developments in their profession.

As we continue to exchange professional ideas and collaborate on laboratory issues, a shared passion and synergy is cultivated. Due to advancing technology, our continent is becoming smaller and collective progress can be more effortlessly shared from one part of the world to the other.ASLM offers a wonderful platform to actualise all of these goals.

ASLM will greatly assist in bringing about visibility and empowerment of medical laboratory scientists and services in Africa and beyond.

What are your hopes and expectations for African laboratory medicine and ASLM in the coming years?

It is my hope and expectation that laboratory services will grow exponentially to meet the high expectations of our people, and that through education and advocacy, our people will take greater control of their health by making positive lifestyles changes. I hope that health laboratory professionals on the continent will utilise the right framework, education, workforce, infrastructure and quality standards that are available to us. It is also my hope that people will be better informed of the need for quality laboratory services and that, in addition to the influx of knowledge exchange through medical tourism, this will lead to greater investments in the health sector.

I strongly believe that ASLM will greatly assist in bringing about visibility and empowerment of medical laboratory scientists and services in Africa and beyond.

Editors: Michele Merkel, MS (Editorial Team) and Rachel Crane (Editorial Team)

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PROFICIENCY TESTING: Diagnosing Threats to Quality



It happens all too often: a tired technician transposes two numbers, and a positive result becomes a negative. Or a piece of equipment goes too long without maintenance, and drifts out of calibration. As every scientist and laboratory technologist knows, laboratory medicine is only as valuable as it is reliable. But in the unpredictable world of real-time diagnostics, how do we ensure that our instruments and protocols remain on target?

Proficiency testing (PT) is a way to identify and prevent quality problems in the medical laboratory. PT programmes send characterised clinical specimens to participating laboratories on a regularly scheduled basis. These laboratories then process and analyse the specimens as if they were ordinary patient samples, and report their results to the organiser. By working with samples that have known values, laboratories can learn how their results compare to both the validated measurements from each sample, and to the average findings of many peer laboratories. The reports from PT programmes help participating laboratories to pinpoint areas where their testing is unreliable, and often include concrete suggestions for improvement.

PT is one element of the broader system of external quality assessment, EQA. Many authorities around the world use results from PT programmes to assess laboratory performance as part of registration and licensing, in conjunction with annual on-site reviews. EQA is also a requirement for every international accreditation process, an important consideration for laboratories seeking this high-level credential.

Proficiency testing: the basics

To learn how a PT programme is designed and administered, Lab Culture spoke to Dr. Jane Carter and Mr. Stephen Munene, who work at the African Medical and Research Foundation (AMREF), which has recently been rebranded to Amref Health Africa. Dr. Carter and Mr. Munene are based in Nairobi, Kenya, and coordinate the East African Regional External Quality Assessment Scheme (EA-REQAS) on behalf of the ministries of health. For the past six years, this PT programme has administered EQA testing targeting peripheral level laboratories in Burundi, Kenya, Tanzania, and Uganda.

Individual laboratories carry out many different types of testing, from yes-or-no diagnostics to more variable prognostics like viral load testing and qualitative examinations such as blood film morphology. Although some PT programmes focus on specific diagnostic tests, especially in high-priority disease areas like HIV and tuberculosis, many programmes cover a broader range of testing to evaluate laboratories on a more comprehensive level.⁴

To test laboratories' proficiency in an assortment of procedures, PT programmes must maintain and characterise numerous types of samples. For example, the South African National Health Laboratory Service (NHLS) offers parasitology slides for a large panel of tests,⁵ while EA-REQAS has included, among other samples, pus smears for Gram staining and peripheral blood films for blood cell morphology.⁶ These samples may be derived from individual patients (e.g. parasitology slides), pooled samples, or samples synthesised specifically for use in PT. The more similar samples are to "clinically relevant challenges", the better, so care is taken that test samples closely resemble real patient samples and should be processed in an identical manner to routine clinical samples.

At present, the pre-analytical phase of sample handling is not assessed via EQA, although many programmes include questionnaires to help recognise pre-analytical sources of error.⁷ Some programmes, such as EA-REQAS, include clinical and public health questions as part of their PT surveys. These questions are designed to underscore the importance of laboratory confirmation of diseases of public health, ensure that clinicians understand the role of laboratory testing in overall patient diagnosis, and promote collaboration between these different health cadres.

⁴ Parkin, de Mendoza, Schuurman, Jennings, Bremer, Jordan, Bertagnolio, WHO DBS Genotyping Workshop. Evaluation of in-house genotyping assay performance using dried blood spot specimens in the global World Health Organization Laboratory Network. Clinical Infectious Diseases. 2012; 54(suppl4), S273.

⁵ Poonsamy, Dini and Frean. Performance of clinical laboratories in South African parasitology proficiency testing surveys between 2004 and 2010. J Clinical Microbiology. 2012; 50(10), 3356-8.

⁶ Proceedings of the first meeting of EA-REQAS: 3-4 April 2003. Accessed at eareqas.org.

⁷ James et al J Clinical Pathology 2014.





Example of a PT process

In addition to participating laboratories, PT samples may also be sent to tertiary level validating laboratories to set target values. In the case of EA-REQAS, a collection of national-level laboratories in Kenya validate positive and negative results and, as a group, set the target values for each survey. Based on these results, the scheme coordinators create a marking key which resides in a central database for automated scoring of proficiency test results and generation of Immediate Feedback reports.

