Setting the Pace for Quality Laboratory Standards in Kenya

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...and much more...
The office of the Chief Medical Laboratory Technologist/Registrar of the Kenya Medical laboratory Technician and Technologists board has a heavy responsibility of registering Medical laboratory Technicians and Technologists who have been recommended by the assessment and registration committee and the full board. Currently there are 4,053 Technologists and 1,283 Technicians registered in public and private practice.

My office also has the responsibility of renewing licenses for Medical laboratory Technicians and Technologists that have been recommended by the KMLTTB to practice privately and in public institutions. The board offers indexing to students from registered institutions comprising of Universities and colleges who later apply for board examinations which on successful completion will lead to registration.

All renewals for the year 2011 were completed and sent out by randomly within the year however, in future this will be done 31st of March of every year. The secretariat receive the various, culminate with a view to awarding them the respective registration certificates/licenses. The board is in the process of redesigning the new generation registration certificates and licenses and recall all old certificates to curb the illegal ones currently in circulation by quarks.

The KMLTTB board launched the website in February this year where services will be made online without necessarily coming to the headquarters for services to be rendered to them. This will not only save time but also improve services and bring services closer to the Kenyan people.

The board has successfully managed to obtain a subsidiary legislation on the validation of equipments and reagents that will be used in all laboratories in Kenya. This is a milestone made to ensure that the Kenyan people are not subjected to unwarranted of being tested using substandard reagents whose efficacy, sensitivity and specificity do not conform to international standards that may compromise quality of laboratory services in Kenya.

My office as the registrar has trained more than seventy inspectors and is in the process of increasing the number to over a hundred to ensure the public are safeguarded against the quarks that operate illegal unlicensed laboratories that exploit the consumers.

In order to help the board supervise and inspect Technicians and Technologists at the grass root level, my office is in constant touch with Provincial Medical laboratory scientific officers, Provincial Medical laboratory Technologists and Association of Kenya Medical laboratory scientific officers at the branches.

Let me congratulate the new board members for having been able to discharge their duties effectively despite the challenges before them and hope that they will do their very best to uphold our noble profession for the benefit of health consumers and the Kenyan people.

It is important to note that although my office is at National public health laboratories where the board offices are situated, we have an established network with the headquarters where much of the Ministry’s decisions and policies are made nevertheless am always in constant consultation and actively participate in matters regarding regulatory policies at the headquarters.

Finally, let me request all Medical laboratory fraternity to give the new board the necessary support and assistance in order to promote quality laboratory services in our country. In view of this, I call upon the public to be weary of the quarks out there practicing illegally and always demand the registration certificate of the one offering laboratory services both in private and public sector before accepting to be tested.
Recognizing the significant role played by Medical Laboratory professionals in the provision of health service. The Board aspires to have all the medical laboratory technicians and technologists fully registered with the Board. Due to the ongoing crackdown of quarks in the country, the Board has so far registered a total of 4,053 Technologists and 1,283 Technicians. This will help elevate the standards of medical diagnostics.

The Registration office is charged with the approval of qualified Medical Laboratory Scientists, Recommending to the Board issuance of registration certificate and practicing certificate to the registered members and gazettement, tracking of the renewal of practicing certificates annually, deregistration of errant practitioners due to ethics issues, forgeries of certificates, frauds, deaths etc and any other responsibilities the Board may assign the committee.

The committee is also mandated to issue registration certificate and Annual License to Training Institutions and Medical Laboratories. As a response to the outcry of Kenyans, the KMLTDB has ensured that the Medical laboratory standards have to be adhered to, to the later in order to realize our dream of quality healthcare in the country!

