SPECIAL ISSUE: COUNTDOWN TO ASLM2012

An Interview with the Hon. Dr. Tedros Ghebreyesus, Minister of Health of Ethiopia

Plenary Speaker Prof. Barry Schoub and the Dream Age of Virology

Winners of the ASLM2012 Travel Award
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November 2012 ASLM Newsletter
COUNTDOWN TO ASLM2012

Early this year, when we began to plan the ASLM2012 international conference, I wasn’t sure what level of involvement to expect from Society members and others in the medical laboratory community. After months of planning, I can say that I have been astonished at the enthusiasm and commitment of conference attendees and planners. Between June and September, we received over 600 conference abstract submissions. We have also received and confirmed 37 satellite session applications and 15 exhibition requests. Over 130 speakers and co-conveners have confirmed conference attendance, and more than 120 people have signed up to volunteer at the venue. ASLM has also honoured 25 exemplary students with conference travel awards.

ASLM2012 will be an exciting event for many reasons. It is our first international conference and we are expecting over 1000 participants from the global scientific community. ASLM2012 will unite laboratory scientists, health professionals, industry members and public health leaders committed to improving laboratory diagnostics in Africa and around the world. Participants will be able to exchange ideas and knowledge, collaborate on projects, and learn about the latest in diagnostic technologies, cutting-edge research and quality assurance methods. Such interactions are crucial to addressing issues specific to public health and laboratory medicine on the African continent.

Apart from planning for our international conference, we have been busy attending meetings, facilitating training courses, and developing opportunities to expand the Society’s reach. In September, ASLM participated in two meetings centred on the advancement of infectious disease diagnostics and the control of HIV/AIDS through improved laboratory capacity and quality. The ASLM SLIPTA (Stepwise Laboratory Quality Improvement Process Towards Accreditation) Independent Advisory Committee hosted its second meeting in late September, and in October the Society expanded its regional Ambassador Programme and facilitated a SLIPTA auditor training in Dar es Salaam, Tanzania. ASLM also co-hosted a SLIPTA auditor training in Abuja, Nigeria, from 29 October to 2 November, and plans to host another SLIPTA auditor training in Johannesburg, South Africa shortly following ASLM2012.

In addition to information on our recent activities and a special insert on the ASLM2012 conference, this edition of Lab Culture features an article concerning healthcare-associated infections (HCAI), which are acquired by patients while in treatment at healthcare facilities. A thorough approach to HCAI surveillance and intervention is long overdue across the African continent. As we scale up laboratory capacity, we must be cognizant of this important medical concern. “Healthcare-Associated Infections: A Neglected Issue Threatening Healthcare Facilities in Africa” is available on page 12. I hope you enjoy Issue 5 of Lab Culture, and I look forward to seeing you at the conference.

Dr. Tsehaynesh Messele, CEO, ASLM
ASLM WELCOMES NEW ADDITIONS TO AMBASSADOR PROGRAMME

In October, ASLM announced the appointment of three new Ambassadors as part of the Society’s regional Ambassador Programme. Professor Daniel Sess, Dr. William Ampofo, Dr. Adil Ismail and Professor Dennis Agbonlahor join Professor El-hadj Belabbes, who became the first ASLM Ambassador in March. Ambassadors provide a crucial link between the Society and its members, communicating the needs of the scientific community so that ASLM may respond accordingly. Ambassadors will play an active role in identifying regional training needs and advocating among government health agencies and professional organisations for improvements in the quality of laboratory diagnoses.

Prof. Daniel Sess
Prof. Sess joins ASLM as the Ambassador to Côte d’Ivoire. He currently serves as President of the Monitoring Committee of the regional organisation CRESAC (Centre Régional d’Evaluation en Santé et d’Accréditation des Etablissements Sanitaires en Afrique).

Dr. Adil Ismail
Dr. Ismail joins ASLM as the Ambassador to Sudan. Ismail has served at the Ministry of Health of Sudan for over 18 years. He is currently an Assistant Research Professor at the National Public Health Laboratory (NPHL) in Khartoum and in early 2012 became the Acting Director of NPHL.

Dr. William Ampofo
Dr. Ampofo joins ASLM as the Ambassador to Ghana. He currently serves as Senior Research Fellow and Head of the National Influenza Centre, Virology Department at the Noguchi Memorial Institute for Medical Research, University of Ghana.

Prof. Dennis Agbonlahor
Prof. Agbonlahor joins ASLM as the Ambassador to Nigeria. He is currently Head of the Medical Laboratory Science department at Niger Delta University, where he teaches medical, veterinary and environmental microbiology.

EXPANDING THE SOCIETY’S REACH THROUGH SOCIAL MEDIA

When ASLM launched in March 2011, the news was announced in a series of printed press releases. However, as the Society has grown in stature and reach, it has not relied solely on traditional media for sharing information. Online mass communication has enabled ASLM to expand its reach exponentially, connecting with both members and the general public to communicate the critical mission of advancing medical laboratory services throughout Africa. The ASLM communications team takes full advantage of social networks and e-mail marketing programs to stay connected and keep its members engaged.

Last year, ASLM began disseminating Society news and events to members, partners and interested parties via e-communications campaigns. Starting at just 330 e-mail recipients in September 2011, ASLM now has a community following of over 5,000 contacts. ASLM has also established a presence on several social networking sites: through Twitter (username @ASLM_News) and Facebook, ASLM posts Society updates as well as public health and development news, with the ambition of reaching a broader audience within the global health community. Followers are encouraged to interact, voice their interest and support ASLM campaigns. To date, ASLM has issued over 1,050 tweets to over 230 Twitter followers. On Facebook, ASLM

(Continued on page 6)
As Minister of Health of the Federal Democratic Republic of Ethiopia, how do you balance and prioritise the health needs of an entire nation? Is this a constantly evolving landscape?

