EMLA Updates

EMLA CONDUCTED SENSITIZATION WORKSHOP ON MEDICAL LABORATORY STANDARDS AND ACCREDITATION

EMLA organized a sensitization workshop on medical laboratory standards and accreditation for laboratory professionals, private facility owners and stakeholders on 21st August 2016 at Embilta Hotel, in Addis Ababa. The workshop was financially supported by PHSP. The purpose of this meeting was to create awareness on the benefit of implementation of QLMS among facility owners and administrators and to review SLMTA enrolment baseline assessment result which was conducted in July 2016 in 14 private health facilities. Short presentations were delivered by Araya F (DG, ENAO) and Gizachew T (ED, EMLA) addressing “An overview of ISO standards and Ethiopian National Accreditation Office” and “Overview of LQMS, and Why quality Management for medical laboratories”. Discussions were carried out and presenters reflect their view on questions raised by the participant after the presentation.

Understanding Laboratory Medicine
DR GIZACHEW YISMAW APPOINTED TO LEAD APHI

The Ethiopian Medical Laboratory Association (EMLA) is pleased to announce the appointment of Dr Gizachew Yismaw Wubetu to lead the newly established institute—Amhara Public Health Institute (APHI) as of December, 2016.

EMLA is excited about the assignment of Dr Gizachew at this time as APHI’s Director General. Gizachew (PhD) is a young scientist, very strong and capable leader and is coming in at a time soon after APHI’s establishment is officially launched and when its roles and responsibilities were proclaimed by the Council of the Amhara National Regional Government Regulation-ZIKIRE-HIG.

EMLA is confident that, Dr Gizachew’s vision, strategic thinking and execution track record are exactly what APHI needs to lead efforts to contribute to the current public health challenges facing the region in particular, and the country, the continent and the world in general.

Dr Gizachew is a faculty member of the University of Gondar (UoG), College of Medicine and Health sciences, School of Biomedical and Laboratory Medicine. Dr Gizachew is Assistant Professor of Medical Sciences, Department of Medical Microbiology, School of Biomedical and Laboratory Medicine, College of Medicine and Health sciences, University of Gondar, Ethiopia.

Dr Gizachew Yismaw was successfully accomplished his PhD in the University of Tokushima, Japan.

Dr Gizachew has received certificate of recognition of the ‘Best Oral Scientific Paper Presentation award’ on the occasion of the 21st EMLA annual conference and continuing professional development held from 01-02 April 02 2016.

He has published several manuscripts in peer-reviewed journals on matters pertaining to laboratory medicine.

EMLA CONDUCTED SLMTA 1 OF 3 TRAINING PACKAGE TO PRIVATE HEALTH FACILITY LABORATORIES

Medical laboratories have always played an essential role in determining clinical decisions and providing clinicians with information that assists in prevention, diagnosis, treatment, and management of diseases in the developed world. Presently, the laboratory infrastructure and test quality for all types of clinical laboratories remain in nascent stages in most
countries of Africa. Consequently, there is an urgent need to strengthen laboratory systems and services. The establishment of a process by which laboratories can achieve accreditation to international standards is an invaluable tool for countries to improve the quality of laboratory services\(^1\).

Currently, EMLA in partnership with regional laboratories and private health sector project is supporting 15 private healthcare facility laboratories using WHO-AFRO SLMTA approach to help improve laboratory service, achieve immediate capacity building and foster laboratory accreditation. At this time, 14 laboratory managers and 13 quality officers were trained in TWO rounds of the scheduled training from 14 – 17 and 23-26 September 2016 in Adama. THREE MONTH project assignments were provided for each trainee participated in the TWO rounds of the scheduled training. The anticipated result will help improve laboratory set-up and services.


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**EMLA PROVIDED ASSESSMENT AND EMBEDDED MENTORING SUPPORT FOR PRIVATE HEALTHCARE FACILITY LABORATORIES**

EMLA in collaboration with and financial support from PHSP provided successful 1\(^{st}\), 2\(^{nd}\) and 3\(^{rd}\) round technical assistance and embedded mentoring support for 30 selected private health facility laboratories in July, August 2016 and September 2016 aiming to help facilities develop continuous human and organizational capacity to ensure comprehensive quality laboratory service.

A total of 30 private health facility laboratories was supported in three rounds of visit and gaps were assessed using a standard check list which gives due attention to ART monitoring tests, TB and Malaria laboratory diagnosis. Among the facilities included are 15 from Addis Ababa, 2 from Bahir Dar, 4 from Dessie, 1 from Gondar, 2 from Dire Dawa, 1 from Harar, 2 from Adama, 1 from Jima, and 2 from Hawassa. And THREE more were on pending from Mekelle. The mentoring tool was developed to attest whether or not facilities have been organized based on national and international laboratory standards. Lab personnel, specimen management, documentation, quality assurance, laboratory equipment maintenance, facility design and laboratory safety were some of the common areas included in the mentoring tool.

