Approaches to improving laboratory quality

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Levels of quality implementation

**Quality management:** coordinated activities to direct and control an organization with regard to quality activities and techniques to achieve and maintain the quality of a product, process or service.

**Quality system:** the organizational structure, resources, processes and procedures

**Quality assurance:** prevention of quality problems through planned and systematic activities around processes

**Quality control:** steps taken during the generation of a product or service to ensure product/service quality.
**Licensing, certification and accreditation**

**Licensing:**
issued by authorities, to allow an *activity* that would otherwise be forbidden. It may require proving a capability.

**Certification:**
confirmation of certain *characteristics* of an organization. This confirmation is often provided by external assessment.

**Accreditation:**
process in which certification of *competency*, authority, or credibility is presented.
National laboratory policy and strategic plan development

- Sign of political commitment
- Provides direction
- Provides criteria for accepting or refusing activities
- Makes sure the country is in the driving seat
- Essential for developing sustainability
**Education**

- A well-trained workforce with up to date knowledge is essential for well-functioning laboratories
  - Pre-service training should reflect daily practice
  - In-service for refresher or additional knowledge

- Training epidemic, but quality of trainings is variable
- National laboratory policy can give direction to education development
- Implementation of a QMS means laboratory decides training needs
Management and leadership skills

- Most laboratory managers have technical background, not managerial background
- Management and leadership skills are crucial

Management training initiatives:
- SLMTA (Strengthening Laboratory Management Towards Accreditation)
- LQMS (Laboratory Quality Management System Training)
- WHO Leadership Course for Laboratory Directors
Proving your quality: Accreditation

- Laboratory testing is increasingly recognized as being crucial for diagnosis, treatment, screening and public health

- Laboratories want to provide reliable results
- Clients want to be certain of the results they get
- Funding agencies want to know that there is no waste of resources

The most widely used accreditation scheme for medical laboratories is ISO 15189: Medical laboratories — Particular requirements for quality and competence

Before

After

Uganda NTRL accreditation process
2008-2013
**Needs in establishing a Quality Management System**

**PROBLEM:** Standards don’t provide (daily) guidance on implementing requirements

- Standard requirements translated into activities
- Explanation on why and how and when to carry out activities
- Examples of documents, background information on quality management aspects, etc.

**No laboratory should have to reinvent the wheel.**
GLI tool

The Global Laboratory Initiative has developed the “Stepwise Process towards TB Laboratory Accreditation”

• Online tool

• Designed to guide National TB Laboratories to ISO 15189:2007 accreditation (soon to be updated to ISO 15189:2012)

• Translation of complete ISO 15189 into activities
  • Divided over 4 phases of implementation with each phase having a specific focus
  • Supplemented with descriptions on the why and how
  • Links to additional materials (TB CAP, SLMTA, LQMS)
  • Checklists for monitoring progress
**GLI tool – 4 phases**

1. Assure technical competency of testing performed.
2. Implement quality control measures and create traceability.
3. Establish the policy cycle with proper management, leadership and planning.
4. Create continuous improvement and accumulate quality evidence.
GLI tool

Available online at: www.GLIIquality.org

• Tool for ALL clinical and public health laboratories that want to achieve ISO 15189 accreditation

• Available mid-2013 in English
Laboratory network structure

ISO 15189

Most patients
Laboratory network evaluation

• Not for individual laboratories, but for laboratory networks
• Evaluates network management
• To ensure quality of all laboratories in the network
• Based on predefined standards
• John Ridderhof will present on microscopy network evaluation
Designing a tiered quality management system for different levels of laboratories

- ISO 15189 as the basis
- Identify and select the key elements (principles) of ISO 15189
  - Standardization
  - Competence
  - Traceability
  - Controls
  - Customer satisfaction
- Design activities and tools that are suitable for lower level laboratories
- For licensing or certification
Improving laboratory quality - summary

• National laboratory policies and strategic plans
• Well trained technical and managerial staff
• (National reference) laboratories striving for ISO 15189 accreditation
  • GLI tool
  • LQSI tool
• Network evaluation
• Tiered quality systems
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Examples of specific tools and activities

- Laboratory handbook
- Registration book
- Plastified work instructions
- Equipment logbooks
- Monthly work meetings
- Standardized statistics with interpretation tool
Accreditation or certification?

• Each laboratory individually or laboratory networks?
• According to a national or international standard?
• Accreditation:
  • Only by official accreditation body, member of ILAC
• Certification:
  • By national body
Creating advantages of accreditation or certification

- License
- Payment by insurance
- Inclusion in social franchising schemes
- Rebates on consumables/tests from national medical stores
- Additional training possibilities