Equity is the basis for balancing and prioritising the health needs of our nation. The emphasis is on primary healthcare with universal coverage. The priority is mainly focused on our health sector development plan (HSDP), which has been crafted in four phases over the course of 20 years. We are now in the fourth phase, which is very much in line with the target set for the Millennium Development Goals (MDGs).

Yes, we could say it is a constantly evolving landscape. One thing is certain: our strategy is well thought out and consists of a long-term plan and impact. We take advantage of our practical experience through monitoring and evaluation and continue to improvise a dynamic approach to health system strengthening.

During your career you have served as Board Chair of the Roll Back Malaria initiative and Global Fund. Did your early career in malaria research impact your contribution to health policy in this arena?

Yes, to a great extent my early career in malaria research has helped me gain insights to influence some of the policies with which I have been involved. As some of my early research experiences were operational in nature, their policy implications were obvious. For instance, the need for prevention in terms of prompt treatment and diagnosis, and for universal coverage of insecticide-treated bed nets for the most vulnerable segment of society—children and pregnant women—was clear from my early research experience.

During Prime Minister Zenawi’s time in office, child malnutrition in Ethiopia fell significantly; between 2005 and 2011, child mortality and malaria rates were cut in half. What would you say were the key interventions that led to such great strides in healthcare improvement?

Our late Prime Minister Meles Zenawi was a wise and committed leader who made remarkable achievements in all aspects of his work, particularly in the health sector. The key to our success has been a strong government commitment and a clear national strategy set for a 20-year period in the form of a health sector development plan (HSDP). The other crucial factor is the innovative programme to deploy more than 37,000 health extension workers at the community level, fully engaged with 16 packages [containing basic services required] for primary health care. Increasing the numbers of trained health workers at the primary health level has made it possible for the community to promote healthy living and to manage many health issues closer to home. Importantly, the expansion and improvement of health care infrastructure through new construction has enabled many more patients to access high quality facilities.

ASLM benefits greatly from your support and from that of other African nations. What kinds of support would you like to see ASLM provide to African scientists in the next few years?

(Continued on next page)
I would like ASLM to provide support to African scientists in the domains of laboratory services and accreditation, capacity building, training, strengthening of research capacity and exchange of knowledge, inter-country collaboration, advocacy and resource-mobilisation, and networking.

Are there any key health-related projects planned in Ethiopia that you would like to exclusively share with ASLM?

I would like to share two announcements with ASLM. Firstly, until now our Health Enhancement Programme has produced tremendous results. We are now coming up with a new health development initiative for the faster and more sustainable achievement of MDGs goals. This is a very innovative and comprehensive approach to mobilising the community at a grassroots level, as well as to owning every initiative in a more organised manner. We believe our strategies will achieve success more quickly and with sustainability.

Secondly, over the past two years Ethiopia has engaged in implementing the Strengthening Laboratory Management Towards Accreditation (SLMTA) programme. We have introduced over 59 laboratories to the first and second phases of the programme. We are already seeing a lot of enthusiasm towards quality management and a keen interest in progressive improvement. As Ethiopia is a big country, we are keen on expanding to include as many laboratories as possible in SLMTA in a national roll-out approach.

Do you have anything else to add?

I wish you a successful conference! Let us all join hands in promoting the laboratory agenda to take root in Africa for quality services!

Editors: Paula Fernandes, MBA, PhD (Editorial Team) and Rachel Crane (Editorial Team); Contributors: Tsehaynesh Messele, PhD (Editorial Team) and Corey White, MPA (Editorial Team)

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ASLM EXPANDS SOCIAL MEDIA REACH

ASLM leaders recently hosted a satellite meeting at a forum themed, “Moving Forward in the Diagnosis of Infectious Diseases in Resource Limited Countries,” organised by Fondation Mérieux in Veyrier du Lac, France from 7-9 September. The ASLM satellite meeting, entitled “ASLM – Advancing the Laboratory Profession and Networks in Africa”, took place on 8 September and featured six presentation topics.

Dr. John Nkengasong, Chief of the International Laboratory Branch at the US Centers for Disease Control and Prevention (CDC) and former Chairman of the ASLM Board of Directors, presided over ASLM’s satellite meeting. Delivering the opening speech for the session, Dr. Nkengasong discussed the Society’s role in promoting laboratory standards across Africa.

Dr. Tsehaynesh Messele, ASLM CEO, presented a summary of the first year of the Society in which she discussed the challenges overcome and achievements made. Mr. Teferi Mekonen, ASLM Accreditation Officer and SLIPTA (Stepwise Laboratory Quality Improvement Process Towards Accreditation) Focal Point, talked about the impact of the SLIPTA programme and defined the roadmap for its expansion across the African continent. Dr. Trevor Peter, ASLM Board Chair and scientist at the Clinton Health Access Initiative (CHAI), covered the role of ASLM in supporting laboratory science, research and training and stressed the importance of a collaborative approach from partners. Dr. Fausta Mosha, Secretary of the ASLM Board of Directors and Laboratory Director of the National Health Laboratory Quality Assurance and Training Centre of the Tanzanian Ministry of Health and Social Welfare, focussed on collaborations and encouraged more institutions to step up in support of the ASLM network. Mr. Jonathan Lehe, Programme Manager of Point-of-Care (POC) Diagnostics at the Clinton

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Get Involved with ASLM through Social Media

Facebook: facebook.com/pages/African-Society-For-Laboratory-Medicine/332528796775345
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ASLM HIGHLIGHTS LABORATORY MEDICINE AT FORUM FOR INFECTIOUS DISEASE DIAGNOSTICS

ASLM has over 295 “Likes” and a weekly reach of over 470 users. In addition to e-mail communications, Facebook and Twitter accounts, ASLM has a Flickr page (ASLM_news) where it posts event photos, and a YouTube channel (ASLMnews) for its videos and health-related video content.