Due to the ongoing crackdown of quarks in the country, the Board has so far registered a total of 4,053 Technologists and 1,283 Technicians.
• Receiving, compiling and vetting of membership registration application forms by verifying the following documents and information:– ID/PP
– Academic certificates
– Professional certificates and other testimonials
• Approval of the qualified applicants
• Recommending to the Board for the issuance of registration cert & practicing cert to the registered members
• Gazettement of qualified medical laboratory sciences practitioners
• Tracking of the renewal of practicing cert annually

Other responsibilities
• De-registration of errant practitioners due to ethics issues, forgeries of certificates, frauds, deaths etc.
• Any other responsibilities the Board may assign the committee

LINKS WITH OTHER COMMITTEES
• Quality Assurance Committee which:-
  – Inspects the training Institutions
  – Awards the approval certificates to the approved training Institutions
  – Does continuous standard assessments to the approved training Institutions
• Education committee which:-
  – Develops/harmonizes curriculum to the approved training Institutions

CURRENT APPROVED TRAINING INSTITUTIONS
• The Kenya Polytechnic University College (Diploma)
• The Mombasa Polytechnic University College (Diploma & Certificate)
• All Kenya Medical Training Colleges (Diploma)
• Eldoret Polytechnic (Diploma & Certificate)
• Kenya Institute of Applied Sciences (Diploma & Certificate)
• Ol’Lessos Technical Training Institute (Diploma & Certificate)
• Jomo Kenyatta University of Agriculture and Technology (BSc. Degree)
• University of East Africa-Baraton (BSc. Degree)
• Kenyatta University (BSc. Degree)

PROVISIONALLY APPROVED TRAINING INSTITUTIONS
• Nairobi Technical Training Institute (Diploma)
• Gusii Institute (Diploma)
• Outspan College
• Rift Valley Technical Training Institute
• Mt. Kenya University
• Kenya Methodist University

REGISTRATION CODES
Pool of required subjects for qualification for registration
• Parasitology
• Bacteriology
• Haematology
• Immunohaematology & Blood transfusion
• Medical Virology
• Immunology
• Clinical Chemistry
• Cytohistopathology
• Medical Mycology
• Any other subject that the Board may approve

Support Subjects
• Medical terminologies
• Instrumentation
• Clinical Psychology, Counseling and ethics
• Microscopy
• Chemistry
• Biostatistics
• Information technology and computers
• Entrepreneurship
• Medical lab safety
• Molecular Biology
• Anatomy and Physiology
• First Aid
• Medical lab law
• Any other subject that the Board may approve

Academic entry requirements & Training Duration

Technicians
• C- Aggregate + cluster subjects
• 2 Years minimum training period

Technologists (Diploma & HND)
• C plain aggregate + cluster subjects
• 3 years min training for Dip (freshers)
• 2 years min training for cert holders & registered by Board
• HN, Dip, registered, 1 year min training period

Graduate technologists
• BSc C+ aggregate + cluster subjects for freshers
• 4 years min training period
• Dip & HND holders, 2 years experience, registered, 2 years min training period

Direct registration
Technologists
– Trained at KMTCs before Dec 2005
– Trained at Kenya and Mombasa polytechnic University Colleges before Dec 1998

Technicians
– Trained at KMTCs for 2 years before

Dec 1998

Registrable applicants
• From all Board approved training Institutions & passed Board exams
• Who have done min 6 core subjects from recognized training Institution by the Board and passed Board exams

Un-registrable applicants
• From un approved training Institutions
• Who have not covered the required min 6 core subjects
• Who are trained for less than 70% required training period
• As may be decided by the Board

From 2006 until further notice, all qualified applicants
• Must have students’ index numbers
• Must meet minimum academic entry requirements
• Must be from Board approved training Insts.
• Must sit and pass Board registration exams
• Must apply to the board for registration, submit required documents and pay required fees

Re-designation/Upgrading
• The Board will register an applicant after upgrading from Technician to Technologist in Technologists register at a prescribed fee upon relinquishing the Technician’s registration certificate.

