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MEMBERS NEWS
Keeping you updated!
Special focus on laboratory quality

Why have "Quality" in Laboratories?

Empirical, laboratory-generated data are indispensable for worldwide disease surveillance, for informing healthcare policy development, and for diagnostic decision-making for many diseases, including the major infectious diseases, such as tuberculosis, HIV/AIDS and malaria. However, the medical laboratory sector has long been a neglected component of the healthcare systems in low- and middle-income countries (LMIC). As a consequence, many laboratories in LMIC operate without meeting international standards. They perform at sub-standard levels leading to problems with responding appropriately to public health events of national or international concern.

Fortunately, the value of the laboratory in health systems is increasingly being recognized. Consequently, the availability of funding, resources and assistance for laboratory strengthening initiatives have been increasing over the past five years.

Generally, the best laboratory strengthening method is considered to be the implementation of a quality management system according to ISO 15189, the international quality standard for medical laboratories. A quality management system enables a laboratory to continuously assure the quality of its results and services. However, the implementation of this system is often a challenging task.

As the ISO 15189 standard only states the requirements for a quality management system and provides no further information with regard to understanding quality and the implementation of a quality management system, various guidelines and educational sessions have been developed. Although these provide insight into the basic elements of

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quality management, they do not provide guidance for day-to-day implementation of a quality management system. As such, laboratories face obstacles as to where to start with the implementation of the quality management system, what to do next and how to translate specific ISO 15189 requirements into systems and processes that are optimally integrated in routine laboratory processes. To address this issue, the WHO published in January 2014 the Laboratory Quality Stepwise Implementation (LQSI) tool.

Tjeerd Datema, KIT Biomedical Research, Royal Tropical Institute (KIT), Amsterdam, (Netherlands)

LQSI: a tool to enhance quality in your laboratory

In January 2014, the WHO published the Laboratory Quality Stepwise Implementation (LQSI) tool (see: https://extranet.who.int/lqsi/). The tool was developed for the WHO by the Royal Tropical Institute of the Netherlands, a designated WHO Collaborating Center for Laboratory Strengthening. It meets the criteria of being accessible and available to anyone free of charge.

The LQSI is a practical guidance tool in the form of a website that provides a stepwise plan to guide medical laboratories towards implementing a quality management system in compliance with ISO 15189. The individual steps - or 'activities' - of this plan are presented in roadmaps in a suggested order for day-to-day implementation. Each activity is divided into three sections comprising a description of why something should be done; what should exactly be done; and how it should be done by whom. The different steps build up to the twelve quality system essentials. Next, the LQSI tool divides the implementation of a quality management system into four phases with each phase having a specific focus:

- Phase 1: Ensuring that the primary process of the laboratory operates correctly and safely
- Phase 2: Controlling and assuring quality and creating traceability
- Phase 3: Ensuring proper management, leadership and organization
- Phase 4: Creating continuous improvement and preparing for accreditation

One phase builds upon the activities of the previous phase. However, it is not strictly necessary to adhere to this framework. For example, following an assessment, a laboratory may find that it has already completed some activities from Phase 3 while still needing to implement activities from Phase 1. Or, in a different approach, a laboratory may prefer to focus on one of the twelve quality system essentials at a time, such as document management, before commencing work on other aspects of the quality management system.

The LQSI tool also has a feature that allows users to make their own comprehensive checklists based on the focus and purpose of the assessments they are planning to perform. With this, the user can verify correct and complete implementation of the LQSI tool activities in a specific area of the laboratory.

Designed as a practical guide, as opposed to a theoretical one, the LQSI contains many useful documents available on the different pages of the website. There are, for example, publications with in-depth information on a topic, sections from the WHO Laboratory Quality Management System handbook for further reading on the twelve quality essentials, as well as many templates that can be adapted for use by any laboratory.
A key supporting document is the template for a laboratory quality manual.

To overcome the issue of poor internet connectivity, users can request a copy of the tool for offline use. The download versions include all supporting documents available on the web site, such as reading material and templates. Furthermore, the individual pages of the LQSI can be printed or saved as a PDF file.

Uptake of the tool appears to be strong. Using data taken from the requests for download versions, the tool appears to be utilized in high-income developed countries as well as in low- and middle-income countries. The fact that the tool follows an international standard gives it universal relevance. As one reviewer of the tool stated, “It will have a truly global use and many will benefit from it, including Western countries”.

