

ASLM

AFRICAN SOCIETY FOR LABORATORY MEDICINE

SPECIAL GLOBAL HEALTH SECURITY EDITION



LAB CULTURE

THE ASLM
NEWSLETTER

February 2016, Issue 15

**ANSWERING
THE CALL:**

**A PLAN FOR THE
FUTURE OF PUBLIC
HEALTH IN AFRICA**



Table of Contents

Answering the Call: Officials Convene in Freetown to Plan for the Future of Public Health in Africa	2
Freetown Declaration	4
Preventing, Detecting, and Responding: Moving the Global Health Security Agenda (GHSA) Forward in Africa, An Interview with US Ambassador and GHSA Champion Dr. Bonnie Jenkins	6
Ready for Lift-off: Initiating a Pilot Programme for Laboratory Network Assessment in Uganda	8
Combatting Drug Resistance in Africa: New Stepwise Framework Aims to Provide Guidance for Establishing Sustainable Surveillance Programmes	10
“The Whole is Greater than the Sum of its Parts”: A Framework for Functional Tiered Laboratory Networks	12
Integration of Tiered Networks within Public Health Institutes: The Ethiopian Public Health Institute (EPHI) Experience	14
Regulatory Harmonisation: Safer and Faster Access to Life Saving Products	16

Lead Editors:

Paula Fernandes, MBA, PhD (GSSHealth)

Corey White, MPA (ASLM)

Editorial Team:

Mah-Sere Keita, MPH (ASLM)

Michele Merkel, MS (GSSHealth)

Rachel Crane (GSSHealth)

Rosalie Whedbee, MPH (GSSHealth)

Laurel Oldach (GSSHealth)

Sam Donnenberg (GSSHealth)

Talkmore Maruta (ASLM)



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



Answering the Call: Officials Convene in Freetown to Plan for the Future of Public Health in Africa

As Ebola devastated West Africa in 2014, laboratories were left caught lagging behind the high volume need for diagnostic services. Although great strides have been made in laboratory improvements since the Maputo Declaration of 2008 ^[1], the outbreak uncovered gaps in laboratory connectivity that challenged efforts to contain the spread of disease. Epidemiological investigations suggest that several clusters of cases went undetected for several months before the official declaration in March of 2014 ^[2]. Delayed detection, coupled with the infrastructural challenges to sample transport, communication, and alerts, all contributed to the spread of the outbreak ^[3].

Delays in diagnosis and epidemic tracking meant that response activities were always one-step behind the outbreak. As people raced to catch-up, progress was made. For example, by August of 2015, partners from the WHO Emerging and Dangerous Pathogens Laboratory Network (EDPLN) and the Global Outbreak Alert and Response Network (GOARN) had deployed 32 laboratories into Guinea, Liberia, Sierra Leone, and Nigeria, to support identification, monitoring, and treatment of Ebola infected individuals ^[4]. The Ebola outbreak highlighted the need for systems that are proactive rather than reactive, ensuring that resources and mechanisms are already in place, so that response efforts for future outbreaks are timely and effective.

In October 2015, public health experts from around the world and across the African continent came together in Freetown, Sierra Leone to respond to the Global Health Security Agenda (GHSA), and launch the next phase of laboratory strengthening in Africa. The GHSA aims to make health security an international priority to reach the goal of a world safe and secure from infectious disease threats. With GHSA in mind, high-level Ministry of Health officials from 21 African countries worked to develop frameworks for systems designed for *Africa, by Africa*, to ensure preparedness to prevent, detect, and respond to emerging infectious disease threats.

An overarching theme of the Freetown consultation, convened by ASLM and WHO AFRO, was the need for national functional tiered laboratory networks; attendees worked to design a framework for such a system. Integrating each pillar of the laboratory system with public health institutes allows connectivity at all levels of the laboratory system. Each laboratory, no matter its size, will support and be supported by others in the network, contributing to a stronger, united system.

The shift towards integrated national networks will strengthen the efforts of wider regional and pan-African laboratory networks, such as the African Public Health Laboratory Network (APHLN), which works to promote collaboration and coordination amongst members to address healthcare priorities on the continent ^[5]. At the core of APHLN is the ASLM Collaborating Centres network, currently comprised of top laboratory systems in Ethiopia, Kenya, Nigeria, Senegal, South Africa, and Tanzania, with internationally recognised expertise in laboratory medicine, research, policy development, technology assessment, and training ^[6]. Through APHLN, these Collaborating Centres and other members benefit from the ability to easily share information, implement standardised procedures and policies, refer dangerous or high-risk pathogens for testing, support workforce development, and harmonise regulations – promoting South-South cooperation for stronger and more effective efforts for disease detection and response. (Cont'd on page 3)

(Con't from page 2)

Regional and pan-African laboratory networks will be beneficial to national programmes, as they will provide access to resources and services that may not be available at the national level.. This relationship works both ways, however, and strong national laboratory networks will be critical to the foundation of effective regional and pan-African networks. Therefore, ensuring functionality of national laboratory systems is paramount. Another key output of the consultation was consensus on such indicators, compiled into a scorecard that will be used across the region to identify areas for improvement and assess functionality of laboratory networks over time. The selection of robust and measurable indicators is critical for ensuring that appropriate efforts to strengthen laboratory networks are effective.

Other concrete achievements of the Freetown consultation, in addition to the framework for functional tiered laboratory networks and the scorecard to assess them, include frameworks for combatting antimicrobial resistance and the regulation of diagnostics during outbreaks. The importance of these outputs was highlighted

“We need to come up with indicators to ensure that the laboratory networks that we put in place are functioning.”

in the endorsement of the Freetown Declaration, which calls upon national governments, partners, and donors to adopt the frameworks developed during the meeting and to make global health security an African priority. It will be the responsibility of all governmental, non-governmental, and multilateral partners, in collaboration with ASLM, to ensure the roll-out and scale up of these activities. The Freetown Declaration, recognising that an

individual actor cannot make these aims on their own, asserts the need for collaborative efforts to strengthen health security in Africa and beyond.

By: Rosalie Whedbee; Editors: Rachel Crane, Michele Merkel, Corey White

^[1] WHO-AFRO, “The Maputo Declaration on Strengthening of Laboratory Systems,” in *Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization*, Maputo, 2008.

^[2] Mbonye et al., “Ebola Viral Hemorrhagic Disease Outbreak in West Africa – Lessons from Uganda,” in *African Health Sciences* 14(3), 495-501, 2014.

