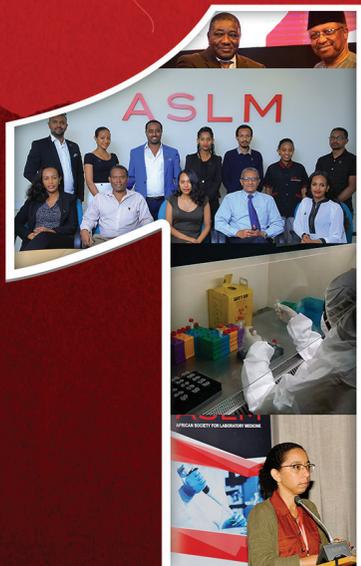




# LAB CULTURE

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

## Celebrating 10 years of ASLM building laboratory medicine in Africa



In this issue

Bringing QMS in Africa into the Next Decade

ASLM Academy

Women in Leadership



November 2021 | Issue 26

# **LAB CULTURE**

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

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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 article or photo proposals, please contact the Editor at [newsletter@aslm.org](mailto: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.



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*Lab Culture* is produced in  
 partnership with *Medical  
 Laboratory Observer*.



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# The African Society for Laboratory Medicine is 10 years old!

The African Society for Laboratory Medicine (ASLM) is a pan-African organization that was launched on 14 March 2011 in Addis Ababa, Ethiopia. The launch ceremony was attended by representatives from 36 countries, officials from eight African ministries of health, and leading organizations specializing in strengthening laboratory systems from Africa and around the world. Former United States (US) President Bill Clinton joined via video stream, and Ambassador Eric Goosby, head of the US President's Emergency Plan for AIDS Relief (PEPFAR) and representatives from the African Union, United Nations Programme on HIV/AIDS, and the World Health Organization (WHO) were all present to salute the birth of ASLM. I remember attending this ceremony and being overwhelmed by the sentiment that, at last, African laboratory professionals were talked about in a positive and hopeful way.

The terms of reference for ASLM at its inception can be summarized in only one line, which by no means indicated that we were short on ambition: **work to advance the quality of laboratory medicine in Africa**. In the 10 years since ASLM set out to improve laboratory medicine science, practice and the profession overall, we have made great strides, learnt many lessons (some were hard!) and, at times, taken unexpected paths to respond to changes and emergencies in the global health landscape.

What stands out most strongly in the

history of ASLM is the expansion of our portfolio. Initially, ASLM almost exclusively focused on HIV-related issues. Now, we also address other health priorities and systems, such as outbreak response, antimicrobial resistance or pathogen genomic surveillance. While we take pride in maintaining the trust of our historical funders, the US Centers for Disease Control and Prevention (CDC) and PEPFAR, we now receive funds from the Global Health Security Agenda (GHS), the United Kingdom Fleming Fund, the Bill and Melinda Gates Foundation, UNITAID, FIND and many more. This expansion of the funding base illustrates the growth of our technical capacity and legitimacy in advancing laboratory medicine in Africa.

ASLM is firmly established as the face and the voice of the laboratory profession in Africa, thereby fulfilling the original vision of Dr John Nkengasong in 2011. Our outreach to around 40 000 members and contacts, bi-annual conferences, journals (*African Journal of Laboratory Medicine*, read the article from Mrs Bethanie Rammer in this issue, and *Lab Culture*) and webinars are some of the ways through which ASLM successfully mobilizes the community of professionals on the continent and builds trust and credibility. For example, our Laboratory Systems Strengthening Community of Practice (LabCoP) has become a privileged forum where countries, stakeholders, manufacturers and scientists debate and craft solutions to

solve laboratory system issues and advance laboratories and diagnostics through the challenges of the future.

Laboratory quality has been at the heart of our work since 2011, in alignment with priorities set 10 years ago. At that time, Ambassador Goosby recommended a role for ASLM in defining norms for the practice of laboratory medicine, through guiding laboratories towards accreditation and the process of certification. Dr Deborah Bix emphasized the need for leadership in African laboratory medicine and to expand on Africa-led advancements.

Towards that end, ASLM has worked relentlessly to champion the WHO Regional Office for Africa's Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) programme on the continent, to defy the lack of resources and capacity and still provide options for demonstrating the implementation of quality management systems (QMS). While the sparsity of institutional support and core funding sometimes makes the implementation of QMS across the entire continent seem like an daunting task, we remain strongly committed to meeting that challenge. Taking each lesson learnt to heart, ASLM has developed innovative ways to address the need for quality assurance and management systems in facilities and networks, in settings with and without a laboratory, and for benches beyond HIV and tuberculosis testing. The article by Mrs Beatrice van der Puije in this issue

highlights how ASLM has found solutions to advance the various aspects of quality in antimicrobial resistance surveillance programmes, under the One Health approach, for COVID-19 response, and for national laboratory services, in general.

The other major achievement of ASLM in the past 10 years is the launch of the ASLM Academy, which now structures and valorizes workforce development efforts within mechanisms of continuous professional development, professional registration and qualification. Achievements of the ASLM Academy are highlighted in papers by ASLM's Chief Executive Officer, Mr Nqobile Ndlovu and by Mr Anafi Mataka, also in this issue.

Learning from knowledge of the field and understanding of the priorities of ministries of health, directorates of laboratories, and technical working groups, ASLM developed practical tools to visualize the capacity of entire laboratory networks (the [LabMaP programme](#)) in collaboration with Africa CDC and in support of the establishment of the Regional Integrated Surveillance and Laboratory Network. Responding to the call of [Dr Nkengasong and Dr Skaggs in 2015](#), ASLM developed the [GHSA LabNet scorecard](#), a unique instrument measuring the function of national tiered laboratory networks against the multitude

of clinical and public health functions. The GHSA LabNet scorecard is now used by the Global Fund for their own assessments, illustrating the relevance of ASLM's vision and technical expertise. These ASLM tools literally diagnose national laboratory networks and systems and offer solutions to fix the problems.

Last but not least, and among so many other commendable achievements, ASLM has grown into a gender-conscious organization, offerings leadership roles and career opportunities for professional African women. In this issue, Dr Winny Koster shines a spotlight on eight women in leadership roles across various branches of ASLM. We hope that their experiences and various paths towards leadership positions will inspire other professional African women to join them.

All along, ASLM has valued the quality of its partnerships with ministries of health, stakeholders, laboratory professionals and others. Looking forward, we hope to establish many more such fruitful collaborations to extend the horizons of laboratory medicine and contribute to a healthy Africa.

**Citation**

Ondoa, P. The African Society for Laboratory Medicine is 10 years old! *Lab Culture* 2021, No. 26, Pages 4-5.



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# The ASLM Academy: A strategy to transform laboratory workforce development in Africa

Human resource development is critical to ensuring a well-performing health delivery system,<sup>1,2,3</sup> particularly in Africa, where there are weak health systems and the constant challenge of emerging and re-emerging infections.<sup>4,5</sup> While diseases and diagnostic technology have been evolving at a faster pace, there has not been adequate effort at either the individual or regulatory level to incentivise continuous acquisition of knowledge, skills, and competencies.<sup>6,7</sup> Moreover, in-service training has been implemented in a non-integrated way, without contributing to structured professional development learning. Many trainings intended to reduce the shortage of skilled human resources did not contribute to career growth or sustainable health programme outcomes, as highlighted by Mataka and colleagues in this issue. In most cases, learning continues to be pushed down to laboratory professionals without them being aware or taking leadership of their learning.<sup>8</sup> A large number of professionals do not benefit from a structured career path based on the recognition of their competencies. Furthermore, there are no national regulatory bodies that recognize the laboratory professional competencies and link them to licensure mechanisms for legal practice.<sup>9</sup> It is also a concern that little effort is made to ensure the educational quality and purpose of those training to ensure that they address knowledge and skill gaps.

Against this background, the African Society for Laboratory Medicine (ASLM) officially announced the ASLM Academy at the ASLM2018 Conference in Abuja, Nigeria. The ASLM Academy was effectively launched on the 26 May 2020, amidst the coronavirus disease 2019 (COVID-19) pandemic, but with widespread acceptance by the laboratory community. The ASLM Academy aims to

establish a system through which existing and new training and learning opportunities can be valorized into formal educational credits and professional designations. The ASLM Academy is led by a steering committee and assisted by an Advisory Committee (**Box 1**).

## Box 1. ASLM Academy Advisory Committee

- **University of the Witwatersrand: Prof Wendy Stevens (Chair)**
- **Africa Centres for Disease Control and Prevention: Dr Yewew Kebede**
- **Fondation Mérieux: Prof. Jean Sakande**
- **Clinical and Laboratory Standards Institute: Melissa Meeks**
- **London School of Hygiene and Tropical Medicine: Prof. David Mabey**
- **Institut Pasteur International Network: Dr Sarah Eyangoh**
- **Institut de Recherche en Santé, de Surveillance Epidémiologique et de Formation: Prof. Souleymane Mboup**
- **American Society for Microbiology: Prof. Joel Mortensen**
- **Medical Laboratory Science Council of Nigeria: Godwin A. Aikpitanyi-Iduitua**
- **Ethiopian Medical Laboratory Association: Dr. Berhanu Seyoum**
- **Abbott Laboratories: Dr Francesco Marinucci**

## What is the ASLM Academy?

The ASLM Academy is an infrastructure through which medical laboratory professionals from Africa and across the globe can access online and face-to-face training and information packages that can be used towards continuous professional development (CPD). The Academy also aims to establish professional registra-



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tion of skills through qualification frameworks. For instance, to verify the achievement of certain standards that are a sub-component of a profession, such as laboratory quality management or molecular testing of pathogens.

## How does it work?

### Facilitating the processing of online training or knowledge sharing

Recently, many online pieces of training have been proposed to quickly build staff capacity for COVID-19 testing. The ASLM Academy can deliver those trainings online to over 1000 participants, while keeping track of their attendance through an online learning management platform. The certificates of attendance are a convenient way to monitor the process. For instance, the ASLM Academy, with funding from UNITAID and in collaboration with the Clinton Health Access Initiative, facilitated the training of 5000 front-line workers on COVID-19 rapid diagnostic tests. The ASLM Academy, in collaboration with the Africa Centres for Disease Control and Prevention, also trained over 200 laboratorians on Biosafety and Biosecurity.<sup>10</sup> ASLM, with funding from the Bill and Melinda Gates Foundation, has delivered 3500 certificates of attendance to participants of the Laboratory Systems Strengthening Community of Practice (LabCoP) webinars, which shares knowledge on various aspects of laboratory systems, diagnostics and COVID-19 response.<sup>11</sup>

### Assigning Continuing Professional Development points

In a bid to further valorise training, the ASLM Academy offers CPD training packages. The ASLM collaborates with the CPD Office of the Wits Health Consortium, owned by the University of Witwatersrand, and

the European Accreditation Council for Medical Education (EACCME)<sup>12</sup> to achieve CPD recognition. Once the courses are accredited, they are delivered to participants who can then claim their CPD points for career development. For instance, the ASLM has delivered a four-module training on Strengthening Laboratory Medicine Towards Accreditation<sup>3</sup>, which awards a total of eight CPD points (two CPD points per module) to participants.

### Qualifying skilled or expert professionals

Training packages and curricula can be further valorized through professional registration or qualification by: (1) ensuring that they address pre-defined competency requirements; (2) standardizing the training delivery; (3) sanctioning knowledge and competencies through a centralized, proctored exam designed by independent experts in the discipline; (4) registering skilled or expert professionals in the ASLM Academy database; (5) maintaining registration upon documentation from professionals that they accumulated a sufficient number of CPD in their field of expertise within a 2 to 3 year period of time. This is the approach taken by the Qualifying Workforce for AMR Surveillance in Africa & Asia (QWARS; see Mataka et al.) and the External Quality Assessment for AMR testing (EQuAFRICA; see van de Puije et al.), both described in this issue.

## What is next?

Looking forward, the ASLM Academy's goal is to become an accredited institution that can assign CPD credentials itself. To this end, ASLM is planning to acquire an ISO accreditation for its educational activities. The ASLM Academy will continue to build a robust registration and qualification database for much needed professional skills, beyond AMR surveillance and external quality

assessment. Building a relationship with national professional councils will be essential to ensure that the credentials delivered by the Academy are recognized by countries and that the trainings offered by the Academy address country and individual needs. In the long-term, the Academy aims to partner with academia and contribute to the certification of entire professional profiles, thereby consolidating the laboratory profession on the continent.

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### Citation

Ndlovu N. The ASLM Academy: A strategy to transform laboratory workforce development in Africa. *Lab Culture* 2021, No. 26, Pages 6-7

# Building qualification frameworks for African experts

## Background

An adequate and skilled workforce is essential in delivering a robust health services system. Many African countries experience a shortage of personnel with the appropriate skillset that supports health systems in general and laboratory services in particular. The laboratory workforce, for instance, is reported to be short of about 850 000 staff<sup>1</sup>, worrisome gap that compromises the effective delivery of diagnostic services. Training is a very popular intervention used by national and international stakeholders to reduce shortages and expand skill sets of human resources for health. However, trainings will effectively reduce the lack of skilled workforce, only if they work towards clear norms-based staffing targets; are deliberately built for country ownership; comply with educational quality standards; and demonstrate effectiveness in developing skills and competence in addition to knowledge. The value of training in generating competence to support health programmes and providing career benefits for individual professionals requires several conditions that extend beyond the mere delivery of certificates of attendance upon completion of a face-to-face or virtual classroom.

## How can training more effectively build competent human resources for health?

Here, we postulate that to effectively reduce shortages in human resources for health and contribute to health outcomes, trainings should (1) deliver skills and knowledge addressing pre-defined competency requirements as formulated by professional councils, (2) deliver validated credentials through standardised unbiased examinations that are tracked over time; (3) embed training into national systems for professional development, registration and

licensing (4) monitor and evaluate the effect of training on career development and indicators of health programmes.

In settings where professions are adequately regulated, trained health professionals enroll through their professional councils (i.e., receive an identification number); are initially licensed (i.e., authorised to practice) based on their competencies (sometimes demonstrated by a certification); and regularly re-licensed, upon ascertaining that their competencies are maintained, and sometimes based on requirements of good conduct. Demonstrating the maintenance of one's competence is usually done through accumulating a sufficient number of relevant continuous professional development (CPD) credits or points. CPD points are validated credentials awarded by a recognised body that validates the content and quality of the learning.

Systems exist that ensure that the skills of health professionals are up to the current standard of practice are essential to quality health services delivery. However, in many African countries, the adequate mechanisms and infrastructure required to maintain professional registration, certification, licensure, and re-licensure are not in place. One worrisome correlate of this situation is that the large numbers of in-service trainings delivered as part of capacity strengthening interventions do not optimally contribute to building sustainable, resilient and effective health professions. In the absence of standardised norms covering entire health professions, delivering speciality credentials (addressing a sub-set of skills in a profession) is an interesting entry point to ensure that critical functions, such as surveillance or molecular testing, are developed as part of across-the-board proficiencies.

The African Society for Laboratory



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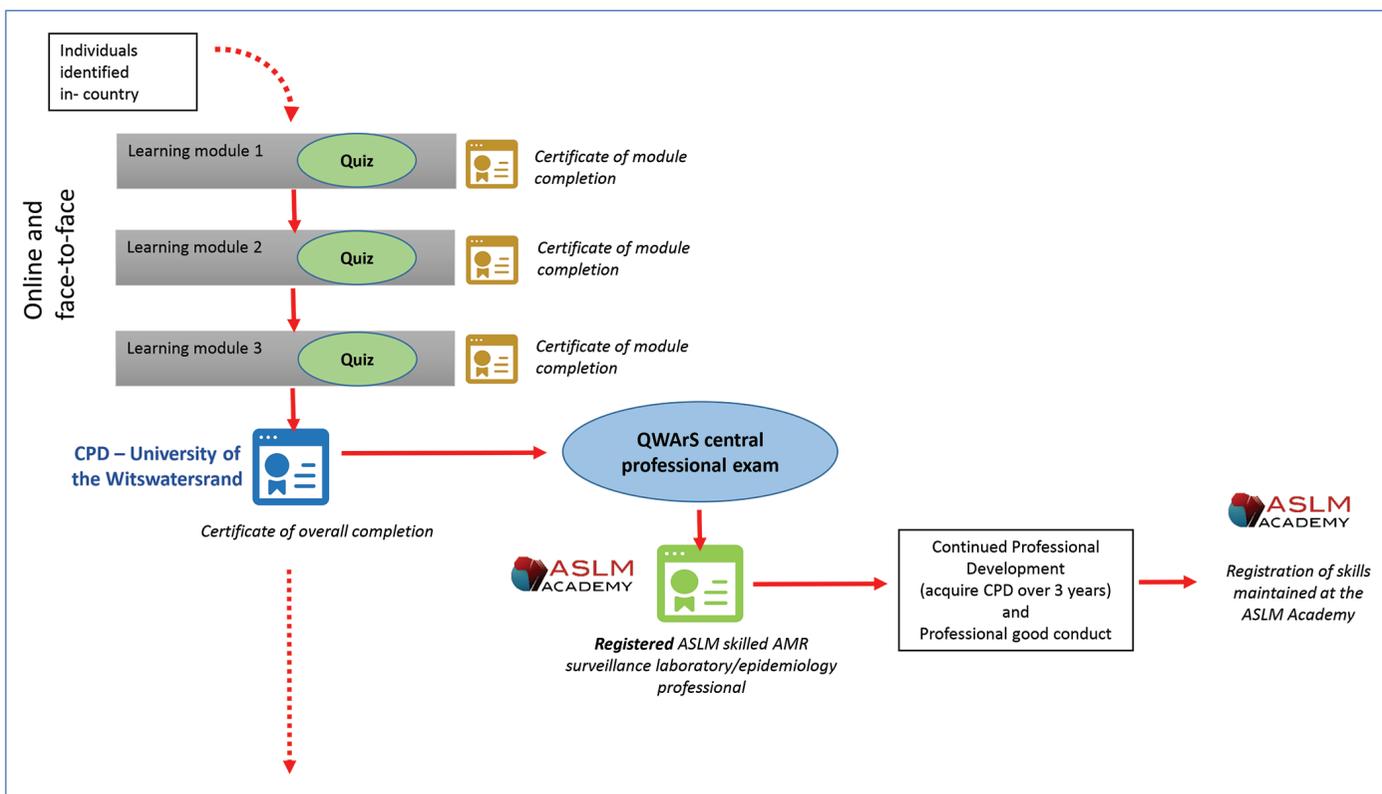


Figure 1. Process for acquiring the Registered ASLM skilled AMR surveillance laboratory/epidemiology professional qualifications

Medicine (ASLM) is using this approach to address workforce gaps in antimicrobial resistance (AMR) surveillance. There are few professionals with the skills to generate quality antimicrobial susceptibility test laboratory results, interpret AMR data or design relevant and representative AMR surveillance protocols required for solid AMR surveillance systems. Furthermore, as for many health-related professions, competency standards for AMR surveillance are not well defined, even in reference laboratories, which complicates efforts to reduce the impact of the workforce shortage.