Foreign Trained Applicants
• From East African Region (Tanzania, Uganda, Rwanda and Burundi)
  – All applicants must have been registered in their country of origin to qualify for direct registration
  – May be subjected to probation or sitting for registration exam as determined by the Board on application

Private Practice Registration
• The applicant must
  – Be a Kenyan citizen
  – Be registered by KMLTTB
  – Apply for practicing license and certificate from the Board
  – Have served as a Med. Lab Technician or Technologist under supervision for not less than 5 yrs in a registered and recognized Med Lab.
  – Have attended a documented prescribed minimum of quality control and accredited CPD as the Board may determine from time to time.

Registered practitioners as at April 2009 (Operational Register)
KMLTTB APPROVED TRAINING INSTITUTIONS

KMLTTB registers Technicians and Technologists after undergoing training for Degree, Diploma or Certificate courses under KMLTTB curricula in the following training institutions:

### Degree
- Jomo Kenyatta University College
- Kenyatta University
- University of Eastern Africa Baraton
- Kenya Methodist University
- Mt. Kenya University

### Diploma
- KMTC
- Nairobi Technical Training Institute
- Mombasa Polytechnic University College
- Kings Medical College
- Outspan Medical College
- Kenya Institute of Applied Sciences
- Eldoret Polytechnic
- Ol lessos Technical Training Institute
- Rift Valley Technical Training Institute

### Certificate
- Mombasa Polytechnic University College
- Kings Medical College
- Outspan Medical College
- Kenya Institute of Applied Sciences
- Eldoret Polytechnic
- Ol lessos Technical Training Institute

Student registration (Indexing)
Student indexing application forms are downloaded from the Board’s website by the training institutions. The forms are filled by the students with the help of the lecturers in the medical laboratory sciences department and submitted to KMLTTB with application fees.

Upon receiving the applications the Board indexes students against set minimum entry requirements as per the level desired, the criteria is availed to training institutions after registration by the Board. When the process is complete the report is sent to the institutions. Upon completion of training, only indexed students would be allowed to sit KMLTTB registration examinations.

Registration Examinations
The Board administers two series (February and September) of registration examinations every year to students who successfully complete training and college qualifying examinations. However the Board can vary the
number and months of examination sitting in a year depending on prevailing circumstances. The approved training institutions act as examination centers during examination administration.

The candidates are examined on 8 disciplines of Medical Laboratory technology as follows:
1. Medical Microbiology
2. Clinical chemistry
3. Haematology
4. Blood transfusion
5. Histopathology and cytology
6. Parasitology and entomology
7. Immunology
8. Medical virology

In addition practical and oral examinations covering all the above disciplines are given. The candidate is expected to score 50% to pass.

KMLTTB Education message for Hon. Minister’s press conference

The Board wishes to inform parents, guardians, sponsors and employers that they should enquire from KMLTTB prior to sending students to pursue medical laboratory training. Institutions masquerading as trainers in this field have duped sponsors and as a result suffered huge losses. Many people especially parents have been shocked after realizing that their children could not be registered to practice by the Board since they trained in unregistered institutions.
A friend of mine while waiting to board a matatu to town noticed a tent perched next the bus stop that had some medical posters and advert appealing to the public to seek medical check up. The tent had a public address system that was used to urge members of the public to know their health status. Of interest, was the message that one was able to be diagnosed of various diseases without removal of any sample including blood.

On further inquiry, he was ushered inside the tent and met a team of purported doctors who were attending to four other clients. There was no privacy, no confidentiality or ethics as he was questioned on very sensitive matters during history taking, measuring his blood pressure, clinical diagnosis, testing and prescription of herbal drugs. He asked if he would have some laboratory tests done to confirm the malaria, typhoid and amoebiasis that they claim he was suffering from. He gave me a call for some advice due cost implication to which I told him that the alleged diseases need laboratory confirmation to avoid wrong diagnosis and resistance to drugs.