"A good PT programme is supportive rather than punitive and provides laboratories with opportunities for learning, and identifying and addressing gaps," say Dr. Carter and Mr. Munene. The EA-REQAS PT programme provides a variety of suggestions on improving performance after each round of proficiency testing. The Immediate Feedback reports received by participating laboratories include their acceptable and unacceptable results, overall performance scores, and advice on how to improve their performance.

A good PT programme is supportive rather than punitive and provides laboratories with opportunities for learning.

The programme's coordinators also post learning materials on the EA-REQAS website, and have a help desk where participants can turn for advice at any time. "In a sense, a good PT programme provides a distance learning opportunity for even the most remote laboratories," add Dr. Carter and Mr. Munene.

Feature Article

A guide for national action

As laboratories address the problems that PT has illuminated, the quality of day-to-day testing improves, with positive outcomes for patient care. Depending on the country, there may also be a requirement to follow-up on corrective actions that have been taken as a result of poor PT results. For example, South African laboratories with unacceptable results must submit corrective action reports to their regional managers.⁸

National ministries of health may also review composite reports on their laboratories' PT performance. These include consolidated data on the laboratories that participate, which may or may not identify these laboratories by name, along with potential sources of error identified by the PT programme. EA-REQAS prepares composite reports after each survey with analysis of results from all countries, which include alerts or policy change suggestions for ministries focusing on laboratory procedures that appear to be suddenly or consistently underperforming.

In the case of EA-REQAS, performance results of named laboratories are sent to the Ministry of Health in which the laboratories are based, with coded information sent to other countries' ministries; this was agreed by the regional committee that oversees the scheme. On the other hand, the National Quality Assessment Programme in Burkina Faso has maintained a nondisclosure policy, even when the Ministry of Health requested identifying information on the laboratories performing below standard, reasoning that the programme's goal is quality improvement, not punishment.⁹

Engagement in PT allows a laboratory to:

- Diagnose methodological, clerical and technical inaccuracies.
- Reduce error rates.
- Gain confidence in performance quality.
- Engage in peer-group comparison and shared learning.

In addition to monitoring existing laboratory and diagnostic networks, PT may also be used as part of a post-marketing surveillance exercise during rollout of new diagnostic tests. A very successful case was described by Dr. Peter Fonjungo and colleagues, who used EQA as a way to confirm that six new laboratories across Ethiopia, which were initiating dried blood spot polymerase chain reaction for diagnosis of HIV in infants, were as effective as the national reference hospital where this test was first made available.¹⁰

PT in isolation, without further efforts or interventions, cannot sufficiently improve a laboratory's performance. A survey of South African laboratories participating in the NHLS stool and blood parasitology PT programme from 2004 to 2010 found only a slight improvement in stool test accuracy, and no discernible change in blood test accuracy.¹¹ This reflects the fact that PT is designed to identify problems, not to fix them. On the other hand, analysis of EA-REQAS results has shown a direct correlation between numbers of times laboratories have participated and improved performance.

⁸ Poonsamy et al J Clinical Microbiology 2012

⁹ Sakande et al.Am J Clinical Pathology 2014

¹⁰ Fonjungo et al.AJLM 2013

¹¹ Poonsamy et al. JCM 2012

However, when used to diagnose a laboratory's weaknesses as if they were a set of symptoms, PT can be a powerful tool. A group of laboratories at clinical trial centres in Burkina Faso and Ghana demonstrated the potential of PT when they undertook a study to find the reasons for poor PT performance and improve their results.¹² With the assistance of an external quality control advisor, and using records kept by laboratory technologists to track equipment maintenance, receipt of new reagents, and archival printouts of instrument readings, the advisory team was able to diagnose most of the problems that each laboratory had encountered. The bulk of errors were methodological, including problems with reagents, infrequent calibration or outdated standard operating procedures (SOPs). The advisory team also observed basic clerical errors, such as mistakes in transcribing data from an instrument onto the PT result form; technical errors such as incorrect in dilution or poor water quality; and, occasionally, problems with sample stability. Having determined these sources of error, the laboratories reduced their error rate by a third, and continue to participate in PT and quality management. An important lesson from this and other PT investigations is that errors in the course of testing are usually not caused by individual misconduct or carelessness, but instead emerge from several contributing features or events.¹³

In addition to finding quality issues in individual laboratories, PT can be a key tool for identifying more widespread technical problems. Dr. Carter and Mr. Munene described a high number of clinically dangerous results in one distribution of an HIV diagnostic PT sample. Although the sample was reactive, as generated by the PT providers at EA-REQAS and confirmed by validating laboratories, many primary level laboratories reported a negative result.

"On further analysis, we found that the erroneous results appeared to be linked to one type of testing kit," say the EA-REQAS administrators. "This was a vital piece of information that may have impacted many patients, and which we reported to the relevant authorities. This is a good example of how PT schemes can play a major role in post-market surveillance of testing techniques and test kits and can impact policy change."

Challenges to proficiency testing and ways forward

PT programmes may face difficulties delivering specimens to remote laboratories. Specimens often require cold chain transport, especially when made to resemble patient samples. Damage to samples en route, or improper storage between their receipt and testing, can affect test results and may alter a laboratory's acceptable outcome rate.

