February 2018 | Issue 18

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

LAB CULTURE

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

Standards and safety

Best practices in the management of laboratory waste

SLIPTA 2.0
A new Concept!

SLIPTA Update

WHO Prequalification Evaluating Laboratory

Meet Dr Nkengasong, Director, Africa CDC

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

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LAB CULTURE

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Contribute to *Lab Culture*

ASLM is currently accepting article and photo submissions for upcoming issues of ***Lab Culture***. We publish timely, informative, inspirational articles relevant to the unique challenges faced by laboratories in resource-limited settings. We are interested in articles on the critical aspects of laboratory medicine, best practices, success stories, leaders in the field, industry news, etc.

To submit articles, proposals, photos, etc., please contact the Editor at newsletter@aslm.org.

Lab Culture. Established along with ASLM in 2011 as a member newsletter, ***Lab Culture*** relaunched in 2017 as ASLM's magazine for laboratory medicine in Africa. Dedicated to bringing timely, informative articles relevant to the unique challenges faced by African laboratories, ***Lab Culture*** seeks to be Africa's premiere resource for laboratory professionals and other stakeholders working on with the continent. Published six times a year as a digital edition, ***Lab Culture*** includes features on critical aspects of laboratory medicine and best practices in resource-limited settings, success stories from the continent, industry news, and more.

Greetings!

Dr Ali Elbireer

First, allow me to extend best wishes for a great 2018 from ASLM to all of our members, stakeholders and partners in improving laboratory medicine in Africa! As I am sure you are too, ASLM is looking forward to an exciting year.

I've worked in the global healthcare and laboratory sector for over 25 years. It's been both an honour and a privilege this past year to serve in ASLM, a society that facilitates improvements in diagnostics services to over a billion people in Africa and advances global heath security around the world. As I look at today's healthcare landscape, it's incredibly clear that the pace of change has never been greater or more exciting.

Rapid changes bring opportunities and risks for laboratory professionals, and we are prepared to address both. There are significant challenges to overcome, but the tools, insights, technologies, innovations—both evolutions and revolutions—make today one of the most promising times for human health and for ASLM. In coming months, ASLM and its Board of Directors will finalise ASLM's five-year Strategic Roadmap, which details the steps ASLM and its partners will take during 2018-2023 to achieve our Strategic Goals, highlight immediate goals for the next 12-24 months, including funding diversification, and guide our activities towards achieving them.

Without a sense of purpose, no entity can achieve its full potential. Thus, ASLM is working to articulate clearer objectives for providing value to ASLM's community of laboratory professionals. We keep that foremost in our minds whether we are providing training to the laboratory workforce in Sierra Leone, providing quality management workshops in Zimbabwe, strengthening biosafety and biosecurity capacity in Uganda, implementing SLIPTA 2.0 in Kenya, or any other activities ASLM staff are leading on the continent. In everything we do, we are committed to raising the medical laboratory agenda and the profile of laboratory professionals.

One way we will do this is to transform the ASLM website into a resource centre for the African medical community. The ultimate goal is to create a centralized, 'one-stop shop' for anything and everything relevant to laboratory medicine in Africa. For a preview of what we have planned, I encourage you to visit the HIV point-of-care (POC) page (**http://www.aslm.org/resource-centre/resource-new/**), which sets the stage for a virtual clearinghouse of POC resources, including efforts by implementing partners, Ministries of Heath, and the global healthcare community. We are currently extending the POC site and expanding coverage of other initiatives from SLIPTA to rofessional development, to global health security, and beyond.

Finally, we are working hard on planning the ASLM2018 conference, which will take place in December 2018 in Abuja, Nigeria. Do not miss this opportunity to experience what the "Giant of Africa" is really like with its thriving human capital, abundance of natural landmarks, and a boisterous and globally renowned scientific community. Details on speakers, sessions, seminars and more should arrive in your inbox over the next few weeks and months. Indeed, we are looking forward to a remarkable ASLM conference in Nigeria (**www.aslm2018.org**).

In closing, I once again wish you all the best in the new year. Let's do great things for our medical and laboratory community and positively impact African healthcare in 2018!

Sincerely,
Dr Ali Elbireer, CEO

LAB CULTURE
ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

For submissions and inquiries, please contact: newsletter@aslm.org

ASLM

Joseph Tito Street, Nega City Mall, Suite 800
Kirkos Subcity, Kebele 08
Addis Ababa, Ethiopia
www.ASLM.org
Newsletter@ASLM.org

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MLO
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Kristine Russell
Publisher/Exec Editor/President
krussell@mlo-online.com

Alan Lenhoff
Editor
alenhoff@mlo-online.com

Lisa Moynihan
Managing Editor
lmoynihan@mlo-online.com

Norma Machado
Design
nmachado@npcomm.com

NP Communications
2477 Stickney Point Rd., Suite 221B
Sarasota, FL 34231
www.mlo-online.com

Is progress towards elimination of malaria in jeopardy?

In late January 2018, a side event was held at the 30th Ordinary Session of the African Union where senior health, finance and foreign affairs sector officials received a high-level briefing on the November 2017 World Health Organization (WHO) report on malaria. Malaria on the African continent accounts for almost 90% of the global malaria burden, and the WHO report showed that the steady progress made towards eliminating the disease by 2030 is slowing.

The numbers of malaria cases and deaths remain below numbers for 2010. However, when compared with 2015, there was an unsettling rise in the number of cases, which went from 211 million in 2015 to 216 million in 2016. While some African countries are showing that beating malaria is possible, others have seen an alarming >20% increase in malaria cases and deaths. Given that African leaders articulated their commitment to the WHO goal of eliminating malaria by 2030 in the Continental development Agenda 2063, this is not a trend that anyone wants to see continue.

So, how to prevent it and what role will African laboratories play in reversing the trend? The WHO report lists a number of challenges to its 2030 malaria elimination goal, including funding levels for malaria programs, regional conflicts, climate change, access to care, and resistance of malaria parasites to medications and mosquitoes to insecticides. The report goes on to say:

'Effective surveillance of malaria cases and deaths is essential for identifying the areas or population groups that are most affected by malaria, and for targeting resources for maximum impact. A strong surveillance system requires high levels of access to care and case detection, and complete reporting by all health sectors, whether public or private.'

That means strong laboratories and strong laboratory networks.

The key to ensuring this is government commitment to adequate funding and Ministries of Health commitment to appropriate allocation of that funding to malaria programs. Such programs should, in part, work towards strengthening laboratories and associated networks to increase access to diagnosis and treatment and ensure proper surveillance and reporting.

Indeed, in a recent story on the briefing, Africa Science News reports H.E. Moussa Faki Mahamat, the Chairperson of the African Union Commission, as saying, 'Malaria alone is estimated to rob the continent of US$12 billion per year in lost productivity, investment and associated health care costs. It is therefore critical that we sustain the political commitment … to eliminate malaria in Africa by 2030 through increased domestic financing, increased access to life-saving malaria interventions, as well as more robust health systems.'

Hopefully, governments will come through. As long as they do, there is hope that the world could, indeed, be largely free of malaria by 2030.

In the 2017 WHO report, Dr Tedros Adhanom Ghebreyesus, Director-General of WHO, says, 'But I am also convinced that this is a winnable battle. With robust financial resources and political leadership, we can – and will – swing the pendulum back towards a malaria-free world.'

Bethanie Rammer

Infectious Diseases

Laboratorians actively involved in identifying Lassa fever. The World Health Organization (WHO) has scaled up its response to an outbreak of Lassa fever in Nigeria, which has spread to 17 states and may have infected up to 450 people in less than five weeks. The acute viral haemorrhagic fever is endemic but for the current outbreak, the areas affected are the southern states of Ebonyi, Edo and Ondo.

'The high number of Lassa fever cases is concerning. We are observing an unusually high number of cases for this time of year,' said Dr Wondimagegnehu Alemu, WHO representative to Nigeria.

From the onset of the outbreak, WHO Nigeria deployed staff from the national and state levels to support the Government of Nigeria's national Lassa fever Emergency Operations Centre and state surveillance activities. WHO is helping to coordinate health actors and is joining rapid risk assessment teams travelling to hot spots to investigate the outbreak.

Between 1 January and 4 February 2018, nearly 450 suspected cases were reported, of which 132 are laboratory confirmed Lassa fever. Of these, 43 deaths were reported, 37 of which were laboratory confirmed. Among those infected are 11 health workers, four of whom died. Person-to-person infections and laboratory transmission can also occur.

With the increase in the number of cases, WHO initially donated personal protective equipment to the Nigeria Center for Disease Control (NCDC) and to the affected states and procured laboratory reagents to support the prompt diagnosis of Lassa fever.

Lassa fever comes with no specific symptoms and clinical diagnosis can be difficult especially at the early onset of disease. The US Centers for Disease Control and Prevention said 80% of those infected will have a mild disease or no symptoms, 20% will get sick and only 1% will die. That is why laboratory testing can be crucial for accurate diagnosis.

Early treatment of Lassa fever is very important for survival and requires specialized treatment using the guanosine analogue ribavirin. Ribavirin is known to be an effective treatment if given early.

According to Dr. Chikwe Ihekweazu, director of the NCDC, three things may be driving the recent outbreaks: 1) Nigeria's growing population; 2) its dwindling land, and 3) people being led closer to the disease host, the Mastomys rats or multimmamate rat.

NCDC through its National Lassa Fever Emergency Operations Centre has continued coordinating and providing support to states in the outbreak. The Lassa virus is transmitted to humans via contact with food or household items contaminated with rodent urine or faeces.

It is endemic to several West African countries. Benin, Liberia and Sierra Leone have all reported cases in the past month. WHO is working with countries in the region to strengthen coordination and cross-border cooperation.

Testing in the Field

3-D-printed smartphone microscope could prevent disease in developing countries. A 3-D-printed device that transforms a smartphone into a fully operational microscope could help diagnose diseases in developing countries.

Researchers from Australia's Centre of Excellence for Nanoscale BioPhotonics (CNBP) developed the clip-on microscope for use in remote areas, where standard microscopes are impractical or unavailable.

Unlike other smartphone microscopes developed in the past, the CNBP's device requires no external power or light source to function. The technology is also freely available to anyone wishing to use it, through public 3-D printing files.