**Laboratory tests and standardization**

More than a million medical laboratory tests that identify and measure disease causing agents are performed each year in the Kenya. Such test results have a significant influence on medical decisions. Medical laboratory Quality Assurance (QA) encompasses a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and the volume of specimens tested. In the fall of 1967, 31 clinicians and laboratory scientists representing 15 organizations met to discuss ways of “improving what we are doing for patients” and to develop a formal consensus process for standardization. Laboratory Standardization is achieved when test results with the same high levels of accuracy and precision can be reproduced across measurement systems, laboratories, and over time. Well-executed standardization programs greatly improve the quality of laboratory measurements that are used to detect signs of illnesses and to guide interventions to prevent or treat illnesses.

Standardization also ensures the production of credible and comparable data across medical laboratories. It is in light of this that medical laboratory practice be regulated in the country. Kenya Medical Laboratory Technician Technologist Board (KMLTTB) core business is to regulate laboratory practice for health care testing in Kenya.

My friend’s experience is a clear indication of the many mushrooming mobile tent clinic that are strategically positioned in open catchment areas accessible by the public. These mobile clinics employ the principle of acupuncture therapy and used a hand acupoint therapy device.

Acupuncture has been the subject of active scientific research both in regard to its basis and therapeutic effectiveness since the late 20th century, but it remains controversial among medical researchers and clinicians. Research on acupuncture points and meridians has not demonstrated their existence or properties. Clinical assessment of acupuncture treatments, due to its invasive and easily detected nature, makes it difficult to use proper scientific controls for placebo effects.

**Acupuncture a traditional Chinese medicine**

So many acupuncture outlets exist in most of the urban centers in Kenya. These facilities offer a paradigm of alternative medicine that treats patients by insertion and manipulation of needles in the body. The World Health Organization and the United States’ National Institutes of Health (NIH) have
stated that acupuncture can be effective in the treatment of neurological conditions and pain, though these statements have been criticized for bias and a reliance on studies that used poor methodology. There is general agreement that acupuncture is safe when administered by well-trained practitioners using sterile needles, but not on its efficacy as a medical procedure. Traditional Chinese medicine (TCM) is based on a pre-scientific paradigm of medicine that developed over several thousand years and involves concepts that have no counterpart within contemporary medicine. In science-based medicine, disease is attributed to specific (often single) causes, for example bacteria, viruses, or genetic conditions. In contrast to the approach of evidence-based medicine, this is based on the germ theory of disease, human anatomy and human physiology.

Traditional Chinese medicine (TCM) attributes disease and pathology to perturbations in the metaphysical force known as qi (a word variously translated as “energy”, “breath”, or “vital energy”), and imbalance of yin and yang, and the Wu Xing (known as the five phases or elements, earth, water, fire, wood and metal). Qi is believed to flow in and around the body in channels called meridians.

Heart-qi is believed to be a force that causes the blood to circulate through the body, whereas in science-based medicine, the blood is propelled by the heart pumping it. The anatomical system of TCM divides the body’s organs into “hollow” and “solid” organs, for example, the intestines are “hollow”, and the heart or liver are “solid”. It is believed that solid organs are related, and hollow organs are related, and that there is a balance between the two “systems” of organs which is important to health. The zang systems are associated with the solid yin organs such as the liver, while the fu systems are associated with the hollow yang organs such as the intestines. Health is explained as a state of balance between the yin and yang, with disease ascribed to either of these forces being unbalanced, blocked or stagnant.

In TCM, there are four diagnostic methods: inspection, auscultation and olfaction, inquiring, and palpation. Research on the electrical activity of acupuncture points lacks a standardized methodology and reporting protocols, and is generally of poor quality. There is scientific agreement that an evidence-based medicine (EBM) framework should be used to assess health outcomes and that systematic reviews with strict protocols are essential. Scientific disagreement over methodological aspects of research into acupuncture is not uncommon. A 2011 review of review articles concluded that, except for neck pain, acupuncture was of doubtful efficacy in the treatment of pain and accompanied by small but serious risks and adverse effects including death, particularly when performed by untrained practitioners. Therefore the begging question is, “who regulates these mobile clinics that purport to offer health services to unsuspecting members of the public?” and keeping charging them colossal amount of money. Do they pay taxes? Some quick action need to be instituted to save innocent Kenyans from this mess.