To address this problem, EA-REQAS uses only materials that are stable at ambient temperature. To prevent delays in delivery, a courier system has been introduced with an additional return service so that laboratories may send paper-based results at no cost back to the EA-REQAS Coordinating Centres in Kenya, Tanzania and Uganda. Laboratories with internet access may also report results online. For laboratories that must depend on the postal service to deliver PT products, the advisory team in Burkina Faso and Ghana suggested ordering shelf-stable tests, carefully monitoring the shipping calendar, and where possible, providing postal carriers with refrigerators and detailed instructions on the importance of maintaining samples at the correct temperature.

¹² Ibrahim et al. PLoS One 2012

¹³ Kristensen et al. Biochemia Medica 2014

¹⁴ Ibrahim et al. PLoS One 2012

Feature Article



PT may present a financial burden to the testing laboratory, which may decrease compliance. Time and reagents spent testing PT samples cannot be used to test real patient samples. Some laboratories may be unable to process PT samples due to unserviceable equipment, shortage of reagents, and lack of staff. However, says Dr. Carter, "we have learnt that even in very small laboratories that may feel compromised in terms of good equipment and reagents, and staff shortages, participation in a PT programme can start the journey to better quality testing, if participants learn from the reports and from re-examining the PT samples from surveys."

PT requires the participation of not just laboratory staff, but also other members of the clinical team. Laboratory staff members enrolled in the EA-REQAS programme have reported challenges in persuading clinicians and public health workers to complete their sections of surveys, leading to delayed return of results. Dr. Carter and Mr. Munene have observed that, "once they recognise the importance and value of EQA, [administrators, clinicians and public health workers] will readily participate in answering survey questions – this requires on-going sensitisation and information."

How to implement proficiency testing

A PT plan for a participating laboratory should be relevant to the tests performed in that laboratory; offer all staff the opportunity to participate in the PT exercise and see the results; and include a plan to use the results and materials to improve performance. The PT plan should address all components of quality management systems, including staffing, infrastructure and utilities, equipment, supplies, record keeping and quality assurance.

Dr. Carter and Mr. Munene have the following advice for laboratories planning to enrol in a PT programme: "Identify an appropriate scheme for your own laboratory; fully participate in it; learn from it; ask questions; and use the results to systematically improve the quality of your work and provide continuing education for your laboratory and other health facility staff."

It is important for the integrity of PT that the samples be treated as normal patient samples. If the test does not represent average analysis of an average sample, the results will be of little practical use.¹⁵ When PT results are not acceptable, it is vital to look back, document the problems, and report on any corrective actions taken. Both staff members responsible for and familiar with the tests at issue, and health facility management and supervisors, should review PT reports to address technical and administrative issues. Dr. Carter and Mr. Munene also advise laboratories to keep the samples they are sent for re-examination after making the recommended changes.

There are many PT schemes available, and laboratories should take care in choosing a relevant and well-validated plan. This may not be a straightforward choice, as the field is crowded with international, governmental, and private options, both integrated and disease-specific. A good first step is to consult with the national ministry of health, which will likely have a complete list of appropriate programmes, including any available at national level. Among the national programmes are the Burkina Faso EQA programme; the Ethiopian Public Health Institute (http://www.ehnri.gov.et/); and the Medical Laboratory Science Council of Nigeria (mlscn.gov.ng). The US Centers for Disease Control and Prevention

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Identify an appropriate scheme for your own laboratory; fully participate in it; learn from it; ask questions; and use the results to systematically improve the quality of your work.

also provides laboratory quality assurance programmes that include PT services (http://www.cdc. gov/labstandards/index.html).

For laboratories located in EA-REQAS countries, more information about the programme can be found at www.eareqas.org. The programme is in the process of obtaining ISO 17043 accreditation and is scaling up its operations. Other internationally available PT programmes are administered by the South African NHLS, which offers a range of tests (www.nhls.ac.za/?page=proficiency_testing&id=42). The World Health Organization administers quality assessment schemes for HIV, HBsAg and HCV serology involving reference laboratories in both Francophone and Anglophone Africa, through the South African National Institute of Communicable Diseases and the Senegalese National Reference Laboratory (www.who.int/diagnostics_laboratory/quality/serology/en/).

New opportunities for quality control

Today, most laboratories that are enrolled in PT programmes are located at the national or reference level. Peripheral laboratories, which serve the majority of patient communities, have been slower to participate, in part because integrated programmes, which serve many disease areas, are not always available at the village or community level.

As a result, PT has not yet made its full impact felt at the local level, even under Ministries of Health that have embraced EQA as an essential part of a quality management system. EA-REQAS has been one organisation that has struggled to expand its influence, even after initial successes. According to Dr. Carter and Mr. Munene, "The main challenges for EA-REQAS have been in ensuring Ministry of Health ownership and buy-in; convincing peripheral laboratories of the importance and value in participating; producing materials for the region on an expanding scale; establishing an electronic database and a marking system that can cope with the large numbers of participants; and securing adequate funding for on-going operations."

Sustainability at the national level is a concern for PT programmes. Currently, the East African scheme is free of charge to government laboratories, but to promote sustainability, and to remind administrators of the cost of quality, EA-REQAS is in the process of proposing a modest charge to all laboratories, however small. Similarly, the Burkina Faso EQA scheme is seeking a line item in the national budget.