^[3] WHO, “Factors that contributed to undetected spread of the Ebola virus and impeded rapid containment,” 2015, accessed 23 February 2016 from: <http://www.who.int/csr/disease/ebola/one-year-report/factors/en/>

^[4] WHO, Weekly epidemiological record, “Laboratory response to the West African Ebola outbreak 2014-2015,” 2015. Accessed 23 February 2016 from: <http://www.who.int/wer/2015/wer9032.pdf?ua=1>

^[5] African Public Health Laboratories Network (APHLN). ASLM. Accessed 14 December 2015 from: <https://aslm.org/what-we-do/aphln/>

^[6] Collaborating Centres. ASLM. Accessed 14 December 2015 from: <https://aslm.org/what-we-do/collaborating-centres/>

Freetown Declaration

We, country delegates, multilateral agencies, development partners, public health institutions, professional associations, and academic institutions, are gathering for the Regional Global Health Security Consultation for Laboratory Strengthening in Freetown, Sierra Leone, on 15-16 October 2015, and:

- **Appreciate** that this first-of-its-kind Consultation has brought partners together at the doorstep of the deadliest and costliest Ebola outbreak in history in order to develop strategies to establish the political, legal, and practical frame works for resilient laboratory networks to address the global health security agenda in Africa.
- **Acknowledge** that >11,300 lives have been lost in West Africa because of the Ebola Virus Disease outbreak, and that >\$2.2 billion in economic growth has been lost in 2015 for Guinea, Liberia, and Sierra Leone as a result of the epidemic. ^{[1][2]}
- **Acknowledge** only 1.3% of the world's healthcare workers are found in Africa, and they care for 25% of the global disease burden. ^[3]
- **Acknowledge** the increase of antimicrobial resistance (AMR) in Africa due to inappropriate use of antibiotics and inadequate capacity to detect resistance. Drug resistant infections may cause 10 million deaths a year and cost up to \$100 trillion a year globally by 2050. ^[4]

Collectively, we:

- **Recognise** the need for multi-sectoral, multi-country, and pan-African strategies for prevention, control, and response to disease outbreaks.
- **Recognise** the risks posed by the emergence and spread of new and existing microbes; the globalisation of travel and commerce; the rise of drug resistance; and the potential for accidental or deliberate release, theft, or illicit use of biological agents requires the strengthening of public health laboratory networks and surveillance systems.
- **Recognise** that integrated tiered laboratory networks and surveillance systems are the cornerstone of effective healthcare, and essential to the robust detection and early response to public health threats.
- **Recognise** the significant progress made in strengthening laboratory networks since the adoption of the 2008 Maputo Declaration for Strengthening Laboratory Systems and Resolution AFR/RC58/R2 at the 58th session of the World Health Organization Regional Committee for Africa (WHO AFRO), both resulting in the scale-up of diagnostic services for HIV, tuberculosis, and malaria.
- **Recall** the African Society for Laboratory Medicine (ASLM)'s Ministerial Call for Action to Strengthen Laboratory Services in Africa, launched in Cape Town, South Africa in December 2012, and its impact on laboratory services and quality improvement initiatives.
- **Acknowledge** the key role and need for a standardised monitoring and evaluation framework to measure progress in strengthening laboratory improvements, such as the WHO AFRO Stepwise Laboratory Quality Improvement Process Toward Accreditation (SLIPTA).
- **Recognise** that emerging threats now require even more responsive, harmonised, and significant integration and alignment of laboratory networks with public health institutes for effective laboratory-based surveillance responses.
- **Recognise** the functionality of tiered laboratory networks in Africa has significant gaps, the resolution of which must be given high priority in national health systems strengthening efforts.

(Cont'd on page 5)

(Con't from page 4)

Collectively, we:

- **Call** on national governments to strengthen functional tiered laboratory networks from national reference laboratories down to the primary healthcare level, as an integral part of public health institutes in Africa.
- **Call** on national governments, nongovernmental organisations, donors, partners, and the private sector to support the implementation of a standardised score card to routinely assess the preparedness and capacity of functional laboratory networks to prevent, detect, and respond to current and future global health threats.
- **Call** on ASLM and WHO AFRO to help guide countries to revise or establish national laboratory strategic plans and policies that support and strengthen functional tiered laboratory networks for an effective response to disease threats, and a score card to measure progress of implementation and improvements of the networks.
- **Call** on national governments, nongovernmental organisations, donors, partners, and the private sector to develop innovative strategies for laboratory workforce development to support functional tiered laboratory networks, especially at the primary healthcare level.
- **Call** on national governments, nongovernmental organisations, donors, and partners to develop a framework for a phased-approach to establish laboratory-based surveillance for monitoring antimicrobial resistance in Africa.
- **Call** on the African Union, national governments, donors, and partners to develop supranational reference laboratories for each of the regional economic blocs within the framework of the African Centres for Disease Control to enable effective disease surveillance and control in Africa.
- **Call** on national governments, nongovernmental organisations, donors, and partners to develop and implement guidance on evaluation and regulation of diagnostics, especially in outbreak settings.
- **Call** on national governments and regional bodies to work collaboratively to streamline regulations governing diagnostic tests to ensure quick, reliable access to services for the more than 1 billion Africans.
- **Call** on private industry and research and development institutions, with support from national governments, donors, and partners to accelerate development of innovative diagnostic tools for resourced-limited settings.

Agreed to in Freetown, Sierra Leone, on 16 October 2015.

^[1] United States Centers for Disease Control and Prevention (CDC), 2014 Ebola Outbreak in West Africa – Case Counts. Accessed at <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html> on 5 October 2015.

^[2] World Bank Group Ebola Response Fact Sheet, 1 September 2015 briefing. Accessed at <http://www.worldbank.org/en/topic/health/brief/world-bank-group-ebola-fact-sheet> on 5 October 2015.

^[3] Shortage of healthcare workers in developing countries–Africa. Naicker S et al. *Ethn Dis*, 2009 Spring; 19 (1 Suppl 1), S1-60-4. Accessed at <http://www.ncbi.nlm.nih.gov/pubmed/19484878> on 5 October 2015.

Preventing, Detecting, and Responding: Moving the Global Health Security Agenda (GHSa) Forward in Africa, an Interview with US Ambassador and GHSa Champion Dr. Bonnie Jenkins

Since shortly after being nominated by President Barack Obama in 2009, Bonnie D. Jenkins, PhD (pictured), has served as the Coordinator for Threat Reduction Programs at the US Department of State. Ambassador Jenkins works with US



Bonnie D. Jenkins, PhD

governmental programmes and international partners to ensure a coordinated approach to threat reduction, security programme development, and harmonised operations. In addition, she is a strong advocate for the Global Health Security Agenda (GHSa) initiative – a collaborative effort among governments, international organisations, and civil society to accelerate progress toward a world safe and secure from infectious disease threats and to promote global health security as an international priority.

In October 2015, she travelled to Sierra Leone to participate in the 'Regional Global Health Security Consultation for Laboratory Strengthening', co-convened by the African Society for Laboratory Medicine (ASLM) and the World Health Organization's Regional Office for Africa (WHO AFRO), which gathered regional and international health professionals to build consensus around a framework for GHSa implementation across Africa.

High-level Ministry of Health officials from more than 20 countries in Africa participated in the Consultation and worked with ASLM and WHO AFRO to develop and publish the 'Freetown Declaration' – a landmark consensus document calling for a new framework for tiered laboratory networks, their integration with public health institutes and surveillance systems, and implementation of a score card to assess their readiness to ensure early disease detection across Africa.

From your experience in preventing and reducing proliferation of WMD (weapons of mass destruction), particularly in the area of nuclear threats, what lessons do you think might be most applicable to the biomedical community?

The number one lesson is to focus on people because you have to have aware and well-trained personnel who can do the work. If you don't have people, nothing gets done.

