

LAB CULTURE

The ASLM Magazine
February 2015, Issue 13

Highlights from ASLM2014: Expanding Access, Developing Guidance and Increasing Investment for Diagnostics

In This Issue:

- Pioneering New Diagnostics: Addressing Challenges and Implications for Point-Of-Care Testing in African Settings
- Young Professionals Thrive at ASLM2014
- Using Community Engagement to Contain Ebola

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Success of ASLM2014 Leads ASLM into a Promising New Year

This issue of Lab Culture, in addition to providing updates on ASLM programmes, trainings and other activities, highlights the Society's extremely successful second international conference, ASLM2014, themed "Innovation and Integration of Laboratory and Clinical Services: Shaping the Future of HIV, TB, Malaria, Flu, Neglected Tropical Diseases and Emerging Pathogens in Africa".



During ASLM2014, participants and stakeholders reinforced the collaborative relationships formed at the ASLM2012 conference, and discussed short- and long-term goals and action steps for the expansion of diagnostics access, quality, regulation and investment across Africa.

This issue contains a special Ebola Section, which reports on topics including the vital, but often overlooked, function of laboratories in outbreak response; and the role of community engagement in containing Ebola.

Strengthening laboratory medicine across Africa remains ASLM's key objective. To improve advocacy for high-quality diagnostic testing at all tiers of the laboratory network, ASLM has enhanced its engagement with two accreditation and standardisation organisations, the African Accreditation Cooperation (AFRAC) and the International Organization for Standardization (ISO) (see article on page 6).

This edition's feature article, "Pioneering New Diagnostic Modalities: Addressing Challenges and Implications for Point-Of-Care Testing in African Settings", on page 7, presents both challenges and opportunities related to the introduction of new point-of-care diagnostic tests in Africa. The feature reviews important areas including reliability and affordability, product evaluation, pricing and funding, deployment and community buy-in, post-market surveillance, and the changing landscape of diagnostic development.

As we move forward into this New Year, I would like to thank all who attended ASLM2014. Through the partnerships formed and lessons learned from this historic event, we will continue engaging in programmes, initiatives and partnerships to advance the laboratory medicine profession across Africa. I hope you enjoy issue 13 of Lab Culture. Thank you for reading.

Dr. Tsehaynesh Messele, CEO, ASLM

Highlights from ASLM2014: Expanding Access, Developing Guidance and Increasing Investment in Diagnostics



The second international ASLM conference, ASLM2014, was held in Cape Town, South Africa, in December 2014. Participants from throughout the world convened to discuss pertinent issues related to the conference's theme, "Innovation and Integration of Laboratory and Clinical Systems: Reshaping the Future of HIV, TB, Malaria, Flu, Neglected Tropical Diseases and Emerging Pathogens in Africa". Key highlights included sessions and symposia on the current Ebola outbreak in West Africa, the newly launched Diagnostics Access Initiative (DAI) and Diagnostics Access Fund for Africa, the role of government agencies in international public health, and the ASLM roadmap for diagnostics strengthening.



“The reactionary reaction is not helpful...we must keep in mind [a] post-crisis and post-conflict system.”

Dr. Peter Piot, Director of the London School of Health and Tropical Medicine (LSHTM) and co-discoverer of the Ebola virus, speaking at ASLM2014 about the importance of creating new initiatives for infectious disease prevention and containment.

Ebola Presentations

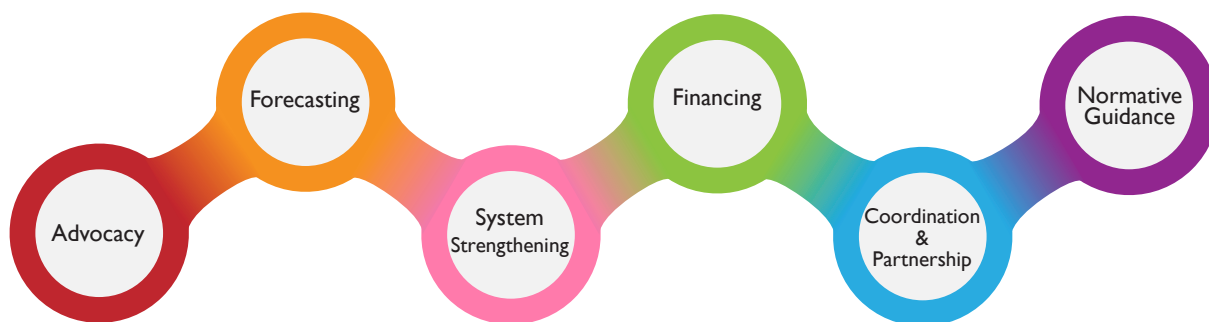
ASLM2014 incorporated a number of important plenary presentations, scientific sessions, symposia and discussions on the current Ebola outbreak in West Africa. The Ebola seminars provided much-needed consolidated information and conversations on the determination of appropriate courses of action in preparing for and responding to Ebola outbreaks.

Other experts presented on the astronomical costs incurred as a result of outbreak unpreparedness and insubstantial healthcare investment. Presenters made it clear that greater resource investment and planning is needed to prevent future outbreaks, including innovative Ebola rapid tests, and more well-defined roles for and coordination of national leadership and laboratory networks. Experts lauded ASLM’s role in outbreak response as that of laboratory medicine advocate, laboratory network developer, and trainer of healthcare personnel.

Diagnostics Access Initiative (DAI)

An ASLM2014 symposium on the recently launched DAI was headed by leaders from the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Health Organization (WHO), the US Centers for Disease Control and Prevention (CDC), and ASLM. Speakers stressed the importance of diagnostics in addressing short- and medium-term global health goals and challenges, such as UNAIDS’ targets for ending the AIDS epidemic, and the growing burden of non-communicable diseases in low- to middle-income countries.

Despite significant gains in HIV diagnostics over the past decade, gaps remain in the pursuit of quality-assured diagnostics. The DAI will help address these challenges by maximising the use of existing and innovative high-quality HIV diagnostic tools, allowing the acceleration and leveraging of appropriate treatment to improve patient outcomes. DAI efforts will include advocacy, financing, forecasting, systems strengthening, coordination and partnership, and normative guidance. The DAI will also incorporate innovations in combatting HIV, including improvements in HIV-related testing, diagnostic campaigns and decentralisation of antiretroviral therapy.



Efforts of focus of the Diagnostics Access Initiative (DAI).

Ministerial Panel

At a closed Ministerial Panel meeting at ASLM2014, African Ministers of Health, policy makers, and members of the private sector met with leading scientific representatives of global health organisations to conduct a broad-ranging discussion on maximising the use of healthcare resources throughout Africa.

During the meeting, Ministers of Health from several African countries shared budgetary challenges in accommodating additional investment for healthcare infrastructure and laboratory systems. Ministers emphasised the importance of prioritising healthcare infrastructure at a time when resource-constrained country economies are being threatened by Ebola and other emerging infectious diseases that impact tourism, economic growth, business ventures and human resource development.