¹⁵ James et al. "External Quality Assessment: Best Practices." J Clinical Pathology 2014.



The testing authorities also incur certain costs. For individuals who want to be involved in the launch of a PT programme, Dr. Carter advises that "to be a PT provider takes a huge investment, not so much in money, but in time, effort, diplomacy, advocacy and determination." Among the resources required for starting a PT programme are a process, including SOPs, for production of test materials;

For every individual country to create comprehensive EQA programmes is a huge task, but regional cooperation can work

staff to produce these materials, manage results, and answer questions from enrolled laboratories; a database for entering and analysing results; and good survey development and report-writing skills.

A model for expansion may emphasise local improvements, while building on the infrastructure already developed by successful authorities like EA-REQAS. International cooperation can save redundant efforts, while allowing individual health authorities to exercise some control over local challenges.

"We think regional hubs for EQA are a good idea," say Dr. Carter and Mr. Munene. "For every individual country to create comprehensive EQA programmes is a huge task, but regional cooperation can work. We have made many mistakes and learnt from them, so there is no need for others to go through the same learning curve."

This kind of effort will benefit from the assistance of organisations like ASLM, which has experience reaching out to individual laboratories and fostering collaboration across national borders. Dr. Carter and Mr. Munene believe ASLM can lay the groundwork for regional cooperation, while EA-REQAS can assist with advising potential PT providers on how to set up schemes and run them. A multi-organisational structure like this will build on the talents of proven leaders in enhancing laboratory quality, bringing PT to a wider set of laboratories with the ability to address local concerns.

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Accreditation Gains Traction in Egypt



Laboratory accreditation, a means of determining the technical competence of a laboratory to perform specific activities, allows clients to identify reliable, high-quality testing services. Benefiting the laboratory as well as the client, accreditation provides a benchmark against which a laboratory can measure its competence and identify areas for improvement.

Eng. Mohamed Adel Rezk, Accreditation Director of Egyptian Accreditation Council (EGAC), says, "Many people receive different results from different medical analyses because not all labs understand the importance of concepts like traceability, proficiency testing and quality control." Accreditation encompasses these concepts, says Director Adel, and, in his words, "ultimately raises the quality of laboratory analyses and harmonises standards for testing services."

First established by a presidential decree in 1996, EGAC, housed under the Ministry of Trade and Industry, became the sole accreditation body in Egypt when the decree was modified in 2006. EGAC has since functioned as a separate independent entity, both at the administrative and technical levels, to address quality and standards for all industries in Egypt.

Medical laboratory practices have evolved within Egypt, becoming more and more standardised

As decreed by the Minister of Health and Population, EGAC is responsible for the accreditation of medical laboratories in Egypt. While increasing awareness of the benefits and importance of accreditation has been an arduous feat, there has been remarkable progress in recent years. In 2012, to encourage accreditation, the government limited medical insurance coverage to only accredited medical laboratories. As a result, today medical laboratories only receive medical insurance through the government if they are ISO 15189 accredited.

Funding from the European Union further aided in the campaign for accreditation. A twinning project called, "Building the capacity of the Egyptian Accreditation Council to deliver accreditation services" engaged the British Standards Institute (BSI) and the Swedish Board for Accreditation and

Standards and Accreditation

Conformity Assessment (Swedac) in assisting EGAC in training assessors, the number of whom has doubled as a result of overwhelming interest in accreditation by laboratories throughout the country. Nine medical laboratories have already been accredited and nine more have applied, including government and university laboratories.

"Since the founding of the EGAC, medical laboratory practices have evolved within Egypt, becoming more and more standardised", says Eng. Rezk. By lobbying to improve standards in laboratories and disabuse the public of a falsely held belief that quality healthcare comes at higher costs, EGAC has gradually succeeded in improving the state of Egypt's laboratories. Through pursuit of accreditation, laboratory professionals are learning to standardise their practices, resulting in more reliable test results. This notable outcome of accreditation has a positive impact of the sometimes-fragile relationship between laboratory staff and patients and physicians. With an increasing awareness in the importance of laboratory accreditation and its impact on healthcare, the international stamp of approval not only offers laboratories a competitive edge, but also garners them greater respect from technicians, physicians and patients.

By: Jessica Fried, MPH (Editorial Team); Contributor: Eng. Mohamed Adel Rezk (EGAC); Editor: Rachel Crane (Editorial Team)



Key Dates

Early Bird Registration Closes	31-Aug-2014
Late Breaker Abstract Submission Opens	01-Sep-2014
Late Breaker Abstract Submission Closes	26-Sep-2014
Onsite Registration Opens	29-Nov-2014
Pre-Conference Seminars Begin	29-Nov-2014
ASLM2014 Opening Ceremony	30-Nov-2014

Learn more about the conference at www.ASLM2014.org

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New Tests Provide Breakthrough In The Fight Against Drug-Resistant Malaria

The emergence and spread of drug-resistant malaria threaten international efforts to combat the disease. Despite stakeholders' commitment to malaria control and treatment, the current global health landscape has failed to yield a sustainable solution to the problem of drug resistance. Parasites resistant to artemisinin, the first-line treatment for malaria, have already emerged in the Greater Mekong subregion of Cambodia, Laos, Myanmar, Thailand and Vietnam.¹⁶ The emergence of artemisinin-resistant malaria in Africa would cause a public health catastrophe, as the continent has the highest malaria burden in the world and no effective replacement treatments.¹⁷

Monitoring the efficacy of antimalarial drugs and understanding why parasites develop resistance is essential to preventing, treating, and containing the spread of drug-resistant malaria. Two ground-breaking laboratory-based and field-based tests aim to do just that, providing a platform for tracking malaria cases in real-time and improving researchers' understanding of the mechanisms of drug resistance. We recently spoke with Dr. Didier Menard, a malaria researcher and expert on antimalarial drug resistance, about his role in the development of these novel tools. Dr. Menard is Head of the Malaria Molecular Epidemiology Unit at Institut Pasteur in Cambodia.