These social networking and e-mail marketing sites provide the Society with the opportunity to establish new connections, boost the ASLM brand, promote events and increase traffic to its website. However, interest in the possibilities of online communication extends beyond public visibility and disseminating the Society’s message. ASLM has always been devoted to the exchange of ideas and information between working scientists and members of the health community, understanding that these connections can spark innovation and help the most successful tools and strategies take hold in laboratory systems around the world. That is why the ASLM website (www.aslm.org) includes its own, growing social network tailored specifically to African laboratory scientists, public health workers and advocates. Member profiles, community forums, links to open access journals, an online library of essential information on the state and practice of laboratory medicine in Africa, and upcoming online collaborative workspaces enable members to share research and engage in dialogue from across the world, accelerating the pace at which the best ideas rise to the top. ASLM understands that this free, virtual, collective workspace is the future of medical communication, and aims to provide access to the most up-to-date online resources to all of its members.

By: Aaron Krol (Editorial Team) and Rachel Crane (Editorial Team)
ASLM ATTENDS REGIONAL HIV/AIDS PUBLIC HEALTH LABORATORIES NETWORK MEETING

ASLM participated in the sixth meeting of the Regional HIV/AIDS Public Health Laboratories Network, hosted by the World Health Organisation Regional Office for Africa (WHO/AFRO) from 11-13 September in Abidjan, Côte d’Ivoire. The meeting, themed, “Improving Quality and Access of Laboratory Services,” convened leaders from the WHO and the US Centers for Disease Control and Prevention (CDC), as well as from the Ministries of Health of Cameroon, Côte d’Ivoire, Ghana, Tanzania, Senegal and Zimbabwe.

The purpose of the Regional HIV/AIDS Public Health Laboratories Network is to contribute to HIV/AIDS prevention and control by improving the quality and capacity of public health laboratories and laboratory networks in the African region. The Network strives to improve laboratory capacity and quality by promoting joint advocacy and resource deployment for laboratory services, common procedures and policy approaches, the exchange of information and technical expertise within networks, and the use of the existing laboratory structures within the AFRO region as regional reference centres.

The objectives of this meeting were to review the status of implementation of the 2008 recommendations of the HIV Laboratory Network; to review the current management and challenges of HIV laboratory services; to advance solutions for maintaining high-quality and reliable diagnostic support for HIV prevention, treatment and care; and to finalise a plan of action for the Laboratory Network for 2012 through 2014.

Dr. Celestin Hakiruwizera, Acting Director of Programmes of ASLM, provided an update on the Society, while Mr. Teferi Mekonen, ASLM Accreditation Officer and SLIPTA (Stepwise Laboratory Quality Improvement Process Towards Accreditation) Focal Point, presented the WHO/AFRO SLIPTA process. ASLM staff also served as co-facilitators of the two plenary sessions of the meeting, with Dr. Hakiruwizera facilitating a Francophone group discussion while Mr. Mekonen facilitated an Anglophone group discussion.

By the end of the meeting, the discussion groups had produced the following specific recommendations for the Regional HIV/AIDS Public Health Laboratories Network:

1. Further sensitize countries and governments to the need for accreditation, and support the elaboration of country action plans to achieve accreditation;
2. Harmonise tools employed to help achieve accreditation;
3. Expand training for laboratory professionals to include quality management system components such as record keeping, document control (SOPs), internal audit, etc.;
4. Support WHO/AFRO member states to elaborate and implement a national laboratory strategic plan;
5. Provide normative guidance on post-market surveillance (PMS) (WHO activity);
6. Mobilise resources for the continued sustainable scale-up of external quality assessment (EQA) schemes using the dried tube specimen approach.

By participating in this meeting and helping produce specific recommendations for the Regional HIV/AIDS Public Health Laboratories Network, ASLM leaders help to advance the goals of the Network shared by the Society, including the goals of improving laboratory quality management and information systems. For more information on WHO/AFRO efforts in the fight against HIV/AIDS, please visit: http://www.afro.who.int/en/clusters-a-programmes/dpc/acquired-immune-deficiency-syndrome/overview.html.

By: Rachel Crane (Editorial Team) and Teferi Mekonen, MSc, MPH (ASLM); Editor: Laurel Oldach (Editorial Team)
Professor Schoub, you are the Head of the Centre for Vaccines and Immunology at the NICD (National Institute for Communicable Diseases, South Africa) and were the first Professor and Head of the Department of Virology at Wits (University of the Witwatersrand, South Africa). How has the field of virology changed over the years, in South Africa and the African continent as a whole?

Virology has really changed globally, and what we see in South Africa is a reflection of what has happened worldwide. In terms of scientific research, the country is now on par with Europe and the United States. The changes I have seen span about 40 years of work. We were in what we colloquially call the “Steam Age” of virology; now the technologies and interpretations are virtually unrecognisable from what they were. If you look at diagnostics from the mid-70s, back in the day when one would need to grow viruses to make a diagnosis, it was very time-consuming and the patient would either be healthy or dead by the time the virus was detected. Plus, serological technologies were based on finicky tests. In reality, the lab was often unable to rapidly and accurately support the physician. Now we are in what can be called the “Dream Age” of virology. We detect [viruses] with molecular techniques such as PCR and sequencing, so it’s possible to discover a virus before it can be seen. In addition, sequencing has greatly helped our understanding of the epidemiology of viruses.

Your plenary speech at ASLM2012 also concerns the evolution of virology as a discipline in Africa over the past several decades. Why did you choose this topic? What aspect of your presentation do you think attendees will find most interesting?

My plenary speech will indeed cover this topic, and to some extent the subject was given to me because I’ve had such a long career in virology. When you get to my age and [level of] experience, you want to look back. It’s a story of a successful and very enjoyable career. I would do it again if I had the chance. I modified the speech somewhat away from the laboratory as I now work more on the clinical side, though I will bring in the lab side, too.