One outcome of the Ministerial Panel was the introduction of the Diagnostics Access Fund for Africa, which will channel financial investments directly into the adoption of new diagnostic technologies, laboratory infrastructure, workforce training, harmonised regulations and quality assurance practices.

Panel participants explored ways to expand healthcare access; increase health insurance coverage; improve workforce development; and control current and future epidemics. Private sector collaborations were seen as an underutilised mechanism to improve training and service delivery.

ASLM Diagnostics Roadmap

ASLM hosted a roundtable session at the conference entitled, “A Roadmap for Strengthening Laboratory Diagnostic Services in Africa,” which outlined plans for achieving ASLM2020 goals to ensure better health outcomes for all. The roadmap corresponds to the pillars of the ASLM Strategic Vision for 2020, which include laboratory workforce development; quality improvement and accreditation; harmonisation and enhancement of regulatory standards; and network strengthening. The Society’s plan will guide the approach to diagnostic testing within the laboratory and the community.

Dr. Trevor Peter, ASLM Board Chair, opened the session, noting that robust diagnostic systems are central to achieving international public health initiatives. Advances in laboratory systems and laboratory involvement in healthcare decision making, he said, will result in improved health outcomes, reduced healthcare spending, greater public health security, and the attainment of health targets. To that end, the ASLM structured roadmap will provide guidance for governments, donors and implementing partners to realise meaningful progress in key areas of laboratory and diagnostic development.



Dr. Trevor Peter of ASLM presenting at the ASLM2014 conference.

ASLM CEO Dr. Tsehaynesh Messele outlined the ASLM roadmap and its steps for strengthening laboratories in Africa. She discussed the current laboratory landscape and specific mechanisms to ensure access, equity and efficiency for laboratory services, stressing the importance of continued stakeholder engagement in the development and implementation of the diagnostics roadmap for 2020.

By: Rachel Crane (Editorial Team); Editor: Jessica Fried, MPH (Editorial Team) and Caroline DeLuca (Editorial Team)

Young Professionals Thrive at ASLM2014

ASLM2014 offered a unique opportunity for young laboratory professionals to attend technical workshops, events and practical teaching sessions specifically designed to promote professional development and networking. The Young Professionals course series aimed at building the analytical and communication capacity of young African laboratory professionals. The series was sponsored by the African Journal of Laboratory Medicine (AJLM), the official peer reviewed journal of ASLM.

ASLM2014 Young Professionals courses included the following:

- Abstract Writing
- Writing News Articles and Award Nominations
- Developing Killer Presentations
- Free Educational Opportunities Online
- Statistical Secrets Revealed: Analysis and Presentation of Data



Participants of a Young Professionals Workshop at ASLM2014.

ASLM2014 attendee Mr. Victor Fondoh, a medical laboratory scientist at the Bamenda Regional Laboratory in Cameroon, says, “My experience at the ASLM2014 Young Professionals workshops was magnificent. The courses improved on my knowledge on writing abstracts, preparation and presentation power points, writing news articles and award nominations.”

When asked about his overall experience at ASLM2014, Mr. Fondoh says, “My expectations were met. I succeeded in networking with many colleagues and companies, and in attending the Young Professionals courses, plenary sessions, and poster and oral presentations. I also presented my scientific poster, and networked with many companies that provide external quality control schemes to laboratories.”

ASLM2016, the next international conference of ASLM, will continue to build on the knowledge and networking gains by offering continued opportunities for learning and career development among young and emerging medical laboratory and healthcare professionals.

“I’m planning to attend the next conference...I will encourage my friends, colleague and others to attend,” says Mr. Fondoh.

ASLM Approved as AFRAC Member and Liaison to ISO Technical Committee

ASLM recently became a member of the African Accreditation Cooperation (AFRAC), and was approved to be a Category A Liaison to the International Organization for Standardization, Technical Committee (ISO/TC) 212 on clinical laboratory testing and in vitro diagnostic test systems.

AFRAC is a cooperation of accreditation bodies and stakeholders across Africa, whose goal is to protect and improve the continent’s quality standards for health, safety and the environment. By joining AFRAC’s efforts, ASLM seeks to help build capacity and sustainability for healthcare accreditation in Africa. As a member of AFRAC, ASLM can participate in AFRAC General Assemblies and Technical Committees; access relevant organisational documents; and create committees to advance the interests of accreditation bodies and accreditation service users.



ISO is an international standard-setting body whose norms and regulations are essential to the international accreditation of clinical laboratories and the quality assurance of medical devices. As a Category A organisational liaison to ISO/TC 212 on clinical laboratory testing and in vitro diagnostic test systems, ASLM will provide technical expertise and address questions and issues relevant to medical laboratory and diagnostic standards. Furthermore, ASLM will have access to important documentation and can nominate experts to participate in relevant working groups.

Through its involvement with these accreditation and standardisation organisations, ASLM will promote the use and efficacy of self-assessment and external assessment processes among clinical laboratories, diagnostic manufacturers, and other significant contributors to health services in Africa, with the aim of promoting continuous quality improvement.

By: Rachel Crane (Editorial Team); Contributors: Tsehaynesh Messele, PhD (Editorial Team) and Corey White, MPA (Editorial Team). Editor: Michele Merkel (Editorial Team)

Pioneering New Diagnostics: Addressing Challenges and Implications for Point-Of-Care Testing in African Settings

Point-of-Care Testing: Why is it important ?

Imagine yourself in a city at the centre of one of the world's deadliest disease outbreaks. You watch as your friends and relatives are struck down by an aggressive illness that kills roughly 50-90% of those affected. One evening, you go to bed tired and achy, awakening the next morning with fever and headache. You do the right thing and call the emergency number. You are told to head to the nearest healthcare facility, a holding centre far from your neighbourhood. You are greeted at the holding centre by security personnel wearing face masks, face shields and gloves. From a distance, they tell you to wash your hands in bleach solution and then point you through a metal door into the facility grounds. A nurse shows you to the "dry" waiting area on the far side of a bright orange plastic fence, an area reserved for suspect cases not yet exhibiting the "wet" symptoms of diarrhoea and vomiting. A few metres away, in another fenced area, you see a chaotic scene: sick people lying on the floor, outnumbered workers in protective suits diligently working to clean diarrhoea and vomit from around them. A nurse in a protective suit approaches you and asks about your symptoms from a distance. She takes your temperature using an infrared device and asks you to wait. Six hours go by and the surveillance team arrives to take a blood sample. Then you wait. Your symptoms worsen the following day. You wait for days at the holding centre. You share bathrooms, eating utensils, and living quarters with up to 100 other sick people. On the third day, your result comes back: you have tested negative for Ebola.