The Write is a Technical advisor and board inspector, KMLTTB.
How did your expectations for the launch meeting compare to the meeting outcome?

The outcome of the launch of ASLM greatly exceeded my expectations. Six ministers of health, two ambassadors, and over three hundred partners and participants attended. The objectives of the meeting were to engage stakeholders in the development of a strategic plan to advance the eight pillars of the society (see Feature Article: Welcome to Your ASLM).

We received valuable input and over 80% of participants signed up to be ASLM members. Receiving that type of support and feedback from our community was invaluable. We are still riding the positive waves of enthusiasm expressed during the launch.

What role do you play as Chairman of the Board of Directors of ASLM?

As Chairman of the Board I am charged with helping ASLM achieve its mission of advancing professional laboratory medicine practice, science, systems, and networks in Africa needed to support preventative medicine, quality care of patients, and disease control. In order to achieve this mission I am here to support the ASLM Leadership staff, provide mentorship when I am called upon, and work with the rest of the board to guide ASLM.

Who are the members of ASLM?

ASLM is very inclusive. Our services are targeted at laboratory scientists, scientific researchers, ministries of health, national institutes of health, public health laboratories, professional organizations, NGOs and private entities across the African continent.

What can ASLM do for its members?

ASLM plans to help its members by providing a number of services, including tools to aid laboratory accreditation and the development of standards; online programs for science education and training; technical assistance for grant writing, publications, and presentations; and access to journals, essential documents, and forums to network and engage with the laboratory community.

Dr. John Nkengasong, Board Chair, Shares His Vision for ASLM

Why and how was ASLM started?

In developing countries, health systems are often inadequately resourced and the critical role of medical laboratories is frequently underappreciated. With the lack of capacity to provide the scope and quality of laboratory services required by the community, misdiagnoses and, consequently, inappropriate treatments are a reality.

This presents significant economic and public health challenges locally, nationally, and internationally. Recognizing these challenges, the Ministries of Health in several African countries came together with the WHO, CDC, and other partners to form ASLM.

The origins of ASLM can be traced back to a conference held in Harare, Zimbabwe in February 2001. The idea was planted at the time, but wasn’t developed until January 2008 with the Maputo Declaration, which called on national governments, donors, and partners in resource-limited settings to prioritize laboratory systems and develop strategic laboratory plans.

The foundation for ASLM was then established and, two years later, the organization took form as a result of the Kampala Statement, which directly called for the creation of the African Society for Laboratory Medicine. The rapid formation of the society since June 2010 is a great accomplishment and underscores the continent’s need for improved laboratory capacity.
For many years, health ministries and international aid organizations have worked to strictly regulate the quality and supply of medical drugs provided in low-income countries, understanding that substandard drugs pose threats not only to individual patients, but also on a societal level by cultivating drug-resistance.

However, equal attention has rarely been given to reforming the medical diagnostics industry, where many of the same dangers are regularly encountered. Low-quality diagnostics that yield false negatives may cause hospital or laboratory staff to miss early signs of an outbreak, while false positives can result in wastage of valuable medications. In addition, misdiagnoses can lead doctors to overmedicate or undermedicate patients, reducing the quality of care and creating a breeding ground for drug resistance.

The diagnostics industry suffers from many of the same faults as the more closely monitored drug industry. Manufacturers and suppliers operating in low-income countries are not always required to adhere to international standards, with governmental authorities imposing insufficient quality control. Even when adequate standards are theoretically required, ministries of health may lack the financial or legal resources to thoroughly implement these standards; in addition, interconnections between the industry, procurement agency and quality control boards may provide incentives that result in poor quality diagnostics reaching the market. A general shortage of diagnostic equipment also creates demand for unscrupulous back-alley vendors, who peddle low-quality diagnostics with no oversight.