Secondly, sustainability is important because resources are required to implement GHSa in the laboratory, and a strong and enduring health system needs to be established. Therefore, whatever the situation, GHSa must be incorporated into a system that can be sustained. We need to look at how countries can work together and help each other to sustain programmes. We also need to think across countries, not just one country at a time, and build that into each country plan.

Thirdly, we need to find a way to retain the lessons learned during the Ebola outbreak as we move forward. The outbreak highlighted the importance of what GHSa is trying to do: prevent, detect, and rapidly respond to infectious disease threats. The fact that it happened when it did helped to really strengthen the reasoning behind GHSa; it's unfortunate, but it has given GHSa such clarity.

How do you view the role of public health laboratories in the mission of the GHSa?

Laboratories are important in strengthening the health system; laboratories are where pathogens of concern are located in an identified space. In the case of biosecurity, for example, we need to ensure pathogens in laboratories are secure. Similarly, regarding nuclear materials, you have to secure the facility where those materials exist to ensure no one with intent to do harm can access them. It's the same with the laboratory and biological facilities— they must be kept safe and secure. If something gets out of the laboratory that shouldn't have, you have to go to the second line of defence, which can be more of a challenge: You have to figure out where it is, and get it out of the hands of potentially dangerous individuals.

(Cont'd on page 7)

(Con't from page 6)

How much risk is there for the supply chain during transport of laboratory materials? Is there a growing threat from outside of the laboratory?

We have to ensure the security of the supply chain as it is part of the overall structure of a strong health system. We want to strengthen a culture of safety and security among all those engaged in the supply chain, to mitigate risk and prevent unintentional accidents. We can build fences, or exert some safety control, but it is the individual workers that are going to be using safety and security protocols, so we need to pay attention to them.

With biosecurity, culture must be incorporated into education. We fund training programmes when people are out working in the field, but really the education needs to happen earlier.

It would be good for ASLM to include both safety and security as part of their training curriculum, to include the supply chain, and coordinate directly with Ministries of Education to implement it. There must be a consistent effort. It is something to include in GHSA national road maps and other strategies for strengthening a country's health systems.

The Maputo Declaration of 2008, with support from Ministers for Health, catalysed an unprecedented wave of laboratory strengthening efforts across Africa. GHSA and the 2015 Freetown Declaration will spur a second wave focused on real-time surveillance, connectivity, and promoting a more inclusive approach under the One Health agenda. What do you see as the key factors in maintaining momentum?

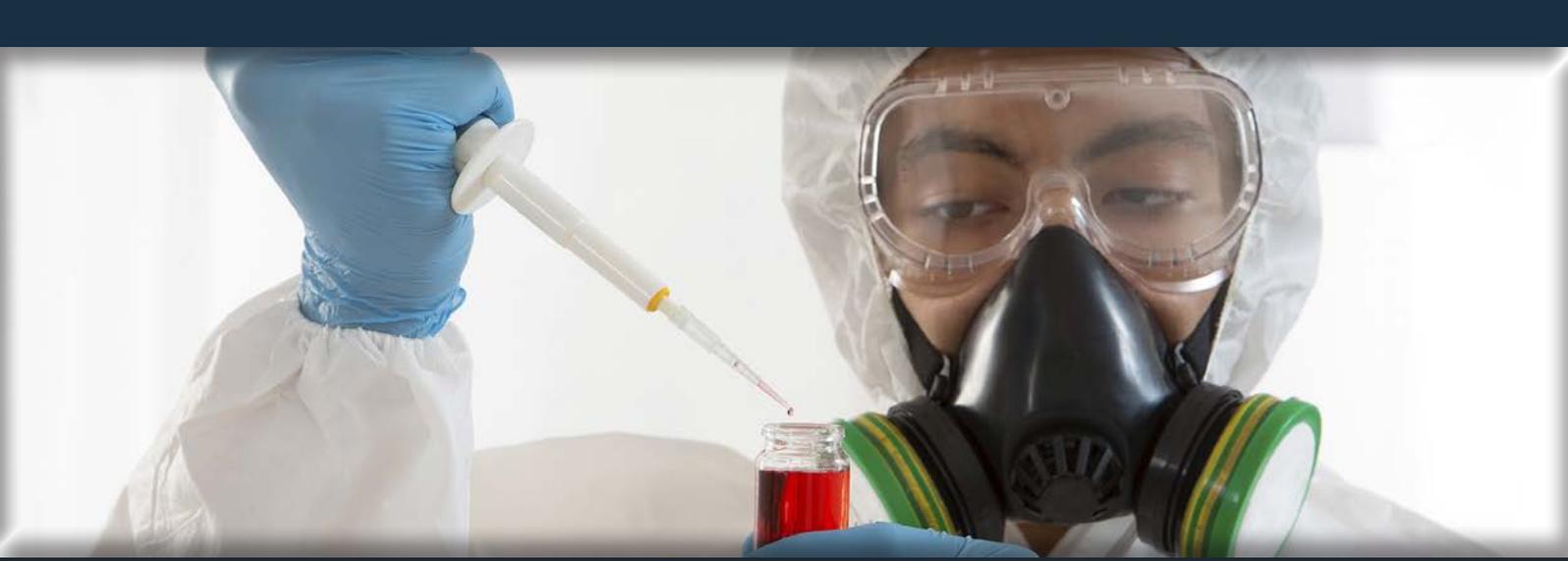
It is critical for the countries themselves to lead this work. The GHSA steering committee, consisting of representatives from a number of countries, is also a way to make sure GHSA goes forward. Each GHSA action package has ongoing coordination in place, and various meetings hosted by countries; the World Health Organization (WHO), World Organization for Animal Health (OIE), the Food and Agriculture Organization (FAO) and others have also taken advantage of existing platforms.

The reasons why we had an Ebola outbreak are not going to go away. Risk factors for the spread of infectious disease, such as frequent travel across borders and close interaction between humans and animal vectors are not going away. There will be more diseases, but hopefully we will be better at preventing, detecting, and responding. The Freetown Declaration's targeted calls for action are an important way to track and maintain momentum for GHSA-focused activities.

What do you see as the key take home messages from the recent Freetown GHSA Consultation, convened by ASLM and WHO AFRO?

It was heartening to see so many African countries having a discussion and deciding what is best for Africa. It is also good to see a focus on regional or sub-regional collaboration, rather than these important issues remaining at the national level. The meeting was much needed to ensure dialogue and to keep things moving forward. It was good to have the Freetown Declaration document at the end as a concrete takeaway, which will be a great advocacy tool. We have to try to encourage more communication with everyone in government, but it's not going to happen if it's not taken seriously. Improving health systems will require perseverance, programming and assistance, assessment of possible pitfalls, and strategy development. This meeting – and the Declaration itself – has shown that many countries in Africa are taking the need for moving forward seriously. This was an important meeting, and a positive effort.