The microscope works by clipping an additional lens to the camera lens on the smartphone and using the phone's existing flash to illuminate the subject matter. This setup allows for either brightfield imaging (flash on) or dark field imaging (flash off), meaning both plant and mammalian cells can be visualized.

Lead developer Anthony Orth, and his team detailed the clip in the journal *Scientific Reports,* describing how the smartphone microscope is powerful enough to visualize specimens as small as 1/200th of a millimeter.

These capabilities allow people working in remote areas to use the small microscope to analyze water cleanliness, test blood samples, and detect disease at an early stage.

Their use in remote areas can be essential—for determining water quality for drinking, through to analyzing blood samples for parasites, or for disease diagnosis—including malaria.

Cellphone-based microscope leads to possible strategy for treating river blindness. River blindness, or onchocerciasis, is a disease caused by a parasitic worm found primarily in Africa. The worm (*Onchocerca volvulus*) is transmitted to humans as immature larvae through infected black fly bites.

Symptoms of infection include intense itching and skin nodules. Left untreated, infections in the eye can cause vision impairment that leads to blindness. Mass distribution of ivermectin is currently used to treat onchocerciasis. However, this treatment can be fatal when a person has high blood levels of another filarial worm, *Loa loa*.

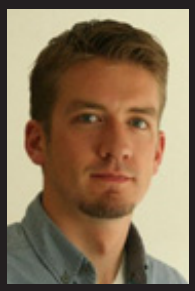
In a paper published in the *New England Journal of Medicine*, scientists from the National Institute of Allergy and Infectious Diseases (NIAID), describe how a cell phone-based video-microscope can provide fast and effective testing for *L. loa* parasites in the blood, allowing these individuals to be protected from the adverse effects of ivermectin.

In the new study, 16 259 volunteers in 92 villages in Cameroon where both *L. loa* and *O. volvulus* are commonly found provided finger-prick blood samples. These samples were then tested for *L. loa* using the LoaScope, a small microscope that incorporates a cell phone.

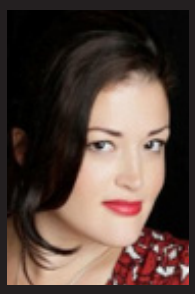
Developed by a team led by researchers from NIAID and the University of California, Berkeley, the LoaScope returns test results in less than three minutes. Using this strategy, 15 522 study volunteers were successfully treated with ivermectin without serious complications.

Which laboratory quality management system tool should I use?

Overview of tools for implementing laboratory quality management systems



Tjeerd Datema, MSc.
Advisor Laboratory Strengthening, DATOS, Hoofddorp, The Netherlands



Pamela Hepple, DrPH
Advisor Laboratory Strengthening, DATOS, Hoofddorp, The Netherlands

Linda Oskam, PhD
Advisor Laboratory Systems Strengthening, DATOS, Hoofddorp, The Netherlands

Laboratory strengthening tools are plenty in number, scope, and structure. Some are available for worldwide use, whereas others were developed for a specific region. Some were developed for health laboratories in general, others for specialist laboratories, such as tuberculosis (TB) laboratories.

The two best known programmes in Africa to assist medical laboratories with implementing a laboratory quality management system (LQMS) are: the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) and the Strengthening Laboratory Management Toward Accreditation (SLMTA) training and mentoring programme. Without claiming to be comprehensive, this article provides an overview of some of the other tools available to medical laboratories to assist them with implementing a LQMS based on the international standard for quality and competence for medical laboratories: ISO 15189.

Laboratory strengthening tools with a worldwide scope

The following laboratory strengthening tools, developed by the WHO, are free and available for worldwide use:

- The WHO Laboratory Quality Stepwise Implementation (LQSI) tool, available in six languages: https://extranet.who.int/lqsi.
- The WHO/CDC/CLSI Laboratory Quality Stepwise Implementation (LQMS) training toolkit, available in three languages: http://www.who.int/ihr/training/laboratory_quality/en/
- The WHO Laboratory Assessment Tool (LAT), available in four languages at http://www.who.int/ihr/publications/laboratory_tool/en/

Laboratory strengthening tools with a regional scope

Laboratory strengthening initiatives have also been launched in specific regions of the world. SLMTA and SLIPTA, both (initially) developed for use in sub-Saharan Africa, are examples. Similarly, the Laboratory Quality Management System Stepwise Implementation Plan (LQMS-SIP) was developed for laboratories in the Caribbean region.

Tools specific to TB laboratories

Aside from tools that can be used by any type of health laboratory, several efforts have led to development of tools for laboratories with a specific scope. Best known are the tools to strengthen tuberculosis laboratories:

- Global Laboratory Initiative (GLI) 'Stepwise Process towards TB Laboratory Accreditation' (GLI tool), available at www.GLIquality.org
- 'TB-SLIPTA' and 'TB-SLMTA', information available at http://www.who.int/tb/laboratory/afro-slipta-checklist-guidance.pdf and https://www.finddx.org/wp-content/uploads/2016/11/TB-SLMTA-flyer-28NOV16.pdf

Reviewing tools side by side

Focusing on the purpose of laboratory strengthening tools, they can roughly be divided into three different categories:

- Education
- Stepwise LQMS implementation
- Laboratory assessment

Table 1 provides an overview of the characteristics of each of the tools briefly discussed below.

The LQSI tool (Figure 1) helps medical and public health laboratories

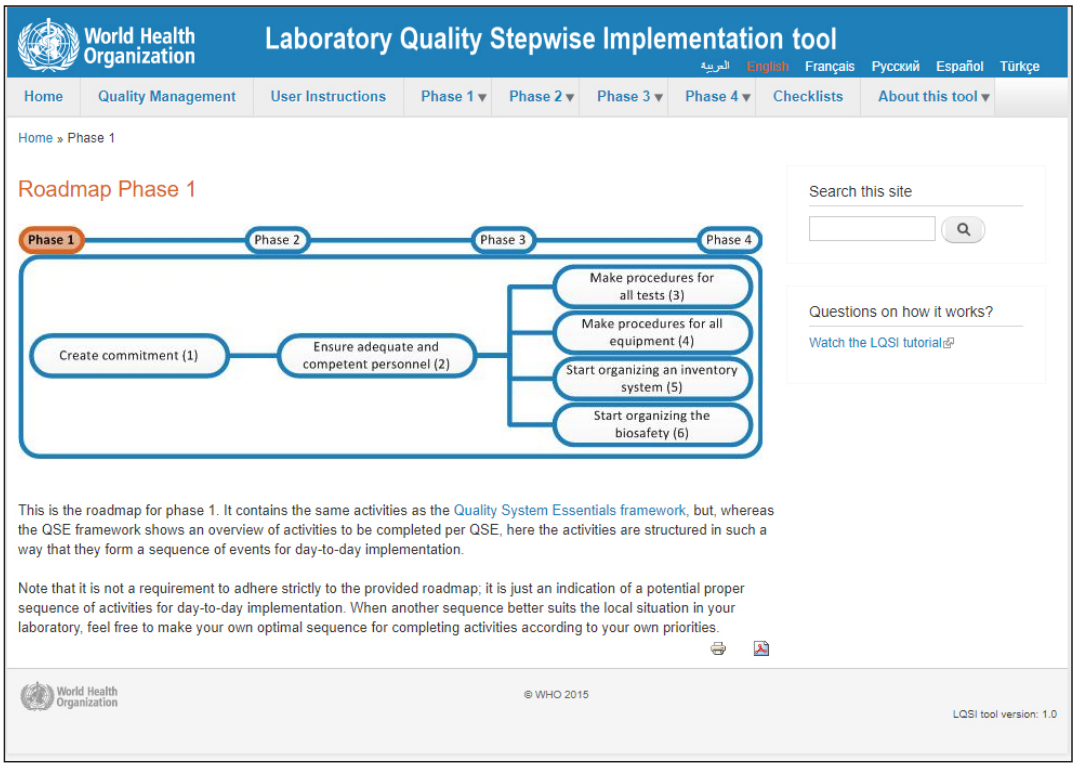


Figure 1: Screenshot of the stepwise plan of the LQSI tool

implement an LQMS, based on international quality standards, on a daily basis. The tool provides a stepwise plan and contains templates of documents, for example, Standard Operating Procedures, that laboratories can use to implement their LQMS. This is a publicly available, online tool.[1]

The WHO LQMS training toolkit provides training materials to educate laboratory professionals about quality management principles and LQMS. Part of this is the LQMS handbook, which includes information on all the LQMS elements, and a comprehensive template of a laboratory quality manual. The LQSI tool contains many links to the LQMS training toolkit.[2]

The WHO LAT can be used to assess both laboratory facilities and the country's laboratory system. It is an Excel-based checklist that, when completed, provides a semi-quantitative indication about performance (Figure 2).[3]

The LQMS-SIP consists of a three-tiered checklist that laboratories in the Caribbean region can use to implement an LQMS in a stepwise manner (Figure 3). Tier 1 is the simplest and can be used to license laboratories. Tier 2 and 3 are gradually more extensive and after reaching compliance with tier 3, laboratories can proceed towards ISO 15189 accreditation.[4]

The GLI tool is the forerunner of the LQSI tool. It provides a stepwise plan for tuberculosis laboratories to implement a quality management system. Where relevant, it also provides templates of documents, registers, and background information.[5,6]

The TB-SLIPTA checklist is, as the name implies, based on the original SLIPTA checklist. The SLIPTA checklist was harmonised with the GLI tool by the Foundation for Innovative New Diagnostics (FIND) in 2012 to address specific elements for tuberculosis laboratories and is referred to as the 'TB Laboratory

Figure 2: Laboratory facility assessment at the National Tuberculosis Reference Laboratory of Myanmar using the WHO LAT tool

Table 1: Overview of laboratory quality management system implementation tools and their characteristics