The tool is currently available only in English, but plans are underway to offer it in other official WHO languages, including Russian, French, and Spanish.

Katrina Roper, WHO, Lyon (France)

Interview with Dr. Alex Costa

Dr. Alex Costa is a technical officer at the World Health Organization in Cambodia where he is the focal point for laboratory diagnostics and antimicrobial resistance (AMR).

He was the director of the Laboratory program for the Clinton Health Access Initiative in Liberia, West Africa, where he supported the establishment of a national laboratory diagnostics program. He has been working in Cambodia since 2011, in coordination and collaboration with other countries in the region, to strengthen laboratory diagnostics for clinical management, surveillance, preparedness, and outbreak response.

You have been working in Cambodia for 3 years. What is the current stage of development of the clinical laboratory system?

As in other countries in the region, laboratory services in Cambodia were, until recently, given low priority in the development of the health sector. As a result, resources have

been inadequate, and funding has mostly focused on improving laboratory services for specific disease-control programs (e.g. HIV/AIDS, malaria, and tuberculosis). This has contributed to fragmentation and increased inequalities in the laboratory system.

The Sub-technical Working Group for Blood Safety and Laboratory Services established in 2006 and the Bureau of Medical Laboratory Services established in the Ministry of Health in 2008 provide support and oversight for implementation of the National Policy for Medical Laboratory Services (2009) and the National Strategic Plan for Medical Laboratory Services (2010-2015).

Strengthening laboratory capacity in Cambodia, particularly in the detection of priority pathogens of concern for public health, is a priority for the government and partners, since Cambodia is located in one of the regions showing the highest risk of emerging pathogens with pandemic potential. In recent years, Cambodia has made significant progress in a number of areas in clinical laboratory diagnostics. These include the development and implementation of an electronic laboratory information system, development of national laboratory quality standards, implementation of an External Quality Assurance (EQA) program, establishment of a national laboratory network, and strengthening of microbiology diagnostic capacity nationwide.

What challenges do you face?

The following are some of the most significant challenges facing the laboratory system in Cambodia:

- Weak regulations and limited enforcement of existing regulations
- Fragmentation of efforts to strengthen laboratory diagnostics
- Low laboratory biosafety standards
- Limited laboratory quality management
- Irregular provision of laboratory supplies
- Limited maintenance of laboratory equipment
- Inefficient use of laboratory data for clinical management and surveillance
- Low competency levels of laboratory staff

Why was a quality program based on ISO 15189 created in Cambodia? What guidance did you find to implement it?

Laboratory quality management is essential to ensure the accurate, reliable, and timely provision of laboratory results. ISO 15189 specifies particular requirements for quality and competence of medical laboratories. It provides guidance for laboratory quality management and technical processes to ensure quality in medical laboratory examinations. Although other organizational and laboratory standards are available, ISO 15189 offers the most comprehensive set of standards specific to medical laboratories and applicable to all currently recognized disciplines of medical laboratory services.

Implementation of ISO 15189 can be very challenging, resource-intense and time-consuming. As a result, several organizations have developed tools

(e.g., SLMTA (Strengthening Laboratory Management Towards Accreditation), GLI (Global Laboratory Initiative),…) to facilitate the implementation of Laboratory Quality Management Systems (LQMS) based on ISO 15189 standards. The latest tool is Laboratory Quality Stepwise Implementation (LQSI), presented as a website.

Although some laboratories in Cambodia had already started implementation of SLMTA, the widespread need for a LQMS in laboratories across the country, coupled with limited availability of resources to expand SLMTA, led the government to also adopt LQSI. Both tools have similar requirements and use complementary approaches to implement ISO 15189 in a stepwise manner.

How was the program launched in Cambodia?

The program was first piloted in Cambodia in 2013 on a very small scale, but it was only recently that a partner organization (International Training and Education for Health (I-TECH)) has taken over the role of leading LQSI implementation in reference and referral laboratories. The program was launched through a 5-day workshop that was attended by national leaders in the Ministry of Health, provincial leaders in the health sector, hospital directors and the laboratory directors and biosafety officers they supervise. The contribution of national, provincial, and hospital leaders improved their understanding of the program and its objectives, and ensured political support for implementation of the LQSI in laboratories.
LQSI implementation is supported by laboratory quality mentors through in-service mentorship. In Cambodia, laboratory quality mentors rotate regularly through laboratories implementing the LQSI to provide technical support and mentorship and to monitor progress using checklists taken from the LQSI tool and adapted to Cambodia.