Interview by: Paula Fernandes, Rosalie Whedbee; Contributors: Amb. Bonnie Jenkins, Marc Forino; Editor: Corey White



Ready for Lift-Off: Initiating a Pilot Programme for Laboratory Network Assessment in Uganda

The strength of national medical and public health laboratory network systems serve as a reflection of how well a country will respond to a disease threat. As the global community remembers the devastation caused by the Ebola outbreak, retrospection exposed vulnerabilities in laboratory network linkages. But how can laboratory networks be quantitatively assessed to identify areas for intervention to meet international standards as outlined in such documents as the International Health Regulations (IHR), Integrated Disease Surveillance and Response (IDSR) Guidelines, and the GHSA Action Packages, amongst others?

In Africa, national stakeholders have developed laboratory networks to meet individual and public health needs, such as the Southern African Development Community (SADC) Laboratory Network and the East Africa Public Health Laboratory Network (EAPHLN), and health leaders are striving to attain high standards for these networks. When laboratories are effectively interconnected, with strong communication between peripheral and higher level hubs, all of which adhere to proper standards, a country stands a good chance of curbing an outbreak before it becomes widespread.

The African Society for Laboratory Medicine (ASLM) and the World Health Organization's Regional Office for Africa (WHO AFRO) are leading the effort to develop a solution to evaluate and ensure laboratory network strengthening.

The solution comes in the form of an innovative tool: a scorecard to assess a laboratory's capacity and functionality based on given numerical metrics. The main objective of the scorecard will be to highlight areas that need to be addressed within a laboratory network. The tool is now in the early testing and implementation stages, which has included a pilot assessment conducted in Uganda from 12-18 December 2015. Following the pilot assessment, which will help assess the tool's utility and replicability, the tool will be refined, finalised, and prepared for further implementation across the continent. The tool will provide countries with an accurate outlook on the status of their laboratory networks and guidance on the way toward network strengthening.

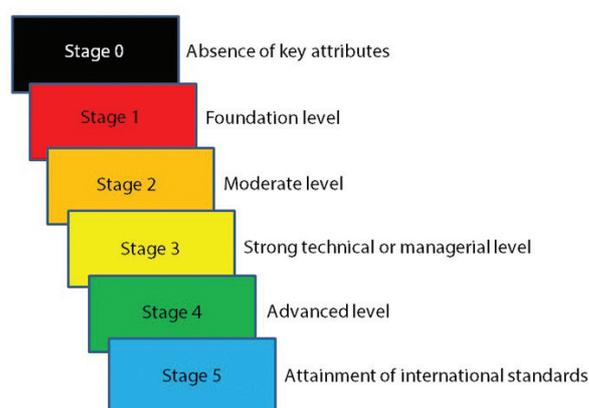
To maintain consistency between each evaluation, the tool measures the nine core capacities for every network assessed, including: political, legal, and regulatory framework; structure and organisation of the network; network coverage and rapid response; laboratory information; infrastructure; human resources; quality of the laboratory system; bio-risk management; and priority diseases. Each of these capacities includes a variety of components and indicators that scorecard users will assess. Additionally, the scorecard is meant for multiple long-term assessments to measure a network's maturity and improvement over time. After an initial assessment, the scorecard can be used again within the same laboratory network to see how far it has advanced along the five steps, or capacity levels, ultimately leading to full network functionality and adherence to all international regulations.

Leading up to the roll-out of the pilot in Uganda, a series of steps were taken to prepare for the country's assessment to ensure that the pilot was conducted as consistently as possible with an official assessment. Pre-assessment visit preparation requires several actions to be taken. (*Cont'd on page 9*)

(Con't from page 8)

Firstly, a Ministry of Health member responsible for laboratory coordination should chair and convene an assessment committee. Committee members will serve as global health ambassadors who will guide the team of assessors through the laboratory network when they visit the country. Once the committee is formed, they will be sent the scorecard and assessment manual to ensure collection of all necessary documentation before the on-site assessment visits. Finally, the committee should choose four representatives from clinical, district, provincial, and national level laboratories in the country to ensure that the assessment accurately covers the inner workings of laboratories at all levels and the efficiency with which they communicate and collaborate together.

Score Card Maturation Stages



Dr. Steven Aisu, Director of the Laboratory Department for the Ugandan Ministry of Health, chaired the assessment committee in Uganda, which gathered a number of other leading public health figures in the country, including the Director of the National Reference Laboratory, the Dean of the Faculty for Laboratory Education at Makerere University, and the Director of the National Public Health Laboratory. In Uganda, the entire assessment visit spanned five days and was led by a team from ASLM and WHO AFRO. During the first and second days of their visit, the team met with the Ugandan committee members to review the components of the pilot and the nine core capabilities of the scorecard, and to reach a consensus on how the ratings should be distributed for each capacity. The third and fourth days consisted of site visits of four representative laboratories, which demonstrated

“Health leaders are turning to laboratories as an essential component of disease prevention, diagnosis, tracking, and containment.”

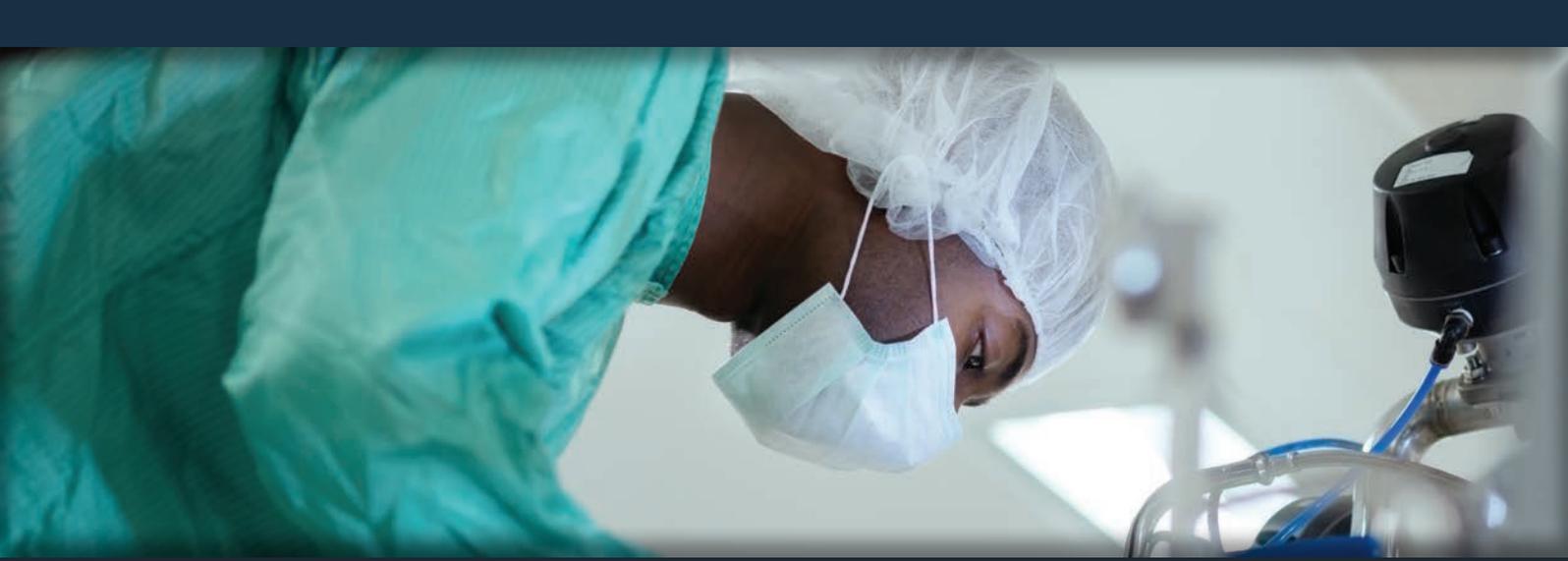
the various levels of capacity that comprise the overall country network. Finally on the fifth day, the entire committee and the assessment team met to discuss what went well and what needs to improve for future implementation of the scorecard. Since this was the first pilot, a debriefing session was key for gathering the necessary feedback before the tool can be officially used to score a laboratory network.