Findings from a survey carried out by ASLM in 2020 show that eight of 14 Fleming Fund priority countries in Africa have defined some staffing norms and workforce development targets supporting AMR surveillance. However, while some countries reported the existence of regulatory activities via professional councils governing laboratory and epidemiology professionals in the

human and veterinary sectors, AMR units in human and veterinary health seem to be poorly regulated. Of the 14 countries, 11 countries (79%) have professional councils regulating the training of laboratory scientists in the human health sector, and 10 countries (71%) have councils in the animal health sector. Only 4 countries (29%) in the human health sector and 5 countries in the animal health sector (36%) have professional councils for the regulation of training of epidemiologists (or para-medical professionals). Some countries do have provisions for continuous learning. A total of 11 countries (79%) in the human health sector and 6 countries (43%) in the animal health sector have implemented CPD programmes for laboratory scientists. However, only 5 countries (36%) in the human health sector and 4 countries (29%) in the animal health sector had implemented CPD programmes for epidemiologists.

### ASLM registration of AMR surveillance skills: how does it work?

A registry is a listing of individuals (registered professionals) who have demonstrated that they possess the knowledge and skill required to competently perform the tasks addressed by the registry. Registries provide governments, employers, and the public with a level of confidence in the ability of the registered professional to perform a certain set of tasks and acknowledges the individual's commitment to maintaining that competence in the future through continued professional development. Unlike a license, a registry may be maintained outside of a governmental agency. In a country setting, a professional council is most suited to coordinate professional registration. However, if no such professional council is available in a country, international or regional organisations can coordinate on behalf of member countries. This is important particularly if the intent

Module No.	ASLM AMR Microbiology Skilled	ASLM AMR Epidemiology Skilled
	Able to perform the field and laboratory tasks required to identify and track AMR	
1	Introduction to AMR (core module)	
2	AMR data management (core module)	
3	Bacteriology testing	Basic data management and analysis
4	Equipment maintenance	Sampling and surveillance
5	Quality management	Communication skills
	ASLM AMR Microbiology Expert	ASLM AMR Epidemiology Expert
	Able to design and manage systems for AMR surveillance	
6	Advanced techniques	Spatio-temporal analysis of AMR
7	Supervision skills	
	Master Trainer Microbiology or Epidemiology	
	Able to create and deliver educational programmes for AMR professionals	

Table 1. Content modules for professional qualification in microbiology and epidemiology AMR.

is that recognition of registration credentials will carry across a number of countries. For this reason, ASLM, through its ASLM Academy, was set up to house and coordinate the registration of specified relevant competencies in laboratory and surveillance fraternities on the African continent.

The Qualifying Workforce for AMR surveillance in Africa and Asia (QWARS) programme, funded by the Fleming Fund, provides a convenient opportunity to pilot and apply the system to the development of ASLM-associated AMR laboratory experts and ASLM-associated AMR epidemiology experts. The programme builds on state-of-the-art standardised training modules developed by expert organisations. QWARS ensures: (1) delivery of modules to professionals pre-selected based on their educational background and role in national AMR surveillance; (2) awarding of CPDs from an international accreditation body (Wits Health Consortium); (3) trainees are qualified for registration

through a centralised professional exam; and (4) that the registration can be maintained through the accumulation of a pre-defined number and scope of CPD points (Figure 1).

### Overview of QWARS Development of training materials

ASLM leads a consortium of partners that include the Africa Centres for Disease Control and Prevention, the American Society for Microbiology, Institute Pasteur Network, Institute Recherche en Santé de Surveillance Epidémiologique et de Formation, Fondation Mérieux and Technical University of Denmark. The consortium develops and delivers a comprehensive standardised training curriculum for laboratory and epidemiology staff contributing to national AMR surveillance under the One Health approach. Each partner contributed to the training content based on their skills, with additional skills needed to complete the skillsets sourced from

the Uganda Infectious Diseases Institute, ReAct Africa and DATOS. The content ensures attainment of ‘skilled’ level (able to perform the field and laboratory tasks required to identify and track AMR) and ‘expert’ level (able to design and manage systems for AMR surveillance) for staff in either microbiology or epidemiology.

### Training delivery

The training modules for each skill level address practical skills for AMR surveillance in various low- and middle-income countries (Table 1). The courses combine online self-paced studies that equip learners with essential theoretical background before taking on face-to-face training modules. The face-to-face modules target laboratory professionals and epidemiologists designated by countries to better acquire practical knowledge and skills to support the national AMR surveillance. The progress of learners is captured using a learning management system under the ASLM Academy.

## Qualification framework

The QWArS registration system trains and recognises microbiology AMR and epidemiology AMR professionals at two certification and testing programmes levels, skilled and expert (**Table 1**). The design, management, and administration of the professional exams at these levels are conducted in partnership with the American Society for Microbiology through The Caviart Group, seasoned experts in certification and testing programmes. The courses have received formal assessments and are accredited by the University of the Witwatersrand CPD systems. Each participant who qualifies for University of the Witwatersrand CPD points will receive a formal CPD certificate over and above the ASLM Professional QWArS Registration certification.

## Where are we now, and what comes next?

Participating countries nominated a total of 386 people to be part of the QWArS project. Between 12 April and 12 May 2021, 356 learners from 16 countries in Africa and Asia were enrolled on the e-learning portal to undertake AMR training. By mid-September 2021, 49% (72/146) of those enrolled in the epidemiology track had completed the first four online modules. Likewise, 45% (85/190) had completed the first five online modules for the microbiology track. On average, partici-

pants need two attempts to pass the end-of-module quiz and move to the next module. Given the current pandemic, travel restrictions have resulted in delays and postponement of some of the face-to-face learning components. Initially planned to be delivered as regional trainings, the modules have been converted into in-country trainings by tapping into available subject matter experts (SMEs) to provide the training on behalf of the QWArS consortium partners. In addition, the partners provided orientation on training content and facilitator guides for the SMEs. The inclusion of local SMEs has provided an opportunity to promote and recognise the expertise of SMEs in the countries. This is a great step towards capacity building, accompanied by hands-on mentorship activities and geared towards the implementation of the countries' national action plans.

We expect all learners to have completed modules and sit for the centralised ASLM professional examination by the end of November 2021 and to qualify as Registered ASLM Skilled AMR surveillance laboratory/epidemiology professionals upon passing the examination. ASLM will maintain the registration, although countries may take up the training in their own systems. To ensure countries are ready to take up the training modules and deliver them to more groups in the future, select students will be enrolled into a Master trainer track. Master trainers will be equipped with skills to create and deliver educational programmes for AMR professionals ensuring that competency levels in AMR key functions are standardized across countries and endorsed by countries' professional councils. We hope that this approach and programmes such as QWArS will better resolve some of the gaps in human resources development and sustainably.

## Acknowledgements

The authors would like to thank all the consortium partners, the expert organisations that developed the modules, the subject matter experts, the trainees and their governments, the ASLM QWArS project team, and the Fleming Fund for their dedication in their respective roles to improve the AMR workforce in Africa and Asia.

### References

1. Fleming et al, 2021. The Lancet Commission on diagnostics: advancing equitable access to diagnostics. *Lancet*. 2021 October 7.

#### Editor:

Mrs Bethanie Rammer, African Society for Laboratory Medicine

#### Citation

Mataka A, Asante K, Chaffee C, Rosales A, Mupfumi L, Idigbe O. Building qualification frameworks for African Experts. *Lab Culture* 2021, No. 26, Pages 8-11.

## Have a moment?

Investigators at the University of Washington in Seattle, WA, USA are interested in your experiences with certain practices in Pathology and Laboratory Medicine (PALM). These include unofficial payments, absences, and different types of referral and billing. We hope to use this information to improve the delivery of PALM services.

Please consider filling out this **5-10 minute, anonymous survey** using the link or QR code below. Thank you!

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**W**  
UNIVERSITY of  
WASHINGTON

# Leading Laboratory Quality Management Systems in Africa into the Next Decade

## Background

The growing recognition of the critical role of laboratory services in combatting regional and global health threats, led to the Maputo Declaration of 2008, which advocates for commitment from global stakeholders and national governments to prioritise support for the harmonisation of laboratory systems through the development of comprehensive national laboratory strategies and policies in sub-Saharan Africa. This led to an influx of funding to the region for programmes and initiatives aimed at strengthening laboratory diagnostic systems and networks. As a result, the last decade has seen substantial improvements in diagnostic systems and networks through the establishment of laboratory quality management systems (QMS) and the training and development of laboratory professionals.

From its inception in 2011, the African Society for Laboratory Medicine (ASLM) has been at the forefront of advancing laboratory medicine and transforming the standards and quality of diagnostic laboratories on the continent. At the forefront of these efforts has been the administration of the World Health Organization Regional Office for Africa's (WHO-AFRO) Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) process. SLIPTA was launched in 2011 with an innovative approach to improving the quality of health laboratories in resource-limited settings to International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) 15189 standards, based on the principles of affordability, scalability, measurability, and accessibility. The SLIPTA framework promotes country ownership of the process to ensure the sustainability of improvements made to laboratory quality systems and networks. To date, over 314

laboratories in 27 countries have been enrolled into the SLIPTA process. By the end of 2020, a total of 78 laboratories were reported to have achieved ISO accreditation from bodies accredited by the International Laboratory Accreditation Cooperation or African Accreditation Cooperation on the continent, in the United States and in Canada.

This result is commendable but far from the target of 2,500 ISO-accredited laboratories that ASLM had set out to achieve by 2020. Lack of funding dedicated to sustaining QMS at facility level, poor definition and enforcement of national quality standards and the difficulty for lower tier level facilities to achieve certification, are some of the bottlenecks that undermined the advancement of QMS as previously planned. With the continuous decentralization of testing services at the community level and the recent importance of the One Health approach, implementing QMS in various context and sectors has become critical and requires new approaches.

This article outlines how ASLM is building on the gains and lessons learnt from the last decade to advance the next phase of laboratory QMS in Africa through innovative and forward-thinking approaches that advocate regional ownership and leadership, with a One Health approach.

## Strengthening laboratory quality management systems through the implementation of antimicrobial resistance surveillance and the One Health approach

Since 2018, ASLM has been at the forefront of efforts to advance the agenda for a One Health approach to laboratory system strengthening. Leading these efforts are its three Fleming Fund Regional Grants:



**Beatrice van der Puije**  
African Society for Laboratory Medicine  
Ghana



**Tjeerd Datema**  
DATOS  
Netherlands



**Blessing Marondera**  
African Society for Laboratory Medicine  
Malawi



**Jennifer Anderson**  
African Society for Laboratory Medicine  
Canada



**Stephen Adjei-Kyei**  
African Society for Laboratory Medicine  
Ghana



**Edwin Shumba**  
African Society for Laboratory Medicine  
Zimbabwe

**Melissa Meeks**  
Clinical Laboratory Standards Institute  
USA

**Rubeina Badat**  
National Institute for Communicable Diseases  
South Africa

- Mapping Antimicrobial Resistance and Antimicrobial use Partnership, (MAAP)
- Qualifying the Workforce for AMR Surveillance in Africa and Asia (QWArS)
- External Quality Assurance Grant for Africa (EQuAFRICA))

Through these projects, ASLM is working closely with in-country, regional and global partners, including the Africa Centres for Disease Control and Prevention (CDC), Public Health England (PHE), the National Institute for Communicable Diseases (NICD), South Africa and the Technical University of Denmark (DTU), to strengthen antimicrobial resistance (AMR) surveillance systems across One Health sectors.

### Critical QMS gaps of bacteriology laboratories under One Health

The exploration of national laboratory networks capable of conducting antibiotic susceptibility testing in 14 priority countries revealed that only 12% (26) of the 221 facilities included in the data collection are currently implementing QMS and or are ISO 15189-accredited. For the most part, laboratory quality systems in this sector are either absent or fail to meet very basic standards as illustrated from baseline assessments conducted in 2020 across these

countries (**Figure 1**).

A landscape analysis performed under EQuAFRICA by ASLM and PHE in 2019 also revealed that despite the gains made in laboratory QMS implementation over the last decade, uptake and participation in external quality assessment (EQA) programmes remains low. A 2009 study con-

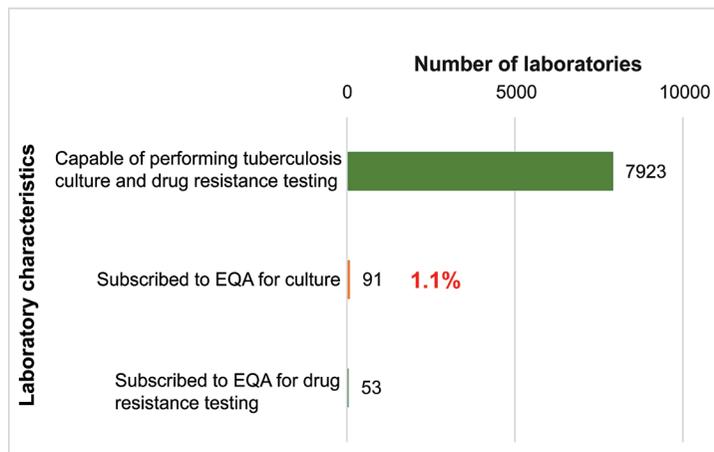


Figure 2. Laboratories available in the African region for tuberculosis diagnostic testing subscribing to an external quality assessment programme.

Similarly, a 2009 published study of the uptake and participation in EQA programmes for bacteriology in 102 countries across Asia, Africa,

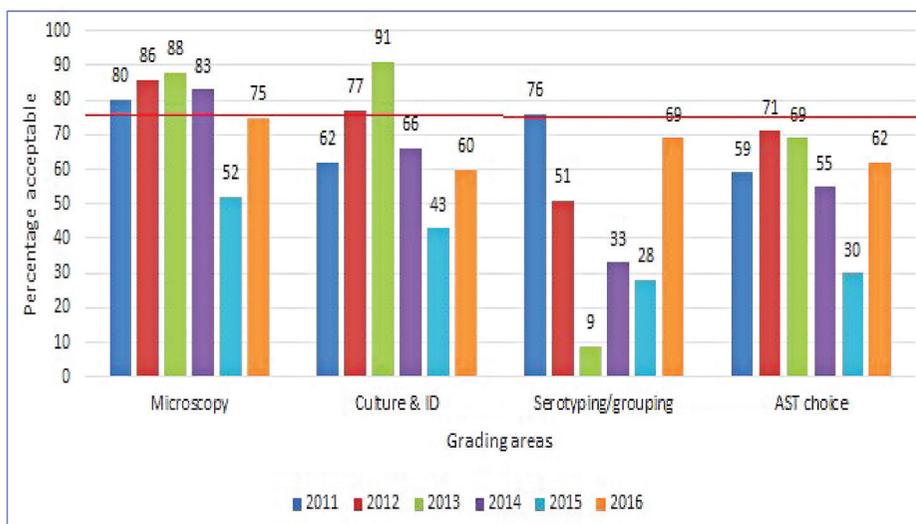


Figure 3. Comparison of acceptable results from 2012 -2016 – all bacteriology samples from the WHO Regional EQA programme for bacteriology.

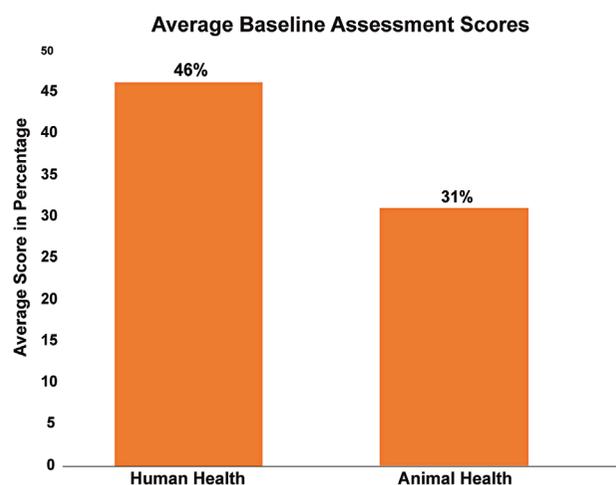


Figure 1. Laboratory quality management system baseline assessment score for animal and human health laboratories.

ducted by WHO-AFRO and the United States CDC on tuberculosis diagnostics, found that of the 15 847 laboratories performing tuberculosis microscopy in the African region, just 42% (6,798) were enrolled in EQA programmes. For laboratories performing tuberculosis culture and drug resistance testing, the numbers were even lower (**Figure 2**).

the Middle East, and South America found that only 34% of laboratories in the African region maintained consistent participation over the seven years of the study. Analysis of the performance of laboratories also shows that the impact of participation in strengthening their capabilities was marginal, as highlighted by a performance trend analysis of the WHO Regional EQA programme for bacteriology (**Figure 3**).