In my speech, I will look at the consequences of improvements of lab technologies, and how improved technologies and hitherto unknown technologies affect the diagnosis of illnesses. Technological improvements have helped immensely in the diagnosis and clinical management of HIV and the infectious causes of hepatitis. I am planning to illustrate just how rapidly evolving technologies have led to different approaches and improvements to infection control.

What impact do you think a meeting like ASLM2012 will have on science in Africa?

I think it will have a great effect—it’s a tremendous venture. It will make an impact by bringing together African scientists and facilitating collaborations. There are problems unique to the continent, and the conference will help synthesise the capabilities of the scientists who attend. It will also encourage clinical and epidemiological collaborations.
Looking forward, what do you think will be the greatest public health challenges in Africa in the years to come? How does NICD plan to address these challenges?

HIV is ravaging sub-Saharan Africa, and efforts to control the disease will hopefully lead to a vaccine. Then, of course, there is also tuberculosis and malaria. These diseases will remain the biggest public health challenges for Africa, from an infectious diseases point of view. They have not yet been overcome, and scientists are challenged to develop vaccines for them. At NICD, our three biggest research units are the HIV/AIDS research unit, the TB reference centre, and the malaria research unit. About 75% of NICD’s research resources are spent on efforts to prevent and cure these diseases.

What kinds of support would you like to see ASLM provide to African scientists and to public health initiatives in the next few years?

The [African Journal of Laboratory Medicine] is great, because it’s a forum for communication. Within the journal I would like to see different opportunities advertised. We don’t want scientists to be recruited away from Africa, and it would be useful if the journal advertised opportunities for research, for grants, for training, etcetera. I would also like to see further development of the ASLM website as a place where people can find, share and contribute SOPs in an easy-to-use interface. ASLM could also facilitate electronic communication between labs.

For more information about ASLM2012 speeches and presentations, please see the main conference schedule at-a-glance: http://www.aslm2012.org/docs/AtaGlance.pdf.

Editor: Paula Fernandes, MBA, PhD (Editorial Team); Illustrator: Rachel Crane (Editorial Team)
ASLM is excited to announce that it has selected 25 recipients for the ASLM2012 Student Travel Award. The award provides financial support in the form of US $1,500 to students and recent graduates interested in attending ASLM’s first international conference.

When asked how she felt upon discovering she had been accepted for the award, recipient Dr. Chinelo Onyenekwu of the Lagos University Teaching Hospital, Nigeria, says, “Exhilaration is the word. I was exhilarated...the next thing I did was to accept the award and then thank my colleague for encouraging me to apply for it.”

By attending the ASLM2012 international conference, Student Travel Award recipients will be able to network with leaders and professionals of laboratory medicine, broaden their understanding of issues related to laboratory diagnostics, and exchange ideas for moving forward in promoting laboratory medicine in Africa.

Dr. Onyenekwu says she was first interested in attending the conference because “it will be an opportunity to meet and rub minds with people from all over Africa who are interested in the advancement of laboratory medicine.”

Award recipient Mr. Ernest Lango-Yaya (National Laboratory of Clinical Biology, Central African Republic) says he became interested in attending the conference because it would allow him “to meet other lab professionals, learn about others’ working processes and compare them to the processes in my lab, and to be a part of the network of laboratory professionals in Africa and the world.”

Mr. Moussa Thiam of the Laboratory of Bacteriology and Virology, Le Dantec Hospital, Senegal, another recipient, says he will be “happy to be able to exchange expertise of different aspects of HIV research” at ASLM2012. He goes on to say that he expects the conference to “facilitate the sharing of experiences from different countries and from different areas of biomedical research in Africa.”

To qualify for consideration, individuals submitted abstracts to the conference along with proof of their status as current or recent graduates (2012 graduation). ASLM selected the abstract submissions with the highest scientific quality relevant to the field of laboratory medicine and the Society’s mission. In accepting the award, recipients agreed to provide eight hours of volunteer service at the conference.

This award highlights ASLM’s commitment to supporting the next generation of laboratory scientists, who will determine the future of laboratory medicine in Africa.

Recipients of the ASLM2012 Student Travel Awards include: Abdi Samuel (Ethiopia), Abou Abdallah Malick Diouara (Senegal), Anthony Ahumibe (Nigeria), Awa Ba Diallo (Senegal), Babatunde Odetoyn (Nigeria), Chinelo Onyenekwu (Nigeria), Ernest Lango-Yaya (Central African Republic), Franklyn Egbe (Cameroon), Grace Bartonjo (Kenya), Ifeinwia Osegbe (Nigeria), Innocent Umwana (Rwanda), Jacques Simpore (Burkina Faso), Jeremiah Ogoro (Kenya), Lee Schroeder (USA), Jennifer Gandhari (South Africa), Lilian Okeke (Nigeria), Loveness John Urion (Tanzania), Moussa Thiam (Senegal), Mura Ngoi (Tanzania), Nasir Umar-Tsafe (Field Epidemiology and Laboratory Training Programme, Nigeria), Chioma Nwuba (Nigeria), Oladimeji Abisola (Nigeria), Pierre Mukadi Kaningu (Democratic Republic of Congo), Sarr Am (Senegal), Silvia Kadima (Kenya).