Please provide us some information about the problem of drug resistance. How has drug resistance evolved since you began working on malaria? What are the dangers of resistance to antimalarial drugs, and what are the ways to tackle drug resistance?

Parasites in western Cambodia are the most resistant to antimalarial drugs. Healthcare professionals first observed chloroquine-resistant malaria parasites in Cambodia in the 1960s. Until that time,

chloroquine had been very effective in the treatment of malaria. Physicians began using sulfadoxine-pyrimethamine to treat patients with malaria; however, resistance to the drug emerged in the late 1970s and early 1980s in the province of Pailin, Cambodia. Then, in the 1990s, mefloquine was introduced as a new treatment for malaria. Less than five years later, it became apparent that malaria parasites were becoming resistant to mefloquine as well. This pattern was repeated again in early 2008, when scientists discovered parasites resistant to artemisinin-based combination therapy (ACT), which is currently the best antimalarial treatment available.



Chloroquine can be used to prevent and treat some forms of malaria, but in many areas P. falciparum is resistant to chloroquine.

¹⁶ Thomas, G. (2013, April 24). WHO launches emergency response to antimalarial drug resistance. World Health Organization. Retrieved May 19, 2014, from http:// www.who.int/mediacentre/news/releases/2013/world_malaria_day_20130424/en/

¹⁷ Yong, E. (2014, March 25). How malaria defeats our drugs. BBC. Retrieved May 19, 2014, from http://www.bbc.com/future/story/20140325-malarias-next-ticking-timebomb



When it comes to malaria drug resistance, our fear is not that it will spread within Cambodia, as transmission is generally low throughout Southeast Asia. Our fear is that drug resistance will spread to Africa, where 90% of malaria deaths occur. Plasmodium falciparum, the deadliest malaria parasite species, is already very prevalent in Africa. We know from past experience how dangerous the spread of drug-resistant malaria can be. In the 1970s and 1980s, chloroquine-resistant and sulfadoxine-pyrimethamine-resistant P. falciparum spread throughout sub-Saharan Africa, causing a dramatic increase in malaria-associated morbidity and mortality. Today, there is a risk of reliving this public health emergency if we cannot contain the spread of new drug-resistant malaria parasites. Since 2008, artemisinin-resistant malaria has spread rapidly to new geographical regions, causing higher rates of treatment failure. Researchers in Cambodia, Thailand, Myanmar and Vietnam have observed cases of resistance in numerous clinical studies. They noted significant reductions in the rates of parasite elimination in patients treated with artemisinin alone or with ACT. Though clinical studies on emerging drug resistance are critical to detecting parasite resistance to artemisinin, they cannot be implemented as frequently as necessary, as they are often logistically cumbersome, expensive and difficult to deploy at a large scale. This presents a significant obstacle to efforts to contain the spread of drug resistance.

Until recently, we did not have an in vitro test to characterise resistance in the laboratory, nor a molecular marker, both of which are essential to studying parasite resistance to artemisinin. This gap has hindered efforts to better understand the mechanisms of drug resistance. There is an urgent need to better understand how malaria parasites develop resistance, so that we may better detect and treat malaria.

In collaboration with the National Malaria Centre of Cambodia and the US National Institutes of Health, Institut Pasteur in Cambodia recently developed two tests to discern whether malaria parasites in a patient will be resistant or susceptible to artemisinin within a period of three days. When did you start to develop these tests? How do they work?

As I mentioned before, one obstacle to the study of artemisinin resistance has been the lack of in vitro tests to detect resistant strains. So, in 2012, to address this problem, we developed a novel in vitro test that consists of mimicking physiological conditions to which parasites are subjected in humans. The in vitro ring-stage survival assay (RSA), whose name refers to the ring-shaped young malaria parasites, allows us to define the precise age of the most artemisinin-resistant parasites and associate clinical data with this phenotype. Instead of exposing the parasites to sub-therapeutic doses for 48 hours, we exposed the parasites to a dose identical to that observed in humans during a treatment with artemisinin derivatives. This test allowed us to better identify the precise stage of parasite development where artemisinin. This work not only demonstrates that this approach is relevant for an in vitro phenotype, but also proves that resistance is stage-dependent and caused by the arrested development of the exposed parasites.

In addition to the in vivo test, we have also developed an adaptable and easy-to-implement ex vivo test that can be applied for large-scale monitoring purposes. In an ex vivo test, a single blood sample is taken from a patient suffering from malaria. The parasites in the blood are then cultured in the presence of a strong antimalarial dose for a few hours. The degree of resistance is evaluated

Research

after three days based on the number of parasites that have survived exposure to treatment. The higher the parasite number is, the greater the drug resistance. Using blood samples from patients in different regions of Cambodia, where parasite response to artemisinin differs greatly, we were able to confirm that parasites from slow-clearing infections survive artemisinin much better than those from fast-clearing infections. By using both the *in vivo* and the *ex vivo* assays, we are able to track the emergence and spread of antimalarial drug resistance.