Key barriers and challenges to uptake, participation and performance were identified during a regional stakeholder’s sensitization

and consultation meeting held in Johannesburg, South Africa, in February 2020. The lack of regionally owned, cost-effective programmes was identified as a key barrier, with countries finding the cost of participation in international programmes prohibitive.

Where programmes are available, the majority are partner funded and programme focused, which restricts uptake and has significant implications for long-term sustainability post programme implementation. Other barriers and challenges identified include:

- Poor capacity of staff to process EQA panels
- Perceived lack of support from EQA providers to address performance issues and support laboratories to improve
- Performance in EQA programmes without the foundation of robust pre-existing QMS
- Lack of enabling regulations that would include participation and performance in EQA programmes as a quality requirement (at least at reference-laboratory level).

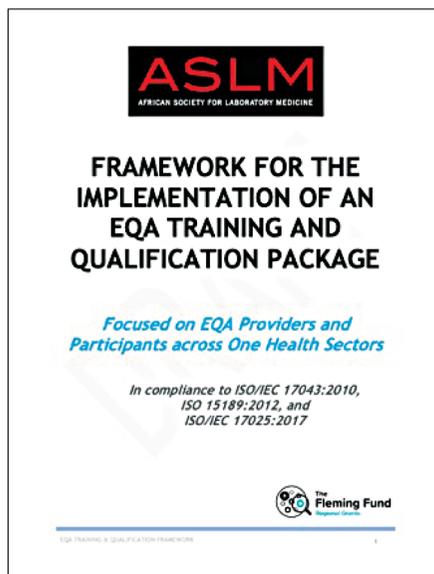
Against this background, ASLM and partners have been implementing the new strategies outlined below to better implement QMS in the AMR laboratory network.

## Building regional end-to-end capacity for establishing regional EQA programmes

### A proficiency testing (PT) programme building on local capacity

The success of EQA PT programmes depend on the ownership of the providers and having enough participants to ensure a return on investment. In collaboration with Africa CDC, NICD, PHE and DTU, EQuAFRICA aims to strengthen the availability and uptake of EQA across the continent, through the establishment of regionally owned

EQA programmes that build on local capacity. In our view, the ideal regional EQA programme is one that can achieve sustainability and cost-effectiveness and can be customized, scaled-up and expanded to meet regional needs across diseases.



EQuAFRICA is building capacity at NICD, Institute Pasteur Dakar and AMREF Health Africa to serve as regional EQA providers, who can establish and provide AMR EQA programmes to all AMR reference laboratories and surveillance sites

under One Health in Africa.

To date, the AMR EQA programme has been successfully piloted with 67 laboratories across 14 target countries (Figure 4). Two further sets of panels for the AMR EQA programme are expected to be distributed between October 2021 and March 2022 to over 80 AMR reference laboratories and surveillance sites within the 14 target countries. In the long-term, the providers are being capacitated to expand the coverage and uptake of the AMR EQA programme beyond the current target countries and to provide programmes for other disciplines. To provide support to participating sites to address poor performance, post cycle workshops have been scheduled and ASLM established the AMR community of practice with 150 participants representing the 14 target countries.

### An open-source EQA informatics package

The programme takes advantage of the United States CDC's open-source e-PT informatics system. The EQuAFRICA is an open-source, regional EQA informatics pro-

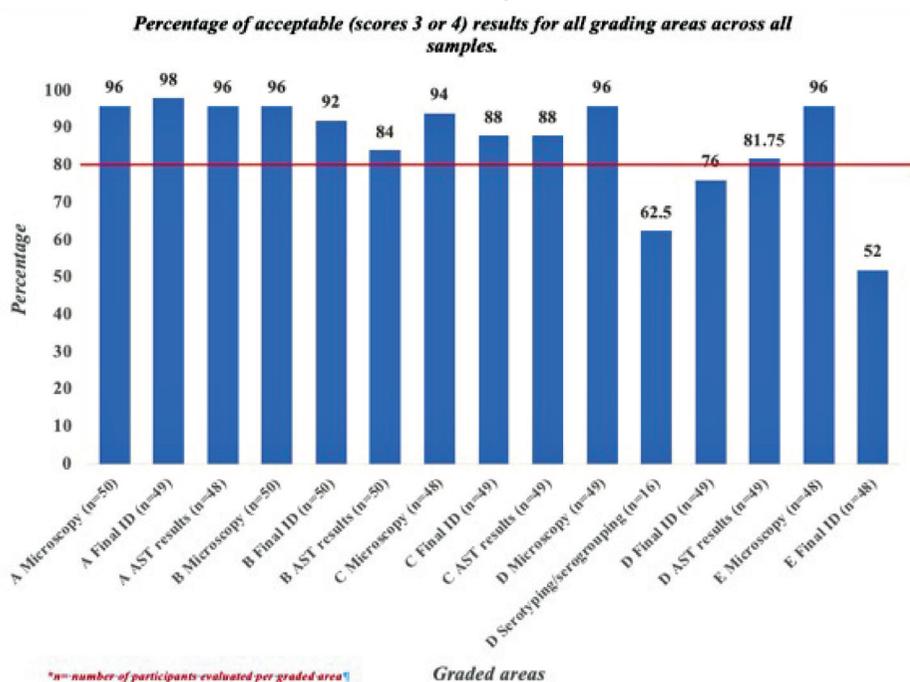


Figure 4. Performance of participating AMR reference laboratories and surveillance sites during regional AMR EQA programme pilot. Chart shows percentage of acceptable (score of 3 or 4) results for all grading areas across all samples. For each category, n is the number of participants evaluation per graded area.

gramme, which has cutting edge functionality, is capable of running any type of EQA programme and is made available through ASLM to any aspiring EQA provider. The open-source nature of the system will help foster innovation and collaboration, as all enhancements made by any EQA provider would be shared with the EQA community. All code from every release will be published to GitHub to allow users access to the most recent enhancements. Currently, the system has been successfully used in managing the EQAfrica AMR EQA pilot cycle. The expectation is to have the system operating in all regional providers and in at least six countries to provide AMR EQA by early 2022. Upcoming developments for the system include: allowing EQA providers to create their own EQA programmes in any discipline, automating grading and scoring of EQA results and implementing algorithms for detecting causes of error and applying corrective action suggestions.

**A training and certification curriculum for EQA providers and participants**

Whilst many guidance documents exist on the development and management of EQA programmes, none were found that comprehensively enumerate needs for the training and qualification of EQA providers beyond stating requirements for positions and qualifications as outlined in ISO/IEC 17043. There is also minimal guidance available on supporting participating sites to improve their processing of PT panels and performance in EQA programmes. To address this, ASLM has partnered with the Clinical Laboratory Standards Institute to develop a framework for the training and qualification of EQA providers and participants.

The framework provides guidance and recommendations to ensure

the effective implementation of a training and qualification package for EQA programmes in accordance with international standards and best practices. It outlines the elements that should be addressed to ensure strengthened the capacity of EQA and PT programme providers and participants through completion of standardized training and achievement of qualifications.

The capacity of EQA providers and participants is strengthened across key elements through targeted training and competence assessment within a qualification curriculum programme. Currently, training is ongoing for 90 personnel across the 14 countries. The qualification exam, administered through the ASLM Academy, is expected to be completed in December 2021. This intervention is expected to increase in-country EQA programme establishment to strengthen the availability, coverage, and uptake of EQA programmes by laboratories to further strengthen the quality of laboratory diagnostics systems across the continent.

**Specific lessons learnt from the COVID-19 pandemic**

The roll out of PT activities through a coordinating body has also been successful in the case of EQA for

PCR assays for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Between 2020-2021, ASLM and Africa CDC worked with external providers (One World Accuracy and Thistle) and successfully enrolled 781 laboratories in 30 countries across four rounds of EQA with >84% performance. ASLM collaborated with WHO-AFRO, to ensure the liaison of in-country receiving hubs and providers, supported countries for sub national distribution and ensured online orientation by the providers, all of which were identified as keys to success.

**Adapting SLMTA and SLIPTA tools to implement quality standards relevant to bacteriology testing in animal health laboratories**

A key activity is training of the workforce on laboratory QMS and international standards. This enables members of the workforce to lead the development, implementation, and sustainability of the QMS in their laboratories (Figure 5). To initiate activities, baseline assessments were conducted on the laboratory QMS and AMR diagnostics processes in each facility using the SLIPTA checklist, a ISO 17025 checklist and the Foundation for Innovative New

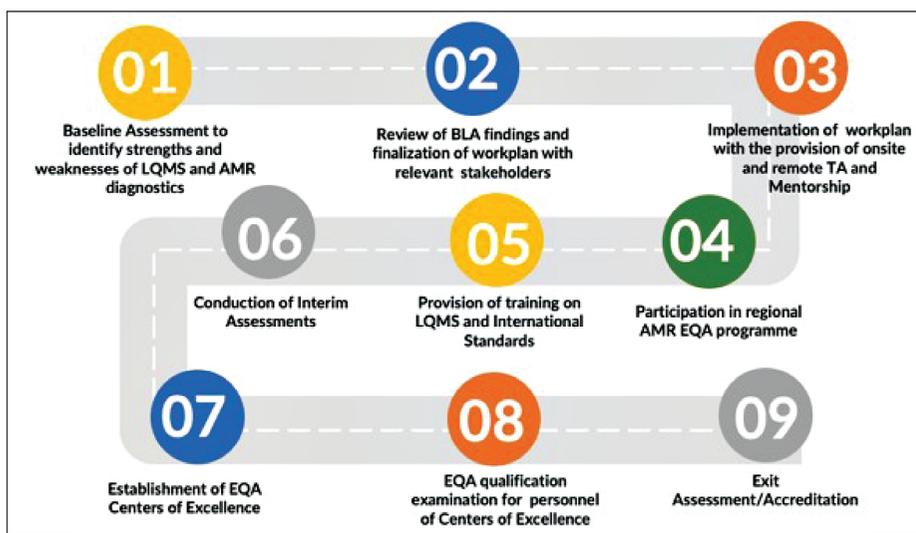


Figure 5. In-country implementation roadmap. Abbreviations: BLA, base line assessment; LQMS, laboratory quality managements system.

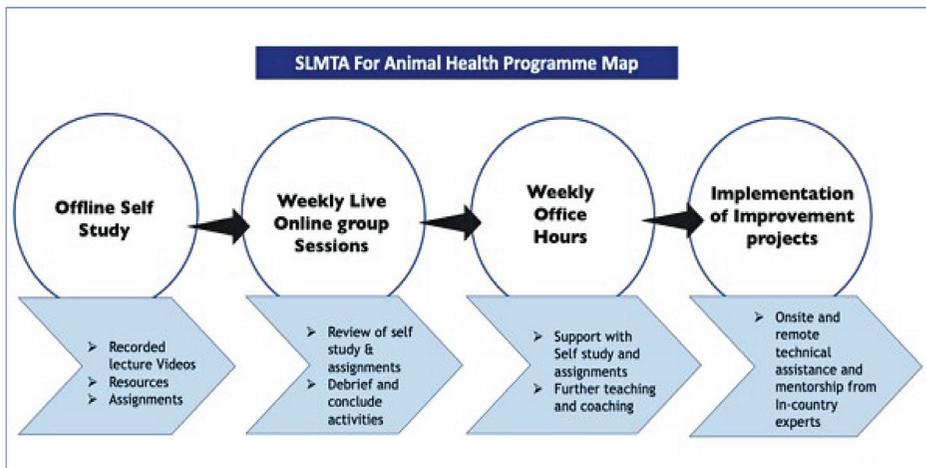


Figure 6. Laboratory quality management system baseline assessment score for animal and human health laboratories.

Diagnostics AMR scorecard. Findings from the assessment were used to develop country- and facility-specific workplans. To support these activities in the animal sector and address the general lack of animal health-specific laboratory QMS training toolkits, ASLM led the development of an e-learning programme for the training of animal health laboratory professionals. Adapted from the Strengthening Laboratory Management toward Accreditation (SLMTA 3) classroom and e-learning programmes, the animal health e-learning programme adopts the format of modules, subdivided into sections and activities (Figure 6). The e-learning programme includes an off-line/self-study component (lecture recordings and homework assignments) and an on-line/live component, as well as office hours and a peer support discussion forum. As with the SLMTA programme, the WHO-AFRO SLIPTA checklist is used to guide system establishment and check for compliance to the conformity standard, which necessitated its adaptation to develop an ISO/IEC 17025 compliance checklist.

Currently the animal health e-learning programme is being utilized to train over 110 personnel across 14 countries. Training is still ongoing with feedback from participants being used to refine and final-

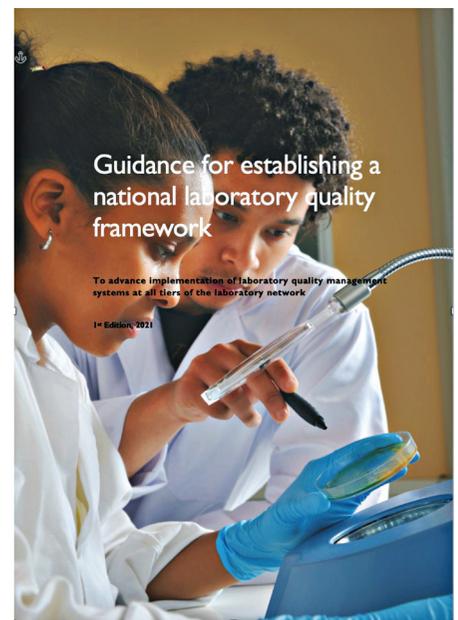
ize the training programme. The programme is linked to a structured qualification component: this means that the participants will go through a final central exam and receive an official credential, as an ‘ASLM Expert’ in EQA, for their successful participation in the programme. Once finalized and packaged, the training curriculum and the qualification exam will remain accessible through the ASLM Academy. Moving forward, ASLM intends to continue to lead the One Health agenda by advocating for and adopting One Health principles in the development of strategies and the implementation of its laboratory strengthening activities.

### Guidance to develop National Laboratory Quality Systems

The most critical bottlenecks identified to sustainable implementation of QMS in laboratories has been the lack of political commitment and insufficient implementation of national policies and regulations for laboratory systems and networks. Therefore, despite initial momentum, laboratories have been unable to maintain QMS because of critical gaps in national laboratory systems and networks. As most of these programmes are also partner-driven initiatives, they lack country ownership, which results in the gaps in

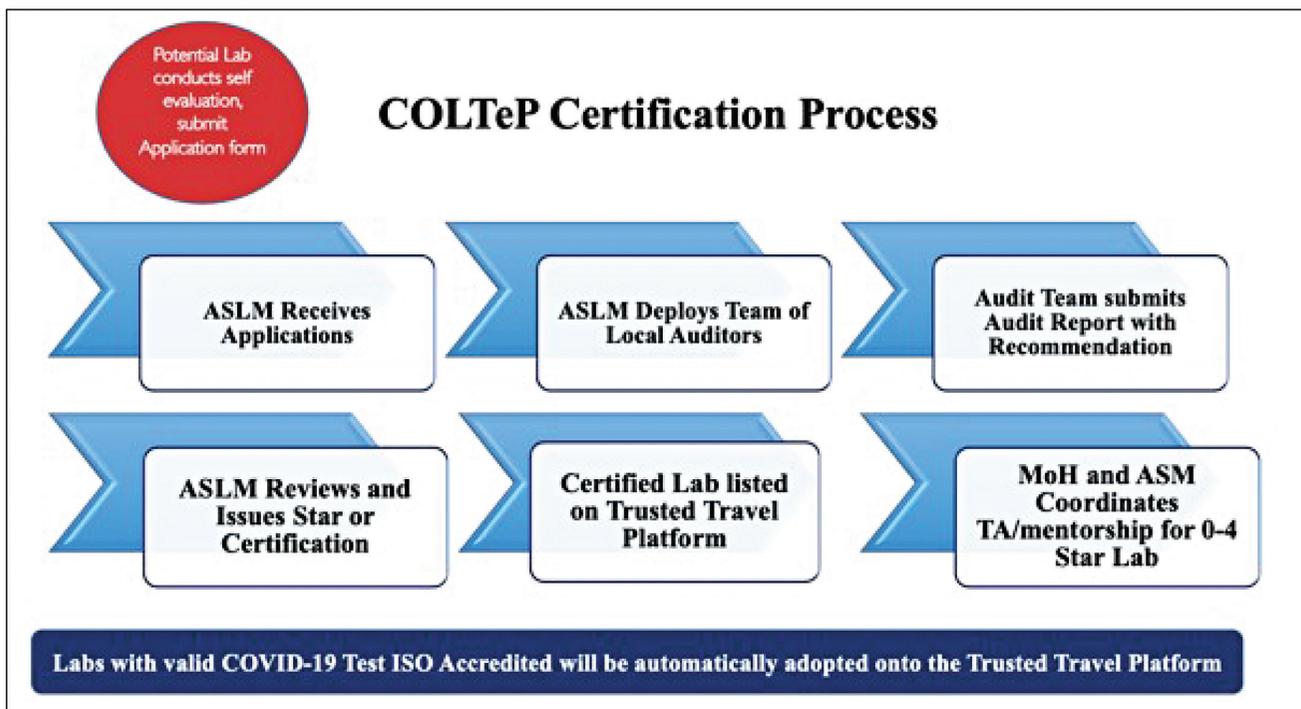
national laboratory networks and systems remaining unaddressed. Strengthening national laboratory networks and systems must be a key priority in the advancement of laboratory QMS in the next decade to ensure successful and sustainable implementation and maintenance of QMS in laboratories.