To measure the impact of the program, baseline data was collected as part of a comprehensive assessment of the national laboratory system, which included laboratory facilities selected for implementation of the LQSI. The assessment was performed using the WHO Laboratory Assessment Tool adapted to Cambodia through the collective efforts of various stakeholders working in the laboratory system in Cambodia. The assessment also involved theoretical and practical training of local laboratory assessors, who build local capacity and effectively monitor the impact of LQSI implementation.

Fondation Mérieux's Quality Initiative

Laos

Reinforcing the quality and accessibility of diagnosis is one of Fondation Mérieux's main objectives. The development of quality in clinical laboratories is part of the foundation's strategic plan for 2015. The Fondation Mérieux Quality Initiative was therefore launched in January 2014 to meet ISO 15189 accreditation requirements and to help laboratories reach those standards.

Haiti

Several tools, one mission: quality improvement

Auto-evaluation for GABRIEL members: A specific tool for this has been created in collaboration with Fiocruz, Brazil.

It is a web-based questionnaire that covers the different aspects of a quality program: Organization, Documentation, Non conformity and Audit, Reagents and Supplies, EQA, Equipment and Training.

The tool will enable GABRIEL members to periodically evaluate the quality of their laboratory procedures to monitor their own progress in reaching ISO standards.

Moreover, this tool will help to provide an overview of the quality system implemented by GABRIEL members to achieve ISO 15189 accreditation.

Paraguay

ISO 15189 quality initiative: The first step of this initiative is an assessment of the laboratory. The LQSI tool has been adapted by IQLS (http://www.iqls.net/) into an MS Excel spreadsheet with a modular structure. Each sheet is linked with one of the quality system essentials (QSE). Automated indicator calculations include tables with the module and the scores for each phase.

Based on this assessment, gaps are identified and a plan is proposed to monitor performance.

Four pilot sites have been selected to be part of this initiative: the Christophe Mérieux Infectiology Center in Laos, the Charles Mérieux Infectiology Center in Mali, the Rodolphe Mérieux Laboratory at the GHESKIO Centers in Haiti, and the Molecular Biology and Genetics Department of the Instituto de Investigaciones en Ciencias de la Salud (National University of Asunción) in Paraguay.

The laboratories were selected based on the following factors:

- Keen to develop or reinforce their quality program
- Representing a very wide range of organizational structures, such as an administratively independent laboratory, or an institutional laboratory
- Conducting very different types of activities, ranging from clinical diagnostics, to research in public health

Charles Mérieux Infectiology Centre of Mali

At each site, a 4 to 5 day audit was performed. The resulting audit report was reviewed with the laboratory staff, and depending on the time available, a road map was established and discussed with them.

The above laboratories will follow each step of the Quality Initiative to achieve ISO 15189 accreditation.

Nicolas Steenkeste, Fondation Mérieux, Lyon (France) and Arnaud Orelle, IQLS, Lyon (France)

Interview with Pr Souleymane Diallo

Professor Souleymane Diallo, PharmD, MSc, Director of the Charles Mérieux Infectiology Center (CICM) in Bamako, Mali, previously headed the Gabriel Touré University Hospital Laboratory and worked at the Research Laboratory of the Center for Vaccine Development (CVD) in Bamako, in collaboration with the Center for Vaccine Development in Baltimore, MD in the United States.

How do you view the role of a quality assurance program for laboratories in developing countries?

A quality assurance program for laboratories in developing countries must raise awareness among decision-makers and all laboratory professionals that quality is imperative at all levels. A quality assurance program must satisfy the needs of lab professionals, practitioners, decision-makers, and patients, who will benefit from improved diagnosis and treatment monitoring for better care.

In addition, the role of a quality assurance program is to have all of a country's laboratories agree to internal and external quality assessments.

A quality assurance program must also demonstrate that it is cost-efficient.

How has the subject of quality been approached at CICM?

The issue of quality has been a hot topic at the Charles Mérieux Infectiology Center in Bamako from the start.

One quality assurance program, the National Quality Plan of Mali, was put in effect from 2007 to 2009 along with quality training. In 2009, the heads of the laboratory in Mali were educated about and made aware of ISO 15189. We now have available the Guide to Proper Performance of Medical Laboratory Analyses.

At the CICM, we have shown that quality is our business. We want our laboratory, the Rodolphe Mérieux Laboratory, to be accredited. It was recorded as one of our priorities in the report of the 3rd CICM Board of Directors meeting, held November 27, 2013.