Resource	Purpose	What is it?	Developed by	Method of implementation	Source
Tools for all types of health laboratories, worldwide scope					
WHO LQSI tool	Stepwise LQMS Implementation	Stepwise Iplementation plan and assessment checklist	WHO	Self-implementation. Roll-out in the WHO European Region as part of the 'Better Labs for Better Health' initiative; WHO/EMRO includes the LQSI tool in LQMS trainings.	http://www.who.int/ihr/lyon/hls_lqsi/en/
WHO LQMS training toolkit	Education	Training files	WHO, CDC, CLSI	Self-implementation	http://www.who.int/ihr/training/laboratory_quality/en/
WHO LAT	Laboratory assessment	Checklist	WHO	Self-implementation	http://www.who.int/ihr/publications/laboratory_tool/en/
Tools for all types of health laboratories, regional scope					
SLMTA	Education and Mentoring	Mentoring process	CDC, CHAI, ASCP, APHL, CLSI, ASM	Laboratories are enrolled after endorsement by the country's Ministry of Health.	Most training materials available for download at https://slmta.org/
SLIPTA	External assessment and internal benchmarking	Assessment process with checklist	WHO/AFRO	Self-implementation for internal benchmarking. Laboratories are enrolled in the external assessment process by ASLM and WHO/AFRO after endorsement by the country's Ministry of Health.	The checklist can be downloaded at http://www.afro.who.int/publications/who-guide-stepwise-laboratory-improvement-process-towards-accreditation-slipta-african
LQMS-SIP	Guidance, monitoring and external assessment	Tiered licensing system with checklists	PAHO/WHO, CDC	Rolled-out by CROSQ and stakeholders in the Caribbean Region	https://crosq.org/index.php/projects/lqms-sip
Tools for tuberculosis laboratories, worldwide scope					
GLI tool	Stepwise LQMS implementation	Stepwise implementation plan and assessment checklist	KIT, KNCV, UNION*, CDC. Supported by USAID through TB CARE I	Self-implementation	http://www.gliquality.org/
TB-SLIPTA	External assessment/audit	Checklist	FIND	Rolled out by GLI Africa	https://www.finddx.org/wp-content/uploads/2016/07/NEW-TB-Harmonized-Checklist-v2.1-2-2016.pdf
TB-SLMTA	Education Mentoring	Mentoring process	FIND	Rolled out by GLI Africa	https://www.finddx.org/wp-content/uploads/2016/11/TB-SLMTA-flyer-28NOV16.pdf

Abbreviations: AFRO, Regional Office for Africa; APHL, Association of Public Health Laboratories; ASCP, American Society for Clinical Pathology; ASLM, African Society for Laboratory Medicine; ASM, American Society for Microbiology; CDC, US Centers for Disease Control and Prevention; CHAI, Clinton Health Access Initiative; CLSI, Clinical & Laboratory Standards Institute; CROSQ, CARICOM Regional Organization for Standards and Quality; EMRO, Regional Office for the Eastern Mediterranean; KIT, Royal Tropical Institute, The Netherlands; KNCV, KNCV Tuberculosis Foundation; PAHO, Pan American Health Organization; UNION, International Union against Tuberculosis and Lung Disease; WHO, World Health Organization.

CHECKLIST FOR THE STEPWISE IMPROVEMENT PROCESS FOR STRENGTHENING LABORATORY QUALITY MANAGEMENT SYSTEMS INDICATING THE EQUIVALENCE WITH ISO 15189

MANAGEMENT REQUIREMENTS

ISO 15189 Clauses	Requirement	What to look for	Status			Quality Improvement Levels			Comments
			Y	N	NA	Tier 1	Tier 2	Tier 3	
4.2 Quality Management System									
4.2.1	Has Management established, documented, implemented and maintained a QMS and continually improved its effectiveness in accordance with the International Standard ISO 15189?	Documented policies, processes and procedures Evidence of communication of this information to all staff Evidence that laboratory management has ensured that all documents are understood and implemented Evidence of Management reviews Data of corrective and preventive actions						x	
4.2.2 Documentation requirements									
4.2.2.1	Does the QMS documentation include procedures and records required by the International Standard ISO 15189? Does the documentation include copies of applicable regulations, standards and other normative documents?	Master list of documents SOP manuals Copies of national regulations, ISO 15189:2012, other applicable standards as referenced by the lab in its QMS, e.g. ISO 15190					x	x	
4.2.2.2 Quality Manual									
4.2.2.2	Has the laboratory established a quality manual that is accessible to and used by staff? Does the manual include all the requirements of ISO 15189:2012 Clause 4.2.2.2?	Established and documented Quality Manual Evidence of sessions to train staff on the use and applicability of the manual				x	x	x	

Figure 3: Part of the LQMS-SIP checklist

Quality Management Systems Towards Accreditation Harmonised Checklist'.[7]

The TB-SLMTA programme is a modified version of the SLMTA programme that includes tuberculosis-specific modules and guidance (in areas such as safety, sputum collection and specimen transport) and tuberculosis-specific activities, examples and tools.[8]

Complementary

Because all tools described in this article are based on the same ISO 15189 requirements, they are complementary to one another, and laboratories can make use one or more of them depending on their goals. For example: a tuberculosis laboratory may enrol in the TB-SLMTA initiative. However, this laboratory can also use the GLI tool as additional reference resource. Similarly, a laboratory that wishes to conduct an assessment, can use the LAT and/or the checklist from the LQSI tool, but can also choose to use the SLIPTA checklist.

It is key that laboratory professionals realize that one tool does not exclude the use of other laboratory strengthening tools. They should use what best fits their needs at a particular point in time; Table 1 may be of help in making this choice. After all, every tool was developed with the same purpose: to assist health laboratories to implement ISO 15189 requirements and improve the quality of their services, and as such improve patient care and prevent disease outbreaks – the reason why we all choose to work in laboratory science!

RESOURCES

1. World Health Organization. Laboratory Quality Stepwise Implementation tool [Internet]. 2014 [cited 2017 Dec 15]. Available from: https://extranet.who.int/lqsi

2. World Health Organization. Laboratory quality management system training toolkit [Internet]. [cited 2017 Dec 15]. Available from: http://www.who.int/ihr/training/laboratory_quality/en/

3. World Health Organization. Laboratory assessment tool [Internet]. [cited 2017 Dec 15]. Available from: http://www.who.int/ihr/publications/laboratory_tool/en/

4. Caricom Regional Organization for Standards and Quality. LQMS-SIP [Internet]. [cited 2017 Dec 15]. Available from: https://www.crosq.org/index.php/projects/lqms-sip

5. Datema TAM, Oskam L, Engelberts MFM, Van Beers SM, Shinnick TM, Baker M, et al. Global laboratory initiative tool for a stepwise process towards tuberculosis laboratory accreditation. Int J Tuberc Lung Dis. 2012;16(5):704–5.

6. Global Laboratory Initiative. GLI Stepwise Process towards TB Laboratory Accreditation [Internet]. [cited 2017 Dec 15]. Available from: http://www.gliquality.org/

7. Foundation for Innovative New Diagnostics. TB Laboratory Quality Management Systems Towards Accreditation Harmonized Checklist [Internet]. 2.1. 2016. Available from: https://www.finddx.org/wp-content/uploads/2016/07/NEW-TB-Harmonized-Checklist-v2.1-2-2016.pdf

8. Foundation for Innovative New Diagnostics. TB Laboratory Accreditation - A training and mentoring programme. 2016; Available from: https://www.finddx.org/wp-content/uploads/2016/11/TB-SLMTA-flyer-28NOV16.pdf

This paper was written by experts from DATOS. DATOS is an organization that works on all aspects of improvement of medical laboratory services under the One Health approach with a special focus on low- and middle-income countries. Its staff combined has more than 30 years' experience in providing training and advice for improving the quality of services of medical laboratories, networks and systems all over the world and believe in capacity building through interactive training and designing sustainable, tailor-made solutions together with local experts. Read more at www.datos-advice.com

Successes and challenges of expanding the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) programme in Africa: 2012-2017

Introduction

In July 2011, the World Health Organization Regional Office for Africa (WHO/AFRO) convened a consultative meeting in Kenya to finalize the development of the SLIPTA programme. SLIPTA is a framework for auditing and improving the quality of public health laboratories in a stepwise manner to fulfil all the requirements of the International Organization for Standardization (ISO).[1] WHO/AFRO published the SLIPTA Guideline and Checklist in line with the ISO 15189 standard's particular requirements for the quality and competence of medical laboratories. SLIPTA helps to evaluate, recognize and reward the quality improvement processes by using a 0-to-5 Star Level rating system. This makes SLIPTA affordable, sustainable, effective and scalable for developing countries.[2]

The SLIPTA Guideline provides details on how policy makers, Ministries of Health, government and management officials, public health and medical professionals, laboratory scientists, clinicians, technical experts and partners can implement the initiative to strengthen the laboratory systems in their countries. The roles and responsibilities of these stakeholders are specified in the Guideline.[1] Currently, SLIPTA is used to encourage, support and recognize the implementation of quality management systems in public health laboratories in the African Region and contribute to the provision of quality test results; i.e. accurate, reliable and timely results for patient care, treatment and public health services.

Background

In October 2012, WHO/AFRO requested that 47 Member States designate a SLIPTA Focal Person to coordinate, share information and oversee the programme's implementation. More importantly, the newly established ASLM was designated as an independent pan-African laboratory association to implement the SLIPTA programme in Africa. ASLM's role would be to train auditors, coordinate and oversee laboratory audits, and provide certificates of recognition, line with ASLM's 2020 Vision[3] to improve healthcare in Africa by strengthening quality laboratory services. That same year, ASLM developed standardized materials for training of SLIPTA auditors and mentors and for auditing laboratories. The SLIPTA Guideline and Checklist, as well as the ISO 15189 and ISO 19011 standards,[4,5] were used in developing a five-day training curriculum to be cascaded at the country and regional levels.

The SLIPTA Training: The first three days of the training are allocated for didactic sessions, the fourth day for conducting a mock audit, and the final day for providing feedback and discussion. Trainees are then examined for their understanding of the SLIPTA programme, SLIPTA Checklist, and audit procedures. Participants must score at least 70% to pass the final examination. In order to quality as a certified SLIPTA auditor, successful participants of the 5-day training are assigned 3-5 SLIPTA audits under the close supervision and guidance of ASLM's certified lead auditors.

Accomplishments

Since 2011, ASLM has trained more than 350 laboratory professionals in 17 countries, of whom 167 are certified. Ninety percent (150 of 167) of these certified auditors are Anglophone, 8% (n=14) are Francophone and the remaining 2% are Portuguese speaking. In 2014, the certified auditors took over training and mentoring of SLIPTA trainee auditors from the three ASLM Program Managers. This has ensured the efficient expansion of the SLIPTA programme through mobilizing certified auditors within the same or nearby countries. This also helps to build a country's capacity and ensure ownership. ASLM maintains responsibility for coordination, communication and supervision of training, auditing and issuing certificates.