During this period, many African countries have developed National Laboratory Policies and/or National Laboratory Strategic Plans to focus and harmonize initiatives and activities towards the establishment of national laboratory quality infrastructure and sustainable QMS implementation for their laboratories. However, most of these policies lack sufficient guidance on



strengthening laboratory systems and networks to adequately support implementing QMS in laboratory facilities. To address this gap, ASLM has worked in collaboration with Africa CDC and other regional and international experts to develop a guideline for the establishment of national laboratory frameworks.

The guidelines aim to advise policy makers and regulators on the establishment and amendment of relevant national policies and strategic plans to build a national laboratory



quality infrastructure and address critical gaps in laboratory systems and networks that hamper sustainable implementation and maintenance of QMS in laboratories. The guide can be used in two ways. It can be used to guide countries in *amending* their National Laboratory Policy and/or Strategic Plan with specific quality-related statements

and objectives. Alternatively, it can be used to *establish* a separate National Laboratory Quality Policy and Strategic Plan. The guidelines are expected to be launched by the end of 2021 with a stakeholder sensitization and consultation meeting, followed by a workshop, to train countries on how to use the guide.

### Implementing quality management systems to facilitate travel during the COVID-19

To support the Africa Union's Trusted Travel Platform, ASLM is implementing the COVID-19 Laboratory Testing Certification Program (COLTeP) in collaboration

**African Society for Laboratory Medicine**  
 COVID-19 Laboratory Testing Certification Program (CoLTecP)

**AFRICAN SOCIETY FOR LABORATORY MEDICINE**

COVID-19 LABORATORY TESTING  
 CERTIFICATION ASSESSMENT CHECKLIST

Requirements	Scope	Recognition and Certification																																																						
<ul style="list-style-type: none"> <li>ISO 15189:2012</li> <li>ISO 15190: 2020</li> <li>WHO Biosafety Manual 4th Ed</li> <li>WHO Interim Guidance on Diagnostic testing for SARS-COV-2</li> </ul>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3">Audit Score sheet</th> </tr> <tr> <th>Section</th> <th>Total Points</th> <th>Score</th> </tr> </thead> <tbody> <tr> <td>Section 1: Laboratory Policies and Procedures</td> <td style="text-align: center;">27</td> <td></td> </tr> <tr> <td>Section 2: Laboratory testing capacity</td> <td style="text-align: center;">29</td> <td></td> </tr> <tr> <td>Section 3 : Quality Control &amp; Assurance</td> <td style="text-align: center;">25</td> <td></td> </tr> <tr> <td>Section 4: Test result and data management</td> <td style="text-align: center;">17</td> <td></td> </tr> <tr> <td>Section 5: Biosafety and Biosecurity</td> <td style="text-align: center;">32</td> <td></td> </tr> <tr> <td><b>TOTAL SCORE</b></td> <td style="text-align: center;"><b>130</b></td> <td></td> </tr> </tbody> </table>	Audit Score sheet			Section	Total Points	Score	Section 1: Laboratory Policies and Procedures	27		Section 2: Laboratory testing capacity	29		Section 3 : Quality Control & Assurance	25		Section 4: Test result and data management	17		Section 5: Biosafety and Biosecurity	32		<b>TOTAL SCORE</b>	<b>130</b>		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>No Stars (0 – 64 pts) &lt; 50%</th> <th>1 Star (65-77 pts) 59%</th> <th>2 Stars (78-90pts) 69%</th> <th>3 Stars (91-103 pts) 79%</th> <th>4 Stars (104-116 pts) 80 – 89%</th> <th>5 Stars (117-130 points) ≥90%</th> </tr> </thead> <tbody> <tr> <td style="background-color: #ff0000; color: white; text-align: center;">0 Stars</td> <td style="background-color: #ffcc00; text-align: center;">1 Stars</td> <td style="background-color: #ffcc00; text-align: center;">1 Stars</td> <td style="background-color: #ffcc00; text-align: center;">1 Stars</td> <td style="background-color: #ffcc00; text-align: center;">2 Stars</td> <td style="background-color: #ffcc00; text-align: center;">2 Stars</td> </tr> <tr> <td></td> <td></td> <td></td> <td style="background-color: #ffcc00; text-align: center;">2 Stars</td> <td style="background-color: #ffcc00; text-align: center;">2 Stars</td> <td style="background-color: #ffcc00; text-align: center;">3 Stars</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td style="background-color: #ffcc00; text-align: center;">3 Stars</td> <td style="background-color: #ffcc00; text-align: center;">3 Stars</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td style="background-color: #ffcc00; text-align: center;">4 Stars</td> <td style="background-color: #ffcc00; text-align: center;">4 Stars</td> </tr> </tbody> </table> <div style="text-align: center; background-color: #ff0000; color: white; padding: 5px; font-weight: bold;">             CERTIFIED TO TEST COVID         </div>	No Stars (0 – 64 pts) < 50%	1 Star (65-77 pts) 59%	2 Stars (78-90pts) 69%	3 Stars (91-103 pts) 79%	4 Stars (104-116 pts) 80 – 89%	5 Stars (117-130 points) ≥90%	0 Stars	1 Stars	1 Stars	1 Stars	2 Stars	2 Stars				2 Stars	2 Stars	3 Stars					3 Stars	3 Stars					4 Stars	4 Stars
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Figure 8. Overview of COLTeP checklist.

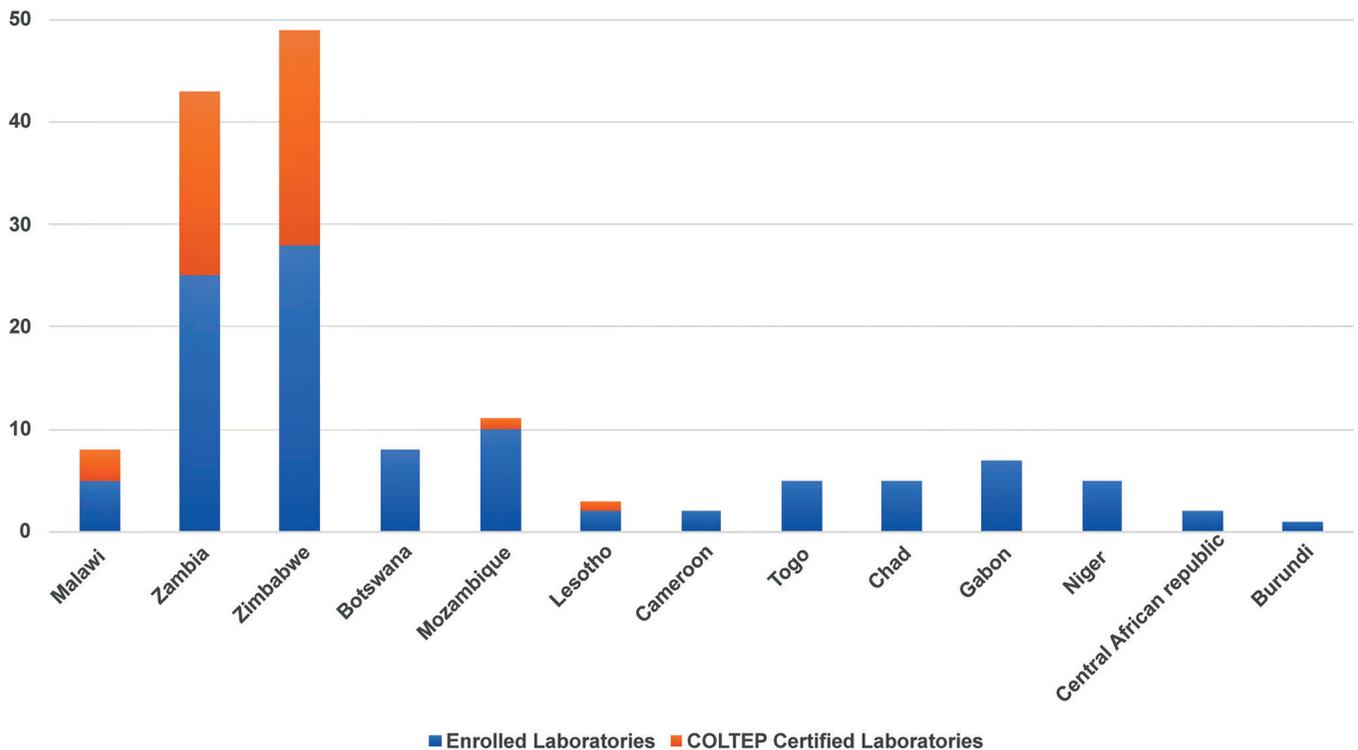


Figure 9. Laboratories enrolled in and certified by COLTEP.

with Africa CDC. The certification programme provides a regionally acceptable framework for collecting objective evidence of the competency of laboratories to provide quality-assured COVID-19 testing results for travellers and to create trust between Member States. The programme was launched in April 2021 with an emphasis on the need to ensure that the expansion of the *capacity* to test is matched with assurance of the *quality* of the testing through the implementation of international standards of quality and safety. A framework for evaluating laboratory QMS for compliance to international standards was developed with laboratories meeting set standards certified and subsequently enrolled onto the Africa Union Trusted Travel platform (Figure 7).

COLTEP has three main building blocks: its structure, process, and recognition of audited laboratories (Figure 8). A standard checklist was developed and is used for assessment of compliance. The checklist evaluates laboratories

in five critical areas of policy and procedure, laboratory testing capacity, quality assurance and quality control, data management and biosafety and biosecurity. The scored checklist recognizes the incremental implementation of COVID-19 testing requirements, as stipulated by WHO in their interim guidance, as well as ISO 15189, ISO 17025, ISO 15190, WHO Biosafety Manual, 4th Edition and Good Laboratory Practices.

To ensure sustainability and rapid scalability, ASLM uses locally trained and certified auditors to conduct assessments. A three-day training programme was developed where laboratory personnel with experience in implementing QMS and audits are trained on the use of the checklist. The highly interactive training adapted for both virtual and physical delivery models, covers critical areas of the ISO standards, WHO Biosafety Manual, WHO guidance on SARS-CoV-2 testing and the COLTEP audit process. Auditors write a qualifying online examination administered by the

ASLM Academy. To date, 104 laboratories have been enrolled across 13 countries, with 44 laboratories already certified (Figure 9).

## Conclusion

The experience shared here illustrates the dynamism of quality activities and the role of ASLM in advancing QMS for laboratories across sub-Saharan Africa over the last decade. Flexibility, innovation, country ownership and synergistic planning are some of the critical ingredients that ASLM has identified for successful implementation. As we move into the next decade, ASLM will continue to collaborate closely with its regional and international partners, as well as African Union Member States, to build quality diagnostic capacities across the continent.

**Editor:**

Mrs Bethanie Rammer, African Society for Laboratory Medicine

**Citation**

van der Puije B, Datema T, Meeks M, Anderson J, Badat R, Adjei-Kyei S, Shumba E, Marondera B. Leading Laboratory Quality Management Systems in Africa into the Next Decade. *Lab Culture* 2021, No. 26, Pages 12-18

# The African Journal of Laboratory Medicine (AJLM)

*10 years of building research capacity for laboratory medicine in Africa*

## Introduction

The African Journal of Laboratory Medicine (AJLM) is the African Society for Laboratory Medicine's (ASLM) peer-reviewed scholarly journal and was launched in 2011, the same year as ASLM. Originally funded by PEPFAR, in its very first year of existence, AJLM received a total of 22 article submissions. By 2020, that number had increased nearly 1000%. This is impressive for a small journal with a very specific topic area and a focus on Africa, all the more so for a journal based on a continent with limited resources.

Despite these challenges, AJLM is thriving. The journal ranks among the top 10 laboratory medicine journals globally and in the top 20 African medical journals, according to Google Scholar's h-index. In its first 10 years, AJLM has published half a dozen special issues and hundreds of articles, and has become an established venue for publication of research on laboratory quality improvement in developing countries. In fact, according to a recent search of PubMed, AJLM has published the majority of peer-reviewed literature on the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and Strengthening Laboratory Management Toward Accreditation (SLMTA) programmes. In spite of the COVID-19 pandemic, or perhaps because of it, 2020 was a banner year for AJLM, with the most submissions ever received and the most articles published in a year in its history. These achievements were made possible because of the dedication and hard work of authors and reviewers, as well as the journal's Editorial Board, its committed editorial office staff, and excellent support from its South Africa-based publisher, AOSIS. ASLM is indebted to all of them for their commitment and contributions.

'AJLM is a society-based journal that

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assists us by providing high-quality, rigorously reviewed, and well-cited articles from the African continent. Their diverse editorial board, reviewer database and author affiliations are a testament to their impressive African footprint,' said Trudie Retief of AJLM's publisher AOSIS. 'Typically, the journal will have approximately 75% of authors with a non-South African address. The journal was also read in over 54 African countries with more than 90 579 African users since its inception in 2012.'

## Free to Publish, Free to Read

AJLM is a 'gold open access' journal, which means no subscription or access fees are charged to readers or authors. All published articles are free to read for anyone with an internet connection. Most journals with this type of open access support themselves with fees paid by authors. However, these fees are often exorbitant, even for authors in high-income countries. More importantly, even nominal fees are not affordable for many of AJLM's authors. Thus, AJLM is fully funded by its owner, ASLM, and AJLM authors pay no fees to submit or publish their articles.

'It is important for ASLM as an organization that AJLM remain open access and free of financial burden to authors. This has been affirmed repeatedly by the Editorial Board,' says Dr Pascale Ondo, Director of Science and New Initiatives at ASLM, under whose purview AJLM falls. 'Many researchers in resource-limited settings, such as many countries in Africa, are not supported by grants or institutional mechanisms. They must fund their research directly out of their own pockets, and they simply cannot afford fees to publish that research.'

## Mentorship

One tenet of ASLM's Strategic Pillars is increasing medical laboratory capacity in



**Bethanie Rammer**  
African Society for  
Laboratory Medicine  
United States



Africa. Biomedical and operational research on laboratory medicine in Africa – and the ability to publish that research – is one aspect of this that AJLM directly supports through its Technical Editing programme.

While most journals will automatically reject articles that have English language usage or organizational issues, AJLM makes a point of allowing articles with solid science that have such issues the opportunity of peer review. Those that make it

through review but still need writing support to reach publication quality are ‘provisionally accepted’ and enter Technical Editing, whereby the manuscript is assigned to an AJLM Editorial Assistant who edits the manuscript and works with the article’s authors to address remaining deficiencies.

Prof Iruka N. Okeke, AJLM’s current Editor-in-Chief describes the programme this way: ‘AJLM’s Technical Editing programme is one of only a handful of such programmes among similar peer-reviewed journals. Very

few journals will take the time to help authors with writing and organization, which means authors with less writing experience, who may be

writing in English as a third or fourth language, or who may not have access to a mentor to help them write, are precluded from publishing. Our programme seeks to bridge that gap.’

At the biennial ASLM conferences, AJLM has traditionally hosted scien-



tific writing workshops and seminars. These have featured speakers from the London School of Hygiene & Tropical Medicine, Public Health

England, and other journals such as BMJ Global Health, The Journal of Infections in Developing Countries and The Lancet Diabetes & Endocrinology.

These workshops and seminars provide opportunities for early career researchers to interact directly with journal staff and editors on their current writing projects and have proven to be ‘standing room only’ popular at past conferences.

## Challenges

As may be expected, rapid growth does not come without challenges. Increases in submissions, means increases in workloads for all editors, including those working in the Technical Editing programme, and AJLM has occasionally struggled to keep up as demand outpaced capacity. For day-to-day operations, this has sometimes meant peer-review turnaround times that are not within



## AJLM Editorial Leadership

### Souleymane Mbou

University Cheikh Anfa Diop, Senegal  
Senior Editor, 2011-2016

### Barry Schoub

National Institute for Communicable Diseases, South Africa  
Senior Editor, 2011-2016

### Wendy Stevens

University of the Witwatersrand and National Health Laboratory Services, South Africa  
Senior Editor, 2011-2016

### Oyewale Tomori

Redeemer’s University, Nigeria  
Senior Editor, 2011-2016

### Elizabeth (Luman) Bigman

United States Centers for Disease Control and Prevention, United States  
Founding Editor  
Managing Editor 2011-2012  
Senior Science Editor, 2013-2015

### Amadou Sall

Institut Pasteur de Dakar, Senegal  
Editor-in-Chief, 2013-2015

### Bethanie Rammer

Managing Editor, 2014-present

### John Nkengasong

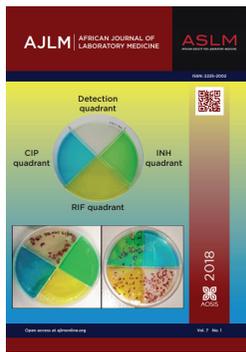
United States Centers for Disease Control and Prevention, United States  
Interim Editor-in-Chief, 2015-2016

### Iruka Okeke

University of Ibadan, Nigeria  
Editor-in-Chief, 2017-present

expected ranges. To accommodate the increased volume, editorial staff restructured workflows to be more efficient, but such measures can only do so much. Even in the best circumstances, the biggest challenge is finding good reviewers.





Reviewer contributions are critically important for improving articles and helping ensure the integrity of the journal. Finding them is the one part of the process that cannot and should not be rushed. Against the backdrop of a global pandemic that occupied all the spare time of many laboratory professionals, it was particularly tough.