“In the wake of the 2014 Ebola outbreak, as the international community moves forward with strengthening health systems and becoming more prepared for infectious disease threats, health leaders are turning to laboratories as an essential component of disease prevention, diagnosis, tracking, and containment,” says Mah-Sere Keita, ASLM Director of Global Health Security. “ASLM and WHO AFRO are hopeful that the new scorecard will be the answer the international community is looking for to collaboratively strengthen laboratory networks. Once the pilot programme is evaluated and approved, full-scale implementation of the scorecard assessment can begin to change the way we think about evaluating and improving laboratory network capacity.”



Project leadership from the Uganda Ministry of Health and ASLM

By: Sam Donnenberg; Contributor: Talkmore Maruta, Mah-Sere Keita; Editors: Rosalie Whedbee, Michele Merkel, Rachel Crane, Corey White



Combatting Drug Resistance in Africa: New Stepwise Framework Aims to Provide Guidance for Establishing Sustainable Surveillance Programmes

Once an ignored threat, antimicrobial resistance (AMR) – commonly known as drug resistance – has become an international priority (see ASLM’s previous article). Drug resistance impacts public health in a profound manner, leading to negative outcomes for patients and wasting valuable medicines on battles that cannot be won. Drug-resistant infections could cause 10 million deaths a year and cost up to \$100 trillion a year by 2050. ^[1] Health officials in Africa are moving forward a stepwise approach for monitoring drug resistance in order to address this growing threat.

“Drug-resistant infections could cause 10 million deaths a year and cost up to \$100 trillion a year by 2050.”

Integrated functional tiered laboratory networks and surveillance systems are the cornerstone of effective healthcare, and essential to the robust detection and early response to public health threats. Both the World Health Organization (WHO) and the Global Health Security Agenda (GHSA) ^[2] recognise the critical role played by laboratory testing in monitoring and combatting drug resistance. The African Society for Laboratory Medicine (ASLM) and the WHO’s Regional Office for Africa (WHO AFRO) recently co-convened a Regional GHSA Consultation meeting in Freetown, Sierra Leone, where discussions focused on strengthening laboratory frameworks in Africa to better prevent, detect, and respond to emerging global health threats – including drug resistance (or AMR).

“ASLM is collaborating with other partners to develop a holistic stepwise framework to coordinate laboratory-based drug resistance surveillance in Africa to fulfil the objectives of the GHSA and the WHO Global Action Plan on Antimicrobial Resistance ^[3], as well as to answer the call for action in the recently released Freetown Declaration,” says Dr. Trevor Peter, Chair of ASLM. “The ASLM surveillance framework provides an opportunity to unify laboratory methodology and proactively pursue a ‘One Health’ approach as suggested by WHO, the Food and Agriculture Organization of the United Nations (FAO) and World Organisation for Animal Health (OIE).”

“Drug resistance surveillance is crucial to demonstrating treatment efficacy within communities during outbreaks.”

Despite limited laboratory capacity to monitor resistance, available data suggest that the African Region shares the worldwide trend of increasing drug resistance. Resistance has “dramatically increased the costs of fighting tuberculosis and malaria, and now threatens the push to treat people with HIV/AIDS effectively,” says Dr. Jean-Bosco Ndiokubwayo, WHO AFRO Senior Regional Advisor for Laboratories and Clinical Technologies. “Drug resistance surveillance is crucial to demonstrating

treatment efficacy within communities during outbreaks. The goal of the newly released WHO Global Antimicrobial Resistance Surveillance System (GLASS) Manual for Early Implementation is to enable standardised data collection, analysis, and reporting to better inform decision-making and (Cont’d on page 11)

(Con't from page 10)

understand impact on human populations.^[4,5] Enhancing surveillance networks is vital for effective Integrated Disease Surveillance and Response (IDSR) implementation as envisaged by IHR 2005, and the comprehensive framework launched in Freetown makes a valuable contribution towards monitoring drug resistance and global health security threats.”

“Snapshot Surveillance has great value in establishing drug resistance programmes.”

Leading author of the ASLM framework, Professor Olga Perovic from the Centre for Opportunistic, Tropical and Hospital Infections at the National Institute for Communicable Diseases in South Africa, states that “both the WHO GLASS Manual and draft ASLM framework recommend initiating drug resistance surveillance in a phased approach on selected priorities. As the ASLM framework is

formalised, it is important to bring together medical and civil society across Africa to socialise and strengthen drug resistance surveillance through a stepwise approach to ensure adequate collection of baseline data, allocation of appropriate resources, and continuous education and information sharing.”

Although ongoing, routine surveillance may not be initially possible, the use of *snapshot surveillance* has great value in establishing drug resistance programmes and providing evidence for future advocacy and expansions. A stepwise approach to drug resistance surveillance grounded in international recommendations – as laid out in the forthcoming ASLM framework – builds support and strengthens local capacity to facilitate the development of sustainable surveillance programmes in Africa.

By: Martin Adams, Corey White; Editor: Rosalie Whedbee

^[1] Review on Antimicrobial Resistance: UK Government, Wellcome Trust: 14 May 2015 report. Accessed 5 October 2015 from: <http://amr-review.org/>

^[2] “Global Health Security Agenda: GHSA Antimicrobial Resistance Package. (2014). United States Centres for Disease Control and Prevention. Accessed 11 November 2015 from: http://www.cdc.gov/globalhealth/security/actionpackages/antimicrobial_resistance.htm

^[3] Global Action Plan on Antimicrobial Resistance. (2015) World Health Organization. Accessed 11 November 2015 from: http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1

^[4] Guide for establishing laboratory-based surveillance for antimicrobial resistance. World Health Organization Regional Office for Africa, 2013. Accessed 11 November 2015 from: <http://apps.who.int/medicinedocs/documents/s20135en/s20135en.pdf>

^[5] Global Antimicrobial Resistance Surveillance System: Manual for Early Implementation. (2015). Accessed 11 November 2015 from: http://apps.who.int/iris/bitstream/10665/188783/1/9789241549400_eng.pdf?ua=1



“The Whole is Greater than the Sum of its Parts”: A Framework for Functional Tiered Laboratory Networks

Functional tiered laboratory networks increase access to essential health services. Timely diagnosis, initiation of therapy, and monitoring of disease progression should be a public right – as access to high-quality laboratory services has a major impact on all aspects of daily life.