ASLM started SLIPTA audits with three laboratories in

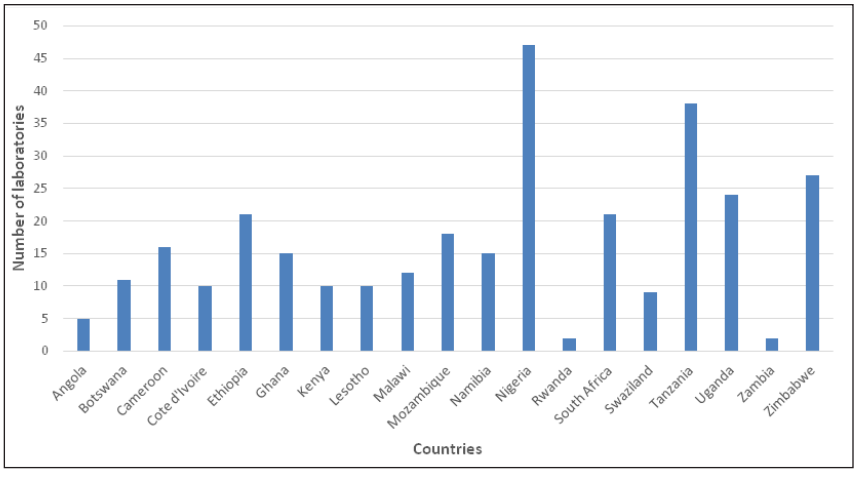


Figure 1. Number of laboratories audited per country (May 2013 to December 2017)

May 2013 in Lesotho. With the rapid increase in the number of ASLM-certified SLIPTA auditors from May 2013 to December 2017, a total of 313 laboratories (Figure 1) have been audited in 19 African countries (Figure 2). Thirty-three percent (n=104) of these laboratories achieved the 2 Star Level, 24% (n=75) achieved the 3 Star Level, 23% (n=71) achieved the 1 Star Level, and 8% (n=24) achieved the 4 Star Level. Only three laboratories (two in South Africa and one in Nigeria) achieved the 5 Star Level and 36 laboratories remained at the 0 Star Level (Figure 3).

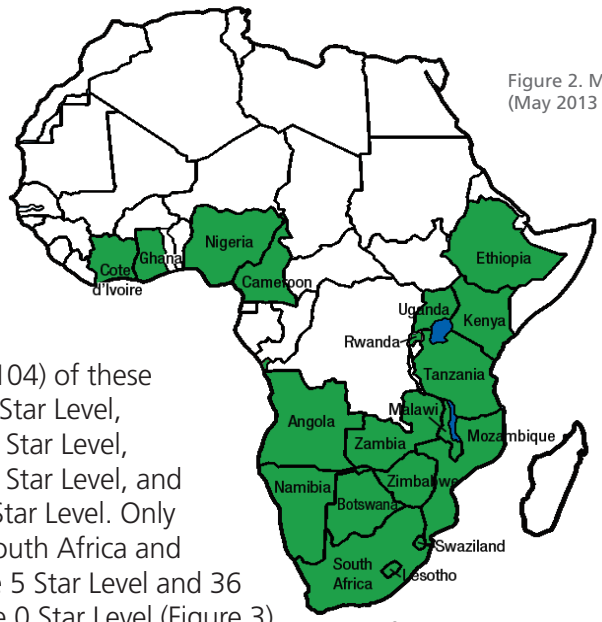


Figure 2. Map of African countries with SLIPTA Coverage (May 2013 to December 2017)

As of 2017, 28 African countries had designated a SLIPTA Focal Person who communicates with ASLM. ASLM has so far visited 15 countries more than once – four times for Ghana, Lesotho, and Tanzania, and three times in Cameroon, Ethiopia, Mozambique, Nigeria, and Zimbabwe. Out of the 313 laboratories, 17 have been audited twice and 4 were audited three times. To date, 20 (6%) of the 313 SLIPTA-audited laboratories have successfully achieved ISO accreditation. ASLM has developed an online SLIPTA database where anyone can view all first-hand data on the number of trained auditors, audited and certified laboratories, and visited countries.[6]

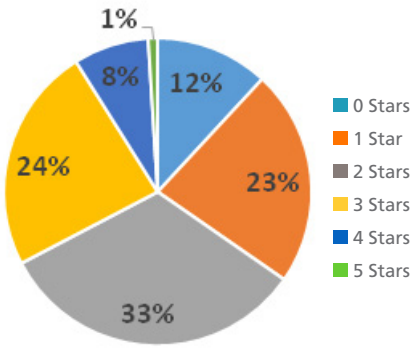


Figure 3. Distribution of star levels amongst the 313 audited laboratories from May 2013 to December 2017.

Challenges

Expanding the SLIPTA programme has not been without challenges. Despite creating awareness at the ASLM biannual conference and other venues, only a few countries have committed to expanding SLIPTA. Countries with a designated SLIPTA Focal Person have limited resources to support the expansion, and ASLM has a limited budget for deploying its certified auditors to facilitate auditor training or audit laboratories. Finally, the existing SLIPTA Guideline and procedures do not encourage private laboratories to be audited or supported, as all SLIPTA applications must be submitted by the SLIPTA Focal Person at the Ministry of Health, which prioritizes public laboratories.

Way Forward

To ensure a sound expansion and full coverage of SLIPTA across all African countries, ASLM is building strong collaborations with various stakeholders, donor agencies and implementing partners. Each country must assign a SLIPTA Focal Person and ensure the availability of appropriate resources for training of auditors and auditing of laboratories. Countries need to have a national laboratory policy and strategic plan that clearly address laboratory quality services. In addition, the SLIPTA Focal Person must proactively share information and coordinate SLIPTA implementation in the country. To sustain its role in SLIPTA's expansion, ASLM is working to establish a dedicated team to oversee and lead SLIPTA implementation in Africa. ASLM must also efficiently utilize its online SLIPTA platform to communicate and update each country and thereby encourage participation in and expansion of the programme. Finally, in order to maintain the competency of certified auditors, ASLM plans to develop an online SLIPTA auditor training scheme and continuing education.

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Teferi Mekonen, MSc, MPH,
SLIPTA Program Manager,
African Society for Laboratory Medicine (ASLM)

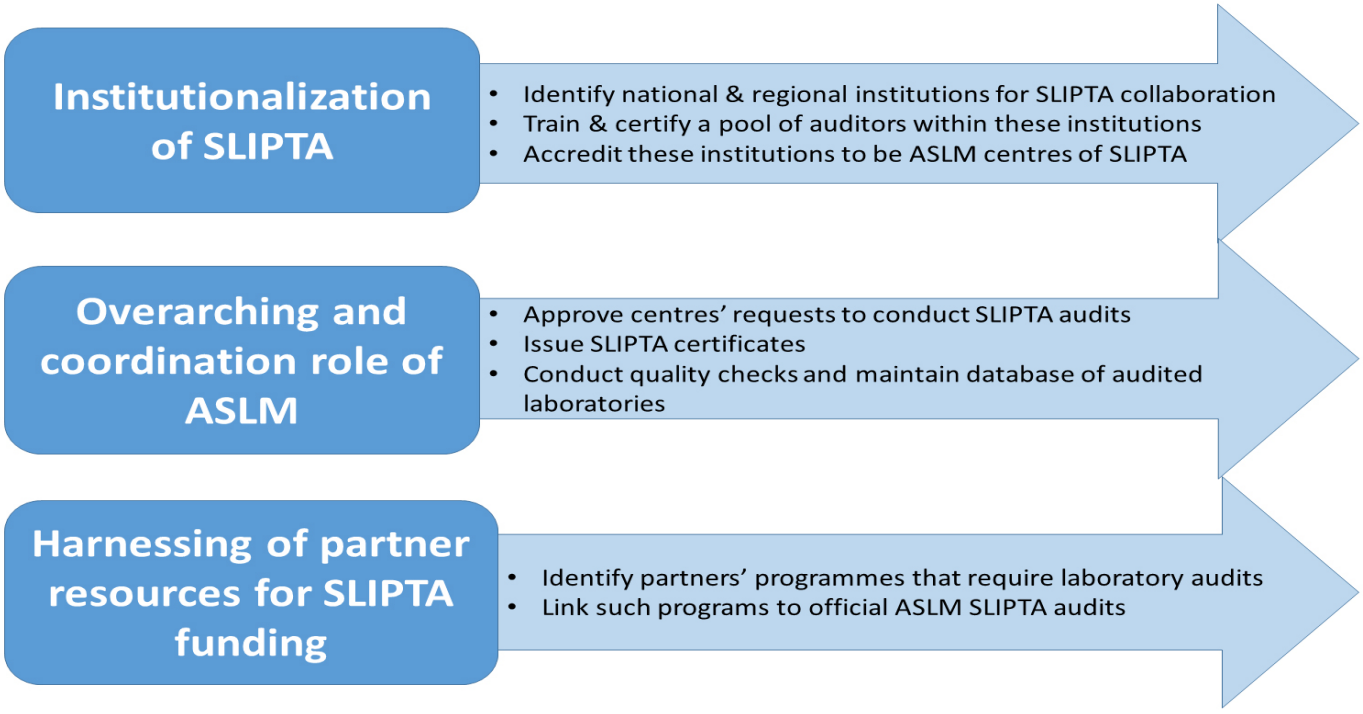
SLIPTA 2.0 – the next "country driven" frontier for laboratory quality improvement

In 2011, the World Health Organization Regional Office for Africa (WHO/AFRO), along with other major stakeholders, launched the Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA)[1]. Since then, it has become a flagship program. SLIPTA is a world-class framework for improvement of laboratory quality management systems (QMS) in developing countries to fulfil international laboratory standards in a stepwise process. The SLIPTA process is intended to encourage, support and recognize the implementation of QMS in medical laboratories in the African region, so that laboratories provide safe, timely and accurate results for patient care and public health purposes.[2]

While the programme has seen many successes, by end of 2017, the African Society for Laboratory Medicine (ASLM), as the implementer of the SLIPTA program in Africa, had audited only a little over 300 laboratories in 19 African countries[3] and trained and certified over 160 ASLM SLIPTA auditors on the continent. Although the exact number of medical laboratories in Africa is not known, Uganda alone had 1234 government laboratories in 2007.[4] This is a clear indication on how small the coverage has been over the years and the urgent need for a rapid scale-up of the SLIPTA programme. The SLIPTA programme, like most programs supported by the US President's Emergency Plan for AIDS Relief, (PEPFAR), was rolled out largely in sub-Saharan Africa[5], while other regions still remain underserved. Private sector laboratories (where an estimated of 60% of the population in Africa seek diagnostic services), and faith-based or non-governmental organization have remained behind as the programme's initial reach was to public health laboratories. In addition, there still remains inadequate in-country capacity to conduct SLIPTA audits.