On the funding side, complete support for journal expenses from the journal owner is a somewhat unique funding model for a society-owned journal. Such journals are often funded by membership or subscrip-

tion fees (or both), which is not a mechanism ASLM will pursue for the same reason its journal does not charge its authors fees to publish. It may be challenging to maintain that structure long-term. ASLM and the Editorial Board of AJLM continue to explore funding options, such as charitable donations, which could support the journal as part of a larger goal of increasing laboratory medicine research capacity in Africa.

### Conclusion

Nevertheless, ASLM is committed to increasing access to and capacity for

scholarly research on the continent through AJLM, and its programmes and processes, as the journal continues to grow. Former AJLM Interim Editor-in-Chief, now Director of the Africa Centre for Disease Control and Prevention, Dr John Nkengasong explained in a recent interview, Africa must develop its own capacity. Although he was speaking about capacity to produce diagnostics and vaccines, the same approach applies to research and its publication.

#### Citation

Rammer B. The African Journal of Laboratory Medicine: 10 Years of building research capacity for laboratory medicine in Africa. *Lab Culture* 2021, No. 26, Pages 19-21

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# Spotlight On Eight African Women In Leadership Positions At The *African Society For Laboratory Medicine*

## Introduction

For an African woman, reaching a leadership position within an organisation is rather exceptional. Mah-Séré Keita, Director of Programmes and Operations for the African Society for Laboratory Medicine (ASLM), formulated the difficulties faced by African women in pursuing education and a career and being leaders in their fields as follows:

Blockades to career development for African women emerge even in childhood, with the issue again tracing back to limited opportunities. ...In rural areas, it is not uncommon for young men to be prioritised by their families when it comes to education, meaning that young women are often left behind....For women that do engage in healthcare careers, there is a significantly lower chance that they will be in the top positions, meaning lower earning potential and fewer opportunities to mentor and lead by example.<sup>1</sup>

As part of its 10th anniversary, ASLM commissioned this paper to put the spotlight on eight African women who overcame the difficulties that Mah-Séré refers to. These women got opportunities to obtain advanced education and are presently in leadership positions within and related to the organization. They share their personal backgrounds, aspirations, professional careers, influential people, structural factors, and the advice they have for other African women with leadership aspirations.

At ASLM, about 40% of staff and affiliated positions, such as board members, are African women. At the leadership level, women comprise seven out of 21 members of the Board of Directors, two of

three executive directors, three of nine regional programme managers and advisors, and two of nine country programme managers. From this group, ASLM's Executive Directors selected eight of the most experienced women leaders for this paper: Professor Alash'le Abimiku (AA) is a founding member and is presently Chair of the Board of Directors; Mah-Séré Keita (MSK) is the Director of Programmes and Operations; Dr Pascale Ondo (PO) is the Director of Science and New Initiatives; Dr Adama Sangare Traore (AST) is the Regional Laboratory Advisor for West Africa; Dr Marguerite Massinga-Loembé (MML) is the Regional Senior Laboratory Advisor for Central Africa; Beatrice van der Puije (BP) is a Regional Programme Manager; Caroline Bih (CB) is a Country Programme Manager; Professor Iruka N. Okeke is the Editor-in-Chief of the *African Journal of Laboratory Medicine* (AJLM), ASLM's peer-reviewed scholarly journal.

These women have and continue to contribute to the impressive development of ASLM in the 10 years of its existence from a 'convening' organisation to the vital technical organisation it is today in the domain of public health in Africa. Until 2016, ASLM was mainly working on getting African laboratories accredited towards ISO15189 standards and was closely tied to the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and Strengthening Laboratory Management Toward Accreditation (SLMTA) laboratory quality improvement programmes through 95% PEPFAR funding. Over the last five years – the period during which most of the women started working at ASLM – ASLM



**Winny Koster, MSc, PhD**  
Amsterdam Institute for Global Health and Development  
Netherlands

has grown both in terms of increased budgets and diversification of donors and programmes. The contributions of the eight women include writing scientifically sound project proposals, securing funding, recruiting capable people to implement projects, managing (regional) programmes, liaising with national ministries of health to set up laboratory systems, write national laboratory policies, and strengthen national public health laboratories, writing training curricula (and redesigning it for online delivery), mentoring African laboratory scientists, and advancing AJLM to be a renowned journal indexed in PubMed Central.

In-depth individual interviews were conducted via Zoom by the author<sup>2</sup> in July and August 2021 using similar interview themes with questions tailored to each woman based on their curricula vitae and internet searches. The goal was to track the women's paths to their present leadership positions, highlighting their personal backgrounds, education and careers, and to show how their paths were influenced by their personal aspirations, people and circumstances. The women narrate how they navigated gender inequality and the common social pressure on African women of prioritising marriage and having children over pursuing a career, as well as their views on the advantages and drawbacks of a leadership position.

## Personal background

The women in ASLM leadership

**Iruka N. Okeke (IO)**  
 2017: Editor-in-Chief,  
 African Journal of  
 Laboratory Medicine  
 (AJLM)



**Caroline Bih (CB)** ▲  
 2019: Country Project  
 Coordinator, Cameroon



▲ **Marguerite Massinga  
 Loembe (MML)**  
 2019: Senior Laboratory Adviser,  
 seconded to Africa CDC Regional  
 Coordinating Centre for Central  
 Africa



**Alash'le Abimiku (AA)** ▲  
 2011: Founding Member,  
 Board of Directors  
 2016: Chair, Board of Directors



**Mah-Séré Kelta (MSK)**  
 2015: Director, Global Health  
 Security Agenda Programme  
 2019: Director of Programmes  
 and Operations



▲ **Adama Sangare-Traoré (AST)**  
 2019: Regional Laboratory  
 Adviser for West Africa,  
 USAID/IDDS  
 2020: Laboratory Advisor United  
 States Centers for Disease  
 Control and Prevention / Global  
 Health Security Agenda 2, and



**Pascale Ondoa (PO)** ▲  
 2017: Director of Science and New  
 Initiatives; Head (unofficial), ASLM  
 Communications; Section Editor,  
 African Journal of Laboratory  
 Medicine



▲ **Beatrice van der Puike (BP)**  
 2019: Regional Programme  
 Manager, for Fleming Fund and  
 PEPFAR countries

positions are from different generations and were born between 1956 and 1986. They described the economic status of their families as simple, relatively poor, or average level income. Four women were born in Africa; three lived in a rural area (AA, Nigeria; CB, Cameroon; AST, Mali), whereas BP lived in a town (Ghana). Four women were born outside Africa (IO, United Kingdom; MML, Canada; PO, France; MSK, Spain); two (PO and MML) have a European mother and an African father. The mothers of five women had professional training and jobs (teacher, nurse, accountant), whereas the mothers of the others were housewives and businesswomen. The fathers of four women (IO, MML, BP, PO) had a university education and high-level professions (lawyer, aeronautical engineer, neurosurgeon, computer programmer), while the fathers of four women had jobs that did not require high-level education (mechanic, policeman, transit agent, professional football player [had a university education]).

All four women who were born outside Africa went back to their country of origin at the primary or secondary school level. Three went back with their whole family when their fathers felt homesick and/or wanted to contribute to the development of their country. MML recounted: *‘My father [a neurosurgeon] always wanted to come back and contribute to his own country [Gabon] instead of gaining money in Canada. This meant that wanting to contribute to my country was imprinted in me from young age.’* IO, who was born in the United Kingdom, went temporarily with her family to Nigeria and, thereafter, her parents returned to England. Her parents had decided that she and her three siblings should have their secondary education in a boarding school in Nigeria and get to know their country, learn the culture, and build a network. Most women who went back at a young age described this

as enriching, although not easy at the beginning. *‘It felt like home, but was not home,’* PO said. MSK, upon going back to Mali, was struck by the plight of poor people, especially poor women.

BP, born in Ghana, went to the United Kingdom when she was of primary school age. Her mother, a British Ghanaian, decided, after divorcing her husband, that there were better schooling opportunities for her two daughters in the United Kingdom than in Ghana.

For all the women, their parents considered the education of their children, both boys and girls, a priority, and all or most children in their families attended school. At the time that most of the women had their primary and secondary education in the 1970-80s, public schools in African countries were of good quality and the levels were comparable with those in Europe. In Gabon, the baccalaureate level was the same as in France (MML). Schooling was free (MML, AST, PO) and good students even got small scholarships from the government to buy pens and books (MML).

At the time of the interview, all but one of the women were married, and all but two had one or two children; some have children still living at home, while others have them studying abroad. By African standards, four women (IO, AA, PO and AST) married late and those with children therefore had their child(ren) at a relatively advanced age: late 30s to early 40s. The circumstance of marrying late can facilitate a career; IO mentioned that in a way, her marrying late unintentionally gave her a leg-up in building a career.

### **Aspirations as a child**

Asked about their aspirations as children or after secondary education, some said they already aspired to contribute to health as medical doctors or researchers, and others had completely different aspirations. Several women pointed out

that in African families, children who get the chance to advance their education after secondary school have a restricted palette of professions to choose from such as medicine, accountancy, law, or engineering, and so not all could follow their aspirations. PO loved art and history but this was not in the scheme of professions one could choose from – she studied medicine instead. IO could not study biology as she would have preferred because, according to her mentors, biology was not a profession; she ended up studying pharmacy. CB went against her family’s wishes for her to become an accountant and secretly enrolled in biochemistry instead as her first choice and accountancy as her third choice. *‘In secondary school I loved biology and chemistry and that is why I chose biochemistry – although I did not have an idea about my career’*, she said.

Three women aspired to become medical doctors because they wanted to contribute to improving people’s health, but they refrained from it for different reasons. MSK’s aspiration was to contribute to alleviating the health problems of poor people in Mali, many of whom were dying of preventable diseases. A parent’s friend pointed out that, in addition to considering the poor status of health facilities in Mali, she could have more impact as a public health specialist working on preventive medicine than as an individual medical doctor. BP recounted that before choosing A-level subjects, she had the chance to spend six weeks in the hospital. She remembered crying all day as a sixteen-year-old because she could not handle the misery of all the sick and dying people and was unable to detach from patients she had met two or three days before; it made her seriously depressed. Her teacher then advised her to study biomedical science, pointing out that this was another way she could help people. AA had already started studying medicine, but after her first

anatomy practical and after seeing human cadavers, she changed to microbiology, reasoning that she could still work on human health: *'[with microbiology] you're coming to the human from the angle of the microorganisms that can affect the human. Yeah, that made a lot of sense to me.'*

### Professional education and career

Three women studied microbiology, two up to PhD level (AA, MML) and one up to MSc level (BP). Two women obtained PhD degrees in the pharmaceutical sciences (IO, AST). One woman studied biochemistry (bachelors

degree; CB). Two women switched studies between BSc, MSc, and PhD: PO did medicine up to the MD level and got an masters and doctorate in biomedical sciences. MSK did a masters in public health after a bachelors in biology. Three women completed all their studies in African universities (AST, CB, IO), three in universities outside Africa (BP, MML, MSK), and two did the first part in an African country and got scholarships to study for their masters and doctorate in Belgium (PO) and in the United Kingdom (AA). Other women at universities in African countries also got the opportunity through scholarships to do internships and modules in the

United States or Europe.

For this paper, it is impossible to detail the impressive careers of the individual women; a very short summary is presented in this paper (**Table 1**), and further details can be found in their curriculum vitae and on websites. Suffice to say that all eight women built up relevant qualifications and experiences to arrive at their present leadership positions at ASLM.

Four of the women started their professional careers as laboratory scientists or technicians in laboratories in the United Kingdom, United States, or an African country. Two women began their careers outside

of the laboratory domain: MSK, after several jobs as a researcher and consultant in public health programmes, became a senior programme specialist for sustainable development at the American Society for Microbiology. PO began as a medical doctor in a tuberculosis hospital in Cameroon and realised after three years that she did not want to be in patient care and seeing the misery of ill people daily, and thus went into microbiology studies and laboratory work. AA and IO began and are still in academia (although IO did work briefly as a pharmacist). AA started as an associate professor at the University of Jos, teaching medical microbiology and virology to medical students. However,

**Table 1: Summary of the pre-ASLM professional careers of eight ASLM women leaders**

Name	Selected employment
Alash'le Abimiku (AA)	1988 – Assistant Professor, University of Jos, Nigeria 1991 – Postdoc in Robert Gallo's laboratory, United States Assistant Professor (1996), Associate Professor (2010), and Professor of Medicine (2016) at the Institute of Human Virology, University of Maryland School of Medicine, United States. Executive Director of the International Research Center of Excellence of the Institute of Human Virology Nigeria (that she co-founded), Nigeria. Fellow of the African Society of Sciences
Adama Sangare-Traoré (AST)	2000 – 2001 Assistant of the Chief of HIV/STI Laboratory, Centers for Disease Control (CDC)-Mali 2001 – 2012 HIV/STI Laboratory Director, CDC-Mali 2013 – 2019 Laboratory Technical Advisor, CDC-Mali
Beatrice vd Puije (BP)	2004 – 2009 Biomedical Scientist in London, UK 2009 – 2019 Employment as (regional) manager and implementor for Global Health Systems Solutions (GHSS), PHI; and Independent Consultant, mainly working on Integrated Quality Laboratory Systems, based in Ghana.
Caroline Bih (CB)	2008 Technician in several hospital laboratories, Cameroon 2012 Laboratory mentor and trainer at GHSS, Cameroon 2018 Consultant at PharmAccess Foundation, Netherlands 2019 Regional consultant for World Health Organization, Regional Office for Africa
Iruka N. Okeke (IO)	2000 Universities in the United Kingdom, United States, teaching faculty member, associate professor; became a full professor at Haverford College, United States in 2014 2014 Nigeria; University of Ibadan – setting up training programmes, teaching, and research 2018 Fellow of the African and the Nigerian Academy of Sciences
Marguerite Massinga Loembe (MML)	2004 – 2007; Postdoc scientist for Université Laval, Canada; STI Laboratory Director for Study in Benin 2007 – 2011 Field study coordinator for TB-IRIS clinical study, Kampala; position at Institute of Tropical Medicine, Belgium 2011 – 2018 Senior scientist and head of research laboratory at Centre de Recherches Medicales de Lambarene (CERMEL), Gabon
Mah-Séré Keita (MSK)	2002 – 2007 Various research and consultancies on public health 2007 – 2014 American Society of Microbiology, Senior Programme Specialist, Washington DC; developed, implemented, and managed programmes. 2015 Health Lead for Catholic Relief Services, Mali
Pascale Ondo (PO)	1992 – 1995 MD in tuberculosis unit of Jamot Hospital, Yaoundé, Cameroon 1996 – 2016 (senior) laboratory scientist microbiology at institutes and universities in Belgium and Netherlands; principal investigator, project lead, and scientific manager for various studies

frustrated that she was not given time for research as promised, she applied for and got a postdoctoral position to study HIV in Robert Gallo's laboratory in the United States in 1991.

During their studies and/or careers, all the women who were based in non-African countries (IO, MML, PO, BP, MSK, AA) had already worked on research projects related to laboratories. Several recounted that they were selected to work in research programmes in African countries for their United States or European employers because they were African. MML reported that she advocated for herself and other African people when attending a conference by saying that there was a brain drain from Africa, and that although there were a lot of (mixed) African scientists living in North America who wanted to work in Africa, they did not have money or opportunities. That was how she got a research position in Benin.

### Coming back to be based in Africa

MML realised that after so many years of studies and laboratory research work in Africa while based in Canada and Belgium, she did not want to spend the rest of her life in Canadian or Belgian laboratories. She came back to Gabon in 2011, where she got a job as senior scientist and head of the research laboratory at the Medical Research Centre in Lambaréné (CERME).

MSK, during her studies and employment in the United States, was already focused on projects all over Africa. The travelling back and forth between the United States and Africa became too much, with her two sons in the United States. In 2014, she decided to go back home to Mali to be close to the projects she was working on and to take care of her father who was widowed.

IO, already having much of her work in Nigeria, had wanted to come back and be based in Nigeria earlier, but returned from the United States only when her daughter was 2 years old.

BP came to Ghana with her husband in 2008 and believes her career really took off after she moved there. If she had stayed in United Kingdom, she would still be working in the laboratory. In Ghana, she started in a medical laboratory, but her manager advised her that she was more suited to the non-governmental organization public health field. The manager advised her to apply for a job at Global Health Systems Solutions (GHSS) that had been offered to her but that she was unable to take.

### Coming back to be based in Africa or their country of origin.

Of the six women who lived and worked in the United States or Europe, four came to be based in their country of origin; three returned because it was their decision, and one because she came with her husband; AST and BC were already based in Africa. AA commuted between the United States and Nigeria, where she co-founded the Institute of Human Virology Nigeria, which is linked to the Institute of Human Virology in the United States. PO was based in Belgium and the Netherlands, but all her work was in African countries.

### Coming to work at ASLM

Several women who were working in laboratories considered working for ASLM as a way to get 'out of the laboratory, out of academic research and off the bench', which was not satisfactory anymore because it did not directly advance the health of people. Working for ASLM allowed them to contribute to overall laboratory systems and public health in Africa.

### From work at the laboratory bench to laboratory systems

PO recounted that after seven years of working in a laboratory and seeing the problems of people in Africa who do not have access to diagnostic tests, she realised that her holding a pipette in a laboratory in Belgium and developing new tests would not solve the problem of lack of access to services and diagnostic tests in Africa. She wanted to get out of it. Being a medical doctor, she knew who the end users were. 'Many laboratory people are obsessed with viruses and do not consider the end-users.'

MML, who was doing clinical research with a priority to make as many publications as possible, ('clinical trial, publication, clinical trial, publication, etc.') said: 'Maybe as you get older, your priorities change, you start wondering "what do I contribute"?'

CB noted that ASLM makes it possible to develop a career in the field you love but away from the bench. 'In this way, I can have more impact. I cannot do that sitting at the bench, holding a pipette in my hand. Now I can influence policy.'