Accurate and timely diagnosis of patients has been a key aspect of the response to the current Ebola epidemic in West Africa. Early isolation and care of patients suspected to be infected with Ebola is a critical public health measure required to prevent transmission of this deadly disease. The process for differentiating those who have Ebola from those who do not can pose a great danger to patients. Patients with unexplained fever that could be caused by Ebola virus are placed in quarantine wards until diagnostic tests can be completed. A special surveillance team is usually required to collect the sample and initiate contact tracing. During the height of the epidemic, laboratory and surveillance professionals were overwhelmed, which often led to long wait times and caused the patient a great deal of anxiety. Even after samples are collected, they must be transported to a laboratory with the capacity to perform the complex PCR-based tests required. Samples may have to be transported via numerous facilities, and then travel for hours by road or even air. Once samples arrive at the laboratory, they are stored until the test can be run. Collection delays, transportation difficulties, test capacity and result communication challenges often lead to average result turnaround times (in this case the time from sample collection to receipt of result) greater than six days.¹

These delays present patients with an excruciating wait and, more importantly, put uninfected individuals at risk of being infected.² To reduce the delay between a patient's arrival at the clinic

¹WHO call for diagnostics. "Urgently needed: rapid, sensitive safe and simple Ebola tests." 7 November 2014. Retrieved from: http://www.who.int/medicines/ebola-treatment/emp_ebola_diagnostics/en/

²Oldach, L (13 February 2015). Personal communication with Paula Fernandes.

and a confirmed diagnosis, researchers are working on rapid Ebola diagnostics at the point of care (POC). Two Ebola POC tests that have been developed in the last few months are an equipment-free serological test, which awaits prequalification by the World Health Organization (WHO)³; and a rapid integrated nucleic acid PCR test, which is undergoing clinical trials in Conakry, Guinea.

POC update for Ebola: On 19 February 2015 the WHO approved the ReEBOV Antigen Rapid Test Kit eligible for WHO procurement. The test is able to detect Ebola protein, not nucleic acid, within 15 minutes. For more information visit: http://www.who.int/medicines/ebola-treatment/1st_antigen_RT_Ebola/en/



Dr. Amadou Sall (Institut de Pasteur, Dakar) presenting at ASLM2014.

As to exactly what “point-of-care” means, definitions differ. The WHO developed the ASSURED criteria of affordability, sensitivity, specificity, user-friendliness, rapid results, equipment-free and delivered to patients to describe the ideal POC diagnostic, which would bring the test to the patient in an expedient and timely manner.⁴ This vision resembles a pregnancy test: a sensitive, accurate and specific test that requires little technical training to administer or interpret. In practice, very few POC diagnostics meet all of the ASSURED criteria. No one would call the nucleic acid Ebola POC test fully “equipment free”, since it requires a laboratory in a suitcase. Likewise, although the scale-up of GeneXpert MTB/RIF testing has revolutionised the availability of rapid, accurate diagnosis of tuberculosis (TB) and drug-resistant TB, the platform is designed for use in a laboratory

³ Chembio Update on DPP® Ebola and DPP® Febrile Illness Assays. Press release. 12 January 2015. Retrieved from: <http://chembio.com/news-and-events/press-releases/>

⁴ Low-cost tools for diagnosing and monitoring HIV infection in low-resource settings. WHO Bulletin. Volume 90, Number 12, 2012 December, 914-920. Retrieved from: <http://www.who.int/bulletin/volumes/90/12/BLT12-102780-table-T1.html>

and takes several hours. Although these and other diagnostics marketed as POC tests cannot be carried out literally at the patient's bedside or in the examining room, they improve on earlier methods by reducing the time and infrastructure required to deliver a diagnosis. However, some POC diagnostics, including HIV and CD4 rapid tests, are readily available and highly transportable.

"I think we're at a point where the technologies we need are here, but we really need to accelerate their uptake," says Jonathan Lehe, who manages the Point-of-Care Diagnostics programme at the Clinton Health Access Initiative. At this stage, experts agree that increasing access to existing technologies is a high priority for global health.



Mr. Jonathan Lehe (Clinton Foundation) presenting at ASLM2014.

The question, then, is what currently keeps the tests that exist from being used? Among the major barriers to POC diagnostic access are the regulatory processes, pricing and funding, implementation challenges, and quality assurance, which will be further explored in this article.

Accuracy and affordability: A balancing act

In 2013, 58 million people were tested using HIV rapid tests; studies show that in various settings the performance of HIV rapid tests can be variable,⁶ resulting in misclassification of false positives and false negatives.⁷ Although this is startling, it has to be considered against the number of correct diagnoses that would not have been made, or would not have reached patients, with the more

⁵Tuberculosis diagnostics technology and market landscape (3rd Edition).UNITAID Secretariat, 2014.
Retrieved from: http://unitaid.org/images/marketdynamics/publications/UNITAID_TB_Diagnostics_Landscape_3rd-edition.pdf

⁶Kagulire et al. Field evaluation of five rapid diagnostic tests for screening of HIV-1 infections in rural Rakai, Uganda. 2011 Jun, 22(6):308-309

⁷WHO reminds national programmes to retest all newly diagnosed people with HIV. 22 October 2014.
Retrieved from: <http://www.who.int/hiv/pub/vct/retest-newly-diagnosed-plhiv-full/en/point-of-care>

expensive and complex gold standard of ELISA (enzyme-linked immunosorbent assay) serological testing followed by confirmatory Western blot. Ministries of Health (MOHs), non-governmental organisations (NGOs) and diagnostic experts around the world continue to debate whether expanding access is enough to justify sacrificing some measure of accuracy. According to one school of thought, if a test increases the number of diagnoses that can be made and reduces patient loss to follow-up, a higher false negative rate should be acceptable—the total number of correct diagnoses is still increased. However, another opinion holds that quality is paramount, keeping in mind that if costs are cut, then simpler and cheaper tests such as HIV rapid tests will not have the same accuracy as the gold standard.



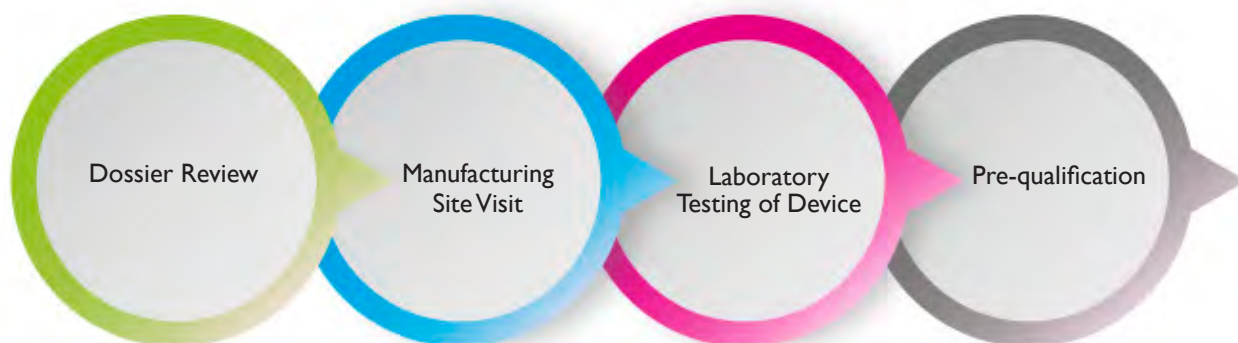
The responsibility for setting accuracy parameters within a country or smaller markets within the country falls to each country's MOH. "I think it's appropriate for the WHO to set guidance on this sort of question, but in the end I think it should be up to the MOHs that are setting policies for the healthcare of their people," says Lehe. As MOHs strike the balance between access and affordability, they must consider the consequences of each inaccurate outcome. For infectious diseases such as Ebola and HIV, the risks of an inaccurate test result are very high for the individual, for the health of others susceptible, and for the country's healthcare budget. The dangers of a false negative on, for example, a pregnancy test are much milder. In either case, knowing the true accuracy of a test is important in making an informed regulatory decision about whether and where to allow it to be sold. Therefore, the first step in choosing to license, procure or implement a POC diagnostic is independent confirmation that manufacturers' claims about false positive and false negative rates are accurate.