By: Rachel Crane (Editorial Team); Editor: Laurel Oldach (Editorial Team); Contributors: Elizabeth Luman, PhD (CDC-Atlanta), Chinelo Onyenekwu, MD (Lagos University Teaching Hospital, Nigeria), Moussa Thiam (Le Dantec Hospital, Senegal), Ernest Lango-Yaya (National Laboratory of Clinical Biology, Central African Republic)
ASLM's first international conference, to be held from 1-7 December in Cape Town, is rapidly approaching. Participants of ASLM2012 have much to anticipate from the seven-day event. In addition to keynote addresses, plenary sessions, round table discussions, break-out periods and exhibits, the conference will feature 37 satellite sessions from 1-4 December, organised around the common theme of quality laboratory diagnostics. Satellite sessions provide opportunities for a wide array of organisations to share information and experiences on dozens of specialised subjects related to diagnostic practice. Non-profit associations, multilateral organisations, academic institutions, government organisations and industry members will host satellite sessions in the form of workshops and trainings, group meetings, equipment demonstrations and seminar presentations.

A large selection of satellite sessions allows the conference to cover more ground, while offering participants the opportunity to explore those topics most relevant to their own practice in greater detail than conference-wide events can provide. Satellite sessions will engage ASLM2012 attendees in practical demonstrations and training in the correct use of the latest rapid, mobile and cost-effective diagnostic solutions in the fight against tuberculosis (TB), AIDS and malaria. Symposia hosts will also present on the implementation of laboratory information and quality management systems necessary to the application of new technologies. Inattention to these systems makes it more difficult for the new technologies to become established in the market. These systems facilitate the exchange and management of data, comprise tactics for maintaining high-quality diagnostics, and are essential to the adoption and long-term use of new disease control technologies.

In addition to presenting new technologies and methods, satellite hosts will provide information on the implementation, maintenance and improvement of formal quality management and information systems. Many satellite sessions require pre-registration, or are by invitation only. Eight of the symposia are open to all registrants without a pre-registration requirement. The number of attendees allowed in a symposium may be contingent on space available.

For more information on ASLM2012 satellite sessions, please visit: http://www.aslm2012.org/satellite-meetings.

By: Aaron Krol (Editorial Team) and Rachel Crane (Editorial Team); Contributor: Glen Fine, MS, MBA, CAE (CLSI).
According to the World Health Organisation (WHO), healthcare-associated infections (HCAI) affect hundreds of millions of patients worldwide each year, contributing to an estimated 136,000 deaths in Europe and the US alone. The associated costs of HCAI are substantial, amounting to an estimated €7 billion and US $6.5 billion annually in Europe and the US, respectively. The estimated prevalence of HCAI varies between 3.5% and 12% in high-income countries and between 5.7% and 19.1% in low- and middle-income countries.

Current estimates, particularly those for low-income settings, are based upon limited data obtained using non-standardised methods and are unlikely to provide an accurate picture of the burden of HCAI. Given the likelihood that projections of HCAI prevalence across low-income countries are grossly underestimated, more research is desperately needed in order to quantify the extent and impact of HCAI on patients, their families and on health care costs.

Healthcare-associated infections (HCAI), or nosocomial infections, are acquired by patients, staff or visitors while in a hospital, clinic, or other healthcare facility. These infections can wreak havoc in both high- and low-income countries; however, with reliable data difficult to collect, the global burden is not known and the control of HCAI remains a public health challenge.

HCAI can originate within the population of a healthcare facility, can be associated with the use of medical devices or procedures, or can result from the introduction of infectious agents from the community served by the health care facility. In some circumstances, a healthcare facility can act as an amplifier, leading to the spread of infections—sometimes caused by drug-resistant organisms—not only within the facility, but also to surrounding communities. These infections prolong hospital stays, create long-term disabilities, increase resistance to life-saving medications, and drive up costs for patients and their families. They are a major cause of morbidity and mortality worldwide, but have an underestimated impact on quality of life globally and particularly in Africa where low-income countries face challenges in keeping these infections at bay.

Factors Contributing to HCAI

WHO has identified a number of factors that increase the risk of HCAI, including: prolonged use of invasive devices; widespread and prolonged use of broad- and narrow-spectrum antibiotics; high-risk procedures; immune-suppression and other severe underlying patient conditions; and insufficient application of standard isolation procedures (adapted from 1).
In many countries across Africa, the impact of HCAI is further compounded by a range of issues related to lack of resources for health (see figure 1). To be fully effective, programmes aiming to control HCAI must address all of these risk factors. This requires hiring, extensive training, and developing more sophisticated infrastructure, all of which place a great financial burden on healthcare facilities. Moreover, a HCAI clinical/laboratory surveillance programme is required to confirm, track and support intervention efforts.

The Situation in Africa

Although some countries in Africa have sufficient resources to develop a strong health infrastructure and establish active and extensive programmes for control of HCAI, the majority have limited capacity for healthcare. More than 70% of African countries are ranked as “low” on the United Nations (UN) Humanitarian Development Index 4, which categorises countries based on life expectancy, literacy, education, and standards of living 5. These African countries lack the funding needed to fulfil even the most basic healthcare needs; healthcare facilities are generally poorly developed, undersupplied, and overcrowded. Due to severe staffing shortages, healthcare providers are overworked and may lack sufficient training. The management of these facilities is often weak and policies and guidelines for infection control are inadequate or non-existent.

What then is the best way to tackle the problem in Africa?

Solving the problem of inadequate infrastructure and equipment is often beyond the means of low-income nations; however, without great expenditure, it is possible to address other risk factors to dramatically reduce the incidence and prevalence of HCAI. With good basic training and comparatively little expense, programmes to improve surveillance, hygiene, and waste disposal systems can be implemented rapidly without the need for extensive improvements in infrastructure.

Surveillance

Surveillance provides data on the incidence and prevalence of different infectious agents, on who is affected, and where the infections are occurring, helping managers and policy makers identify priorities for controlling HCAI and allowing them to understand the nature and size of the problem so appropriate measures can be taken. Truly effective control of HCAI requires the introduction of stringent infection control policies and practices aimed at specific infectious agents, or groups of agents. This necessitates reliable laboratory-based identification of organisms and their antimicrobial resistance patterns, and consequently, increased capacity of diagnostic laboratories. Such laboratories should be equipped to identify causative organisms either by culture and biochemical testing or at least by the use of Rapid Diagnostic Tests. Molecular methods are becoming more suitable for use at a local level as costs reduce and techniques improve. Ideally, laboratories should also be able to undertake drug susceptibility testing. Furthermore, internal and external reference laboratories are needed both to confirm identifications and to help ensure quality control.