The fact that ASLM is growing and has the vision to be an all-African organisation was considered an opportunity by many women. Increas-

ingly, ASLM has resources available through gaining new projects that require local human resources to run the programmes. Women mostly got jobs at ASLM through personal contacts who alerted them to vacancies and asked them to apply for positions. Personal contacts already working at ASLM had appreciated the women's professional qualities during conferences, field visits, via publications, or while working at the same institute. Four women were made enthusiastic

### Recruitment through personal contacts

AST was working at CDC-Mali when she met MSK for the first time at the first ASLM conference in Cape Town, South Africa, in 2012. They then worked together on the CDC/GHSA program and on the IDDS project implementation in Mali. In 2019, at the end of a joint USAID/CDC/IDDS meeting, MSK alerted AST that there was an unfilled position at ASLM for an IDDS laboratory advisor and requested that she send her curriculum vitae.

BP was made aware of a programme manager vacancy by one of the executive directors and asked to apply as she was known to have exactly the right qualifications and skills.

AA knew JN because her institute, IHVN, was one of the main laboratories working with the United States CDC. They had already been working together on the African AIDS vaccine program. 'From the beginning [of ASLM] he pulled everyone in through his passion for the concept.' He pulled her in as a member of the Board of Directors.

After JN read IO's book 'Divining Without Seeds. The case for strengthening laboratory medicine in Africa' (2011), he asked her in 2017 to apply for the vacant Editor-in-Chief position at AJLM. IO, who had been a member of ASLM since its beginning, accepted the invitation. As a productive scientist on the editorial board of various journals, she wanted to contribute to more science being published from Africa; AJLM is a foremost journal on laboratory medicine in Africa.

JN who had known PO since 2001 when they had worked together at the Institute of Tropical Medicine of Antwerp, convinced her in 2016 to apply for the position of Director of Science and New Initiatives.

MSK knew JN from working together in the United States, where she was a member of a subcommittee writing the by-laws for the inception of ASLM. Working for CRS Mali and submitting a proposal to Africa CDC, JN asked her to apply for a vacancy at ASLM (Director GSSS), motivating her by saying that with her background and experience, she should work regionally and not only in Mali.

MML was asked by PO, who had known her since they worked together in Antwerp, to apply for the position of Regional Laboratory Advisor for Central Africa.

about contributing to ASLM by Dr John Nkengasong (JN), the former Head of Laboratories at the United States Centers for Disease Control and Prevention (CDC) in Atlanta and now Director of Africa CDC, who envisioned ASLM in 2011 as an African technical non-governmental organization that would advance the quality, use and status of laboratories in Africa, led by African scientists and managers.

## People and circumstances influencing studies and career

All women mentioned people and circumstances that facilitated their pursuit of higher education and building a career – only a few mentioned an obstacle that delayed their career for some years. Certain people also inspired them and influenced how their characters developed, their philosophies of life and work ethics.

### Parents

Most of the women consider the family they were born into as an enabling environment. AA said, *‘My parents are the bedrock of my success.’* They appreciated that their parents gave them the opportunity to go to school, pushed them to do well, and instilled in them their hard work ethics. Parents were ambitious for their children; most parents wanted a better education and career for their children than they had had. If finances allowed, they sent their daughters to the best schools, where the women got admitted because they were among the best students. As children and adolescents, the women were aware of the sacrifices (one of) their parents made, which motivated them to be serious about their studies.

All the women said their parents taught them by example and gave crucial lessons that were mainly related to work ethics, gender equality, and self-confidence. Many mentioned their mother, and some also their father, as role models. They saw their parents working hard,

### Parents’ role in the success of their daughters

AA’s father, being unable to afford education for his eight girls and two boys, urged them to be the best, so they could get scholarships for good schools and universities. *‘So, I am growing up with a father figure that says I must come first in school, get scholarships, and that he believes that I can do it. My father told us very early, you’re my girls, nobody is better than you, the boys are not better.’* She considered her mother as a role model in her philosophy of life, being assertive, knowledgeable, gracious, and never intimidated by the fact that she had no formal education.

MML’s father said: *‘You will not have inheritance; our inheritance is giving you an education to be able to fend for yourself.’*

CB is grateful to her parents for still, with the help of her elder sister, paying her university fees, despite not supporting her choice of study.

PO says she learnt from her mother and her godmother that women can do the same things as men. Her mother *‘carried the family on her shoulders’* financially when her father was no longer able to.

BP sees her artistic mother as a role model with a strong character. *‘As her daughters, we were never afraid of anything. This helped me throughout my life to be confident and be independent to just get on and do it.’*

MSKs mother was a role model as an activist for the plight of women.

AST praises the courage and strength of mind of her mother (her father had passed) who, with love and dignity, instilled right and rigorous education and spared no effort for the success of her children. Her mother funded her postdoctoral studies by borrowing from the bank.

IO’s mother was a role model in being independent; she left home on her own in 1960 to enrol in nursing school and later did a specialisation midwifery at a time when all her female age-mates married and had children.

with optimism, to make the best of their lives. The parents of many of the women instilled in them the love of and pride for their country of origin and Africa. Mothers helped their daughters financially with their education when fathers had passed away or were not financially able and supported their daughters on choices that went against gender norms.

### Teachers, mentors, and colleagues

During their secondary and university education, postdocs, and careers, all the women had inspiring teachers (often mentioned were the biology teachers), supportive PhD

thesis supervisors, wise mentors, and colleagues who helped them to arrive where they are now. These people inspired them and pointed them to opportunities for specific courses, scholarships, and jobs; advised them in a certain direction; and took them to conferences and meetings where the women could exhibit their work and build a network. When living in African countries, many of the women were not aware of the full range of possibilities; these inspirational

### Supportive and inspiring teachers, mentors and colleagues

AA: *‘Dr Gallo taught me “hearing science”, that is, understanding that there may be some important scientific finding in whatever accent it is presented and to not automatically switch off as I used to, when it is presented in an accent that was difficult to understand.’*

CB is appreciative of all the colleagues she has had along the way – including at ASLM – who pointed at opportunities for training and jobs, who mentored and coached her, and instilled in her a passion for the work, which enabled her to learn, progress and be engaged. They gave her the opportunity to attend many (12) training workshops for laboratory professionals between 2012 and 2021.

IO, without going into the specific obstacles, acknowledged Professor Chinedum Peace Babalola, a Nigerian colleague, who created a research institute and showed her the way to go about building institutes in a country like Nigeria.

BP pointed to people during her studies and career who saw something in her that she did not see herself, such as the manager in the laboratory who said she should go into public health. From certain inspiring role models, she took the passion they have for their work and their training and management styles.

teachers, mentors and colleagues saw something in them and helped them to see opportunities.

### Disease circumstances

The HIV / AIDS, Ebola, and coronavirus disease 2019 (COVID-19) epidemics caused laboratory systems to play a bigger role in their public health containment measures. Internationally and nationally, there was more attention and money for accreditation of African laboratories (SLMTA and SLIPTA programmes), referral systems, and quality control. The women pointed out that these circumstances facilitated their careers because of the increased job opportunities, funding for

**Disease circumstances facilitating careers**

MSK mentioned that previously, people who were not medical doctors did not count in the health field; laboratories were not budgeted for. She observed that laboratories are increasingly acknowledged to be of vital importance in public health. For instance, the COVID-19 PCR tests must be done in a laboratory.

In AA's experience, HIV created significant opportunities; 70% of her research work is focused on HIV. 'COVID-19 is opening additional doors as well, for instance, where currently I'm working on evaluation of diagnostic platforms and with some of the immunization groups and those that are monitoring adverse effects to COVID vaccination.'

PO said the COVID-19 pandemic has been an opportunity to show that Africans on the ground can do the job without 'international' consultants who could not travel.

research and programmes, and higher status of laboratory work.

**Influence of gender and being an African woman on careers**

All the women mentioned the pressure on a single African woman to get married and have children. All experienced (some) pressure to get married, if not from their parents, then from the extended family or community. Some resisted because

**Pressure to get married**

AST's aunts were pushing her to get married; her mother (a widowed teacher) never pressured her and even told her aunts: 'Leave her to finish her studies'. In the end, AST married at 38, because of advice from her CDC-Mali supervisor who said: 'I know you love your mom and give her everything she needs. But what will make your mom most happy now is when you get married.'

CB, who is not married yet, constantly gets reminded by her family that she should get married and have children because only then is a woman fulfilled. She withstands the pressure by telling her mother: 'Happiness is what you define your happiness to be; finding fulfilment in anything I am doing – now it is my job.'

IO's mother supported her daughter's choice to do a PhD. Family and other people advised against it, saying that she would out-educate herself, meaning that no man would want to marry her. IO said: 'I ignored it [the pressure to get married]. I thought, "I will show them that this girl can get things done."'

they wanted to finish their education or go for a PhD or job.

Several women reported that married African women may face gender-related challenges when they aim to advance their career:

husbands may feel threatened when their wives' ambitions reach beyond the family or when they get higher jobs than themselves. However, most married women said that although they observed this with other women, their own husbands are supportive. AA, speaking from experience, gave the advice that women should not remain in a bad marriage where she feels she must submit and is unable to express herself for the sake of being married, even if society or extended family speak badly about divorce. 'Marriage should not define you,' she advises.

Most women did not feel that being an African woman had a negative influence on their studies or career. Several even reported feeling it was an advantage as being an African and a woman meant there were opportunities for scholarships and conferences. MML in Canada and PO in Belgium experienced positive 'discrimination' for women and minorities in selection for scholarships and postdoctoral positions. Being based in the United States or Europe, MML, BP and MSK experienced that their dual citizenships / coming

**Negative experiences related to gender inequality**

AST had a negative experience in 1998 when her PhD thesis supervisor got her a scholarship for an internship in a tuberculosis laboratory in Lyon, France. She was eager to study the disease that caused her father's death. When the sponsor found out that she was a woman, which they did not know initially because her given name is usually a man's name, they cancelled the scholarship. As they told her thesis supervisor, the reason was that they could not fund studies that could be interrupted by marriage and/or children.

Although not having experienced it personally, IO sees the negative influence of unequal gender relations among her mentees who struggle with meeting the expectations of being a wife, mother, daughter(-in-law) and professional.

PO noted that she met more gender inequality with women having difficulties reaching leadership levels in European organisations than in an African non-governmental organization such as ASLM, where she feels that women are considered equal to men.

AA had negative experiences where men claimed sole ownership of certain collaborative research findings and over-criticized women's presentations on research findings, thereby intimidating them.

from an African background served as a positive selection criterion for work overseas in Africa.

With respect to opportunities, some women did have negative experiences related to gender inequalities and pressures to abide by gender norms or noted this happening to other African women.

**Leadership experiences**

Generally, women consider ASLM a safe place for women to work and be leaders. They feel appreciated by male and female colleagues. Female leaders at lower levels (programme managers/coordinators) are coached and mentored by the more senior (female) leaders (directors, technical advisors) who are very approachable and provide guidance in leadership style. Several of the women said they had to learn to be leaders because of social constructs in which girls are brought up to question their capacity.

Most women pointed to differences in the leadership styles of women compared to men. They believe that female leaders like themselves are generally team players, lead more democratically, are more collaborative and communicative, are more empathic and compassionate with others, and are more considerate of the well-being of staff than the male leaders. Having more female leaders, the women believe, brings another perspective to management, balances leadership style, and advances an organization. It brings diversity, with women, unlike men, discussing tough issues openly and being patient enough to listen to different perspectives.

**Reflections on advantages and disadvantages of being a female leader**

The women see many advantages of being leaders in their fields. The advantages concern increasingly knowing and seeing opportunities through a bigger network, being able to make decisions, moving

### Female leadership styles

MSK has a participatory leadership style. She wants the people she supervises to manage their own projects while she is mentoring and coaching them. For example, her programme managers write implementation plans, she comments, and they must make their own decisions; this breaks from the typical African hierarchical leadership style, where leaders make the decisions and workers implement them.

AST thinks her democratic leadership style comes naturally to African women, because they are used to managing and leading the household diplomatically and strategically to keep everyone happy. Men impose and lead with force. She sees leadership not as a position but a behaviour, a way of acknowledging everyone's contribution to the team, and motivating and leading a team towards achieving a common goal. This style boosts employee morale and makes workers loyal and hardworking.

PO notes that female leaders, like herself, first question before acting. Female leaders confront the problems and try to find solutions. Not many men will admit that they are wrong or do so openly because they see it as a failure. By her leadership style she hopes to contribute to creating ASLM as an enabling environment for people to develop themselves. She tries to be a role model leader by being approachable and fair, and by not being rude to other women, unlike some of the female leaders she has met in public health.

AA makes a point of listening to people because she has experienced many male leaders who did not listen to her and dismissed her because she was a woman. Like PO, she points to the different style of women where during meetings, women bring up tough issues to discuss, direct the discussion to underlying problems, and then come up with solutions, whereas men do not really want to stir things up but say that problems that are not considered big solve themselves with time. *'I think women like to process the issue, practically, analyse it before coming to conclusions.'* She thinks this helps organisations because women tend to nip problems in the bud and not deal with them only when they are out of control.

BP tends to be a micromanager. However, she has been forced to rely on a team approach more as the programme she is managing has developed. She has now developed her leadership style by giving opportunities to others to make decisions. She was inspired by the management style of PO who told her: *'I believe in you, I gave you this project, the successes are yours, but also the failures.'* She believes that female leaders bring an aspect of empathy, unlike men. *'The higher men go, the higher the ego becomes. Then they feel like God. There is massive misuse of resources, men do not care for their people, cannot identify with the poor people.'*

things forward, changing things, generating resources, coaching people, advancing other women, and having people listen to you. The women feel useful in that, as leaders, they can affect the lives of young African women (and

### Advantages of being a leader

IO says that as a leader, you can get things done, people listen to you, and you can enable people who are lower on the ladder to get where they want. The better you become in your work, the more resources you can generate to support the next generation to become successful. *'You can live some of your dreams through other people.'* As a female leader, you can take part in networks of (female) professionals, like men do. Not being part of networks limits the opportunities for women.

According to AA, being a leader allows you to show by example, such as with ministries of health, that women can be leaders; or as a principal investigator, you can tell senior male researchers sitting around the table to listen to everyone, including junior (female) scientists.

MSK says that while in a leadership position, you can assist by identifying and recruiting staff who were hidden in laboratories all over the continent to work on ASLM programmes, including from Francophone Africa, whereas the previous focus was on Anglophone. You can mentor staff, giving them opportunities to lead and to express themselves and turn expertise in the laboratory into management opportunities.

PO opines that being in a leadership position makes people listen to you and take up what you say. You can orient people, programmes, and the profession. She notes that African people and scientists are often shy towards international consultants, who can be arrogant. Being in a leadership position, you can place people in optimal positions based on their strengths, having seen them in their work.

CB says that working for ASLM already makes you a leader because ASLM is now increasingly known and appreciated in the laboratory and health domains. She likes to be a role model to younger laboratory technicians, showing them opportunities outside the bench, also with only a bachelor's degree. Seeing more women in power, other women will get motivated to do the same. Up to now, many women have thought: *'I can go to school, but in the end of the day it is still a men's world [a world with male leaders]'*.

men) by building their capacity and giving them self-confidence. They actively promote women and gender equality. They like to coach and mentor qualified women into good positions where they can evolve in areas where most higher positions are still occupied by men. They note that with more female leaders, there will be more role models that may inspire other women and younger generations.

The disadvantages of being a leader as mentioned by the women relate to the heavy workload, with many responsibilities that may weigh heavily, including time pressures to combine work, family,

### Disadvantages of being a female leader

AA: There are just not enough hours in the day; there is not enough time to strategize and think about bigger things or to sit with like-minded people and generate ideas to advance public health. In the African context, there are many personal things such as extended family responsibilities and being involved with your staff and mentees. On the author's question as to whether there is a difference with male leaders, she says: *'Possibly I get more of staff approaching me with their personal problems than male leaders do; it could be because I am a mother figure, or I am older.'*

BP: Leadership comes with a lot of responsibilities that may weigh heavily on you. There is the pressure to ensure continuity, that you are responsible for the programme to succeed, whereas people may think leadership is nothing but directing other people to do the work.

IO: People think that you can arrange everything. For instance, when you support their application for getting training, grants or jobs, people are disappointed in you if they do not get it.

PO: As a leader you are responsible for your decisions; it means that if you make a mistake, you must own it and try to find solutions. A drawback of being a leader is also that you cannot be nice all the time and to everyone and some may get the idea that you are not a nice person, but then: *'My job description is not to be nice, my job description is to get things done.'*

CB: The stress that comes with leadership, working for ASLM, is that you are seen as a role model and people think you know everything. You are supposed to meet everyone's criteria concerning what they – the ministry, the laboratories you are working with, the donors – expect of you.

children, and friends and to allow reflection beyond the immediate issues. Another disadvantage is that people may expect too much from a leader, i.e., expecting that you can arrange everything.

Interestingly, many women stated that if you like what you do, the work is less heavy, because you are self-motivated. CB is philosophical on the challenges she faces every day to live up to the expectations by reflecting that it also works as a motivation. *'Challenges are an opportunity to improve yourself. It is an advantage, because at the end of the day I get better.'*

A past disadvantage, mentioned by some, was that before COVID-19, the work involved a lot of (international) travel. This was a problem for those with (small) children, and

some noticed that it started affecting their health. The COVID-19 travel restrictions have shown that much work can be done without international travel. Interestingly, it was previously not allowed to give remote presentations at conferences, whereas with COVID-19 this has been made possible. IO will plead (as a leader) that it stays this way because this would make it easier for African women with young children to take part in conferences.