**OBSERVATIONS**

**LABORATORY INFRASTRUCTURE, SAFETY AND ARRANGEMENT**

- In majority of the health facilities space dedicated to laboratory services do not meet the standard and has only one small insufficient room. AFB staining, equipment washing, routine tests, laboratory supplies, and other laboratory related activities are performed in this room. Most commonly, specimen collection and processing is performed in the laboratory.
Most health facilities don’t have space dedicated to sample collection. Sample collection space is within the main laboratory and is not conducive to protecting patient privacy and confidentiality.

Most laboratories are not well structured, designed, and organized to accommodate all laboratory activities. Some laboratories are in need of significant facility renovation. Most laboratories must be redesigned to ensure that the work space is appropriate for performing laboratory tests.

Most laboratory personnel are not familiar with all safety precautions required for bio-hazardous material and hadn’t got annual safety training—e.g., documented tuberculosis exposure control plan.

LABORATORY PERSONNEL AND STAFF TRAINING

Most laboratories found to have no organizational structure. There was no chart or organizational diagram that depicts the level of hierarchy. Staff was not provided with clear written job descriptions and responsibilities. Laboratory heads are not assigned formally. Even in some health facilities, the laboratory doesn’t have a person who is responsible to oversee all laboratory activities.

Majorities of the health facilities don’t have assigned Quality Officer. The number of laboratory technician and technologist assigned in many health facilities does not meet the standard.

The ability of laboratory technicians or technologist to provide sound quality laboratory services is questionable due to lack of training and competency assessment.

Poor or lack of knowledge about quality management system among laboratory personnel.

LABORATORY EQUIPMENT, REAGENTS AND SUPPLIES

Most laboratories have sufficient and functional laboratory equipments, reagents, materials and supplies for the type and volume of testing they are doing. However, in most case, lacks back-up instruments or procedures for instruments breakdown.

In most cases, there is no scheduled preventive maintenance for laboratory analyzers.

Routine instrument calibration and verification is not performed.

The function of electrical or mechanical equipment isn’t routinely monitored and recorded—e.g., checking RPM of centrifuge, calibration of pipettes.

QUALITY ASSURANCE PROCEDURES

Most labs don’t have defined internal quality control/Assurance system.

Majority of health facilities doesn’t have SOPs for all tests performed by the laboratory. Unapproved, out dated and none standardized SOP was found in few laboratories. In general, a document control system was not put in place to ensure that records and all copies of policies or procedures are current, read by personnel, authorized by proper authorities, and reviewed annually.

No system or procedure for document and record control and retention.
Documentation of Internal Quality Control (IQC), temperature monitoring logs and equipment preventive maintenance log sheet were seen as a major gap of most health facilities.

- Instrument calibration and test verification, graphical representations of QC data were not performed consistently in most facilities. Few laboratories check each batch of reagents using known positive and negative controls.

**OPPORTUNITY AND STRENGTHS**

- During mentoring, Mentors have noticed that laboratory staffs were highly cooperative, have courage and committed to improve their laboratory services. Their motivation and courage has witnessed that they become highly interested, if they are provided an immense mentorship and technical support.
- Equipment was functioning and reagent was available for laboratory activities.
- Most laboratories participate in external quality assurance or proficiency schemes for HIV testing, and AFB smear.

**CHALLENGES**

- Poor or lack of knowledge about quality management system among laboratory personnel.
- Lack of some sort of briefing for mentors about the check list before the actual work. There are some ambiguous statements in the check list.
- Lack of communication with the concerned body of selected site about the mentorship, who and how is going to conduct the activity.

**RECOMMENDATIONS**

- Each laboratory requires a well-planned quality improvement plan that will first include a key improvement phase to create the basic and fundamental lab system that will precede future strategy. Laboratory services shall include key attributes such as; strong laboratory management, a comprehensive quality management system which focus on all areas and aspects of laboratory services, and appropriate space and state of the art equipment.
- The management of the health facilities should be dedicated to improve the quality of laboratory service and provide a good resource to its achievement. Establishing, Implementing and maintaining LQMS needs strong management support. With this connections briefing meeting with the administration of the health facility is needed.
- The laboratory personnel’s require refreshment training on laboratory quality management system. It is recommended that following the refreshment training providing embedded mentorship that will leads the laboratory to implement LQMS effectively and improve the quality of the laboratory service provided in each health facilities.
- Refreshment and onsite training on SOP preparation, malaria microscopy, AFB microscopy, and on ART laboratory tests also needed.
EMLA TO FINALIZE ITS SECOND VERSION STRATEGIC MANAGEMENT PLAN (2017 – 2021)

EMLA conducted ‘Strategic Plan Revitalization Workshop’ from 03-04th December 2016 at Embilta Hotel here in Addis Ababa.