Our staff is now aware of the 3-year accreditation plan of the West African Economic and Monetary Union (UEMOA) and of the French Committee for Laboratory Accreditation's (COFRAC) 2015 plan.

The head of the laboratory has been sent to Dakar, Senegal, to be trained on the implementation of Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA).
The laboratory has recently been reshuffled

with the appointment of Department Heads in Microbiology, Biochemistry, Hematology, Sero-Immunology, plus a Manager for Quality, a Manager for Health and Safety, and a Lab Manager.

Some of our accomplishments:

- SOPs have been updated, validated, and are being monitored.
- The departments Hematology, Hemostasis, and Biochemistry have recently agreed to have quality assessments. Reference strains have been ordered and steps are being taken for them to go through an external quality assessment in conjunction with a partner laboratory.
- External quality assessments are being conducted in the areas of biochemistry, HIV serology, and the HAIN mycobacteria test through the GABRIEL network.
- Our laboratory has carried out quality control on HIV DBS (dry blood spot) samples as part of the CDC's Demographic and Health Survey in Mali (IV and V).

How long has the CICM been running its quality assurance program?

What were the difficulties in setting it up?

We can say that the quality assurance process was initiated at the start of operations in 2005. For two years, the Rodolphe Mérieux Laboratory has been working toward accreditation.

Practitioners and customers believe in us. This must be supported by international recognition that can only be obtained through accreditation.

As for the difficulties, they are mainly related to the turnover of trained personnel, both managers and technicians.

The lack of specialists for the maintenance of equipment is also a major problem, as is the shortage of space, which makes our facilities unsuitable for some of the operations in clinical biology.

What would be your advice to laboratories wishing to set up quality assurance?

There needs to be a clear vision of what we are striving to achieve, and above all a commitment from the personnel.

How is quality within your own structure perceived by your staff?

Everyone agrees that quality is a good thing, but also that there is still much to do and significant effort and organization are required.

Concerning quality, what are your short- and long-term goals?

We will pursue the activities validated by the auditors, and move forward with the corrective actions and recommendations made in their report.

Our reference is the ISO 15189 standard and we will do whatever is required to become accredited.

In the meantime, we realize it is always a matter of educating and informing our staff,

of training them and motivating them as best we can. We must share all of this with Malian officials and our partners, and especially with the initiator of this program, Fondation Mérieux.

Looking ahead, Mali needs to have the Rodolphe Mérieux Laboratory accredited and have it qualified as a reference laboratory; keeping in mind that we are also a nationally- and internationally-approved training center.

Certification, accreditation and standards for laboratories

ISO 15189 is an internationally-recognized quality standard specifically applicable to medical laboratories. It is centered on its two main chapters: Chapter 4, "Management Requirements" and Chapter 5, "Technical Requirements". Its application is mandatory for all medical laboratories wishing to practice in France.

The purpose of this reference standard of good practices is to assure that quality services are provided to customers, patients, and practitioners in terms of hospitality, care, ethics, advice in biological testing by practitioners, as well as timeliness and interpretation of results.

As a true indicator of the quality of an accredited laboratory for our customers (both patients and practitioners), the application of ISO 15189 can improve our professional skills by enhancing the competencies of staff, the management of equipment, the relationships with suppliers, the evaluation of environmental factors, the expertise in running IT systems, and finally, the control over the factors that have a bearing on the quality and reliability of results.

The application of this approach in a laboratory setting raises some questions:

- What are the needs of my customers?
- Which technical skills are available to me?
- What equipment do I have access to?
- What risks have I identified?
- Are my test results reliable?
- What checks are in place?
- Are my customers satisfied?

Even though at times its vocabulary may be hard to grasp, ISO 15189 is a common-sense guide that urges laboratories to review their performance in terms of the needs of their customers (patients and practitioners) and in relation to other laboratories through accreditation evaluations.

In France, accreditations are issued by COFRAC (French Committee for Laboratory Accreditation) through an audit conducted annually by a quality expert evaluator and a technical reviewer (a biologist specialized in analytical review). These auditors check the adequacy of and compliance with accreditation requirements of the organizational and technical procedures set out by the laboratory, the effective implementation of these procedures, the adequacy of resources to carry out lab tests lying within the scope of accreditation, and the skill sets of lab personnel running these tests.