Realizing the above challenges, WHO/AFRO, ASLM and its key partners have launched 'SLIPTA 2.0' as an effort to refocus the SLIPTA programme to development of in-country capacity and with a focus on reaching all laboratories and countries in Africa. SLIPTA 2.0 is set to be a country-owned programme that is housed and driven by Ministry of Health departments utilizing the resources available. To enable full expansion and increased coverage of SLIPTA, ASLM is looking to build strong collaborations with various stakeholders, donor agencies and implementing partners to improve the quality of laboratory services towards accreditation based on national, regional and international standards.

The SLIPTA 2.0 programme will see ASLM redefining its role to be more overarching and focused on coordination, rather than auditing. In order to increase coverage of the SLIPTA programme to all regions of the continent, ASLM will identify and strengthen national and regional institutions that can support the scale-up of stepwise processes towards accreditation of countries' laboratories. In this new phase, ASLM will build capacity within institutions that have a bigger mandate for many laboratories under them. The aim will be to reduce the travelling of auditors from one country to another to conduct SLIPTA audits



and emphasise using local auditors to roll out the programme. This will not only increase the width and breath of the SLIPTA programme, but also reduce its cost. In so doing, ASLM expects not only to increase partnerships with SLIPTA and increase SLIPTA coverage across the continent, but also see SLIPTA become a national Quality Assurance programme, while diversifying SLIPTA's funding base as collaborations with many partners are established.

SLIPTA 2.0 concept

The SLIPTA 2.0 programme will be integrated into routine Ministry of Health laboratory quality assurance programmes. It is envisioned that this will no longer be seen as an external programme run from the ASLM Secretariat, but a part of the country's laboratory strategic plans with only the coordination, guidance and awarding of certificates being provided by ASLM.

Under SLIPTA 2.0, ASLM will bring together international and regional partners such as Africa Centres for Disease Control and Prevention (Africa CDC), the United States CDC/PEPFAR, WHO and many partners to set the right stage for political buy-in and demand. SLIPTA trainings will be organised to develop the critical mass of a certified pool of auditors locally. ASLM will seek to establish memorandums of understanding with national and regional institutions that will run the programme. The deployment of the certified pool will be managed by these national and regional institutions with the approval of ASLM. ASLM will share its tools with the institutions and provide continued support. ASLM will make a conscience effort to ensure all the regions of Africa, especially the West, Central and North regions, have these institutions / centres established.

As a coordinating body, ASLM will provide online support training programmes for auditors, in order to ensure that they maintain their competence. This will ensure that the quality of audits is maintained. In addition, ASLM will conduct quality spot visits to these institutions / centres to ensure alignment to ASLM standards for the SLIPTA programme. ASLM's website will host all current SLIPTA documents, guidelines and the latest updates on laboratories being audited.

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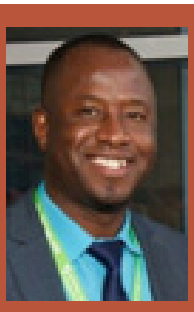
Nqobile Ndlovu, HBMLS, MPH
ASLM, Addis Ababa, Ethiopia



The fundamental challenge of laboratory associated waste management

By *MLO* Staff

The management of solid and liquid waste is an ongoing challenge for both developed and developing nations. Effective and efficient waste management is crucial in terms of land use, economic growth, environmental stewardship and public health. On the African continent, pan-African organizations, corporations and individual nations have made strides in recent years to improve and standardize waste management procedures.[1-4]

The safe disposal of healthcare-associated waste is a crucial part of waste management in every nation, and public health depends on it. Proper management of discarded medical equipment and supplies, sharps, and solid and serum samples is key to good practice and population health management. The clinical lab is at the center of this challenge, and plays a vital role in meeting it.

Initiative for Tanzania

The African Society for Laboratory Medicine (ASLM) instituted an initiative last year to strengthen national efforts in biosafety and biosecurity in Tanzania.[5] ASLM organized a national biosafety and biosecurity stakeholders' meeting in Dar es Salaam, Tanzania, on 15-16 May 2017, in collaboration with its Tanzania-based implementing partners, Health Links Initiative (HLI), the US Centers for Disease Control (CDC) and the US Defense Threat Reduction Agency (DTRA) via its CDC Cooperative Agreement to implement the Global Health Security Agenda (GHSA). The stakeholders worked to find the best strategies possible for Tanzania to implement biosafety and biosecurity nationwide, and developed recommendations for activities to implement overall laboratory strengthening with regard to biosafety and biosecurity in Tanzania. Recommendations included:

1. Work on a legal framework for laboratory biosafety and biosecurity with all relevant components, such as registration, facilities requirements, education requirements, research approval, policies and regulations on imports/exports;
2. Implement the legal framework by incorporating safety issues in all sectors, including human, animal, food, water and environmental health;
3. Consider a harmonized approach for all clinical, teaching and research laboratories.

These broad goals were further refined, as the group determined that efforts going forward should be focused on developing a costed national biorisk management strategic plan; implementing a biosafety and biosecurity training plan at zonal, regional and veterinary laboratories; developing guidelines and procedures for biobanking and inventorying; developing guidelines and procedures for sample transportation; and reviewing guidelines and procedures for waste management (among others). The Tanzanian initiative holds promise as a model for other African states.

WHO guidance

The World Health Organization (WHO) offers a lengthy guidance manual on 'Fundamentals of healthcare waste management[6] that is applicable to the clinical lab and to the development and structuring of national laboratory standards. The most directly relevant section offers 'Guidance for the specific management of hazardous and infectious healthcare waste.' In this section, the WHO offers guidance by category of waste.

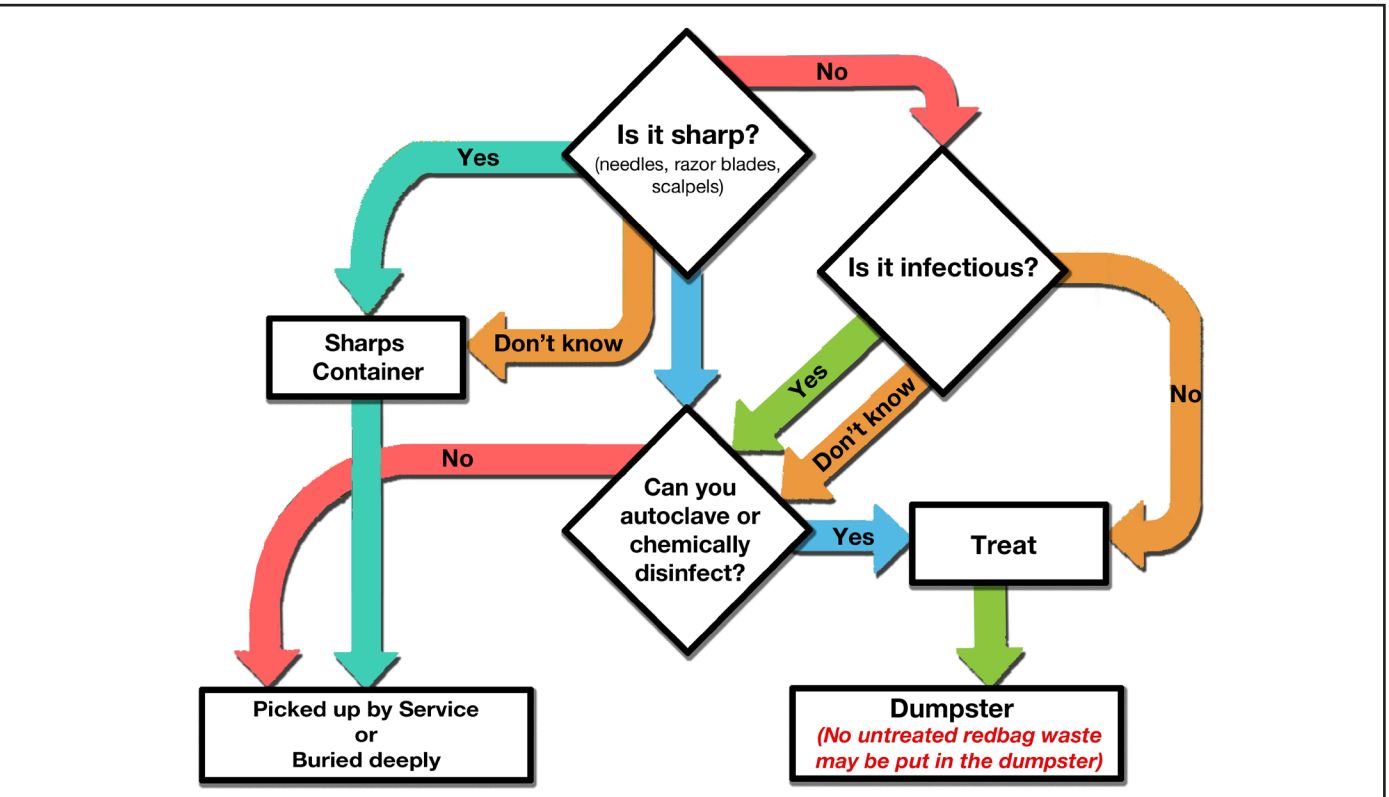
The categories:

- *Non-risk waste.* Non-risk healthcare waste, if well segregated, can be disposed of with domestic waste. Depending on the quantities of this category of waste, it might be worth investigating ways of recuperating/recycling items such as paper and cardboard as well as plastic and metal cans that come from the administration and kitchen. Leftover food from the kitchen as well as garden waste (leaves, etc.) can be recycled into valuable compost.
- *Human anatomical waste.* WHO notes that it is primarily for ethical reasons that special requirements are placed on the management of waste such as human body parts, organs and tissues. The waste must be collected in appropriate containers or bags as soon as possible at the place where it is generated. It must be kept in tight receptacles and under stable low temperature (5-8°C) conditions when stored temporarily for a prolonged period of time. Intermediate storage takes place at a location that is accessible only to trained personnel (in general the mortuary). Normally, the waste must always be incinerated completely in an appropriate facility.
- *Sharps.* Sharps require that measures be taken to prevent injury and infection during their handling within and outside of the healthcare facilities. They have to be collected and managed separately from the other categories of healthcare waste: the collection containers (safety boxes) must always be puncture- and leak-proof. The storage of sharps to be disposed of should always take place at a location that is accessible only to trained personnel. Once the safety boxes are sealed, they can be disposed of with the other infectious waste depending on the type of disposal technology that is selected.
- *Infectious waste.* Infectious wastes must be collected in leak-proof containers, carefully sealed and transported to a central storage facility/delivery point in a way that precludes direct contact. They must either be incinerated or disinfected prior to final disposal using a recognized method, preferably treatment with saturated steam (autoclaving). If autoclaving is the selected option for infectious waste treatment, the efficiency of the vapour disinfection plant must be verified by a recognized institution when the plant is first put into operation and at regular intervals thereafter (for example, twice a year), using appropriate microbiological indicators.
- *Highly infectious waste.* Some medical areas produce healthcare waste that can reasonably be suspected to be contaminated with highly contagious pathogens. Such sources include: all laboratory samples containing body fluids, tissues or faecal stools; isolation wards; and medical research facilities handling class 3 or higher pathogens. Waste from these sources should always be pre-treated at the source and then placed into yellow bags before joining the waste stream within the hospital. Autoclaving at a temperature of 121°C at 1-1.5 bars for at least 20 minutes should be the selected pre-treatment option. However, if a distinct autoclave is not available at the source to ensure a thermal treatment, highly infectious waste can be disinfected in a concentrated 2% solution of sodium hypochlorite and left overnight before being discarded in a specific yellow bag that is properly sealed and itself discarded with infectious waste.
- *Other healthcare waste.* Large quantities of chemicals should be returned to the supplier for adequate treatment. Considering that there is currently a lack of appropriate treatment facilities for chemicals in most of the sub-Saharan countries of Africa, on-site disposal must therefore be foreseen. In such circumstances, non-corrosive and non-flammable chemicals may be encapsulated separately to avoid unwanted chemical reactions after neutralisation. Waste with a high content of heavy metals should normally be treated in specific recycling/ treatment facilities. Alternatively, it may be encapsulated. Waste with high heavy metal content, in particular mercury or cadmium, should never be incinerated.

WHO's healthcare waste fact sheet

Additionally,[7] the WHO shares these relevant facts:

- Of the total amount of waste generated by healthcare activities, about 85% is general, non-hazardous waste.
- The remaining 15% is considered hazardous material that may be infectious, toxic or radioactive.
- Every year an estimated 16 billion injections are administered worldwide, but not all of the needles and syringes are properly disposed of afterwards.
- Open burning and incineration of healthcare wastes can, under some circumstances, result in the emission of dioxins, furans, and particulate matter.
- Measures are needed to ensure the safe and environmentally sound management of healthcare wastes. Such measures prevent adverse health and environmental impacts from the unintended release of chemical or biological hazards, such as drug-resistant microorganisms, into the environment, which helps protect the health of patients, health workers, and the general public.
- On average, high-income countries generate up to



University of Wisconsin—Milwaukee, Department of University Safety & Assurance

0.5 kg of hazardous waste per hospital bed per day, whereas low-income countries generate an average of 0.2 kg. However, healthcare waste is often not separated into hazardous or non-hazardous wastes in low-income countries, meaning the real quantity of hazardous waste may be much higher.

Health risks

The WHO continues: Healthcare waste contains potentially harmful microorganisms that can infect hospital patients, health workers and the general public. Other potential hazards may include drug-resistant microorganisms which spread from health facilities into the environment.

Adverse health outcomes associated with healthcare waste and by-products also include:

- sharps-inflicted injuries
- toxic exposure to pharmaceutical products, in particular, antibiotics and cytotoxic drugs released into the surrounding environment, and to substances such as mercury or dioxins, during the handling or incineration of healthcare wastes
- chemical burns arising in the context of disinfection, sterilization or waste treatment activities;
- air pollution arising as a result of the release of particulate matter during medical waste incineration;
- thermal injuries occurring in conjunction with open burning and the operation of medical waste incinerators
- radiation burns

Sharps-related

The WHO gives special attention to sharps-related hazards. Not all needles and syringes are disposed of safely, creating a risk of injury and infection and opportunities for unsafe reuse. Injections with contaminated needles and syringes in low- and middle-income countries have decreased substantially in recent years, partly due to efforts to reduce reuse of injection devices. Despite this progress, in 2010, unsafe injections were still responsible for as many as 33 800 new HIV infections, 1.7 million hepatitis B infections and 315 000 hepatitis C infections. A person who experiences one needle stick injury from a needle used on an infected source patient has risks of 30%, 1.8% and 0.3% respectively of becoming infected with hepatitis B, hepatitis C and HIV.

Additional hazards occur from scavenging at waste disposal sites and during the handling and manual sorting of hazardous waste from healthcare facilities. These practices are common in many regions of the world, especially in low- and middle-income countries. The waste handlers are at immediate risk of needle-

stick injuries and exposure to toxic or infectious materials. In 2015, a joint WHO/UNICEF assessment found that 58% of sampled facilities from 24 countries had adequate systems in place for the safe disposal of healthcare waste.

The WHO includes as part of its Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist, 'Waste Disposal: Is sufficient waste disposal available and adequate? Is waste separated into infectious and non-infectious waste, with infectious waste autoclaved/incinerated?' and 'Handling of Sharps: Are "sharps" handled and disposed of properly in "sharps" containers that are appropriately utilized,' along with other biosafety and chemical safety checklist items.[8]

Environmental impact

The environmental effects of improper waste management are also addressed in the WHO document. Improper treatment and disposal of healthcare waste may pose health risks indirectly through the release of pathogens and toxic pollutants into the environment.

- The disposal of untreated healthcare wastes in landfills can lead to the contamination of drinking, surface and ground waters, if those landfills are not properly constructed.
- The treatment of healthcare wastes with chemical disinfectants can result in the release of chemical substances into the environment, if those substances are not handled, stored and disposed of in an environmentally sound manner.
- Incineration of waste has been widely practised, but inadequate incineration or incineration of unsuitable materials results in the release of pollutants into the air and in the generation of ash residue. Incinerated materials containing or treated with chlorine can generate dioxins and furans, which are human carcinogens and have been associated with a range of adverse health effects. Incineration of heavy metals or materials with high metal content can lead to the spread of toxic metals in the environment.
- Only modern incinerators operating at 850-1100°C and fitted with special gas-cleaning equipment are able to comply with the international emission standards for dioxins and furans.
- Alternatives to incineration such as autoclaving, microwaving, or steam treatment integrated with internal mixing, which minimize the formation and release of chemicals or hazardous emissions, should be given consideration in settings where there are sufficient resources to operate and maintain such systems and dispose of the treated waste.

Awareness and action

The WHO asserts that lack of awareness about the health hazards related to healthcare waste, inadequate training in proper waste management, absence of waste management and disposal systems, insufficient financial and human resources and the low priority given to the topic are the most common problems connected with healthcare waste. Many countries either do not have appropriate regulations or do not enforce them.

The WHO provides an action plan, asserting that the management of healthcare waste requires increased attention and diligence to avoid adverse health outcomes associated with poor practice, including exposure to infectious agents and toxic substances. Key elements in improving healthcare waste management are:

- promoting practices that reduce the volume of wastes generated and ensure proper waste segregation
- developing strategies and systems along with strong oversight and regulation to incrementally improve waste segregation, destruction and disposal practices with the ultimate aim of meeting national and international standards
- where feasible, favouring the safe and environmentally sound treatment of hazardous healthcare wastes (e.g., by autoclaving, microwaving, steam treatment integrated with internal mixing, and chemical treatment) over medical waste incineration;
- building a comprehensive system that addresses responsibilities, resource allocation, handling and disposal (a long-term process, sustained by gradual improvements)
- raising awareness of the risks related to healthcare waste, and of safe practices
- selecting safe and environmentally-friendly management options, to protect people from hazards when collecting, handling, storing, transporting, treating or disposing of waste

The WHO concludes that government commitment and support is needed for universal, long-term improvement, although immediate action can be taken locally.

African nations' guidelines

Ethiopia,[9] Rwanda,[10] and Kenya[11] have published detailed guidelines for waste management in the clinical laboratory. Ethiopia's 'Health and Safety Guidelines for Public Health Laboratories' is a comprehensive document that includes the broad areas of waste separation and storage; waste handling; the various options for infectious disease waste treatment

(e.g., mechanical treatment, chemical disinfection, heat sterilization, sterilization by microwave and incineration); treatment of liquid waste; disposal of solid waste; and radioactive waste management policy. The document discusses separately hazardous biological waste, hazardous solid waste, waste containing sharps, liquid contaminated waste, human and animal tissue waste and chemical waste.

Rwanda's 'National Guidelines on Healthcare Waste Management' focuses on the health effects of healthcare waste; categories of waste; waste management planning; waste minimizing, recycling and reuse; handling, labeling, containment, transport and storage; treatment and disposal options; requirement for occupation health and safety practices; community healthcare waste management; and collection and disposal of waste water from health facilities. The document also explains the framework provided by relevant national legislation, including environmental health policy.

Kenya's 'Health care waste management plan 2016–2021' also stresses the policy and legal framework and includes an ambitious strategic plan with benchmarks and measurable outcomes, and a detailed planning matrix. 'In the planned strategy, all health care facilities in Kenya that generate [healthcare waste] should set up comprehensive waste management systems based on the most appropriate means of achieving human and environmentally safe management of health care waste. The most important step is to begin with commitment of Health System Managers at all levels to address Kenya's waste management challenges.' The document calls on policymakers to allocate the necessary resources for the management of healthcare waste.

Supply chain considerations[12]

Waste management policies and processes often intersect with policies regarding the ordering and utilisation of supplies. Waste management is linked to effective and efficient product selection, delivery frequency, and usage, including choosing the right products in the right quantities at the right time—from simple disposables to kit and tray components to sharps. Implementing just-in-time or stockless inventory programs for low-unit-of-measure distribution enables end users to access products only when needed for selected cases, patients and procedures.