Hygiene

Hand hygiene is the single lowest-cost and most cost-effective infection control measure that can be introduced into healthcare facilities. In 2005 and 2008, WHO launched two campaigns (“Clean Care is Safer Care” and “Save lives: clean your hands”) to promote hygiene and highlight the importance of addressing HCAI for the safety of patients and staff. Hand hygiene formed the basis of both programmes, underscoring the fact that compliance by healthcare workers is a simple and low-cost intervention that has a significant impact on HCAI prevention. Currently, there are infection control initiatives involving hand hygiene programmes in Algeria, Mali, Senegal and Uganda, which have resulted in reduced incidence of HCAI. You can learn more about the WHO hand hygiene programme in a video presentation given by Professor Didier Pittet at http://www.youtube.com/watch?v=uih5sI7TsSKE. You can also download related tools and reference material from the WHO website at http://www.who.int/gpsc/information_centre/en/.

Fig 2: Unsafe disposal of medical waste at a hospital in West Africa.

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WHO ADDRESSES QUALITY OF DIAGNOSTICS FOR PRIORITY DISEASES WORLDWIDE

There are over one million people in Kenya living with HIV today\(^1\). A decade ago reports of the country’s epidemic were universally grim, with over 100,000 Kenyans dying of AIDS every year\(^2\). Fortunately, the concerted effort by governmental and non-governmental organisations (NGO) to increase access to diagnosis and treatment reversed the trend, and today the national prevalence of the disease has nearly halved from its peak\(^3\). Testing for HIV in Kenya is a rigorous process that has reached over two-thirds of the country’s population\(^4\). Participants receive up to three tests (each a different brand of kit) to determine their HIV status as part of most national algorithms, and in 2011, one of these was the Standard Bioline Diagnostic Kit, produced by South Korean company Standard Diagnostics, Inc\(^5\). This kit is an inexpensive and simple blood test that can diagnose both HIV-1 and HIV-2, with the appearance of 2 or 3 red lines on the device indicating a positive result. The wide availability of Bioline in Kenya made it a centerpiece of the country’s successful HIV/AIDS prevention programme\(^6\).

In November of last year, one million SD Bioline HIV-1/2 3.0 test kits were quarantined when a World Health Organisation (WHO) prequalification assessment revealed that 50% of certain lots these tests produced invalid results\(^7\).

Standard Diagnostics Inc. and its parent company, Alere, voluntarily recalled the test kits upon the announcement, and in the meantime have instigated improvements in manufacturing and quality control processes. Thanks to a diagnostic algorithm requiring the use of up to three tests for HIV confirmation, few if any Kenyans received inaccurate information about their HIV status as a result of the severe defect. Kenya was not alone in its reliance on the test. Other countries faced the problem of making rapid changes in national testing algorithms, a challenging task in resource-limited settings where supply chain and logistics management systems may be slow to respond. This episode highlights the need for more rigorous monitoring of diagnostic test kit quality.

Superficially, the state of quality control in medical device manufacturing may appear quite healthy. Numerous international agencies offer certification for companies that produce diagnostics, reportedly based on quality management system standards that must be implemented by the legal manufacturer at the development, manufacturing, packaging and distribution sites. As a result, these companies are commonly internationally certified, and the associated products come with seals of approval tied to manufacturing standards. However, the very proliferation of such agencies means that there are loopholes in the system. Not all agencies are as rigorous in their on-site auditing of the requirements of the international standards. By setting up factories in countries with less stringent regulations, suppliers can produce diagnostics, especially for export, the manufacture of which undergoes little or no inspection. Of the 193 WHO Member States, only about one-third have in place a regulatory system for diagnostics.

The WHO Prequalification of Diagnostics (PQ Dx) Programme confronts this loophole on both the supply and demand level. On the supply side, the Programme offers its own, independent assessment of the quality of the in-vitro diagnostics medical device in accordance with internationally standards. Such assessments are based on rigorous dossier review, site inspections and laboratory evaluations. Inspections are carried out by a WHO-lead team of highly qualified auditors. The prequalification process establishes a trusted outcome upon which all ministries of health and NGOs can rely. WHO also trains national regulatory authorities to review, evaluate, monitor, and regulate diagnostic products thus, contributing to country capacity to monitor the quality of diagnostics.

Meanwhile, on the demand side, the WHO PQ Dx Programme aims to promote and facilitate access to safe and appropriate diagnostics of good quality in an equitable manner, preventing substandard products from slipping through a less reliable agency\(^8\).

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2. Ibid., p. 183.
8. Personal communication: Dr. Gaby Vencavarta, 2011.
Prequalification by WHO is a prerequisite for placing diagnostics on the procurement list used by UN agencies. Other public health partners may also wish to rely on WHO PQ Dx as part of their product inclusion criteria. WHO Member States increasingly look to WHO prequalification to guide their procurement decisions. The Programme offers assurances to public health providers, programs, and governments that the products included on the WHO procurement list have passed rigorous assessments by WHO.

The WHO PQ Dx Programme became fully operational in early 2010 in response to the requirement for increased stringency in regulation of the diagnostics market. The initial focus of WHO PQ Dx has been on tests related to HIV (RDTs, molecular diagnostics and CD4 enumeration), hepatitis and malaria. Flagging of the SD Bioline HIV-1/2 3.0 quality issue is the most high-profile contribution of the Programme to the security of diagnostics in the world health community to date. However, the Programme has also been met with criticism and pushback. The WHO’s stringent prequalification process takes time (up to 12 months) to complete if the manufacturer meets quality requirements. In the case of products whose manufacture occurs at multiple sites and/or of those that do not as yet fulfill international quality requirements, this process can take longer.