Individual consumers and laboratories alike may be forced to choose between under-regulated companies and completely unregulated black market sources.

Diagnostics also face a unique hurdle once equipment reaches the laboratories. Because diagnostics require professional training for effective use, even high-quality equipment can be rendered ineffective if laboratory staff is unprepared to operate it. Many regions distant from city centers suffer chronic shortages of qualified professionals to train laboratory technicians in the use of new diagnostic methods and equipment. Tragically, the increasing availability of more advanced medical technology can compound this problem, as laboratories, clinics and hospitals receive the latest diagnostics but no guidance in their operation. In Kenya, fortunately, the Ministry of Health is setting a sterling example of a systematic approach to addressing the challenges that disrupt the field of diagnostics.

Under the leadership of the Hon. Minister for Medical Services, Prof. Anyang Nyongó, the Ministry has launched an aggressive campaign to implement and enforce international standards for the industry, providing careful oversight on both a national and local level. The key element of Prof. Nyongó’s initiative is increasing transparency in the health care industry. As Dr. Michael Wanga, Chief Executive Officer, KMLTTB - Ministry for Medical Services, told the African Society for Laboratory Medicine in an interview, “Lack of transparency means compromising standards through bribery, dubious registration of personnel, shortcut ways of licensing institutions and lack of a score card or checklist to inspect the laboratories.”

In pursuit of higher standards of transparency, Prof. Nyongó has recently taken two bold measures to reform the practice of diagnostic regulation in Kenya. First, he dissolved the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), under the suspicion of inappropriate ties to manufacturers and suppliers. He invited the Efficient Monetary Unit to investigate the Board’s activities, and after six months, incorporating the Unit’s recommendations, created a new Board to be the sole laboratory regulatory body in Kenya. Prof. Nyongó has extended...
partnerships with the new KMLTTB to several international donor agencies.

Second, Prof. Nyongó has introduced legislation that empowers the KMLTTB to more tightly regulate universities and laboratories, providing oversight on the consumer level. This legislation prohibits the employment of unregistered personnel and criminalizes the failure to provide all staff with relevant medical training, under penalty of fines and even jail time.

This ensures that laboratory and university staff is qualified to correctly administer and interpret diagnostic tests. Specific diagnostics that have been shown to be unreliable have faced immediate clampdowns. Prof. Nyongó banned the use of Widal testing kits for typhoid after studies demonstrated they were leading doctors to regularly over or under-medicate patients. "It’s giving false information about patients’ health status and endangering lives by giving wrong prescriptions," said the Minister in a recent press briefing.

At the same time, the Ministry of Health has aggressively redoubled its efforts in maintaining the stricter standards introduced under Prof. Nyongó. The Ministry has trained 100 new inspectors and auditors and reinspected all organizations that train laboratory staff, closing several substandard institutions. The Ministry has also formed partnerships with local media houses and police units to alert the public to the activities of unscrupulous vendors and labs that use faulty products.

Prof. Nyongó directly addressed the problem of black market suppliers and the laboratories that deal with them in his press briefing, saying, "We don’t want anybody importing all kinds of equipment claiming that it’s lab equipment before it is properly certified."

With these determined reforms underway, Kenya is setting a new standard for quality control of diagnostics and industry transparency. The ASLM will continue not only to support Prof. Nyongó’s work in Kenya, but also to form partnerships with health ministries in other African countries to assist in implementing similar measures.

A functional diagnostic service is the first step to addressing national and international health crises, and the Kenyan model is a powerful blueprint for a sound approach to quality control in this essential industry.
It is time to end the cycle of laboratory systems neglects and eliminate empirical treatment through implementation of quality laboratory evidence based medicine. Health systems in Kenya and across Africa are often inadequately resourced and the critical role of medical laboratories is frequently underappreciated. With lack of capacity to provide the scope and quality of laboratory services required by the community, misdiagnoses and, consequently, inappropriate treatments are a reality.