The way to improve product selection, usage, reprocessing and eventual disposal can involve information technology systems, supply data standards for track-and-trace intelligence and value management processes, including data analytics. Reporting systems can provide access to valuable information concerning waste generation, disposal, and associated costs. Information technology also can be used to monitor waste processing equipment to make sure that it is functioning correctly, to indicate when service is required and to evaluate and improve the waste-pickup process. With better control of supply management, there also can be less waste of supplies. An automated system makes it easier to proactively remove expired, recalled or obsolete products—which, as a result, reduces waste. Information also can be gathered to examine how much and what kinds of waste are being generated in a facility.

Information technology can also help a laboratory get a handle on what might be called 'the hierarchy of waste.' Segregating types of waste is very valuable. Not all waste, for example non-risk waste, needs to be incinerated. Proper waste management goals should be to reduce incineration from an emission perspective, especially when it's more sustainable to dispose of waste with reusable waste containers and autoclave whenever possible.

The long view

As African healthcare systems standardize procedures, national guidelines and requirements that govern waste management and disposal must be taken into consideration as well. This will increase in the years ahead. Everyone's goal—safe, effective healthcare delivery, spearheaded by a dedicated, modernizing clinical laboratory community—will only be further advanced by the coming standardization.

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Meet John Nkengasong, MS, PhD, Director of the Africa Centres for Disease Control and Prevention

Dr Nkengasong has received numerous awards for his service to global public health including the US Secretary of Health and Human Services Award for excellence in Public Health Protection Research, the US CDC Sheppard Award, the US CDC Director's Recognitions Award, and the William Watson Medal of Excellence. He recently received the Power of One Award from Heart to Heart International in recognition of his lifetime of leadership and service to improving global health. He is a recipient of the knight of honour medal from the government of Cote d'Ivoire and was knighted as an Officer of Lion by the President of Senegal, H.E. Macky Sall, for his significant contributions to public health in Africa.

Would you briefly walk us through your journey from the bench to heading the Africa CDC?

I was educated at the Institute of Tropical Medicine in Antwerp and the University of Brussels in Belgium. Between 1993-95 I was Chief of the Virology and the World Health Organization (WHO) Collaborating Center on HIV diagnostics, at the Department of Microbiology, Institute of Tropical Medicine, then joined the US Centers for Disease Control and Prevention (CDC) Ivory Coast, Abidjan office in 1995 as Chief of the Virology Laboratory. I then served as the Chief of the US CDC's International Laboratory Branch at the Division of HIV and tuberculosis and as Associate Director of Laboratory Science in the same Division. Before joining Africa CDC, I also served as the deputy principal director (acting) for the US CDC's Center for Global Health.

In a few words can you describe the mission of Africa CDC and difference from the WHO Regional Office for Africa?

Africa CDC will provide strategic direction and promote public health practice within African Union member states through capacity building, minimization of health inequalities, promoting continuous quality improvement in the delivery of public health services as well in the prevention of public health emergencies and threats, through partnerships, science, policy, and data-driven interventions and programs.

The Africa CDC's five strategic pillars include: 1) disease surveillance and intelligence; 2) innovative information systems, with a focus on improved capacity, improved public health decision making and action; 3) establish functional and linked clinical and public health laboratory networks in the five geographic sub-regions of Africa; 4) support member states to develop public health emergency preparedness and response plans; and 5) strengthen public health science and institutes for improved decision making and practice.

One thing that differentiates us from WHO Regional Office for Africa is Africa CDC's ability to work across multiple sectors, including military, agriculture, finance and economic departments, thanks to its unique location at the African Union Commission. For instance, recently, after a detailed briefing from the Africa CDC, the African Union Peace and Security Council endorsed public health threats as a major peace and security menace to the continent. This is a significant development as this will allow Africa CDC to use the peace and security assets that the Africa Standby forces have in the region to respond to any disease emergences.

Africa CDC was officially launched in January 2017 and you became the first Director. What were the circumstances that lead to its creation?

The Ebola virus disease (EVD) crisis in West Africa accelerated the establishment of Africa CDC, which was officially launched in Addis Ababa, Ethiopia on 31 January 2017, by African heads of state and the leadership of the African Union Commission. By conceiving and launching Africa CDC, African leadership leveraged the EVD public health crisis that exposed the weakness of the health systems in the affected countries, and did not waste the opportunity. Historically, several public health agencies have been established in the aftermath of severe and impactful health emergencies and crisises that necessitated an efficient response. For instance, the creation of the US CDC in 1946 followed malaria outbreaks, and the establishment of China CDC in 2002, the Public Health Agency of Canada in 2003, and the European CDC in 2003 all followed on the heels of the Severe Acute Respiratory Syndrome (SARS) outbreak.

Several compelling reasons further argued for the establishment of Africa CDC: 1) rapid population growth leading to increased and rapid population movement across the continent and the world (the estimated population of Africa was 280 million in 1960 and 1.2 billion in 2016, and will be about 2.5 billion by 2050); 2) existing endemics (HIV, tuberculosis and malaria), emerging infectious pathogens, and the ascendance of antimicrobial resistance; 3) increasing incidence of non-communicable diseases and injuries; 4) persistently high maternal mortality rates; and 5) threats posed by environmental toxins.

Dr John Nkengasong being knighted with the Medal of Honor by the President of Senegal, His Excellency Macky Sall. June 2017, Dakar, Senegal

The resolve to establish a new continental African public health agency started in July 2013 at the African Union Special Summit on HIV, TB and Malaria in Abuja, Nigeria. At the Summit, African leaders recognized the need for an Africa CDC to conduct lifesaving research on priority health problems and to serve as a platform to share knowledge and build capacity in responding to public health emergencies and threats in Africa. In January 2014, these African leaders again re-affirmed their support for Africa CDC. This was followed by commitments from African Ministers of Health at a jointly convened meeting of the African Union and WHO in Luanda, Angola, in April 2014 to provide technical support to Africa CDC. Then, in September 2014, at an assembly devoted to responding to the Ebola outbreak, African leaders formally endorsed an accelerated timeline to launch the Africa CDC, together with the five regional centres, by mid-2015. The new resolution expanded the mandate for Africa CDC to include strengthening of early warning systems, timely and effective response health emergencies, and the coordination and harmonization of domestic health regulations and interventions as well as the dissemination of best practices.

What is the relationship of Africa CDC to ASLM?

Africa CDC sees the African Society for Laboratory Medicine (ASLM) as a strategic partner in carrying out its goals. Africa CDC is a public health agency that will seek to strengthen laboratory systems and networks in Members States. Each Africa CDC Regional Coordinating Centre (RCC) will house a Regional Integrated Surveillance and Laboratory Network (Africa CDC RISLNET) to leverage all available public health assets in their respective regions, including universities, national public health institutes, private laboratories, centres of excellence, non-governmental organizations, and veterinary networks. The Africa CDC RISLNET offers platform architecture to implement Africa CDC's five-year strategic plan, which was endorsed by its Governing Board in March 2017. As part of the RISLNET activities, Africa CDC will support countries and regions to map existing surveillance and laboratory networks, including private laboratories, in order to provide institutional frameworks and governance to these entities. Africa CDC is also committed to combating resistance to antibiotics, which are projected to cause about 4 million deaths per year in Africa by 2050. To begin to address this severe threat, Africa CDC also launched the Antimicrobial Resistance Surveillance Network (Africa CDC AMRSNET). This new network will work closely with the WHO Global Antimicrobial Resistance Surveillance Systems to strengthen continental surveillance by a focus on regional task-based and structured mentorship programs. Africa CDC will use proven models of medical education to build a community of practice to fight antimicrobial resistance, providing better care to more people, right where they live. Additionally, Africa CDC will advocate and promote the establishment or strengthening of National Public Health Institutes (NPHIs) in each member state, resulting in an African Public Health Network (APHN) of NPHIs. With so much laboratory-related work to do, Africa CDC will rely heavily on ASLM and other partners to implement the laboratory and AMR networks.

What will be the most important emerging challenges for public health in Africa in the next 5 years?

As indicated above, Africa faces numerous challenges in pubic health in the next 5 years. We expect to see a rise of emerging and re-emerging diseases due to climate change and environmental factors. Also, because of urbanization, we shall increasingly be fighting the emergence of diseases in urban settings. For instance, Ebola viruses emerging in the capital cities of Liberia, Guinea, and Sierra Leone or plague emerging in the capital of Madagascar. HIV/AIDS will continue to challenge public health systems in Africa in the next 5 years, as will tuberculosis and multidrug resistant tuberculosis. Lastly, cholera outbreaks will continues to test our ability to respond effectively.

What is the best advice you have for young Africans entering the field?

My modest advice is for young Africans entering the field to be focused and committed to public health practice, and understand that good public health practice is about quantifiable impact and improved outcomes. This means that the issues they will face will be challenging and, as such, require commitment. They also need to identify good mentors.

Photo: Bilkis Musa, CHVG

CHVG management, staff and WHO auditors after the closing meeting.

Nigerian Center for Human Virology and Genomics, now a WHO Prequalification Evaluating Laboratory

The Center for Human Virology and Genomics (CHVG) in the Microbiology Department at the Nigerian Institute of Medical Research (NIMR) has just been listed as a WHO Prequalification Evaluating Laboratory. After a successful re-audit of the laboratory to the ISO 15189:2012 standard by WHO Geneva on 22 January 2018, CHVG became the first laboratory in West Africa to attain this designation. The laboratory is now listed as a WHO Prequalification Evaluating Laboratory to perform evaluation of in vitro diagnostics (IVDs) either coordinated by WHO or commissioned by a manufacturer. CHVG can now conduct independent performance evaluations of IVDs for the diagnosis and/or monitoring of HIV-1, hepatitis B and hepatitis C infection.

Call by WHO

The CHVG began its journey in December 2016 at the satellite session of the Strengthening Laboratory Management Toward Accreditation (SLMTA) workshop at the ASLM2016 conference, where participants were challenged to attend a WHO session on prequalification evaluation of IVDs. At the session, WHO extended an invitation to laboratories with experience in conducting independent performance evaluations of IVDs for the diagnosis and/or monitoring of infection with HIV-1/HIV-2, syphilis, hepatitis B, hepatitis C, human papillomavirus and G6PD to submit an Expression of Interest for WHO Prequalification Evaluating Laboratories. To be eligible to apply, laboratories had to be national in scope and provide testing services to the governments of their respective countries, particularly those located in geographical areas corresponding to the intended setting of the IVDs use, such as Africa.