## Advice for other African women with career or leadership ambitions

Based on their own experience, the eight women offered the following general points of advice for other African women who want to advance their careers and become leaders.

1. Keep developing your experience and expertise in your field.
  - Work hard. When given a task, deliver.
  - Always try your best; challenge yourself every time.
  - Set personal goals and milestones; identify what training you need and what steps to take.
  - Always grasp the opportunity to learn during your studies and employment. If there are no training programmes, deepen your knowledge through online training.
2. Find a profession that you really like, are passionate about, and that fulfils you; only then will you be able to work the long hours that a leader must work.
  - As AA put it 'Your passion is key because that's what wakes you up in the morning. That's why you stay up late at night. If you hate what you're doing, there's no way you're going to succeed, there's no way you're going to be a role model, there's no way you're going to make a difference to the world.'
3. Build up your professional network; this will increase op-

portunities (for grants, education, courses, job offers).

- Look for people who encourage your growth and avoid people who are against you.
4. Believe in your capabilities and do not underestimate yourself; as an African woman, do not shrink yourself in the face of men or those from high-income countries.
    - Believe that you are equal to men and that you can do as well as men; never see yourself as lesser.
    - Exhibit your work
  5. Be strategic and a bit selfish, create and take opportunities that can advance your career and avoid being drawn into time-consuming activities that do not advance your career.
    - Communicate your ambitions and aspirations to people who can help you; carefully choose mentors.
    - IO advised: *'One thing to avoid: sitting on too many committees. In academia there are usually many committees, and they need a 50% female representation, whereas there are only 10% of staff female. Thus, those few women are invited to sit on many committees, which takes away their focus on their career.'*
  6. Discuss your options with your family and partner and make your choices in line with your priorities and environment and be responsible for them.
    - Sometimes you must bend to the situation (to marry), but you must be resilient. You can find another way, and you can still be a leader in your 60s!
    - Not everyone has to become a leader, realise that leadership comes with a lot of responsibilities and may involve sacrificing some of your family life for your professional life (MML).
    - CB believes you should follow your priorities: *'People will always have expectations of you, but what matters is what expectations you have for yourself that will make you happy and satisfied*

*with what you do. You can take from other persons what is good for you, but do not live your life satisfying what other people want from you.'*

- Marry a supportive husband; do not stumble on the first person who wants to marry you and *'Do not consider marriage as a means to an end [only way to get happy]'* (CB).
7. Educate your male (and female) counterparts to value daughters and female colleagues equally with men and give them equal opportunities (AA).
  8. If a job at ASLM is an ambition, learn French and English.

## Conclusion

Putting the spotlight on these eight women in ASLM's leadership circle revealed a number of commonalities. Throughout their education, professional training, and career, these women were determined to try their best, created and grasped opportunities that advanced their education and career in directions that concurred with their professional passion, and avoided gender-related obstacles. The women were fortunate to have had a good start in life, in the sense that their parents valued education for all their children, sometimes against the prevailing gender norms.

Unlike the limited leadership opportunities for women in the general healthcare sector that MSK mentioned in the Introduction, ASLM, through the growth in its portfolio of programmes over its first 10 years, is providing professional opportunities for African women in the laboratory sector to advance their careers and be leaders. The eight women demonstrate that being in Africa gives African people chances and that professionals from the diaspora do come back to Africa. ASLM leaders report that they will continue to support such opportunities over the next 10 years. In fact, ASLM is scouting within Africa for both women and men with the right qualifications to apply for current va-

cancies. Obviously, word about these vacancies has not spread widely in

### Current ambitions

PO wants to continue to build ASLM as an organisation that counts, and one that countries see as a good partner. She wants to continue challenging the way global health is working with non-African consultants who ignore the existence of capacity in Africa. ASLM is neutral, not for profit and has the authority to give a voice to laboratories in Africa.

IO wants to support African scientists to really lead research in Africa and ensure that Africans are in decision-making positions and able to solve their own problems. That is why ASLM is such a good example of an African-led organisation. It is recognized and has a voice outside Africa, in addition to doing important work for the next generation. For example, AJLM mentors young African scientists with interesting research findings to publish their work.

AA wants to be involved in policy development related to laboratories in the health system in Africa and find a way for more effective North-South partnerships.

MML said, 'I am proud to be contributing to decolonising global health. The narrative has to change: Africans have to take things in their own hands more.'

networks yet, because people are difficult to find.

Interestingly, the women highlighted here do not see their present leadership level at ASLM as an endpoint or springboard to jobs in other organisations. Instead, their present personal ambitions are linked to the further development of ASLM and African scientists and promoting their equal standing with organisations, consultants, and scientists in high-income countries. Most of the women mentioned that they can still learn a lot and feel that they are part of an inspiring movement and can develop personally if they stay with ASLM. This is a positive sign that ASLM can continue to be a vibrant organisation led by African people through the next decade and beyond, while providing ample opportunities to women and making women feel acknowledged and valued.

## Acknowledgements

The author is grateful to the eight women who so openly shared their experiences and took time for the interview.

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### Editors:

Mr Erkison Odih and Mrs Bethanie Rammer, African Society for Laboratory Medicine

### CITATION

Koster, Winny. Spotlight on eight African women in leadership positions at the African Society for Laboratory Medicine. Lab Culture 2021, No. 26, Pages 22-31.



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# The challenge of determining a National List of Priority Diseases to develop diagnostic services

Diagnostic services are essential to patient care and disease control. The scarcity of resources in most African countries requires them to set priorities and select diagnostics that best serve the health needs of their population. Thus, disease prioritization should be based on the nation's disease burden.

There are a plethora of international 'priority disease lists'. Countries have to interpret, amend, and consolidate these into one comprehensive, appropriate national list of priority diseases, including both communicable and non-communicable diseases.

The Global Burden of Disease Study<sup>1</sup> shows that, in Africa, infectious diseases are responsible for a higher disease burden than non-communicable diseases. As not all countries have access to up-to-date national epidemiological data, the extensive World Health Organization (WHO) list of pathogens for communicable disease surveillance often serves as a de facto national list of priority diseases.<sup>2</sup> However, the question is, to what extent does this list correlate with a nation's highest morbidity and mortality communicable and non-communicable health conditions, which should be the focus of the national priority diseases list to ensure maximum impact.

The availability of national resources and capabilities determines which and how many priority diseases can be effectively

addressed. Disease prioritization informs rational, evidence-based decisions for resource allocation, planning, and impact measurement. This article provides an overview of the various international priority disease lists and calls for the setting of appropriate national priorities.

## International priority disease lists

### Universal Health Coverage

Universal Health Coverage (UHC) is defined as 'all individuals and communities receiving the health services they need without suffering financial hardship'.<sup>3</sup>

Priorities to move towards UHC should be based on the national communicable and non-communicable disease burden. Although the national disease burden differs per country, the WHO has identified four categories with 16 UHC essential health services (**Table 1**).

### International Health Regulations

One of the 16 essential health services under the UHC is compliance with the 2005 International Health Regulations (IHR).<sup>4</sup> The IHR aims to prevent, detect, and respond to the spread of diseases. The IHR recommends detecting 10 priority diseases based on local epidemiology. In addition, it recommends surveillance for priority pathogens included in the Global Antimicrobial Resistance and Uses Surveillance System (GLASS), priority zoonotic diseases, priority foodborne



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Reproductive, maternal, newborn and child health	Infectious diseases	Noncommunicable diseases	Service capacity and access
<ul style="list-style-type: none"> <li>• <i>Family planning*</i></li> <li>• <i>Antenatal and delivery care</i></li> <li>• Full child immunization</li> <li>• Health-seeking behaviour for pneumonia.</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Tuberculosis treatment</i></li> <li>• <i>HIV antiretroviral treatment</i></li> <li>• Use of insecticide-treated bed nets for malaria prevention</li> <li>• Adequate sanitation</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Prevention and treatment of raised blood pressure</i></li> <li>• <i>Prevention and treatment of raised blood glucose</i></li> <li>• <i>Cervical cancer screening</i></li> <li>• Tobacco (non-) smoking.</li> </ul>	<ul style="list-style-type: none"> <li>• Basic hospital access</li> <li>• Health worker density</li> <li>• Access to essential medicines</li> <li>• <i>Health security: compliance with IHR</i></li> </ul>
*Italics indicates services where diagnostics are required.			

Table 1. Sixteen essential health services under Universal Health Coverage.

diseases, priority epidemic-prone diseases, priority conditions for notification at ports of entry, and the four WHO-notifiable diseases (smallpox, poliomyelitis due to wild-type poliovirus, human influenza

- 10 priority diseases (JEE, 5 p. 50)
  - Priority pathogens for reporting to GLASS (JEE, p. 23)
  - Priority zoonotic diseases (JEE, p. 31)
  - Priority foodborne diseases (JEE, p. 35)
  - Priority diseases for national notification (JEE, p. 58)
  - Priority conditions for notification at ports of entry (JEE, p. 98)
  - Priority epidemic-prone diseases (JEE, p. 84)
  - 4 notifiable diseases in all circumstances under IHR (IHR, 4 p. 43)
- Abbreviations: IHR, International Health Regulations; JEE, Joint External Evaluation tool

**Box 1.** Eight priority disease lists recommended for surveillance by IHR and source references.<sup>5</sup>

caused by a new subtype, and severe acute respiratory syndrome) (**Box 1**).

The IHR also recommends establishing the ability to perform at least five of the 10 core tests (**Box 2**). Six of these core tests are pre-defined, leaving limited room for the four national priority tests as determined by the country on the basis of diseases of major national public health concern. In addition, the testing format of the pre-defined core tests is quite prescriptive

1. PCR for Influenza
  2. Virus culture for polio
  3. Serology for HIV
  4. Microscopy for tuberculosis
  5. RDT for malaria
  6. Bacterial culture for salmonella
  7. National priority test 1
  8. National priority test 2
  9. National priority test 3
  10. National priority test 4
- Abbreviations: PCR, polymerase chain reaction; RDT, rapid diagnostic test

**Box 2.** Ten IHR core laboratory tests.<sup>5</sup>

with consequences for the implementation strategy throughout the laboratory network.

### WHO list of priorities in research

Research is important to ‘fast-track the availability of effective tests, vaccines, and medicines that can be used to save lives and avert

large scale crises’.<sup>6</sup> Therefore, the WHO created and continuously

- COVID-19
  - Crimean-Congo haemorrhagic fever
  - Ebola virus disease and Marburg virus disease
  - Lassa fever
  - MERS-CoV and SARS
  - Nipah and henipaviral diseases
  - Rift Valley fever
  - Zika
  - Disease X’
- Abbreviations: COVID-19, coronavirus disease 2019; MERS-CoV, Middle East respiratory syndrome coronavirus; SARS, severe acute respiratory syndrome

**Box 3.** Prioritized diseases for research and development in emergency contexts.<sup>6</sup>

updates a list of priority diseases for research and development (**Box 3**).<sup>7</sup> However, the role of the laboratory network in research is often limited.

The prioritized diseases for research list (**Box 3**) is sometimes confused with the list of 10 priority diseases recommended by the IHR (**Box 1**). These lists are written from different perspectives: the IHR list comes from the public health perspective, whereas the WHO list is written from the research perspective.

priorities, and thus, need to interpret and consolidate them into one comprehensive national list of priority diseases that covers both clinical care and public health, and is feasible for the country’s health system to implement (**Figure 1**).

First, countries must take ownership by developing one national list of priority diseases that is based on their national disease burden and addresses both communicable and non-communicable diseases. Agencies such as the WHO, WHO Regional Office for Africa and Africa Centres for Disease Control and Prevention can support countries with formulating a nationally relevant list of diseases that cause the highest burden or present the most promising opportunity for eradication/control in the context of resource-limited settings. The length of the list should be determined by the resources available and may be increased (or decreased) when more (or fewer) resources become avail-



**Figure 1.** The challenge to interpret and consolidate all the recommended priorities (blue arrows) into one comprehensive, appropriate national list of priority diseases.

### From international to national priority diseases

Without interpretation and selection by the country, the plethora of lists leads to a consolidated national list that includes so many ‘priority diseases’ that is not feasible for the country to cover them all. Countries need to balance their scarce resources against this plethora of

able. Removing a disease from the national priority list does not mean that it should be overlooked. Rather, it means that the country’s ministry of health will take a conscious decision to first allocate public resources to the diseases mentioned on the list. The list should be regularly reviewed and updated to reflect new developments in national

disease burden, funding landscape or technology for disease management and control.

## From a national list of priority diseases to a solid diagnostic network

Next, countries must update their health and laboratory policies and strategies to incorporate the national list of priority diseases. The list can be translated into tiered test menus to be implemented in the national laboratory network. Test menus describe which tests are performed at which level and with which resources (facility, equipment, supplies, trained staff, sample transportation materials). These test menus should also be regularly reviewed and updated to reflect new developments.

Inventive choices such as multiplex-

ing or collaboration between vertical programs may allow for optimal resource utilization. For complex testing or testing for rare diseases with high epidemic potential, countries can decide to pool resources and have one regional reference laboratory in combination with a well-organized specimen referral system and memorandums of understanding to facilitate cross-border sample transportation.

The WHO model list of essential in vitro diagnostics (EDL)<sup>8</sup> is one of the lists that can assist in the formulation of test menus. The EDL is a (non-exhaustive) basket list of recommended diagnostic tests for both communicable and non-communicable diseases in the context of laboratory and non-laboratory settings.

## Conclusion

Developing a clear and context-relevant national list of priority diseases is the cornerstone of building resilient health and laboratory systems addressing both clinical and public health functions. Practical recommendations from countries, on how to translate the various international lists into a usable fit-for-purpose national list of priority diseases, will aid the process of developing implementable, robust, sustainable, and appropriate tiered testing strategies that will optimally impact clinical and public health outcomes.

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### Editor:

Mrs El-Shama Nwoko and Mrs Bethanie Rammer, African Society for Laboratory Medicine

### Citation

Faber D, Oskam L and Ondoa, P. The challenge of determining a National List of Priority Diseases to develop diagnostic services. *Lab Culture* 2021, No. 26, Pages 32-34

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# Continual quality improvement amidst the COVID-19 pandemic: *Attaining, maintaining, and sustaining accreditation to ISO 15189:2012 among selected public health laboratories in Uganda*

## Background

Coronavirus disease 2019 (COVID-19) first appeared in Wuhan, China in late December 2019. The novel disease was officially declared a global pandemic by the World Health Organization on 11 March 2020.<sup>1</sup> The Ugandan Ministry of Health formulated several guidelines to prevent the spread of the contagion during burials of COVID-19 victims, on public transport, for mask use, for mass gatherings, in market places and for village health team operations, among others.<sup>2</sup> These interventions have not only negatively impacted the country's economy,<sup>3</sup> but also affected the smooth implementation of several projects around the country. The difficulties of working in resource-limited settings have been compounded by the pandemic, which escalated already existing

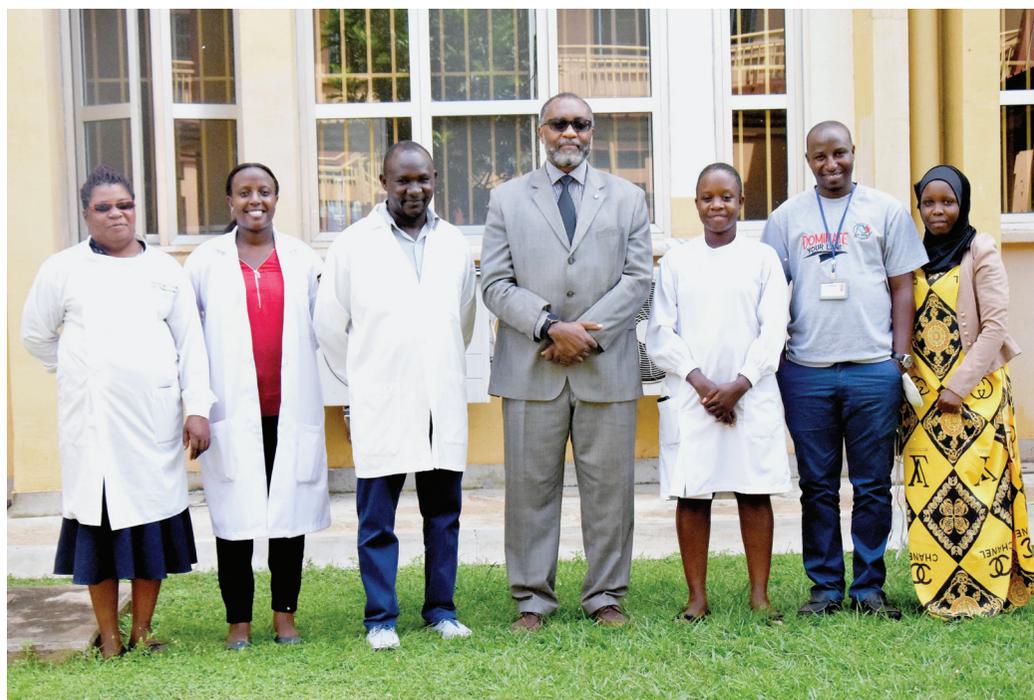
challenges to attaining, maintaining and sustaining accreditation to ISO 15189:2012 by medical laboratories.

Quality management systems (QMS) refers to a management system to direct and control an organization with regard to quality.<sup>4</sup> Accreditation refers to a procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tests.<sup>4</sup> In Uganda, lockdowns and inter-district restrictions affected the implementation of conventional onsite mentorships and technical support supervision for medical laboratories that are implementing QMS. Meeting the managerial and technical requirements of ISO 15189:2012 became extremely challenging, especially in instances where service providers were offsite. For example, access to biomedical engineers

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Entebbe Regional Referral Hospital Laboratory staff and AGHPF Regional Director, Africa(third left) and AGHPF Associate  
(source: Clinton Tumanye, AGHPF)



Laboratory staff participating in face-to-face trainings  
Source: (Clinton Tumanye, AGHPF)

to conduct routine equipment preventive maintenance and repairs, equipment calibration, timely access to external quality assessment materials, such as proficiency testing and inter laboratory comparison samples, and the gradual reduction in funding by donors limited the ability of laboratories to meet the technical requirements of ISO 15189:2012 and ensure quality of examination results.