An Anopheles gambiae mosquito, a known vector for P. falciparum and other malaria parasites. Image credit: CDC/WHO.¹⁸

Finally, since 2013 we have been looking

at the molecular signatures associated with parasite resistance to artemisinin. To do so, we have compared the exome (the genome coding for parasite proteins) of an African strain that was exposed to repeated, increasing doses of artemisinin over the course of five years, to a twin strain grown under the same conditions but without exposure to the drug. The strain exposed to artemisinin developed resistance. After a detailed analysis of the divergence between the genomes of the two strains, eight mutations in seven genes were identified. Genome analysis of three intermediate strains and 49 strains isolated in Cambodia has allowed us to determine the chronology of the appearance of mutations and define a strong association between certain gene mutations and in vitro susceptibility characterised by the RSA. Moreover, we were able to confirm that this molecular marker was indeed a major determinant involved in parasite resistance to artemisinin.

Prior to the development of these tests, what methods were used to determine whether a patient had artemisinin-resistant malaria? How could these new tests improve existing efforts to fight malaria in countries where the disease is endemic?

In the past, clinical studies have screened hundreds of patients for malaria resistance by measuring parasite clearance rates following the onset of treatment. The new in vitro test and molecular marker make it easier to accurately detect parasites



Blood smear revealing the presence of P. falciparum.



- Globally detect artemisinin resistance and seek other molecular signatures associated with artemisinin resistance; and
- Evaluate the effectiveness of new drugs in treating drug-resistant malaria parasites.

We could improve upon existing malaria control efforts by implementing large-scale molecular surveillance based on the detection of parasite strain mutations, using simple and inexpensive techniques including capillary blood samples on filter paper for DNA extraction and polymerase chain reaction sequencing for detection of gene mutations. Implementing such a surveillance scheme would allow us to understand the real-time distribution of drug resistance and organise an appropriate anti-malarial response. Such surveillance activities would prepare us to avoid a repeat of the public health catastrophe that occurred in the 1980s, when chloroquine-resistant malaria swept Africa. Furthermore, employing these new tests will allow us to better understand the evolution of resistance and better inform treatment policies.

Before joining Institut Pasteur in Cambodia, Dr. Menard worked on a variety of biomedical projects in Madagascar, New Caledonia, the Central African Republic and France, covering disease topics including tuberculosis, enteroviruses and parasites. Dr. Menard's current role involves conducting studies to improve control strategies for malaria, particularly in regards to the malaria parasite species P. vivax and P. falciparum.

For more information on the novel assays discussed in this interview, please read the Lancet Infectious Diseases paper on the topic, co-authored by Dr. Menard: http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(13)70252-4/fulltext.

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

Research

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 contributing a photo or an article, please email us at newsletter@aslm.org.



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ASLM Promotes Laboratory Capacity Building Through Collaborative Trainings

ASLM, in collaboration with its partners, continues to demonstrate its commitment to advancing the professional development of laboratory professionals and promoting capacity building within the workforce. As such, ASLM has recently participated in laboratory training activities with the goal of instructing and certifying laboratory professionals who can then, in turn, serve as trainers and laboratory auditors.

In February 2014, 30 laboratory professionals from five East African countries received training to obtain Strengthening Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) auditor certification, during a five-day workshop held in Entebbe, Uganda. The preparation of new SLIPTA auditors will help ASLM and the East Africa Public Health Laboratory Networking Project (EAPHLNP) conduct more SLIPTA audits in the region in 2014. Such audits are essential to the advancement of high-quality diagnostic services. The SLIPTA workshop was conducted by ASLM and the World Bank-supported EAPHLNP with coordination aided by the inter-governmental health organisation the East, Central and Southern African Health Community (ECSA-HA).

Additionally, a two-week Strengthening Laboratory Management Trainings Towards Accreditation (SLMTA) Training of Trainers (TOT) workshop took place in March 2014 in Johannesburg, South Africa. In attendance were 21 laboratory professionals from 11 countries in Africa, Southeast Asia and the Caribbean. The workshop was supported by the US Centers of Disease Control and Prevention (CDC) through the African Centre for Integrated Laboratory Training (ACILT).

Please visit www.aslm.org for more information about ASLM's role in SLIPTA and SLMTA.

By: Michele Merkel, MS (Editorial Team)

Advancing Laboratory Practices Through An Online Professional Community

The Global Health Network (theglobalhealthnetwork.org) is a successful and growing online science park that hosts over 20 online communities for different health research groups and crosscutting health topics. It is built for the health research community by researchers and public health practitioners themselves. It is also well known as a source of high-quality, peer-reviewed information and educational tools. The aim of The Global Health Network is to improve research and health outcomes through knowledge-sharing.

In recognition of the need for a highly interactive resource for laboratories that would offer a range of tools as well as a professional network, the Global Health Network created Global Health Laboratories (globalhealthlaboratories.tghn.org). Global Health Laboratories provides a space on the Global Health Network to support laboratory research in resource-constrained settings by making available a forum for knowledge exchange and skill-sharing between laboratories, laboratory professionals and researchers from around the world.