Product evaluation: The regulatory process

"To make a test available to people, one has to go through the dossier [process]: show that performance is good, that it meets manufacturing criteria, and that it meets the country's rules for in vitro diagnostics," says Dr. Sall. These tests are initially carried out by the manufacturer, but must be verified by third parties including international bodies and national governments. Although these steps are crucial to protecting the health of the population from fraudulent or faulty diagnostic tests, analysts also point to regulation as a barrier to access of POC tests.

International health organisations such as the WHO and US Centers for Disease Control and Prevention (CDC) carry out substantial quality assurance work for POC diagnostics. The WHO prequalification team for diagnostics, for example, follows a workflow that begins with a thorough review of product dossiers, examining the product design and manufacturing quality management systems on paper. Dossier review is followed by a site visit to make sure the product's manufacture matches its quality claims, and laboratory testing to confirm manufacturers' claims about accuracy. If a diagnostic passes these tests, it can be prequalified for procurement by the United Nations (UN). Because the standards for prequalification are quite stringent, many national MOHs use

prequalification or other assessment by organisations such as the United States Food and Drug Administration (USFDA) or the Conformité Européenne (CE) as a precondition for considering a diagnostic. The WHO prequalification branch publishes information including a list of prequalified in vitro diagnostics (IVDs) as well as a guideline for risk-based assessment of IVDs.⁸



Sample workflow of steps toward pre-qualification of a diagnostic product.

Technical assessment by an international agency is an important step toward introducing a diagnostic to a national market, but each country's MOH and subordinate regulatory agencies usually have further regulatory requirements to fulfil. National standards may be different than the WHO standard; moreover, the conditions under which a test is used within the country may be different. For example, a recent field validation study of rapid HIV tests in a clinical setting in South Africa found that identical rapid diagnostic tests performed with lower sensitivity in the clinic than when they had been tested in the laboratory, perhaps because of training differences, environmental factors, or the use of serum in the laboratory and whole blood in the clinic.⁹ In-country assessment can assure that a test will work reliably in the context where it is to be used.

Although national-level testing is important for weeding out low-quality diagnostics, it can also be a barrier to putting effective tests onto the market. Redundant evaluations in many countries can take years and can become very expensive. Meanwhile, companies that produce diagnostics must navigate redundant approval processes in many small to medium markets around the world. Recognising that the regulatory process can become a barrier to the introduction of good and bad products into the market, many groups have made it a goal to hasten the evaluation of diagnostics, without compromising quality. Various actors, notably the Pan-African Harmonization Working Party (PAHWP) on Medical Devices and Diagnostics, are working to harmonise regional regulatory standards, with short-term goals that include a shared Registration File (the form that companies submit in order to apply for permission to market diagnostics); collaborative clinical studies for regulatory approval; regional post-market surveillance; and clearer standards for risk classification.

Another important goal for international bodies is to develop clear guidelines that help MOHs choose between available approved tests. As outlined in the previous section, choosing the appropriate diagnostic test can involve ethical as well as economic and technical considerations.

⁸ WHO. "A risk based approach for the assessment of in vitro diagnostics (IVDs)." 2014.

⁹ Black, Mollendorf, Moyes, Scott, Puren and Stevens. "Poor sensitivity of field rapid HIV testing: implications for mother-to-child transmission programme." BJOG 2009; 116:1805-8.



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Moreover, some markets, especially the HIV rapid test market, are crowded with very similar rapid diagnostic test products, presenting a challenge to individuals trying to choose the appropriate test for a whole country. Disease-specific diagnostic landscape reports compiled by international groups can be a good guide in the short term.¹⁰ These reports incorporate performance, cost, operational characteristics such as throughput and shelf life, and can help MOHs to streamline their decisions about approving and purchasing diagnostics.

Price and funding

After a POC diagnostic passes the regulatory evaluations, it still must be purchased in order to benefit patients. In order to be purchased, it has to be both affordable and cost-effective. The per-test price of a POC diagnostic includes fixed production costs and the cost per unit produced; research and development costs including market assessment and biomarker assessment are also reflected in the price per test. These costs can run from USD \$2 million to over \$10 million and represent an investment of up to ten years, and are built into the cost of POC tests.¹¹ Per test, this can add up to a hefty fee, especially for systems such as the GeneXpert MDR/RIF test for TB (or various CD4 systems), which include both consumable reagents and expensive equipment.

¹⁰ Landscape and Technical reports. (n.d.). Retrieved February 19, 2015, from <http://www.unaids.org/en/resources/publications/technical-reports>

¹¹ Peeling R. and Mabey D. "Point-of-care tests for diagnosing infections in the developing world." Clin Microbiol 16(8):2010.

A good potential pricing solution is for companies to set prices transparently, with a plan to reduce the price per test as sales volume increases. “If companies are afraid that volumes won’t materialise, so they set the price too high, it will be a self-fulfilling prophecy. If countries see an entry price that is too high, they may assume that this will be the price forever, and they may decide they can’t afford to introduce the product at all,” says Lehe. With a transparent, tiered pricing structure, scaling up use of a POC test can evolve from prohibitively expensive to palatable and cost-effective. Non-governmental organisations (NGOs) such as the Clinton Health Access Initiative mediate between producers and end users of diagnostics to improve access by sharing information more openly between the two sides. Meanwhile, countries can contribute to this effort by building test demand, sharing scale-up plans and forecasts, and consolidating testing carried out by many providers within their borders in order to secure bulk discounts.