The slow pace of evaluating the compliance process necessarily conflicts with the urgent need for diagnostics in low-resource countries, and may delay the release of new products. In addition, the process is expensive, and enrolment currently comes with a price tag of US $12,000, an expense that manufacturers may not see as value-added, particularly if they have already passed assessments by other regulatory authorities. For this reason, the Global Medical Technology Alliance, an association that represents medical manufacturers, has called on the WHO to introduce a two-tiered regulatory approach, allowing companies who have already met the requirements of more stringent regulatory authorities in countries like the US, Japan and the EU to bypass prequalification.

In 2011, WHO PQ Dx introduced a stringently regulated and reviewed fast track procedure for diagnostics. However, WHO PQ Dx has observed that companies often produce different regulatory versions of a particular diagnostic product. Consequently, some versions of a single product that are manufactured under less stringent conditions are being sold to countries that lack robust regulatory frameworks.

PQ Dx recognizes that due to differences in public health priorities, the stringency of regulation for some diagnostic products (e.g. malaria RDTs) in settings such as the USA, may not be appropriate for African countries. To respond to country-specific requirements, WHO has adopted a risk-based approach that considers the unique circumstances (such as product stability, end user training etc.) in which diagnostic products are used in resource-limited and environmentally-challenging regions.

While a fast-track approach might speed up the release of new products from well-established companies, it does little to address the barriers to enrolment for smaller companies in particular, those manufacturing in low-income countries. It is not surprising, in these settings, that more than 70% of diagnostic products reviewed for prequalification were submitted by only four countries: India, China, South Korea and the US. ASLM advocates a “twinned” or joint review process whereby national regulatory authorities in purchasing countries are more closely engaged in the assessment process; distributing the cost, increasing the reach and accelerating the pace of prequalification. The long term goal of WHO PQ Dx is to devolve activities to national regulatory authorities reducing the complexity of auditing companies that manufacture in multiple sites often in countries where the product may not even be sold. Building the capacity of local auditors will ensuring universal coverage thus, preventing manufacturers from bypassing rigorous inspections.

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11For more information, please visit: http://www.who.int/mediacentre/factsheets/fs278/en/index.html
Although the WHO PQ Dx programme has been in operation for many years, the fast track process is relatively new and consequently, there will be limitations and lessons to learn. WHO PQ Dx staff members continue to track programme progress of remain committed to continuous quality improvement. One particular challenge is the availability of resources to re-inspect manufacturers on a periodic basis. Manufacturing processes may change over time, particularly in such fluid markets as medical device production, and periodic requalification will be necessary to ensure maintenance of quality standards. The requirement for requalification of diagnostic products must be flagged by the manufacturer. Hence, the criteria, and a mechanism for dealing with requalification is required to manage this process. The main responsibility of WHO is to the end users and recipients of regulated tests. To this end, WHO must work closely with regulatory authorities to defray programme costs. To its credit, the WHO has an on-going commitment to train regulators in countries where WHO PQ Dx operates, a project that over time will improve both the speed and the cost-effectiveness of the Programme and work towards global and regional regulatory convergence.

In addition to reducing costs and increasing efficiency, there is a need to encourage more companies to submit to prequalification, not only to protect people from faulty diagnostics, but to achieve greater economies of scale. Furthermore, as buyers (in particular, UN agencies and governmental and non-governmental organisations) incorporate the requirement for PQ Dx products into their procurement process, WHO will need to work with countries to assist national programmes to expand the scope of their regulatory frameworks to include greater coverage of laboratory commodities.

With greater commitment from the global health community, WHO PQ Dx can establish itself as an essential step in releasing a new diagnostic product of good and sustainable quality, and not as an optional hurdle. This will encourage companies whose products meet the highest standards to view the WHO PQ Dx as their first and most important entry point to the global market. Through increased efforts to build country-level capacity, the WHO’s Prequalification of Diagnostics Programme can have a significant impact on global health, making sure that only the highest quality products are released onto the market.

By: Aaron Krol (Editorial Team) and Jessica Fried, MPH (Editorial Team); Editor: Paula Fernandes, MBA, PhD (Editorial Team); Contributors: Gaby Vercauteren, PhD and Anita Sands, MPH

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**ASLM HOSTS SECOND SLIPTA INDEPENDENT ADVISORY COMMITTEE MEETING**

The ASLM SLIPTA (Stepwise Laboratory Quality Improvement Process Towards Accreditation) Independent Advisory Committee (IAC) hosted its second meeting from 27-28 September at the Radisson Blu Hotel in Addis Ababa, Ethiopia. The IAC convenes annually to develop methods to strengthen laboratory quality management systems (QMS) in Africa. The main objective of the IAC is to improve laboratory services and facilitate evidence-based decision-making.

During its second meeting, the IAC identified four key strategic approaches for strengthening laboratory QMS:

1. Highlighting QMS as an essential aspect of national laboratory strategic plans;
2. Developing an effective communication strategy among TB laboratory stakeholders;

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3. Serving as an outlet for the facilitation and strengthening of QMS implementation;
4. Monitoring the progress of laboratories toward accreditation.

The ASLM blueprint for laboratory accreditation addresses these approaches by identifying specific activities which will aid the achievement of its strategic goals, including the publication of the SLIPTA checklist, the harmonisation of QMS implementation tools, the planning of auditor training courses, the implementation of SLIPTA, and the standardisation of SLIPTA-related documents. Collaborators in these activities include in-country ASLM representatives, ASLM partners, African Ministries of Health and the World Health Organisation (WHO).