Training and Education

Global Health Laboratories is an openaccess, online professional community where laboratory staff can discuss issues, seek help, share resources and methods, give and receive advice, and access quality peer-reviewed information about any aspect of laboratory practice. By enhancing networking and exchange among laboratories in a range of settings and disease areas, Global Health Laboratories seeks to enable equitable access to quality information resources and to promote good laboratory practice.



The range of resources and facilities that Global Health Laboratories offers include:

- Laboratory protocols, standard operating procedures, templates and guidelines.
- Expert input via Question and Answer topical discussions.
- Online training materials including e-seminars and high-quality certified e-learning courses.
- A professional network for laboratory managers, researchers and staff to share experiences and seek peer support and guidance.
- Guidance articles about various aspects of laboratory practice and relevant open access articles from respected journals.

Global Health Laboratories also provides links to partner external websites with similar aims and ethos, such as ASLM and the Global Laboratory Directory (GLaDMap). The latter is a laboratory and laboratory network registry created by the World Health Organization to map worldwide laboratory capabilities that could be searched in situations such as disease outbreaks. GLaDMap is now hosted within Global Health Laboratories and is under ongoing development.

Registering on Global Health Laboratories is free and open to anyone working in global health. With time, more facilities and tools will be added as determined by the needs and interests of its users. As more members join and contribute, the site will grow and evolve, becoming more useful and valuable.

Enhancing networks amongst laboratories globally, and providing forums for discussions and the coordination of effort, could create a plethora of new opportunities, such as enabling the mapping of particular health issues like antimicrobial resistance. The potential for coordinated laboratory interaction is vast, and yet currently untapped. Digital technology, though being greatly utilised by the commercial world, has not been fully harnessed in the public health sphere. The Global Health Laboratories site intends to foster virtual collaboration for the advancement of laboratory practices.

By: Karla Lam, DPhil (Global Health Network)

Training and Education

Global Health Trials Offers Abundance of Free e-Learning Resources

To attend trainings and continuing education courses, hospital and laboratory staff working outside of urban areas may need to travel long distances to reach the nearest referral or teaching hospital. Obstacles such as limited budgets, insufficient human resources, unsafe road conditions and political strife can restrict the capacity-building opportunities of medical laboratory and other healthcare professionals. Global Health Trials (globalhealthtrials.org) is tackling this problem and, consequently, improving the quality of clinical research around the world with its free, online e-Learning Centre.

Launched in 2009, Global Health Trials is a platform for researchers to share and exchange expertise. The programme provides an online platform with an extensive library of free resources for clinical study investigators and staff, made possible through contributions from researchers around the world. With limited resources available to clinical research staff in low-income countries, Global Health Trials' e-Learning Centre of open-access courses, seminars, documents and links to other relevant websites has been revolutionary for the global health research community. Information on the Global Health Trials website is provided in a universally accessible and practical format and is neither disease nor region



Screenshot of the Global Health Trials e-Learning Centre. Image reproduced with the kind permission of Global Health Trials.

specific. The site addresses all aspects of clinical studies, including designing, planning, implementing and reporting.

The Global Health Trials online e-Learning Centre offers e-Learning Courses, e-Seminars, a resource library and access to other e-learning links. The e-Learning Courses are one of the most popular areas of Global Health Trials and provide relevant and applicable training in all aspects of developing and conducting high-quality clinical studies.¹⁹ To ensure accuracy in a frequently evolving field,

¹⁹ e-Learning Centre. (n.d.). Global Health Trials. Retrieved May 1, 2014, from https://globalhealthtrials.tghn.org/elearning

materials for the courses are peer-reviewed and updated regularly. Participants receive a certificate of completion for a course once they achieve a minimum score of 80% in the final course quiz sections.²⁰ The e-Learning Centre provides two types of courses: Short Courses consisting of a single module designed to take 30 to 45 minutes to complete, and Modular Courses consisting of several linked modules covering a range of aspects of a particular subject. There are currently 14 Short Courses on topics including study protocol development, reporting adverse events, and basic malaria microscopy. Some courses have been translated into as many as six languages.

Global Health Trials is responsive to researchers' requests and is always looking for input from experts in the field. As a result, new courses are added regularly to the site; upcoming courses include "Essential Elements of Ethics in Protocol Writing," "Good Clinical Laboratory Practice," and "Laboratory Quality Management Systems".

Additionally, several e-Seminars are available for free on the website. These lectures by senior scientists and researchers in Kenya, South Africa, Thailand and the UK, cover subjects such as ethics, laboratory set-up in resource-limited settings, working with government hospitals, and human immunity to malaria.²¹

Supplementing these dynamic courses and seminars is Global Health Trials' extensive Resource Library of documents, guidelines, templates and tools, aiding researchers in protocol development, reporting adverse events, understanding research ethics and data management.²² Visitors can also find many links to other organisations' websites with e-learning resources.²³



Global Health Trials is presented as a collaborative project, encouraging all visitors to provide feedback and to share new resources with the broader community. It fosters a climate of sharing, consequently improving clinical research and promoting capacity building in areas where access to information and training has been limited or unavailable.