Through the African Society for Laboratory Medicine (ASLM), the Kenya Medical Laboratory Technology and Technician Board (KMTTLB) and ISO accreditation, we can now advance professional laboratory medicine practice and science, as well as quality systems and networks in Kenya. Sustenance of laboratory quality would require continuous strengthening of quality systems and inter-networking of laboratories as well as with the regulatory bodies.

Such a system would facilitate the growth of MOH laboratories from regional to the periphery through the mentorship by existing high quality laboratories such as the AMPATH, WRP, CDC (the Twinsers) among others.

The KEMRI/CDC laboratory has already started providing mentorship to the Kisumu PGH and Siaya district labs as well as working with the regulatory KMTTLB body to provide support for training, equipment and reagent validation.

COURTESY OF KMLTTB.
LIST APPROVED COLLEGES & INSTITUTIONS AS OF 5TH OCTOBER 2011

To Pay for Re-Inspection
1. Kenya Medical Training college – Nairobi
2. Medical Training college – Nakuru
3. Medical Training college – Kitui
4. Medical Training college – Machakos
5. Medical Training college – Kakamega
6. Medical Training college – Nyeri
7. Medical Training college – Embu
8. Medical Training college – Kisumu
9. Medical Training college – Port Reitz
6. Kings Medical College
7. Kenya Institute of Applied Sciences

Provisional Approval – Diploma And Certificate
1. Rift Valley Technical Training Institute – Eldoret
2. O’lessos Technical Training Institute
3. Kabete Technical Training Institute
4. AIC Litein Medical Training College
5. Kericho Technical Training Institute
6. Tracom College – Nakuru
7. Kenya Institute of Professional Studies
8. Royal College – Ruiru
9. Gusii Institute of Science and Technology
10. Kisumu Polytechnic

Provisional Approval Certificate Only
1. Regional Institute of Business Studies
2. Vihomi Technical Training Institute – Kisumu

Full Approval - Diploma & Certificate
1. Kenya Polytechnic University College
2. Eldoret Polytechnic University College
3. Mombasa Polytechnic University College
4. Outspan Medical College
5. Nairobi Technical Training Institute

To Be Inspected And Level Be Determined.
1. Sigalagala.
FHI360 is a global health and development organization whose science-based programs bring lasting change to the world’s most vulnerable people. Our approach is rigorous and evidence-driven. Among our worldwide staff of 2,500 are leading physicians, scientists, and technical experts in health, development, and management. FHI360’s work is global in scale yet country-focused, with international offices staffed by local professionals.

Since 1971, FHI360 has worked with over 1,400 partners in 125 countries, forging strong relationships with governments, diverse organizations, the private sector and communities. By applying science to programs, FHI is helping countries make measurable progress against disease, poverty, and inequity-improving lives for millions. FHI360 has increased access to quality health services by focusing on research and service delivery in HIV/AIDS, reproductive health, TB and malaria, laboratory strengthening process as well as emerging issues in public health including heart disease. FHI360 Laboratory Science Division (LSD0 has provided support to the Ministry of Health, Kenya in many activities.

FHI360 LSD partnered with Kenya Medical Laboratory Technician and Technologist Board (KMLTTB) to facilitate the celebration of 2011 World Accreditation Day and advocated for the support for quality laboratory services through a petition signed by more than 300 professionals across the world. The activity was later published in the African Society for Laboratory Medicine (ASLM) “Lab culture newsletter 2011”.

Laboratory Sciences are an important part of FHI360’s services. Our quality assurance laboratory specialists work with partners and laboratories to improve services through assessments, program enhancements, training, and technical assistance. We also provide services on implementation of ISO 15189 accreditation, Good Laboratory Practice (GLP) and gain approvals for clinical research studies.