Comparing the cost-effectiveness of POC and conventional diagnostics can help MOHs decide which of many options to implement. However, “just because something is cost effective doesn’t mean it’s affordable,” says Lehe. “We did a lot of work to demonstrate that POC CD4 is highly cost effective, but it still requires incremental investment, and if countries don’t have the money it won’t happen.” Supplemental funding for POC tests and other healthcare products often comes from global donors, for example Global Fund grants. While they have greatly improved access, these grants take time to be approved and delivered. Though they are well suited to meet entrenched health needs such as HIV and TB, the pace is poorly suited to respond to an outbreak situation or a ground-breaking new product. As a possible solution to minimise the disconnect between the need for and the availability of funds, a ministerial panel at ASLM2014 proposed a global “Diagnostics Access Fund.” Lehe describes this as funds “earmarked specifically for diagnostics, but flexible enough to meet changing needs.”¹²

When funding dictates that only a limited number of tests are available, targeting POC diagnostics to specific, high-risk populations can optimise the return on each test. For example, a rapid syphilis diagnostic is extremely cost-effective, in terms of preventing negative long-term health outcomes. Subsequent treatment can prevent the devastating long-term effects of congenital syphilis. If resources are limited, guidelines may suggest reserving the tests only for pregnant women, to obtain the greatest possible positive impact from each test, even though health benefits are available for any patient who can be cured of syphilis.¹³

When funds are available, it is often most cost-effective to mix high-volume laboratory tests with POC testing.¹⁴ Cost per test on both existing laboratory diagnostic equipment and POC devices varies depending on the utilisation rate, with the highest cost savings achieved at full capacity.¹⁵ One benefit of many POC tests which are equipment-free is that even with very low test volumes, the cost per test is fixed ahead of time, rendering testing cost-effective even at remote sites with low volume. On the other hand, many POC tests do require simple equipment, which may not be cost effective at very low volumes. At the same time, countries justifiably wish to maximise their return on existing investments in laboratory infrastructure. Developing a balance between diagnostic strategies depends on each country’s demographics, budget, and existing laboratory infrastructure.

¹² Ministerial panel at ASLM2014

¹³ “The Rapid Syphilis Test Toolkit: a guide to planning, management and implementation.” Accessible via idc-dx.org.

¹⁴ UNAIDS Secretariat. “HIV/AIDS Diagnostics Technology Landscape” 4th edition 2014.

¹⁵ Farouk Umaru. “Cost effective mix of POC and conventional instrument deployment in Zambia.” ASLM2014 presentation, Oral Session “Return on investment in laboratory”



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Deploying POC diagnostics: Local buy-in

“You can have the best technology, but if the community does not come to use it, it is useless,” comments Dr. Sall. Implementation of any new diagnostic test on a country-level scale is the result of many earlier decisions taken by its developers and manufacturers, international regulatory bodies, and government MOHs. However, the decision to deploy a test comes down to an individual clinician or community health worker. Without buy-in at the level of individual clinics, diagnostic tests chosen and purchased with great effort may sit unused in boxes.



A robust implementation strategy is required to ensure successful roll-out of new POC diagnostics and must include a plan for training the people who will administer the tests. This strategy may necessitate clinic workflow changes to improve testing efficiency. To reduce the burden an extra diagnostic puts on already-overworked healthcare workers, and to extend the reach of POC diagnostics, many countries have workforces with less clinical or laboratory training who are specifically trained to administer POC tests. In Kenya, the National Public Health Laboratory Service runs a proficiency testing system for these workers, and has found that targeting testers rather than sites helps to ensure quality delivery of diagnoses.

The closer POC diagnostic testing becomes to the patient, the harder it becomes to consolidate data so that national-level authorities can analyse health outcomes countrywide. Thus, greater connectivity between central and peripheral facilities is required. Automated data transmission of test results from central laboratories to clinic sites reduces turnaround time for diagnostic tests performed away from the POC, and has been found to reduce human transcription errors in data reporting. Some companies have taken on the challenge of enhancing connectivity to encourage uptake of their diagnostics; for example, POC products that can be connected to a central database by SIM. Lehe suggests that companies can provide greater technical support, including training and maintenance contracts for their highly specialised equipment, to reduce the logistical burden of delivering POC tests.

Procurement, post-market analysis and continuous quality monitoring

A new diagnostic test must be thoroughly validated prior to use in country. Additionally, standard procedures must be applied to ensure that products are selected, validated and purchased in a transparent manner. Once a product is selected and procured, post-market surveillance is required to ensure appropriate that diagnostic quality is maintained at the same level it had to reach in order to be introduced to the market. Continual quality monitoring is performed at the international level. For example, WHO periodically inspects manufacturing facilities of prequalified products. If a site fails to rectify quality concerns, the result is a Notice of Concern, a red flag that can affect the

reputation of that product. WHO provides an online feedback form for complaints and product alerts, so that problems revealed by post-marketing surveillance efforts can be shared between nations.

Post-market surveillance is intended to provide early warning of product quality issues, but is not designed to serve as a quality assurance program for the users. Therefore, quality assurance programmes at sites that administer tests must be in place to ensure that the quality of diagnostic delivery matches its quality of manufacture. Quality assurance is a costly but critical process. During an ASLM2014 symposium, “Advances in Implementing Quality Assured Point-of-Care Testing”, speakers discussed the feasibility of dedicating one percent of programme costs to quality assurance by factoring these assessments into the cost per test. Countries can then respond to subpar diagnostics by removing them from the market to prevent harm to their citizens, or respond to subpar service delivery by improving operator performance through re-training or site mentorship.

Changing diagnostic landscapes and ways forward

The landscape for diagnostics and especially POC is continually changing. In 2010, WHO updated its recommendations for monitoring treatment effectiveness in HIV patients on antiretroviral therapy (ART). Until that year, the international recommendation was combined clinical monitoring and CD4 count; however, new research showed monitoring viral load to be an earlier and more sensitive way to identify treatment failure.¹⁸ Although the WHO still recommends CD4 testing when a patient is first diagnosed, in order to stage patients and start them on ART when appropriate, routine CD4 monitoring is being phased out in many places in favour of annual viral load monitoring.

“You can have the best technology, but if the community does not come to use it, it is useless.”

- Dr. Amadou Sall

Many in the laboratory medicine field recall the transition from CD4 to viral load monitoring with frustration. Although based on evidence and aimed at improving patient care and stemming the rise of drug resistance, the new guidelines exacted a cost in training time, equipment and supplies. Some countries changed their policies to phase out routine CD4 monitoring before viral load monitoring was rolled out to most patients, while viral load scale-up remains unaffordable in other countries. International funders also changed their purchasing protocols and funding priorities. The change presented a setback for decentralised ART monitoring due to the fact that although some CD4 POC technologies exist, there is as yet no POC test for viral load.

What should a country do when infrastructure it has invested a great deal to implement ceases to be the gold standard? ASLM, in partnership with WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), and representatives from 20 MOHs, developed a set of recommendations to help countries navigate the transition to viral load testing. These include viral load testing on

¹⁸WHO. “Consolidated ARV guidelines, June 2013.”

dried blood spots, which can be transported more cheaply. ASLM also recommends using existing capacity in early infant diagnosis laboratories to perform treatment monitoring, a guideline that underscores the importance of flexibility in both human resources and diagnostic strategies.

As new technologies emerge, what is most cost-effective, most affordable, and most accurate will continue to change. Funding, regulation and implementation must remain flexible to these changing circumstances. In her keynote address at ASLM2014, Dr. Rosanna Peeling of the London School of Hygiene and Tropical Medicine (LSHTM) noted that in an increasingly connected world, roles for the medical laboratory have expanded to encompass surveillance for outbreak situations and resistance monitoring. Although the central laboratory will remain critical to the diagnosis of some conditions, as many routine diagnostic tests are outsourced from the laboratory and closer to the point-of-care, scientists and technicians may take on new roles. By participating in validation and post-market surveillance of POC diagnostics, laboratory professionals can help build a vibrant diagnostic network and make quality diagnostics available to the patients who stand to benefit most.