Tiered laboratory networks are intended to provide appropriate local services based upon demographics, prevailing diseases, and others factors such as geographic location. As such, laboratories within a network are tiered and provide different types of service to the communities within the catchment area. The services provided must be in alignment with national public health policy. Laboratories organised into functional tiered networks improve individual patient and public health outcomes.

Strengthening of laboratory systems stems from country leadership and is guided by seminal agreements such as the 2008 Maputo Declaration ^[1] which set the stage for the development of robust, high-quality laboratory services. The African Society for Laboratory Medicine (ASLM) builds upon the 2008 Maputo Declaration on Laboratory Strengthening by serving as a professional body to advocate for the needs of laboratory medicine and networks. ASLM is currently developing a next-step document to the 2008 Maputo Declaration, a framework to deliver practical guidance to the Ministries of Health (MOH) for functional tiered laboratory networks.

A Framework to Build Tiered National Laboratory Networks

National governments carry the responsibility to drive health enhancement efforts with a unified, strategic direction for laboratory networks and diagnostics for sustainable and impactful solutions. The modification or creation of national laboratory policies and national laboratory strategic plans (NLSP), in compliance with ISO Medical Laboratory Standards (ISO15189), must engender tangible changes. It is important for NLSP's to align with other policies and if possible include directives to empower laboratory professionals within the MOH for implementation of laboratory network activities ^[2]. Successful implementation of NSLPs also necessitate identifying financial strategies for sustained effort, as health leaders have proposed that countries commit 5% of their budgets to laboratory diagnostics strengthening. ASLM's Framework for a Resilient Tiered National Laboratory Network proposes the following phases and considerations:

Phase 1: Create a model for an effective network

- Who, within the government, will direct the technical and administrative efforts to create a laboratory network?
- What laboratory systems already exist? This includes assessing the number of operational laboratories, the interaction between them, the tests that are performed, and the equipment that is used.
- What are the laboratory testing requirements for patient care and public health?
- How can the current laboratory structure be realigned to deliver the required services? What services will be offered at which levels?

(Cont'd on page 13)

(Con't from page 12)

Phase 2: Evaluate and plan requirements to support the network

- The following areas are critical to assess in order to determine the functionality of the network: adequate structure and organisation, well-designed safe laboratory facilities, adequate supply management system and IVD regulation, equipment and maintenance system, quality systems management, laboratory standard operating procedures, workforce development, information management and communication systems, specimen referral and transport network, and biologic risk management.

Phase 3: Develop a plan to implement or improve the network

- What are the goals and expected results?
- For the implementation plan of the network, what specific activities will be taken to strengthen laboratory networks?
- What is the detailed budget and forecasting plan?
- What in-country approvals are needed for the implementation plan and launch?

Phase 4: Develop a monitoring and evaluation (M&E) plan

- What performance indicators will be used to track network progress? Such indicators include staff competency, proficiency panel testing, and operational equipment.

Laboratory Networks in Action

In Africa, numerous networks have been in operation and working to strengthen the systems to prevent, detect, and respond to infectious disease threats. Such laboratory networks throughout Africa include RESAOLAB, a first-of-its-kind network of laboratories in the West African region in partnership with Fondation Mérieux^[3]; the East Africa Public Health Laboratory Network (EAPHLN), a World Bank-funded project for enhanced surveillance and diagnosis of TB and other diseases^[4]; the European and Developing Countries Clinical Trials Partnership (EDCTP), a public-public partnership to support infectious disease research^[5]; the South African Development Community (SADC) laboratory network in partnership with the African Development Bank (ADB)^[6]; the Polio Laboratory Network in the African region, which has been critical in detecting and diagnosing poliovirus^[7]; and AFRO public health laboratory networks^[8]. Additionally, the African Public Health Laboratory Network (APHLN), an ASLM-forged network of public health laboratories in more than 28 countries is poised to “promote collaboration and coordination to address health care priorities in Africa^[9].”

“With diligent political will, strategic planning, and viable financial efforts, whole national laboratory networks will be able to confer great health benefits to the more than 1 billion citizens living in Africa,” says Mah-Sere Keita, ASLM Director of Global Health Security.

By: Michele Merkel; Contributors: Michele Best; Editors: Rosalie Whedbee, Corey White

^[1] WHO-AFRO, “The Maputo Declaration on Strengthening of Laboratory Systems,” in Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization, Maputo, 2008.

^[2] WHO, “Guidance for Development of National Laboratory Strategic Plans,” WHO, WHO-AFRO, CDC, APHL Program, Geneva, 2010. Accessed 17 December 2015 from: http://www.who.int/hiv/amds/amds_guide_dev_nat_lab_strat.pdf

^[3] Fondation Mérieux, RESAOLAB. Accessed 16 December 2015 from: <http://www.fondation-merieux.org/reinforcing-access-and-quality-of-biological-diagnosis-in-west-africa-resaolab>

^[4] East African Community Health Sector, East Africa Public Health Laboratory Networking Project. Accessed 16 December 2015 from: http://www.eac.int/health/index.php?option=com_content&view=article&id=134

^[5] European and Developing Countries Clinical Trials Partnership. Accessed 16 December 2015 from: <http://www.edctp.org/get-know-us/>

^[6] SADC, Assessment Report on Reference Laboratories in the SADC Region. Accessed 16 December 2015 from: http://www.sadc.int/files/4214/1171/6731/Assessment_Report_onReference_Laboratories_in_theSADC_Region.pdf

^[7] WHO Polio Laboratory Network. Accessed 18 December 2015 from: http://apps.who.int/immunization_monitoring/laboratory_polio/en/index.html

^[8] Strengthening Public Health Laboratories in the African Region: A Critical Need for Disease Control. Accessed 18 December 2015 from: <https://www.who.int/afr/ahm/issue/12/reports/strengthening-public-health-laboratories-who-african-region-critical-need>

^[9] ASLM. African Public Health Laboratories Network. Accessed 18 December 2015 from: <https://aslm.org/what-we-do/aphln/>



Integration of Tiered Networks within Public Health Institutes: The Ethiopian Public Health Institute (EPHI) Experience

In the last decade, Ethiopia has achieved numerous public health successes, among them early attainment of health-related Millennium Development Goals, a strong tuberculosis (TB) management programme, and progress toward eradication of Guinea worm disease^[1-3]. Many of these successes are owed to health outreach in the community, but the ongoing development of strong national institutions is crucial to support healthcare at the community level. The Ethiopian Public Health Institute (EPHI) is one such institution, and a close look at its practices can help other central institutions promote public health through integration with national laboratory systems.

One part of EPHI's mission is to lead the national public laboratory system. In addition to national reference laboratories, the tiered system includes 13 regional reference laboratories, 300 hospital laboratories, and about 3,700 health centre laboratories^[4]. The number and complexity of diagnostic tests available increases with each tier of centralisation. Nine national reference laboratories, centred at EPHI, perform all of the diagnostic tests offered by the national health system on a referral basis.