In reviewing its achievements and gaps, the IAC strives to ensure that ASLM procedures, processes, products and services are consistent and of the highest quality. The IAC also helps African laboratories adopt and improve their own quality management systems and achieve accreditation. The expansion of SLIPTA in Africa will help improve disease diagnosis and control, patient care and preventive medicine throughout the continent.

By: Rachel Crane (Editorial Team) and Teferi Mekonen, MSc, MPH (ASLM); Editor: Paula Fernandes, MBA, PhD (Editorial Team)

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**HEALTHCARE-ASSOCIATED INFECTIONS**

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**Waste disposal**

Unsafe handling and disposal of contaminated waste from healthcare facilities can spread infections within facilities, and into the community and the environment. WHO reports that infectious waste makes up 15-25% of the total waste produced by healthcare facilities. Safe waste disposal is often overlooked in resource-poor healthcare settings where complex disposal programmes are not possible and centralised disposal facilities may not exist. A balance has to be struck between the risks posed by the waste itself and those posed by the disposal methods (e.g. air pollution). It is accepted that at present, some countries may have to use incineration; however, applying the international recommendations for best practice in the operation and maintenance of incinerators is not practical in most resource-constrained settings. The problem of waste management still requires a suitable solution.

Some key initiatives for control of HCAI in Africa: African Partnerships for Patient Safety (APPS); Global Infection Prevention and Control Network (GIPC); Infection Control Africa Network (ICAN); Réseau international pour la planification et l’amélioration de la qualité et de la sécurité dans les systèmes de santé en Afrique (International Network for the Planning and Improvement of Quality and Safety in Health Systems in Africa) (RIPAQS); and Clean-HandsNet.

While there are effective and low-cost measures that can be taken by healthcare facilities to reduce the incidence of HCAI, health authorities must establish reasonable infection control guidelines and make funding available to execute policies that address the control of HCAI in order to truly have an impact on this public health challenge. In Africa, more research is needed into the size and extent of the problem and advocacy is essential to ensure that governments make resources available to tackle HCAI.

By: Tim Healing, PhD (GSSHealth); Editors: Jessica Fried, MPH (Editorial Team) and Paula Fernandes, MBA, PhD (Editorial Team)
ASLM FACILITATES SLIPTA AUDITOR TRAINING IN TANZANIA

The East Africa Public Health Laboratory Network Project (EAPHLNP) and the East, Central and Southern African Health Community (ECSA-HC) co-organised a Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) auditor training course from 1-5 October at the National Institute for Medical Research and Training in Dar es Salaam, Tanzania. ASLM facilitated, certified, and provided financial support for the course, which sought to advance the implementation of SLIPTA in the region.

The five-day training course consisted of the following modules: Introduction to Accreditation, ISO 15189 Standards, Assessment Methods, SLIPTA Checklist, the 12 Quality System Essentials, and Professional Ethics. During the course, participants visited three laboratories for mock audit practice. ASLM, the Association of Public Health Laboratories (APHL) and Risk Accredit Management Systems—Africa (RAMS Africa) provided trainers, who presented course material and administered pre-tests, post-tests and final examinations. Representing ASLM at the training was Mr. Teferi Mekonen, Accreditation Officer and SLIPTA Focal Point.

A total of 17 participants (five from Uganda, two from Kenya, two from Burundi, two from Rwanda and six from Tanzania) attended. Through the Auditor training, participants were able to improve their capacity to audit laboratory gaps using the SLIPTA Checklist and to support laboratory personnel in developing quality improvement plans to address the gaps identified in preparation for accreditation. As Auditors, they will greatly contribute to the improvement of diagnostic services.

EAPHLNP and ECSA-HC strive to improve vulnerable populations’ access to diagnostic services in cross-border areas as well as to enhance laboratories’ contribution to disease surveillance through mobile communications. EAPHLNP, a World Bank-funded programme, is being implemented in Burundi, Kenya, Rwanda, Tanzania and Uganda.

By: Teferi Mekonen, MSc, MPH (ASLM) and Rachel Crane (Editorial Team); Editor: Laurel Oldach (Editorial Team)

In addition to facilitating the EAPHLNP/ECSA-HC auditor training course, ASLM co-hosted a SLIPTA auditor training from 29 October to 2 November in Abuja, Nigeria, in collaboration with the Medical Laboratory Science Council of Nigeria. 23 participants from 6 countries attended; 21 of them successfully completed the training. The Society plans to host another SLIPTA auditor training from 10-14 December in Johannesburg, South Africa.
Volunteers Needed!

**Publication Mentors:**
Experienced researchers, epidemiologists and statisticians to help with research methods/analysis, scientific communication skills, manuscript preparation/submission and peer review. Mentors will offer guidance for papers recommended for advisement. Subject matter expertise not necessary. Volunteer time commitment depends on mentee needs.

**Writing Workshop Mentors:**
Researchers, statisticians and epidemiologists with extensive publication experience. Help with daily lectures and discussions and work with a small group of participants on manuscript development. Mentors will provide guidance on research methods, analysis, laboratory or epidemiology subject matter within their expertise, manuscript preparation, scientific interpretation, and communication skills. The time commitment is a two-week workshop.

**Manuscript Submission:**
Laboratory Medicine-related manuscripts. Of particular interest: the role of labs in clinical care and public health; the translation of laboratory knowledge; the juncture of laboratory and medical science; lab-based epidemiology; laboratory investigations. Submissions accepted in French or English.

**Peer Reviewers:**
Objective reviewers with high level of expertise to evaluate the quality of manuscripts. Reviewers will offer detailed comments and suggestions, and make recommendations to accept, accept with revisions, reconsider with major revisions, or reject submissions. Reviewers will be contacted before being forwarded manuscript. A 2-3 week turnaround is expected.

For more information or to volunteer, please contact: ecl7@cdc.gov.