Gemeda Abebe (PhD), President of EMLA, officially opened the workshop after delivering a brief key note in address. Dr Gemeda reflected well enough the need of striving the existing strategic plan of the association by aligning the strategic priorities and objectives with the current realities in the laboratory medicine as well as with ministry’s health sector transformation plan to help EMLA contribute to the maintenance of health and disease control. Dr Gemeda also explained about how to approach to strive for the next five years with workshop goals and expectations.

Mr Gizachew Tadesses, Executive Director of EMLA, in his part presented an overview presentation on ‘How to Write a Strategic Management Plan’ that will clearly clarify EMLA’s organizational businesses and directions so as to help EMLA discharge its scientific, social and corporate responsibilities to our nations.

The workshop was approached with brainstorming discussion on the first version SPM followed by working stream group writing exercise on each pre-established strategic priorities. The inputs from the workshop helped to enrich the SPM document. The workshop was attended by 23 senior experts invited from Universities, Research Institutes, Donors and Regional Research Laboratories.

EMLA AND PHSP ESCALATED SHOPS MASTER GRANT AGREEMENT

It has been recalled that EMLA is a sub-recipient of FoG from PHSP since 2016. The purpose of the previous Master Grant Agreement Modification is to extend the period of performance and to increase the total possible funding opportunities to EMLA. In this agreement, PHSP will closely work with EMLA to support its engagement in tasks of enhancing quality and accessibility of healthcare services in the private sector through administration and provisions of trainings and seminars for laboratory professionals, supporting laboratory capacity building and accreditation with SLMTA program and laboratory mentoring and supportive supervisions. PHSP will also continue support EMLA to ensure that it has necessary organizational systems in place that will ensure it operational sustainability. The basic rationale for continuing the provision of support to EMLA is to strengthen the efficiency of the association as EMLA is promoter of the private health sector and quality health services in private facilities.
Pictures from EMLA’s Annual Conference Photo Gallery

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Plasma—The Preferred Sample Type for Clinical Chemistry Testing?

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Advances in medicine in the 17th century provided the foundation for diagnostic laboratory testing. The discovery of the circulation of blood by William Harvey and subsequent development of procedures to withdraw blood from a patient's vein for therapeutic purposes have enabled physicians to utilize blood to detect and monitor disease. Today, laboratory medicine remains as an integral component of patient care. An estimated 60-70% of medical decisions are based on the results from laboratory testing. Therefore, timely receipt of test results may enable more rapid diagnosis and treatment, which can impact patient outcomes. Yet, laboratory test turnaround time (TAT) has been cited as a primary source of dissatisfaction among physicians and nurses. In surveys conducted by the College of American Pathologists involving physicians and nurses from 138 and 182 institutions, respectively, satisfaction with TAT received below average ratings. Many physicians believed that laboratory TAT caused delays in treatment in the Emergency Department (ED) (42.9%) as well as increased the length of stay in the ED more than 50% of the time (61.4%).

As such, improving turnaround time has become a key barometer of laboratory performance and an addition to quality improvement initiatives in hospitals and institutions. To meet these objectives, laboratories may consider utilizing plasma instead of serum for clinical chemistry testing.

Why Plasma?

While serum has typically been used for clinical chemistry testing due to the ability to test a wide range of assays, it may compromise the time to test receipt due to the required clotting (generally ranging from 30-60 minutes). The clotting time for patients on anticoagulant therapy may be longer. Serum is also subject to latent fibrin formation when clotting is inadequate or may be present in samples from patients receiving anticoagulant or thrombolytic therapy. Fibrin, which may range from thin strands to large cloud-like masses, may be caused by inadequate tube mixing or incomplete or delayed clotting. It may also contribute to obstruction of the sample probe in automated instruments and subsequent instrument downtime.

Plasma offers distinct advantages over serum. Plasma—the liquid component of blood—contains blood cells and anticoagulant following centrifugation of whole blood. Heparin is the most commonly used anticoagulant in plasma, which acts primarily through a complex that it forms with anti-thrombin III, a protein that helps to control blood clotting. It also prevents the formation of fibrin from fibrinogen.