By: Jessica Fried, MPH (Editorial Team); Contributors: Tamzin Furtado (Global Health Trials) and Liam Boggs (Global Health Trials)

²⁰ e-Learning Short Courses. (n.d.). Global Health Trials. Retrieved May 1, 2014, from https://globalhealthtrials.tghn.org/elearning/other-resources/

- ²¹ e-Seminars. (n.d.). Global Health Trials. Retrieved May 1, 2014, from https://globalhealthtrials.tghn.org/elearning/e-seminars-new/
- ²² e-Learning Resource Library. (n.d.). Global Health Trials. Retrieved May 1, 2014, from https://globalhealthtrials.tghn.org/elearning/e-learning-resources/
- 23 Other e-Learning Links. (n.d.). Global Health Trials. Retrieved May 1, 2014, from https://globalhealthtrials.tghn.org/elearning/other-e-learning-resources/



Kenya Medical Research Institute, an ASLM Collaborating Centre, Demonstrates Excellence in Research and Laboratory Strengthening



A laboratory professional working in the KEMRI HIV laboratory. Image reproduced with the kind permission of Dr. Clement Zeh and KEMRI.

In December 2012, ASLM launched its new Collaborating Centres programme, which aims to strengthen laboratory networks and standardise diagnostic services across Africa. The programme provides a platform for Collaborating Centres to foster laboratory linkages, evaluate new technologies, and adopt high-efficiency operating models to improve diagnostic testing. ASLM recently spoke with Dr. Clement Zeh of the Kenya Medical Research Institute (KEMRI), one of ASLM's Collaborating Centres, about the organisation's history and activities. Dr. Zeh serves as Acting Branch Chief for the KEMRI HIV Research branch, as Director of KEMRI's HIV research laboratory in Kisumu, and as principal investigator for the KEMRI/ASLM collaboration.

Background

KEMRI is an organisation of the Ministry of Health of Kenya, and the national body responsible for carrying out health research in Kenya. Established in 1979 with a mandate to conduct research on the major public health challenges of the country, KEMRI has collaborated on research with international institutions (US Centers for Disease Control and Prevention [CDC], the Oxford/ Wellcome Trust of the UK, the Japan International Cooperation Agency [JICA], the Walter Reed Project of the US Military) as well as local institutions and universities.

KEMRI comprises 10 research centres, including the Centre for Global Health Research (CGHR)

in Kisumu, western Kenya. Since its establishment in 1984, CGHR has conducted ground-breaking

research with a focus on infectious diseases of public health importance.

Activities and Expertise

Perspectives

"Initially, the focal point of KEMRI's research activities was malaria," says Dr. Zeh. However, KEMRI's activities have evolved to include research on HIV, tuberculosis, emerging and neglected diseases such as schistosomiasis and helminthiasis, and the role of demographic surveillance systems to assess health needs. Other key research areas include drug efficacy, emerging drug and vector resistance, epidemiology, immunology, molecular and vector biology, environmental and human health, HIV co-infection, and reproductive health. KEMRI has attained International Organization of Standards (ISO) 9001:2008 accreditation in recognition of its high-quality research portfolio. In addition, both the HIV and TB laboratories within CGHR have ISO 15189 accreditation. The HIV research laboratory is one of the major laboratories under the KEMRI and CDC collaboration.

KEMRI's HIV research laboratory has also recently taken a role in implementing a document and quality management system, paperless documentation developed by SoftTech Health, and a Six Sigma metrics analysis approach. Six Sigma is a process quality metric that provides a framework for assessing variability in analytical processes and fostering greater uniformity in the application of statistical methods, which enables the HIV research laboratory to improve its practices.

KEMRI and ASLM

KEMRI became an ASLM Collaborating Centre in 2013, through its HIV research laboratory, following performance evaluations of the laboratory. The evaluations consisted of assessments of the Centre's reputation and work in research, policy making, training, and technology assessment and implementation, amongst other areas.

As a Collaborating Centre, the KEMRI HIV research laboratory has committed to the following activities:

- Strengthening of African laboratory workforce development as part of the commitment to achieve Unite Nations Millennium Development Goals for health through targeted training programmes.
- Participating in regional regulatory harmonisation of diagnostics. Through the evaluation of new technologies, KEMRI produces high-quality data for national and regional regulatory review. Furthermore, KEMRI facilitates the development of regulatory policy, protocols, standard operating procedures and guidance documents.
- Supporting laboratory accreditation initiatives at the regional and national levels to transform the quality of diagnostic services through the expansion and implementation of the World Health Organization Regional Office for Africa (WHO-AFRO) Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA).
- Promoting skills transfer and capacity-building among laboratory scientists. KEMRI participates in South-South collaboration, hosting representatives from laboratories in



various African countries and sending key staff to on-site trainings on laboratory techniques and quality strengthening.

• Fostering the establishment of a network of national public health reference laboratories by playing a key role in training, quality assurance and laboratory capacity-building in the healthcare system.

Future direction of collaboration

Going forward, Dr. Zeh hopes that KEMRI and ASLM further expand their collaboration to maximise the impact of medical laboratory and health improvement efforts across the continent. By pooling resources and exchanging expertise, says Dr. Zeh, the Collaborating Centres programme can expand activities to include joint trainings and publications, in addition to other capacity-building activities in laboratory medicine.

To learn more about ASLM's network of Collaborating Centres: www.aslm.org/collabcentres.

By: Clement Zeh, MPH, PhD (KEMRI/CDC) and Rachel Crane (Editorial Team); Editor: Michele Merkel, MS (Editorial Team)

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