Being available for test referrals is an important role of EPHI in addition to offering technical and equipment maintenance services. However, one of its major goals is to decentralise laboratory services – extending testing capabilities for more consistent availability for the more than 90 million Ethiopian citizens. To that end, EPHI supports laboratories in obtaining new instrumentation for assays like HIV viral load and DNA-PCR. EPHI also spearheads the introduction of new diagnostic technologies. Reference laboratories at EPHI have tested new technology including the GeneXpert TB test and rapid diagnostics for gonorrhoea and malaria. If a new technology is approved, EPHI publishes detailed guidelines for its implementation and coordinates maintenance contracts^[5]. To ensure peripheral laboratories' success as they take on new diagnostics, EPHI administers a national External Quality Assessment (EQA) programme, with 175 laboratories participating in evaluation of one or more assays^[6].

About 20 regional and hospital laboratories use Ethiopia's standardised laboratory information system (LIS) to share information with EPHI. These data enable EPHI to build databases that include EQA results, records of training and equipment maintenance, and disease-specific metrics. Outside of the LIS framework, EPHI also collates and analyses weekly Integrated Disease Surveillance reports from health facilities for the 20 reportable epidemic prone diseases, maternal death surveillance (MDSR), and acute malnutrition. In 2013-2014, EPHI received and responded to over 2,000 notifications of potential public health emergencies from peripheral laboratories and health facilities^[7]. Ninety percent of reported cases of diseases with epidemic potential were laboratory confirmed, and EPHI coordinated rapid responses to a case of polio and outbreaks of measles, dengue, and yellow fever.

In addition to organising information from healthcare providers nationwide, EPHI also provides novel research findings. (Cont'd on page 15)

(Con't from page 14)

Targeting diseases that affect the people of Ethiopia, EPHI scientists and epidemiologists conduct laboratory work and epidemiological surveys that range from infectious diseases of global concern to neglected tropical diseases. The results, delivered as technical briefs or articles, include regional maps of disease prevalence and profiling drug resistance patterns, and can guide clinical decision making throughout the country^[8].

A functional tiered laboratory system needs more than just equipment and protocols. Recognising that a motivated, well-trained workforce is indispensable, EPHI prioritises training and mentoring. The institute regularly hosts short-term direct training of laboratory personnel from across the country, including a surge of sessions last year on prevention, control, and treatment of Ebola.



Dr. Amha Kebede, Director General of EPHI

To extend the impact of training across the country, EPHI also coordinates Ethiopia's SLMTA (Stepwise Laboratory Management Toward Accreditation) and Field Epidemiology and Laboratory Training programmes (FELTP)^{[9][10]}. EPHI's roles of research, public health emergency management, and laboratory quality management were once dispersed across several sectors of the Ministry of Health.

"Putting a central, autonomous body in charge of all three functions has improved Ethiopia's health infrastructure and increased the flexibility of the health system as a whole," says Dr. Amha Kebede, Director General of EPHI. (pictured). "Integrating tiered laboratory networks with a national public health institute allows countries to link knowledge

to action in order to promote public health." In order to institutionalise the training aspect, EPHI has constructed a state-of-the-art training centre with support from the US CDC.

It contains a 500 seat auditorium and 14 syndicate rooms where two are designated for hands-on laboratory training of advanced techniques.

The centre aims to be fully functional by April 2016.

The framework for the integration of tiered laboratory networks with public health institutes, presented during an ASLM-WHO AFRO Freetown Consultation in October 2015, will be a critical tool for guiding country efforts to achieve successes similar to those seen in Ethiopia.

By: Laurel Oldach; Contributor: Amha Kebede; Editors: Michele Merkel, Rosalie Whedbee, Corey White

^[1] Haileamlak. "Ethiopia successfully attaining the millennium development goals." *Ethiopian J Health Sci* 25(2). 2015.

^[2] Burki. "Ethiopia could be a model country for tuberculosis control." *The Lancet* 386(10010), 2015.

^[3] Fighting Disease: Ethiopia. The Carter Center. Accessed on 18 December 2015 from: <http://www.cartercenter.org/countries/ethiopia-health-guinea-worm.html>

^[4] Ayana, Gonfa. "Experience of the Ethiopia Public Health Institute in Building the National Laboratory System". 2015. Presentation Freetown, Sierra Leone. Access 18 December 2015 from: <https://aslm.org/what-we-do/global-health-security/freetown-consultation-presentations/>

^[5] Federal Democratic Republic of Ethiopia Ministry of Health/EPHI. Implementation guideline for GeneXpert MTB/RIF assay in Ethiopia. June 2014, Addis Ababa. Accessed on 18 December 2015 from: http://www.challengeb.org/publications/tools/country/GeneXpert_Implementation_Guideline_Ethiopia.pdf

^[6] Ayana, Gonfa. "Experience of the Ethiopia Public Health Institute in Building the National Laboratory System". 2015. Presentation Freetown, Sierra Leone. Access 18 December 2015 from: <https://aslm.org/what-we-do/global-health-security/freetown-consultation-presentations/>

^[7] WHO-Africa: Ethiopia country topics: IDSR. Accessed on 18 December 2015 from: <http://www.afro.who.int/en/ethiopia/country-programmes/topics/4590-ethiopia-integrated-disease-surveillance-and-response-idr.html>

^[8] Getahun et al. "Molecular typing and drug sensitivity testing of Mycobacterium tuberculosis isolated by a community-based survey in Ethiopia." *BMC Public Health* 2015.

^[9] Hiwotu et al. "Laboratory system strengthening and quality improvement in Ethiopia." *AJLM* 3(2), 2014.

^[10] Ethiopian Public Health Institute. The Second Strategic Plan: 2015/6-2019/20. June 2015.



Regulatory Harmonisation: Safer and Faster Access to Life Saving Products

Health systems in many countries across Africa have long suffered the effects of inadequate resources that impact everything from staff morale to the availability of basic medical supplies. Many national governments, whilst grappling to meet minimum International Health Regulation (IHR) targets, face growing pressure to identify and address gaps in regulatory structures. The call for more robust regulation over medical products, including pharmaceuticals and in vitro diagnostics (IVD), especially during an infectious disease outbreak, appears to stem from two primary concerns: the need for greater control to ensure quality and safety; and the desire to improve access to much needed new diagnostic products in a timely fashion. As such, authorities on the continent are taking strides to address these regulatory concerns.

Regulatory networks in resource-limited countries, particularly across Africa, are challenged in terms of expediency, transparency, and cost-effectiveness. Contributing factors include inadequate resources to enforce regulations, perform validation studies, and audits. Such is the magnitude of the problem that the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) met in Dakar, Senegal in April 2015, with the aim to harmonise regulatory systems^[1]. According to IFPMA, regulatory approvals, which can take five years or longer, can result in delayed access to potentially beneficial products. The harmonisation of regulatory systems is intended to increase transparency and reduce duplication and cost of validation studies.

Regulation of diagnostics during times of outbreaks is fraught with even more challenges, when assessing the safety of new diagnostics must be weighed against the critical need for their immediate use. The urgency of an outbreak situation may also create conditions of ambiguity, due to the possibility of unregulated diagnostics entering the market. It is critical that in these times of outbreak, regulatory processes are harmonised to ensure speedy approval and implementation of trusted new diagnostics.