Conversely, clotting is not required for plasma; enabling plasma to be centrifuged upon receipt of the specimen in the laboratory. Specimens can be processed more quickly, shortening the turnaround time for test results. There is a potentially higher sample volume yield with plasma, with approximately 15-20% more plasma obtainable from whole blood than with serum. This helps laboratories to adhere to ISO standard 15189, in which laboratories should periodically review sample volume requirements to ensure that excessive amounts of blood samples are not collected. In addition, interference due to coagulation is eliminated, as coagulation post
centrifugation does not occur in plasma. There is also a lower risk of hemolysis and thrombocytolysis. In a healthy population, free hemoglobin is about 10 times less concentrated in plasma than in serum. In anticoagulated blood, there is no obstruction to upward gel movement; therefore, the time required for gel to complete its upward course is generally shorter with plasma tubes. This may result in more reproducible gel barrier formation.

Most significantly, it is imperative that the in vivo state of a constituent remains unchanged after withdrawal from the body fluid of a patient. Constituents in plasma are more accurately representative of the in vivo status of the patient than those in serum.

Assay Compatibility – the “True” In Vivo State

Generally, most assays in clinical chemistry are compatible with both serum and heparin plasma, enabling the same reference ranges to be used. However, for certain assays or test methods, both serum or plasma may not be acceptable or differences in results obtained in plasma specimens may warrant a change in reference range. For instance, glucose concentrations were noted to be 5% higher in serum than plasma as a result of fluid shift from erythrocytes to plasma due to anticoagulants. In addition, potassium and phosphorus levels may be increased in serum due to release from cells/platelets during the clotting process. Pseudohyperkalemia has been found over the level of 5.5 mmol/L in patients with essential thrombocythemia and serious thrombocytosis. This appears to have been corrected when measured in plasma. Insufficient clotting of serum specimens and fibrin formation within the analyzer reaction vessel may lead to erroneous follicle stimulating hormone results, with the presence of microclots shown to impact lactate dehydrogenase.

The faster processing time with heparinized plasma samples is preferable when urgent critical decisions are based on STAT test results (e.g. for patients suspected to have an acute myocardial infarction). In clinical studies, cardiac markers Troponin T and Troponin I have shown clinically equivalent or clinically acceptable values in both serum and plasma, although one study showed falsely elevated Troponin I due to fibrin in serum samples. Both Creatine Kinase-MB and Myoglobin have demonstrated clinically equivalent results using both specimen types.

While the benefits of plasma have been discussed, it is important for laboratories to consider the limitations. The presence of anticoagulants may interfere with some analytical methods. A slight increase in total protein may be seen in plasma as a result of fibrinogen. Differences in some enzymes (lactate dehydrogenase, alkaline phosphatase, aspartate aminotransferase) may be present in plasma. In addition, high levels of lithium and sodium may be observed due to contamination with cations from the anticoagulants. For samples collected in plasma gel tubes, rapid gel barrier movement may trap cellular debris and platelets in the plasma compartment prior to complete separation, which may compromise sample purity. It is important to note that variations may depend on specimen handling and processing as well as the assay platform and manufacturer.

Conclusion
Plasma specimens offer the best opportunity for achieving desired turnaround time, which may help laboratories in their performance improvement goals. Faster turnaround of results is particularly vital for STAT testing, in which rapid decisions are necessary for critically ill patients. Additionally, plasma more accurately reflects the patient’s in vivo state and provides a higher volume yield from the sample.
While standardizing the laboratory for one sample type may be desirable, it may not always be practical. Therefore, laboratory professionals should assess each specimen type to determine the most suitable for a particular clinical setting or patient population. It also important to follow established protocols in the laboratory and the appropriate reference ranges for each assay.

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REFERENCES
15. White paper – Comparison of the BD Vacutainer® Rapid Serum Tube with BD Hemogard™ Closure with the BD Vacutainer® PST™ II Tube for Cardiac Markers on the Roche Modular E170 and Abbott Architect i1000SR. Data on file at BD.
Professional Oath

- I Solemnly pledge myself to consecrate my life to the service of humanity
- I will preserve the dignity and privacy of patients and others
- I will lead my life and practice my profession in uprightness and honor
- I will exercise my profession solely for the benefit of humanity and perform no act for a criminal purpose
- I will be loyal to the profession of medical laboratory science
- I will maintain and promote standards of excellence in performing and advancing the art and science of medical laboratory technology
- I will seek to establish a cooperative and respectful working relationship with other health professionals

I make these promises solemnly, freely, and upon my honor

Taken from Code of Ethics for Medical Laboratory Technologists Practicing in Ethiopia, Ethiopian Medical Laboratory Association (EMLA) May, 2008

The principles of doing ‘good’ and not doing ‘harm’ are the essence of every code of Medical ethics!
“Remember the patient is the reason, and the only reason for our professional existence: In order for a patient to receive the best care possible, we must make proper diagnosis”

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