An evaluation is based on a thorough review

of laboratory records, interviews with staff, testing of the traceability of documentation of lab results, analysis of the life history of quality practices (internal audit reports, reports of system reviews, records of corrective and preventive actions, waivers, claims, etc.), feedback on the performance of all or some of the accreditation activities and on participation in inter-laboratory benchmarking of their processes.

Other internationally-recognized standards may apply to medical laboratories, such as ISO 17025 or ISO 9001. ISO 17025 is not a standard specifically applicable to medical laboratories, but rather is designed for the analytical and testing laboratories whose requirements are much more stringent with regards to measurements and metrology: two areas that are not main activities in medical laboratories and that do not contribute to patient care.

Fulfilling an ISO 9001 standard leads to certification and not to accreditation. This means that unless a medical laboratory is accredited, its technical expertise is not officially established. However, the ISO 9001 standard can nevertheless be used by a laboratory to set up a quality system without performance requirements.

Finally, other regulations have come into force in some countries like the United States, where CLIA (Clinical Laboratory Improvement Amendments) standard requirements are much less demanding than those of ISO 15189 and not directed towards patients and practitioners. ISO 15189 is currently the best model for building a comprehensive and consistent quality approach both for the management and technical performance of a laboratory and for the benefit of patients and practitioners.

Pauline Savy and Catherine Blacker, AFNOR (France)

Interesting reading on quality

- LQSI: https://extranet.who.int/lqsi/
- Laboratory Quality Management System Training Toolkit:
  EN: http://www.who.int/ihr/training/laboratory_quality/doc/en/
  FR: http://www.who.int/ihr/training/laboratory_quality/doc/fr/
- E-learning on Quality Assurance (FR): http://www.globe-network.org/en/biology/e-learning/modules/quality-assurance-biology-laboratory
- Laboratory quality management system handbook :
  EN: http://www.who.int/ihr/publications/lqms/en/
  FR: http://www.who.int/ihr/publications/lqms/fr/
- http://www.iso.org/
- Laboratory Biosafety Manual - Third Edition:
  EN: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en
  FR: http://www.who.int/csr/resources/publications/biosafety/LabBiosMan3rdFrenchweb.pdf
- Laboratory Biosafety Guidelines (Canada) – Third Edition:
  EN: http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/index-eng.php
  FR: http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/index-fra.php
- Tuberculosis Biosafety Manual (EN/FR/ SP/

PT/RU/CH): http://www.who.int/tb/publications/2012/tb_biosafety/en/

- Laboratory biosecurity guidance (WHO), Biorisk management: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/
- WHO/NICD Microbiology External Quality Assessment Programme in Africa (EN): http://whqlibdoc.who.int/hq/2007/who_cds_epr_lyo_2007.3_eng.pdf
- Quality Manual template (WHO) :
  EN: http://www.who.int/ihr/training/laboratory_quality/quality_manual/en/
  FR: http://www.who.int/ihr/training/laboratory_quality/quality_manual/fr/
- E-learning on Biosecurity and management of biomedical waste (FR): http://www.globe-network.org/en/biology/e-learning/modules/biosecurity-and-management-biomedical-waste
- Maintenance manual for laboratory equipment:
  EN: http://apps.who.int/iris/bitstream/10665/43835/1/9789241596350_chapters1-9_eng.pdf?ua=1
  FR: http://apps.who.int/iris/bitstream/10665/43991/1/9789242596359_fre.pdf?ua=1
- E-learning on Preventive maintenance of laboratory equipment: http://www.globe-network.org/en/biology/e-learning/modules/preventive-maintenance-laboratory-equipment

We would like to thank all of the authors for their contribution to this special edition of the GABRIEL newsletter focused on Quality.

Applications Open for the Chaire Docteurs Mérieux

The Chaire Docteurs Mérieux enables a French laboratory to host a high-level lecturer-researcher, working in a developing country on research in the fields of infectious disease or zoonoses.

It was created in 2012 by **the French National Academy of Medicine, the French Academy of Sciences and Institut de France with Fondation Christophe et Rodolphe Mérieux**. The first chairholder was Professor Ogobaro Doumbo, Director of the Malaria Research and Training Center of Mali, who was hosted by Professor Didier Raoult's department in Marseille (France).

The Chaire Docteurs Mérieux is funded by Fondation Christophe et Rodolphe Mérieux, which covers the costs of travel and salary for the researcher during the 8 months of his or her stay in France for the Chair.

Applications must be submitted by November 30, 2014. For more information, please contact Marilyne Mériaux:

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