“It is important to emphasise that the goal of harmonisation is to increase efficiency – and not to replace the jurisdiction of existing national regulatory authorities,” says Dr. Trevor Peter, ASLM Board Chair. The important role of the national regulatory authority continues to focus on safety and effectiveness and includes: protecting the public; making evidence-based, lawful decisions; clearly prescribing rules and procedures; communicating information on product risks; enabling access to valuable technologies; enforcing regulations and regulatory decisions; ensuring medical safety and oversight; and participating in international harmonisation efforts^[2]. However, often times, resources are insufficient for every national regulatory authority to regulate every IVD. Implementation of regulatory requirements, including product validation, manufacturer reviews, and a host of functions that ensure product safety, would not only overburden countries but could result in fewer products on the African market.

To pre-empt the challenges encountered in regulating new diagnostics during the Ebola outbreak, ASLM is working with partners to develop a guidance document for the evaluation and regulation of rapid diagnostic tests (RDTs) in outbreak situations. This framework will allow countries to maintain ownership of the regulatory process in their country, while at the same time ensure countries can benefit from existing (Cont'd on page 17)

“The goal of harmonisation is to increase efficiency”

(Con't from page 16)

regulatory processes such as the World Health Organization (WHO) Emergency Use Assessment Listing (EUAL) and the United States Food and Drug Administration (FDA) Emergency Use Authorization (EUA). Advantages proffered by these centralised systems include increased efficiency, public confidence, and product availability and diversity. ASLM's framework will guide countries through the five steps in implementing RDTs for outbreak use (Figure 1), detailing the purpose, necessary actions, roles and responsibilities, assessment for successful completion, and timeframe for each step. The framework highlights the importance of transparency and communication between all stakeholders to ensure the effective and efficient development, acceptance, and implementation of the rapid diagnostic tests (RDTs).



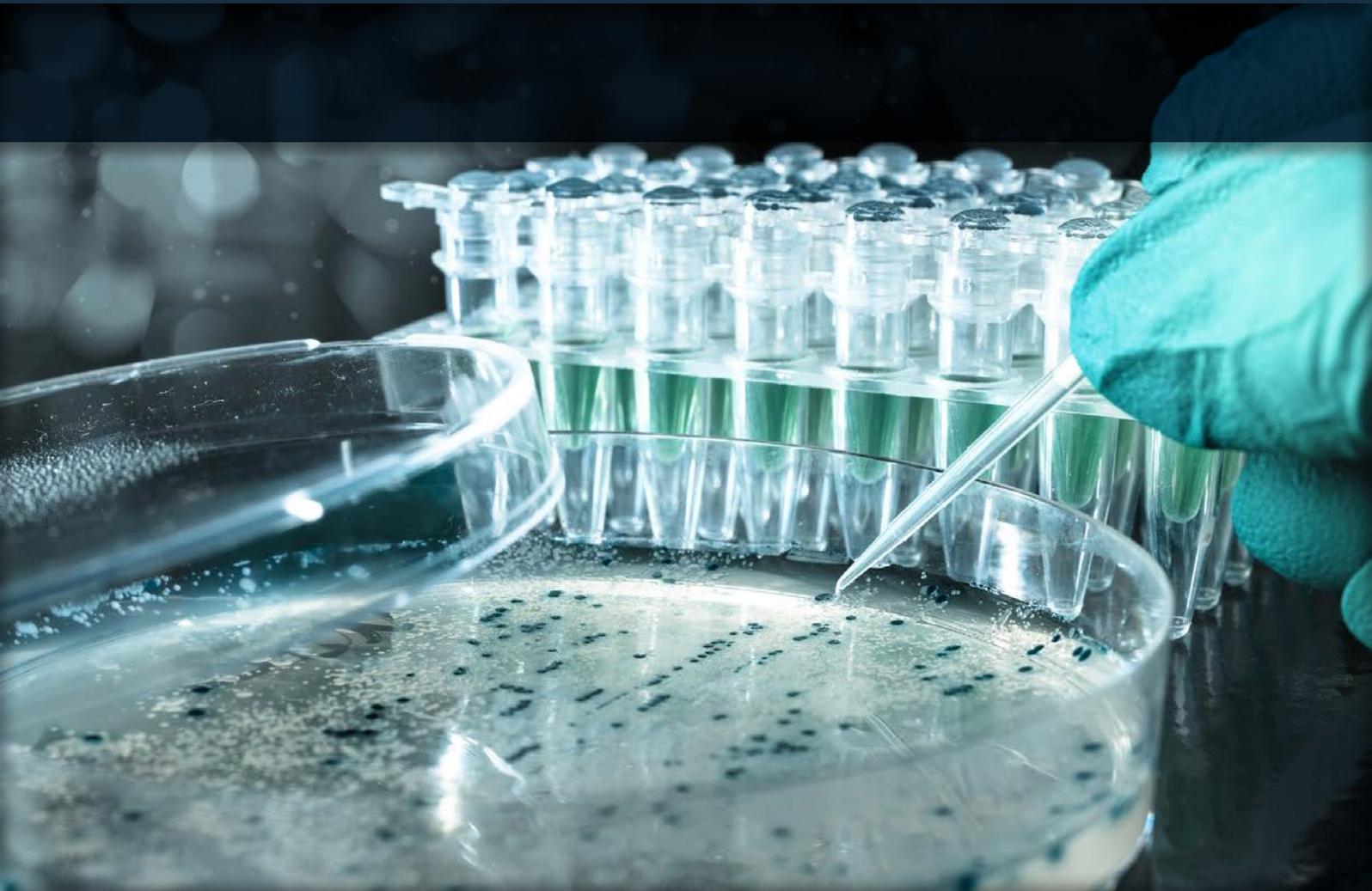
Figure 1. Steps for implementing RDTs for outbreak use as outlined in ASLM's framework for regulating diagnostics

“In preparation for future outbreaks, the forthcoming ASLM guidance framework will form the foundation of a standardised system that clearly defines and harmonises the roles and responsibilities of Ministries of Health, in-country government bodies, and international partners in the process of adopting IVD use in a timely and safe fashion,” says Mah-Sere Keita, ASLM Director of Global Health Security. “This system will allow countries to take advantage of established regulatory bodies, while promoting country-led practices that may help prevent uncertainty of accepted products.”

By: Paula Fernandes; Contributor: Elliot Cowan; Editors: Rosalie Whedbee, Michele Merkel, Corey White

^[1] “Africa needs more efficient regulatory systems to improve access to medicines.” (2015). International Federation of Pharmaceutical Manufacturers & Associations. Accessed on 21 December 2015 from: <http://www.ifpma.org/news/news-releases/news-details/article/africa-needs-more-efficient-regulatory-systems-to-1.html>

^[2] McNerney, R., Peeling, R. Regulatory in vitro diagnostics landscape in Africa: update on regional activities. (2015). *Clinical Infectious Diseases* 2015; 61(S3): S135-40



ASLM

AFRICAN SOCIETY FOR LABORATORY MEDICINE

Joseph Tito Street, Nega City Mall, Suite 800
P.O. Box 5487
Kirkos Subcity, Kebele 08
Addis Ababa, Ethiopia
www.ASLM.org
Newsletter@ASLM.org