For more information on the topics covered in this article, please visit the following sites:

http://www.who.int/diagnostics_laboratory/evaluations/en/

http://www.who.int/diagnostics_laboratory/evaluations/150112_prequalified_products_list.pdf

<http://www.pahwp.org/>

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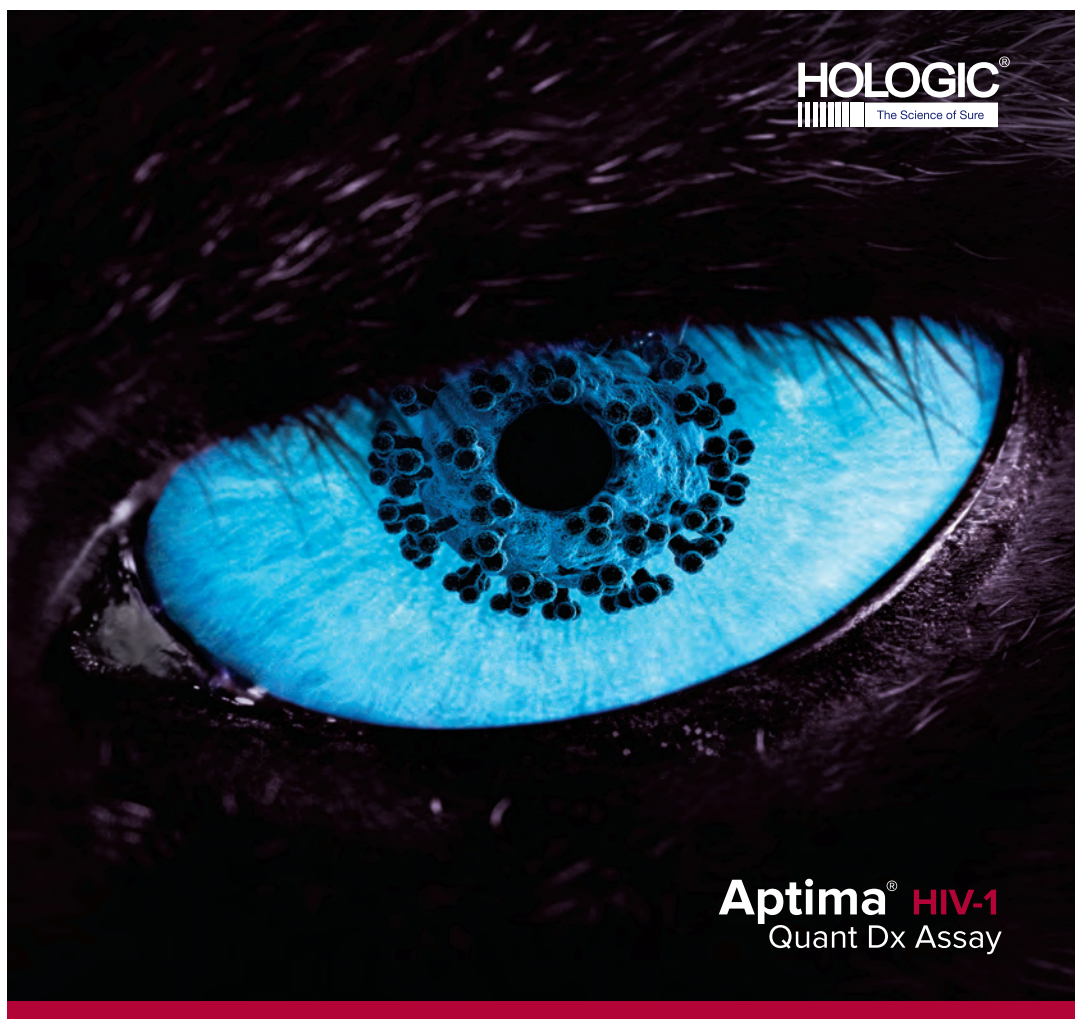
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In Outbreaks, Laboratories Overlooked

In February 2014, the Ebola virus infected close to 50 people in Guinea before the government was able to arrange for testing to confirm and announce the diagnosis for the first suspected patient. This delay occurred, in part, due to the absence of laboratories capable of testing for Ebola in Guinea, which necessitated logistically complicated specimen transfers.²⁰

In June 2014, there were only two laboratories in Sierra Leone capable of testing specimens for Ebola. As recently as late August, the Lofa county of Liberia had to send samples to Guinea (where, by that point, international agencies had established laboratories).²¹ Monrovia, Liberia, faced an already excessive disease burden that strained its laboratory capacity to test samples from other counties that lack laboratories, despite the support of international partners. As recently as December 2014, international agencies continued to scale-up care and treatment centres for Ebola patients whilst there were comparably few laboratories.²²

Ebola is not a new disease. The need for reliable testing should not be surprising -- so why have public health initiatives repeatedly found themselves unprepared for this exact need?

“The laboratory has been an afterthought,” explained Dr. Isatta Wurie, Public Health Laboratory Consultant for ASLM. “Decisions were made for the laboratory, but not by laboratory professionals. We need to have laboratory specialists at the table from the first moment. We can’t do this alone either— it can’t be all laboratorians – but we need people coming from every angle to create a public health lens. Laboratory systems must be put in place with structure, logistics, human resources, health and safety, and with defined roles and responsibilities.”²³

“The laboratory has been an afterthought...Decisions were made for the laboratory, but not by laboratory professionals. We need to have laboratory specialists at the table from the first moment.”

- Dr. Isatta Wurie

Laboratories do, of course, require ample resources and a strong workforce, but most national budgets include limited funds for health; moreover, very few laboratory-specific funding plans exist. As we have learned during the latest Ebola outbreak, it is impossible to care for Ebola patients without the capacity to test for Ebola.

²⁰ Youde, J. (2014, July 26). The Ebola Outbreak in Guinea, Liberia, and Sierra Leone. Retrieved January 20, 2015.

²¹ WHO: Ebola Response Roadmap Situation Report 1. (2014, August 29). Retrieved January 24, 2015, from http://apps.who.int/iris/bitstream/10665/1131974/1/roadmapsitrep1_eng.pdf?ua=1

²² DeLuca, C. (22 January 2015) Personal interview with Paula Fernandes.

²³ Fernandes, P. (17 January 2015) Personal interview with Isatta Wurie.

According to Dr. Wurie, the focus during the outbreak was on contact tracing and PPE [Personal Protective Equipment], two very important aspects of containment. Laboratory capacity was overlooked, in part due to limited understanding of the technical requirements and capacity required to meet demand.

Failure to realise the crucial role of the laboratory has not by any means been limited to the Ebola outbreak. While the US President's Emergency Plan for AIDS Relief (PEPFAR) originally focused on increasing access to pharmaceuticals for people living with HIV and AIDS, less emphasis was placed on laboratories, a requisite component of achieving the goal of increased access.