Activities of CHVG

As a national reference laboratory for HIV and viral hepatitis, the CHVG took up the challenge and submitted an Expression of Interest, because of its past experience. Since 2004, the laboratory has evaluated the performance of several IVDs, including HIV rapid test kits for Nigeria's national regulatory body. Similarly, the CHVG has been evaluating the performance of hepatitis B and C rapid test kits for product distributors in the country. The objective of the performance evaluations is to ensure acceptable performance of test kits either before a product is registered in the country and/or before products are recommended for mass screening exercises, as in the case of hepatitis B and C kits. The CHVG has a biorepository with a pool of characterized panels for HIV, hepatitis B and C prepared for this purpose.

Technical staff working at the CHVG
Photos: Bilkis Musa, CHVG

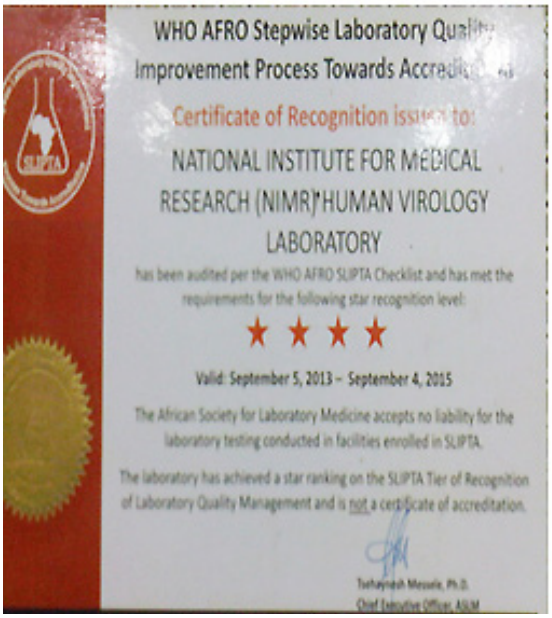
Left and above: Biorepository of samples at the CHVG.
Photos: Gideon Liboro, CHVG

To ensure its own proficiency, CHVG is enrolled with the College of American Pathology and with Quality Control for Molecular Diagnostics, which are independent external quality assessment providers. The laboratory has maintained satisfactory performance in these schemes for many years. The laboratory provides routine diagnostic services for HIV-1 confirmation, HIV-1 viral load and early infant diagnosis to the NIMR HIV treatment center, which cares for over 20 000 of its own patients and patients from other health facilities. CHVG also conducts hepatitis B and C serology and viral load testing for several other hospitals and laboratories across the country. These services provide continuous access to a source of clinical samples from which panels are prepared for performance evaluation. The laboratory has highly skilled and competent personnel who perform these assays and evaluations, maintains a quality management system, and had been previously certified to ISO 9001:2008.[1] In 2010, CHVG was one of the first cohorts of laboratories enrolled in SLMTA in Nigeria and was recognized in 2012 for achieving the 4 Star Level during its surveillance audit.[2] Recently it obtained ISO 15189 accreditation from the South African National Accreditation Scheme.

Journey towards WHO listing

As soon as the ASLM2016 conference was over, the CHVG completed WHO's online forms and by 23 December 2016 had submitted an application to the WHO Prequalification of In Vitro Diagnostics Programme.[3] At that time, CHVG's documents had been successfully reviewed by the accreditation body. However, WHO required some amendments to the method validation reports. The initial audit by WHO was scheduled for May 2017, by which time the pre-accreditation assessment by the accrediting body had taken place. Since the laboratory had been successfully assessed for accreditation about six weeks before this date, staff were able to quickly fix the non-conformities raised and confidently awaited the WHO auditors. However, when the audit took place, additional non-conformities were identified that nearly dashed all hope of being selected. Nevertheless, staff summoned courage and effected immediate action. Root cause analyses were carried out and corrective action plans were submitted to WHO, which accepted them. With

Implementation of Quality Management System in CHVG

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Mr R Josias
Chief Executive Officer

Effective Date: 25 August 2017
Certificate Expires: 24 August 2021

the support of top management, the planned corrective actions were completed within six months. This process improved CHVG's systems tremendously. The re-audit took place on 22 January 2018 and the laboratory was informed that the corrective action plans had been effectively implemented. Consequently, the laboratory was enlisted as a WHO Prequalification Evaluating Laboratory.

In light of this achievement, CHVG staff enjoin other medical laboratories recently accredited in Africa to take up the challenge and identify long existing gaps that limit best practices in our health systems. African laboratories need to harness their strengths to improve medical diagnostics on the continent and justify the SLMTA investment to attain accreditation status.

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Rosemary Audu, PhD
Laboratory Director,
Nigerian Institute of
Medical Research

Emerging pathogens and antibiotic resistance make STIs an urgent challenge

For many sexually transmitted infections (STIs), it is as critical to detect markers of drug resistance as it is to perform pathogen identification.

The landscape of STIs has been shifting rapidly in recent years, with prevalence rates of certain STIs climbing and new diseases taking a toll. There is a disproportionate disease burden among high-risk populations such as pregnant women, sexually active adolescents, men who have sex with men (MSM), and HIV-positive individuals. In some of these populations, STI co-infections are much more frequent than they are in the general population.[1]

Testing for STIs has always been complex due to the asymptomatic occurrence of some of the most common infections, such as herpes simplex virus (HSV) 1 and 2. There are at least 50 million infected individuals with HSV2 in the United States, of which only 10% to 25% have been diagnosed.[2] Diagnostic difficulties are compounded further due to the rapid emergence of antibiotic resistance, with STIs like *N. gonorrhoeae* and *M. genitalium* evolving into STI "superbugs." Prevention of these superbugs warrants the need for widespread antimicrobial resistance surveillance.

Some STIs that were thought to be well contained, such as syphilis, are reemerging. With nearly 28,000 known cases in the U.S. in 2016, a 17.6% increase compared to 2015, syphilis prevalence is on the rise.[3]

For clinical laboratories working to diagnose STIs, these emerging trends and newer diseases can be extremely confounding.

Molecular detection of STIs

Molecular testing offers sensitive and faster STI diagnosis compared to culture-based and other conventional assays, thereby improving patient outcomes. Higher-sensitivity detection of trichomoniasis, which is commonly underdiagnosed due to the low sensitivity of wet mount microscopy methods, is now possible due to the adoption of molecular platforms. Even for diseases such as genital herpes where the infection cannot be cured, higher sensitivity improves patient and partner management.

In some cases, however, FDA-cleared molecular tests are not available. There is a pressing need for a molecular test for *M. genitalium*, a fastidious organism for which culture takes far too long to yield medically actionable results. In select laboratories, *M. genitalium* is diagnosed by molecular testing of urine or urethral, vaginal, or cervical swabs, typically using in-house PCR assays that can be validated as laboratory-developed tests (LDTs).[4] Data generated using these LDTs indicates a 1.1% to 3.3% prevalence rate for *M. genitalium* in the general population.[5,6] However, the true prevalence may be severely underestimated.

Antibiotic resistance

For many STIs, it is as critical to detect markers of drug resistance as it is to perform pathogen identification. *N. gonorrhoeae* and *M. genitalium*, in particular, have very

high rates of antibiotic resistance. The U.S. Centers for Disease Control and Prevention (CDC) made it a priority to fund projects designed to tackle gonorrhea resistance as an urgent threat. The CDC also recently updated its treatment guidelines to slow the emergence of cephalosporin resistance, which will greatly limit treatment options and could cripple gonorrhea control efforts.[4]

The substantial decline in the capability of laboratories to perform essential gonorrhea culture techniques required for antibiotic resistance/susceptibility testing is a major challenge to monitoring emerging antimicrobial resistance in *N. gonorrhoeae.*[7] Molecular testing has been piloted as a means of identifying antibiotic resistance markers, with those results guiding treatment paths for patients. A recent study at the University of California, Los Angeles, demonstrated the use of a rapid genotyping assay to predict whether *N. gonorrhoeae* strains were susceptible or resistant to ciprofloxacin.[8] The study led to reduced reliance on broad-spectrum antibiotics and increased use of more targeted therapies that led to improved patient outcomes.

The need for genotypic resistance marker typing is even more pronounced for *M. genitalium*, as its slow growth rate obviates a phenotypic antibiotic susceptibility testing approach. *M. genitalium* exhibits a remarkable capacity to develop antimicrobial resistance—specifically to the macrolide azithromycin—very rapidly after introduction of treatment.[9,10] In fact, there are high rates of macrolide resistance reported in the U.S. already for *M. genitalium*, with some areas recording resistance rates as high as 50%.[11] One school of thought is that syndromic management of non-gonococcal urethritis using macrolide antibiotic treatments causes strains containing macrolide mutations to predominate, resulting in drug resistance.[12] This has already led to the European STI treatment guidelines advocating for the detection of macrolide resistance-mediating mutations in all *M. genitalium* positive cases.[13]

Looking ahead

Emerging STIs and high rates of associated antibiotic resistance are poised to become major public health threats, caused in part by the syndromic management activities that lead to overuse of broad-spectrum antibiotics. There is a critical need for resistance typing for gonorrhea that might become untreatable, if resistance emerges to the current dual therapy regimen.

Additionally, *M. genitalium* has already become a difficult bacterium to treat on a syndromic basis. In the ideal clinical setting, specific diagnostic tests for *M. genitalium* would be as readily available as tests for *C. trachomatis* and *N. gonorrhoeae,* and detection of both *N. gonorrhoeae* and *M. genitalium* would be accompanied or followed by molecular detection of drug resistance-mediating mutations. Due to the unique aspects of these two STIs, a precision-based treatment approach guided by their resistance profile post-diagnosis might be more useful than the current syndromic approach.

Even when they are not antibiotic-resistant, STIs represent an urgent area of clinical and diagnostic need. The emergence of new STIs, combined with the re-emergence of infections long thought to have been overcome, make this a dynamic and important field. Molecular testing must continue to improve for this segment of public health, in order to provide reliable results for an increasing number of sexually transmitted pathogens with faster turnaround times and more robust workflows.

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Anjana Bhattacharya, PhD, serves as Global Product Manager for Women's Health at Austin, Texas, USA-based Luminex Corporation, with responsibility for its ARIES GBS and HSV 1&2 assays.

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