In providing laboratory services, FHI360, recognizes the importance of quality medical laboratory services regardless of the settings. Through this, FHI360 has developed quality improvement and ISO 15189 comprehensive implementation/program package. The package consist of:

i) assessment of laboratories against ISO 15189 standards and gap analysis exercise
ii) involving hospital and laboratory management in the program and gain their support,
iii) supporting laboratories with generic version of management and technical documents
iv) provide training and technical support to the laboratories and
v) periodic monitoring and assessment on readiness for accreditation. The implementation package has been translated into several languages (Indonesian, Vietnamese etc.) for adaptation by laboratories.

The implementation package has been used in number laboratories (e.g. in Vietnam, Indonesia and Bangladesh) in Asia and (in Nigeria, Tanzania and Kenya) in Africa. The package provides achievable improvement in various key performance indicators in a short time and it is easy to follow and implement at limited cost.

By Valentine Magero MPH (FHI 360 Senior Laboratory Specialist AFRO)
REDUCING RISK IN HEALTHCARE DELIVERY THROUGH LABORATORY ACCREDITATION

Risk Accredit Management Systems (RAMS)-Africa’s motivation and commitment to improvement in quality laboratory service processes is due to the fact that, up to 60% of clinical errors during healthcare delivery have a root course traceable to the diagnostic techniques and processes which under proper quality system can be minimised. RAMS Africa provides a range of mentorship consultancy services, evaluation of implementation of quality management systems and training in implementation of quality systems with a leaning to Diagnostic and Research Laboratories.

Mentorship Program

Through experience, RAMS recognizes the critical role in documentation systems. To mitigate this, RAMS has developed generic documents packages which are comprehensive and covering all aspects of laboratory quality systems (management and technical). They include the generic version quality manual and other quality management documents, forms, work instructions and template for technical SOPs which are also developed to support implementing laboratories for necessary modification and adoption through mentorship.

Assessments and Program Evaluation

We offer quality management systems assessment audits for baseline gap analysis, mid-term evaluation of program implementation and end of program implementation (pre-accreditation in the case of laboratories) assessments. Our team of assessors includes experts with varied experiences in both technical and management requirements the laboratory. RAMS has so far done gap analysis assessments in a number of laboratories including Nairobi Hospital, Aga Khan Hospital Mombasa, AAR Healthcare Services, Mildmay Uganda and Efoulan Diagnostic Laboratory in Cameroon.

Training Programs

RAMS Africa offers trainings in the following Laboratory Quality Management Systems and standards: ISO 15189: 2007 (particular requirements for quality and competence in medical laboratory), ISO 19011 (Internal Auditing in medical laboratories), ISO 15190 (Laboratory safety), Good Clinical Laboratory Practice (GCLP) based on PPD and WHO TDR standards, writing of SOPs and documentation, uncertainty of measurements & validation of laboratory equipments and methods.

Partnership and Collaboration in Laboratory Improvement Processes

RAMS embrace the spirit of partnership and collaboration with organizations and institutions sharing the mission of facilitating the implementation of quality management system while taking a collaborative and customized approach in training and mentorship based on knowledge, expertise and professionalism. Apart from Kenya Medical Laboratory Technologist and Technicians Board, RAMS has partnered with Cameroon Association of Medical Laboratory Science (CAMELS), Mildmay Uganda, ICAP Kenya, EGPAF and KEMRI/CDC in training of over 210 MoH staff on Good Clinical Laboratory Practice (GCLP), 173 laboratory staff on ISO 15189:2007 implementation, and 20 staff on internal auditing of laboratory quality systems. RAMS has so far signed MoU with a number of organizations including FHI 360 with the hope to improve quality systems in medical laboratories.

By Kevin Omondi Jasper
Regional Coordinator- RAMS Africa
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Procession flag-off by Ms Ngari M.W, The Permanent Secretary Ministry of Medical Services-Kenya on her right Mr. Valentine Magero & left Mr. Peter Lokamar Nyanga CMLT&Registrar KMLTTB

Kenya's Director of Medical Services, Dr. Francis M. Kimani, addressing the professionals.
Delegates keenly following the proceedings of the world accreditation day 9th June 2011

Group photo at the entrance of the event venue-KICC!