Dr. Beth Skaggs, Global Disease Detection Laboratory Team Leader at the CDC, described critical steps for outbreak response in the future: "Laboratory confirmation is critical to be able to direct the public health response; for this we need appropriately trained health personnel to safely collect specimens. We have to have materials in place for safe packing and transport of that specimen. We need clearly defined roles for laboratories, so even at the lowest tier of the healthcare system, the public health workforce knows which labs are equipped and capable of testing suspect pathogens. If the capacities of laboratories are not documented, individuals on the front line don't know where to send samples, even if they do have the packaging materials." Skaggs also recommends establishing agreements between countries in Africa to send specimens for testing before outbreaks, as well as agreements with airlines to transport them. The logistics of specimen transfer are a current challenge, because few airlines are willing to transport people or specimens suspected of Ebola.²⁴



Personal Protective Equipment is an important aspect of Ebola containment.

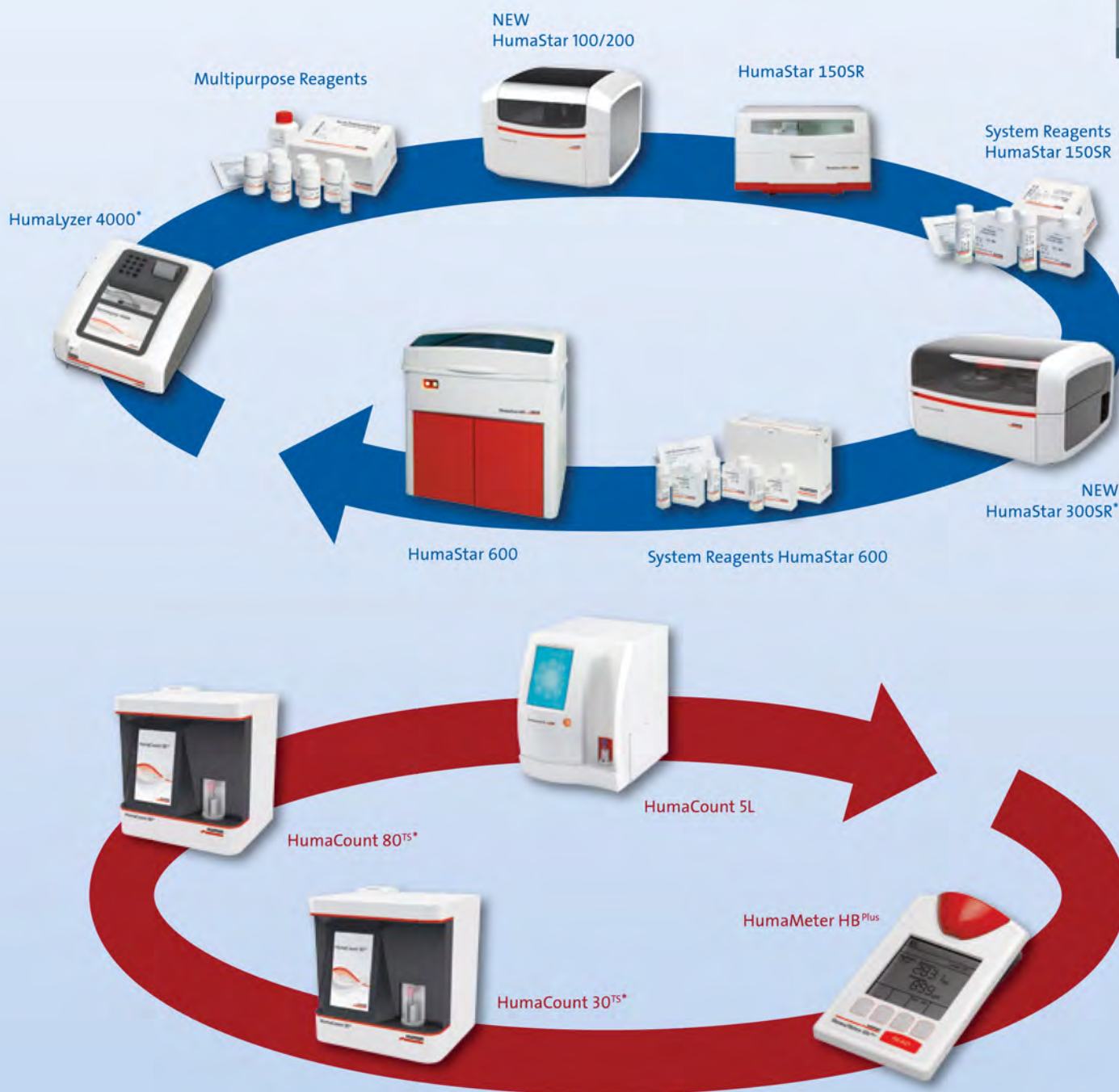
Regarding the role of key partners in future work toward biosecurity preparedness, the first step will be to advocate for individual countries to contribute resources toward global health security. Many nations are already taking action, the Ebola outbreak having crystallised the urgency of strengthening biosecurity. The second step, Skaggs says, is continuing to work with governments and other partners in vulnerable countries and regions, to develop global health strategic plans based on health system gaps identified in prior public health capacity assessments.

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Editors: Rachel Crane and Michele Merkel (Editorial Team)

²⁴ DeLuca, C. (28 January 2015) Telephone interview with Beth Skaggs.

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ASLM Co-Facilitates Auditor Refresher Training in Nigeria

ASLM, in close collaboration with the Medical Laboratory Science Council of Nigeria (MLSCN) and the Centers for Disease Control, Nigeria (CDC-Nigeria), conducted the WHO-AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Auditor Refresher training from 15-18 December 2014, in Abuja, Nigeria. The training was designed to review key topics from the auditor certification courses and to engage participants in improving the quality of laboratories across Africa, with an emphasis on helping laboratories achieve accreditation.

Of the 13 auditors who had been previously trained by CLSI, 12 attended the workshop. Half of the participating trained auditors had completed the field practicum, and are certified as ASLM SLIPTA auditors, while the remaining six will be certified upon completion of the practicum requirement.



Participants of the December 2014 SLIPTA Auditor Refresher Training.

The workshop was structured around lectures and group discussions with a focus on accreditation and quality management systems (QMS); assessment methods; and a review of SLIPTA, ISO 15189:2012, and professional ethics. The training facilitators, Mr. Teferi Mekonen of ASLM and Dr. Lawrena Okoro of the MLSCN, provided feedback to help participants improve laboratory auditing skills. Evaluations were made through the use of pre- and post-tests and a final examination. The post-test scores indicated that the instruction provided during the lectures and discussions either improved participants' understanding or maintained existing proficiency in the topics addressed. All 12 participants passed the refresher course, with final examination scores ranging from 72% to 91%. At the conclusion of the training, participants were given certificates for their successful completion.

With its continued commitment to improving quality and assisting private and public laboratories in Africa to achieve international accreditation, ASLM plans to hold additional refresher courses for auditors in the future. To date, over 150 auditors throughout the continent have been successfully trained in the SLIPTA programme and are currently pursuing certification.