Due to the COVID-19 pandemic, most public health laboratories reported an upsurge in workload, attributed to reassignment of critical staff to handle increasing needs for COVID-19 sample collection, transportation and testing. There is no doubt that too much work in relation to staff ratio is very likely to compromise the quality of testing.<sup>5</sup> Just like other front-line public health workers, several laboratory staff contracted COVID-19 in the line of duty and some died. This not only decreased morale in the workforce, but also increased result turn-around times, hence prolonging timely decisions for patient management.<sup>6</sup>

A well established, documented, implemented and maintained QMS

is an integral part of any diagnostic laboratory and assures accurate, reliable and efficient test results.<sup>7</sup> In Uganda, over 25 public medical laboratories have attained accreditation to ISO 15189:2012. The Uganda National Health Laboratory and Diagnostic Services (UNHLDS), in collaboration with A Global Healthcare Public Foundation (AGHPF) and other implementing partners, and with support from the United States CDC, has supported over 15 of the country's 25 public medical laboratories

to attain international accreditation to ISO 15189:2012 by South African National Accreditation System (SANAS). These laboratories include: Mildmay Uganda Laboratory, Kayunga Regional Referral Laboratory, Kiryandongo General Hospital Laboratory, St Raphael Hospital Nsambya, Atutur General Hospital Laboratory, Tororo General Hospital Laboratory, Masindi General Hospital Laboratory, Entebbe Regional Referral Hospital Laboratory, Kilembe Mines Hospital Laboratory, Hoima Regional Referral Hospital Laboratory, Jinja Regional Referral Hospital Laboratory, Aber Pope John Hospital Laboratory, Rukunyu General Hospital Laboratory, Ssembabule HCIV Laboratory. Conversely, AGHPF in conjunction with UNHLDS has also supported the National Equipment Calibration Laboratory center to attain and sustain accreditation to ISO 17025:2005 (**Figure 1**).

### **Pro-health modifications to prevent COVID-19 spread and maintain accreditation support**

In an effort to sustain the gains achieved by the country in regards to quality improvement in patient care due to accreditation, it was



Jinja Regional Referral Hospital Laboratory staff, AGHPF Associates and SANAS Assessors during Remote Assessment  
Source: (Clinton Tumanye, AGHPF)

imperative to provide continued support, supervision and monitoring of progress in these medical laboratories. To continue with the implementation strategy, several pro-health modifications were adopted, so as to comply with the guidelines set by the Uganda Ministry of Health to prevent the spread of COVID-19.

AGHPF in conjunction with UNHLDS, implementing partners and hospital management adopted mechanisms for attain, maintain and sustain accreditation to ISO 15189:2012 among selected public health laboratories amidst the COVID 19 pandemic. AGHPF reviewed the work plan to increase remote mentorships blended with limited, onsite mentorships to the selected public medical laboratories, in order to comply with the COVID-19 control guidelines. Modifications involved job enrichment for associates at AGHPF through trainings to develop E-content so as to deliver online training, mentorships and audits. Some of the E-content trainings included E- corrective action and preventive action courses. This successfully increased knowledge transfer among participants, which was evident in the pre- and post-participant assessments. AGHPF utilized its E-Platform, Zoom and Google Hangouts, to deliver game changing E-mentorships, E-Audits and E-trainings.

Furthermore, modifications in technical support supervision employed decentralized mentorship, whereby a group of highly competent laboratory staff from different regions of the country were carefully identified as national mentors and empowered with intensified skills and knowledge in delivering technical support supervision. These mentors were assigned to provide technical assistance to different laboratories that were fast-tracked for ISO 15189:2020 accreditation. This strategy provided a quick win

to strengthen national and regional capacity for continual sustainability of implementation of QMS amidst the COVID-19 pandemic. The selected national mentors are supported by AGHPF associates.

To resolve laboratory equipment service, calibration and repair issues associated with the COVID-19 pandemic, AGHPF supported in country biomedical engineers to acquire necessary training with traceable certifications and use of metrologically traceable calibration standards to strengthen national capacity, given inter-country travel restrictions, in a bid to control the spread of the disease.

During modifications, accredited laboratories were encouraged to participate in interlaboratory comparison programmes with other accredited laboratories within their regions. This modification was aimed at eliminating COVID-19-related delays in shipment of intercountry proficiency testing samples.

Modifications encouraged intensified involvement of hospital directors, administrators and district health officers in annual management review meetings. This, in turn, led to addressing the issue of increased workload due to staff shortages associated with COVID-19 task shifting of laboratory staff. Hospital management were also encouraged to identify local funding opportunities, so as to sustain accreditation requirements. For example, Kiryandongo Hospital attracted other potential funders to assist with reagents and other consumable purchases that were not provided through the national grid, but that were key to sustainability of accreditation status. Furthermore, accredited laboratories were encouraged to periodically evaluate referral laboratories and utilize them in reagent shortages or equipment breakdowns, so as to ensure continuity of service delivery with minimal service interruption.

The accredited public health laboratories in Uganda that were due for SANAS remote surveillance assessments were supported through E-mock audits by AGHPF where gaps for improvement were identified and thereafter addressed by the laboratories. The E-mock audits prepared the laboratories for E-assessments by SANAS that took place in 2020 through 2021, directly contributing to the sustainability of international Accreditation status to ISO 15189:2012, even amidst the COVID-19 pandemic. Additionally SANAS assessed five other public medical laboratories and 1 private medical laboratory supported by AGHPF in 2020, which attained international accreditation to ISO 15189:2012 in 2021 after successful closure of non-conformities raised during their initial assessment.

## Conclusion

The modified implementation model provided a sustainable solution for continual quality improvement among public health facilities, even amidst COVID-19-related challenges.

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### Citation:

Cite this article as: Namujuzi G, Mulindwa M, Songwe K.

### Citation:

Cite this article as: Namujuzi G, Mulindwa M, Songwe K. Continual quality improvement amidst the COVID-19 pandemic: Attaining, maintaining, and sustaining accreditation to ISO 15189:2012 among selected public health laboratories in Uganda. *Lab Culture* 2021, No. 26, Pages 35-37.

# Fighting tuberculosis – bringing molecular detection methods to where they are needed

Tuberculosis is still one of the leading global killers. Globally, 2–3 billion people are infected with tuberculosis, an infectious disease that is caused by bacteria belonging to the *Mycobacterium tuberculosis* complex. In 2019, 10 million people became tuberculosis positive, while 1.4 million people died of tuberculosis, including 0.2 million tuberculosis deaths among HIV-positive people. One of the health targets of the Sustainable Development Goals is to end the tuberculosis endemic by 2030.<sup>1</sup> However, it remains an open question whether these targets can be achieved due to the current coronavirus disease 2019 (COVID-19) pandemic. Preliminary data from 84 countries compiled by the World Health Organization (WHO) show that an estimated 1.4 million fewer people have been treated for tuberculosis in 2020 than in 2019.<sup>2</sup>

About 95% of the mentioned cases occur in low and middle-income countries, where the most common method for detecting tuberculosis is smear microscopy. Due to its limited sensitivity, almost every second tuberculosis case remains undetected.<sup>3</sup> In 2006, the WHO recommended bacterial culture as the reference method for diagnosing tuberculosis.<sup>5</sup> However, the result turnaround time takes up to a few weeks. A faster

and more reliable tuberculosis diagnosis is nucleic acid amplification methods. However, this method is limited by the lack of laboratory equipment and well-trained personnel prevalent in remote settings. A shortage of electricity or a lack of logistics additionally limits the use. In remote regions, patients must get quick results. Every trip to the test centres carries the risk of infecting other people. This risk is particularly high when smear microscopy is used because the patient has to deliver sputum samples on two different days. Therefore, a method is needed that is not only sensitive and fast but also does not require such great demands on the environment. A reliable and cost-effective method to close this gap is the Loop-Mediated Isothermal Amplification For The Detection of *M. Tuberculosis* (TB-LAMP). The TB-LAMP was recommended by the WHO in August 2016 as a replacement for smear microscopy in the diagnosis of pulmonary tuberculosis in adults with signs and symptoms of tuberculosis. It can also be considered as a follow-on test to microscopy in adults with signs and symptoms of pulmonary tuberculosis, especially when further testing of sputum smear-negative specimens is necessary.<sup>5</sup>

## TB-LAMP: Sensitive and simple to use

Loop-mediated isothermal amplification

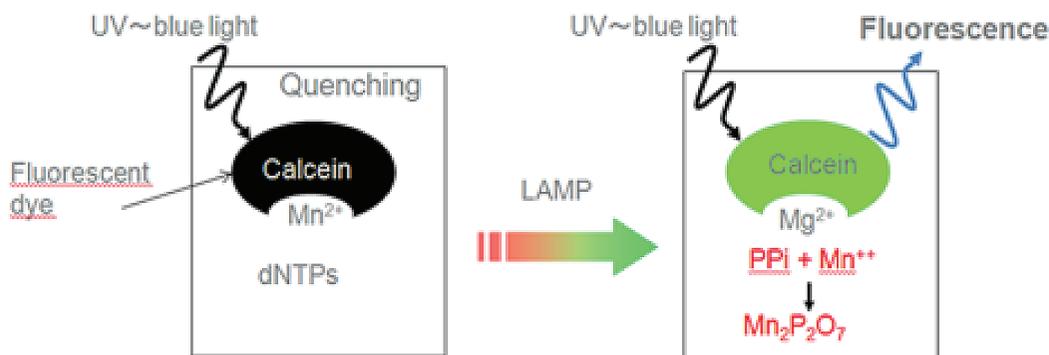


Figure 1. Development of the fluorescence during the amplification.



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(LAMP) amplifies previously determined genes and can be used to detect any pathogen (**Figure 1**). It enables single temperature amplification and the detection of target DNA faster than most conventional PCR-based methods. Similar to real-time PCR, measurement signals are generated during the amplification process. The amplified products are detected visually by reading the green fluorescence.

The entire workflow consists only of four major steps:

- Sample transfer and lysis
- Loopamp™ PURE DNA extraction
- Loop-mediated isothermal amplification
- Result visualisation

The incubation steps, as well as the result reading, are done with the help of the HumaLoop T. With HumaLoop T, sensitive and accurate molecular detection of *M. tuberculosis* complex can be facilitated on a consolidated platform. Two heating blocks with different temperatures for sample lysis and amplification, as well as a module with blue light for result evaluation, avoid the need for additional equipment investment further reducing cost.

All incubation times and temperatures are pre-installed, which makes it easy to operate. Another advantage is the required amount of the sputum sample, of which only 60 µl is sufficient.

In addition to the diagnosis of tuberculosis, it is also possible to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and malaria infections with the LAMP method. Here, a differentiation between the *Plasmodium* pan-species: *P. falciparum* and *P. vivax*, can be done.

## TB-LAMP as a reliable and simple tool for tuberculosis diagnosis in peripheral health centres

LAMP combines the test performance known from other molecular

methods, robustness, easy logistics by transportation at 2–30°C and minimum training efforts. The high specificity of TB-LAMP is due to the detection of two target sequences: Gyrase subunit B and Insertion Sequence IS 6110. In contrast to microscopy, no non-mycobacterium tuberculosis bacteria are detected. These features render LAMP a simple and useful tool for diagnosing *M. tuberculosis* complex in peripheral health centres where smear microscopy is performed. The replacement of smear microscopy by TB-LAMP in remote areas offers early and reliable detection of tuberculosis.<sup>4</sup>

Especially outstanding is the possibility to perform the test with the help of a solar panel and battery (**Figure 2**). Up to four complete runs, i.e. almost a day without electricity, are possible using only solar energy. This enables the use of



Figure 2. Peripheral TB-LAMP site in Uganda with installed solar panel.

this test even in the most isolated locations.

Many studies, especially in Africa such as Uganda, The Gambia, South Africa or Cameroon, confirm the sensitivity and specificity of the TB-LAMP. In Uganda, the TB-LAMP performance was compared to smear microscopy at a district hospital and two low-level health centres in Kiboga District. In this rural, high HIV-tuberculosis prevalence setting, the TB-LAMP performed better than

conventional smear microscopy in the diagnosis of *M. tuberculosis* complex.<sup>6</sup> Similarly, 285 patients in The Gambia were tested with microscopy and the TB-LAMP. When culture was used as the reference standard, the overall sensitivity for TB-LAMP was 99% and specificity was 94%. Thus, it was also proven there that TB-LAMP would be most suitable as a screening test for new tuberculosis cases in peripheral health clinics.<sup>7</sup> In South Africa, Kwa-Zulu-Natal is the epicentre of the HIV epidemic, where approximately 70% of people with tuberculosis are co-infected with HIV. Undiagnosed tuberculosis contributes to high mortality in HIV-infected patients. Delays in tuberculosis diagnosis and treatment initiation results in prolonged transmission and increased infectiousness. Therefore, TB-LAMP must have a significantly higher sensitivity than smear microscopy. The TB-LAMP could accordingly be implemented as a point-of-care test in primary health care settings and contribute to reducing treatment waiting times and tuberculosis prevalence.<sup>8</sup> Also in Cameroon the sensitivity and specificity of TB-LAMP were similar to GeneXpert®.<sup>9</sup>

## Improving tuberculosis diagnosis in Cameroon with TB-LAMP

The challenges in diagnosing tuberculosis in Cameroon were mainly the poor sensitivity of the smear microscopy, the long time to result of the culture and the given conditions in the laboratories. As a result, many cases of tuberculosis remained undetected. In 2017, a pilot project was set up using TB-LAMP in Cameroon. Under the direction of the National Tuberculosis Program, the assay's sensitivity and practicability were tested in four hospitals, including three remote areas. The pilot sites were selected according to their workload.

Therefore, the mix of the four sites was important - from the largest

hospital in the Yaoundé region to a remote laboratory. It was essential to demonstrate applicability in different environments with different conditions. Following the promising results of the pilot project, the government of Cameroon decided to introduce this technology in the country.

Cameroon then applied for a grant from the Global Fund, which was approved at the beginning of 2018. Cameroon was the first country in Africa to implement TB-LAMP on a broad base and therefore enabled fast and reliable diagnosis, especially in remote settings.

‘HumaLoop T is robust, adequate for peripheral laboratories and useful during tuberculosis diagnosis mass campaigns to respect the turnaround time. With TB-LAMP, significantly more positive tuberculosis cases could be detected in Cameroon year after year compared to microscopy, thus contributing to an improvement in diagnostics,’ mentioned Dr Valerie Flore Donkeng Donfack (Scientific Coordinator of TB-LAMP implementation, Centre Pasteur of Cameroon).

Since the implementation of TB-LAMP in Cameroon, the country has had 41 HumaLoop T instruments in the 10 regions. With the scaling up of TB-LAMP in 2019, tuberculosis notification in Cameroon increased from 23,403 to 24,757 between 2018 and 2019 respectively. The use of TB-LAMP as a follow-on test to smear microscopy for sputum smear-negative specimens in adults with signs and symptoms consistent with pulmonary tuberculosis helped to catch up 388 tuberculosis patients out of 3061 sputum smear-negative specimens transfer to TB-LAMP sites in 2019. These

patients could have been released into the community and continue to transmit the disease. In addition, TB-LAMP plays an important role during tuberculosis mass screening campaigns in prisons and communities by reducing the turn-around time.<sup>10</sup> The TB-LAMP is also listed in the national guideline and Global Fund applications for the upcoming years in Kenya, Nigeria and Uganda.

### A constant development – new EQA program and connectivity solution

To close the existing gaps of TB-LAMP, partnerships have been successfully established, which guarantees higher quality and connectivity.



Figure 2. Peripheral TB-LAMP site in Uganda with installed

It is now possible to verify the functionality of the HumaLoop T, the reagents as well as the laboratory procedures with blinded controls for external quality assessment (EQA) and unblinded controls for verification (Figure 3). The SmartSpot patented technology enables the packaging of inactivated Mycobacterium tuberculosis on a simple spot on a card, which is easily and safely tested like a patient’s clinical specimen.

Each card weighs less than 3g, is easy, safe and cost-effective to transport, and is stable for 24 months at ambient temperatures. SmartSpot designs control for both Verification and EQA.

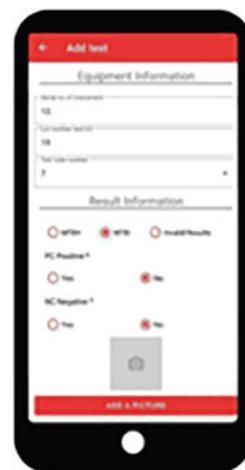


Figure 4. DataToCare App including TB-LAMP.

Furthermore, a new connectivity solution for TB-LAMP helps reduce the gap between diagnosis and treatment of tuberculosis patients (Figure 4). It is now possible to store and send the results obtained with HumaLoop T electronically by mail or SMS. This allows for better patient management, even in remote areas

These examples and developments have paved the way for the broad application of TB-LAMP wherever it is needed.

It’s time for a change – it’s time for TB-LAMP.

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*Editors: Mrs El-Shama Nwoko and Mrs Bethanie Rammer, African Society for Laboratory Medicine*

**Citation:** Jendretzki, A and Rehberger, P. Fighting tuberculosis – bringing molecular detection methods to where they are needed. Lab Culture 2021, No. 26, Pages 38-40