By: Rachel Crane (Editorial Team) and Teferi Mekonen, MSc (ASLM). **Editor:** Michele Merkel (Editorial Team)

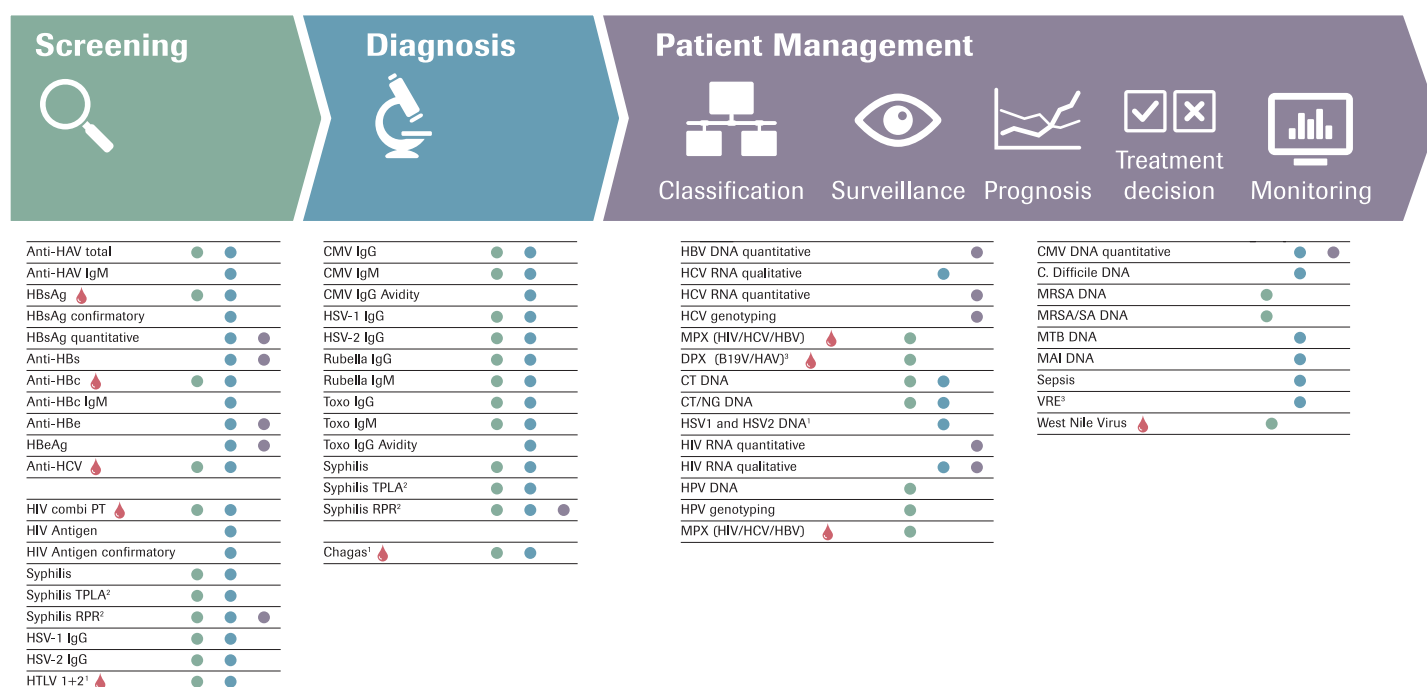
25% of deaths worldwide are caused by infectious diseases.¹

500,000 people die each year from Hepatitis C-related liver diseases.²

780,000 people die each year as a consequence of Hepatitis B.³

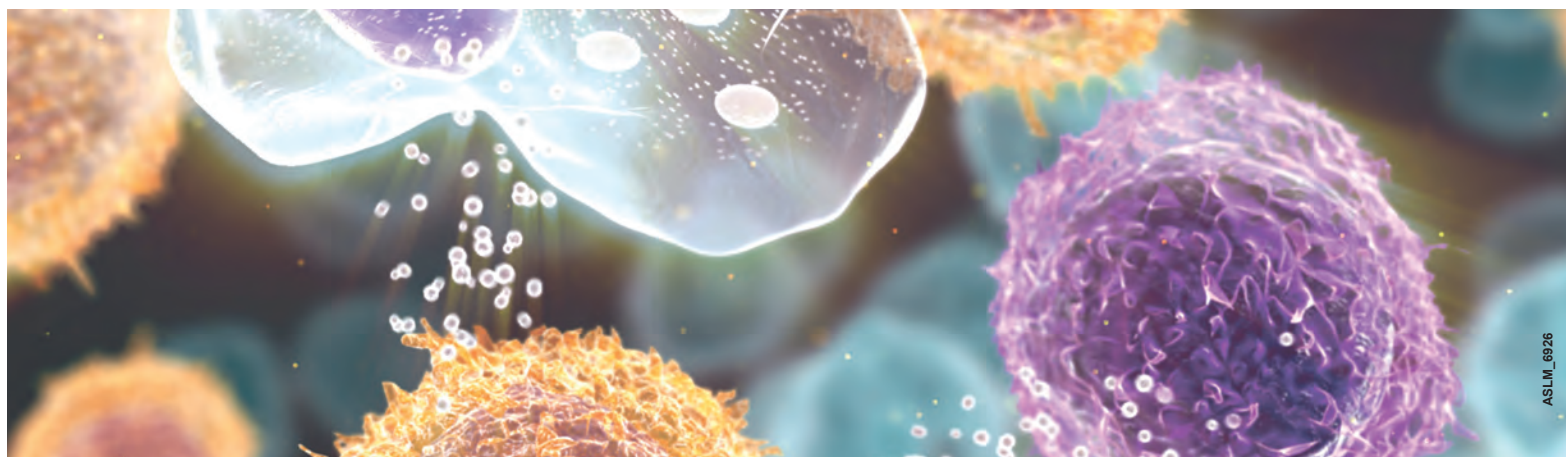
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References 1: Roche Diagnostics (http://www.roche.com/research_and_development/what_we_are_working_on/infectious_diseases.htm)
Reference 2 & 3: WHO 2014 (<http://www.who.int/mediacentre/factsheets/fs164/en/>)



ASLM Conducts Capacity-Building Training Workshop in Abuja

From 19-23 January 2015, ASLM and the Centers for Disease Control, Nigeria, co-organised an ISO International Organization for Standardization (ISO) Accreditation Preparation Training Workshop, with logistics provided by the AIDS Prevention Initiative of Nigeria (APIN). The workshop convened 20 participants with the objective of orienting participants to the rules, requirements and processes of ISO accreditation for medical laboratories.



Participants of the January 2015 ISO Accreditation Preparation Training Workshop.

Workshop participants came from Nigerian laboratories that had been previously audited by ASLM in September 2013, January 2014 and December 2014.

This training workshop was facilitated by Mrs. Vijay Padayachee, an experienced Quality Management Systems trainer and consultant, and Ms. Mponeng Poo, an experienced medical laboratory technologist and accreditation consultant.

By the end of the training, participants were well-versed in accreditation prerequisites; the ISO 15189 and ISO 15190 standards for medical laboratories; and in basic methods to build local and regional capacity to implement Laboratory Quality Management Systems based on ISO standards.



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