Accreditation of TB diagnostic laboratories and services: the way forward

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Quality of labs is essential in health laboratories and health care systems

• Reliable results by laboratories improve the decision making capacity of the clinicians/health workers as well as public health authorities.

• The consequences of poor quality are serious: inappropriate treatment, investigation and responses.

• Quality can only be assured by a well-defined QS, as part of an overall quality management aimed at ensuring consistency, reproducibility, traceability and efficacy of the products and services.

Seventy percent of clinical medicine decision making is predicated upon, or confirmed by, or documented by medical laboratory test results (Dighe AS et al. Semin Diagn Pathol. 2007 May;24(2):98-107).
The Maputo Declaration on Strengthening of Laboratory Systems

We, representatives of governments, multilateral agencies, development partners, professional associations, and academic institutions, participated in a Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization in Maputo, Mozambique, on 22nd - 24th January 2008. The meeting sought to address laboratory challenges that limit the scale-up of services for tuberculosis, malaria and HIV diagnosis and care.
Need for recognized quality assured services

There is a need to develop a laboratory systems approach, with a focus on quality systems and standards to achieve the common goals of quality patient care and public health programs.

Programs gain through a shared system approach

*Picture: PP Lyon April 7th 2008;*
GLI Strategic Priorities

• Establish GLI partnership projects
• Develop templates for country-specific roadmaps for laboratory strengthening
• Develop human resource strategies
• Develop appropriate and adequate laboratory biosafety standards
• Develop a process for the accreditation of labs or sections of labs that do TB testing
• Move new diagnostics into countries
GLI approach to TB Lab Accreditation

IUATLD workgroup led by GLI tasked with:

- reviewing existing documents on TB lab accreditation
- developing consensus on a quality system element (QSE) framework
  - defining QSEs for TB labs performing microscopy, culture/DST, and molecular tests
  - defining QSEs for TB lab networks
- developing roadmaps, checklists, and resources for accrediting/certifying TB labs/networks
## Comparison of 11 international QM standards

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<tbody>
<tr>
<td>GLP [FDA]</td>
<td>GLP</td>
<td>GLP</td>
<td>ISO 9001º</td>
<td>CLSI GP26b</td>
<td>ISO 15189:2007</td>
<td>CLSI HSI¹</td>
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- **Organization**: + = Present, - = Not Present
- **Personnel**: + = Present, - = Not Present
- **Equipment**: + = Present, - = Not Present
- **Purchasing & inventory**: + = Present, - = Not Present
- **Process control QC & specimen management**: + = Present, - = Not Present
- **Information management**: + = Present, - = Not Present
- **Documents & records**: + = Present, - = Not Present
- **Occurrence management**: + = Present, - = Not Present
- **Assessment**: + = Present, - = Not Present
- **Process improvement**: + = Present, - = Not Present
- **Customer service**: + = Present, - = Not Present
- **Facilities & safety**: + = Present, - = Not Present
<table>
<thead>
<tr>
<th>The laboratory</th>
<th>The work</th>
<th>Measurement</th>
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<td><strong>Pre-analytical</strong></td>
<td><strong>Analytical</strong></td>
<td><strong>Post-Analytical</strong></td>
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<td>Organization</td>
<td>Process Control</td>
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<td>Facilities and Safety</td>
<td>Documents and Records</td>
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<td>Equipment</td>
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<td>Purchasing and Inventory</td>
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**AFRO and CLSI - similar headings**

<table>
<thead>
<tr>
<th>Organization and Personnel</th>
<th>Process Control &amp; Internal and External Quality Assessment</th>
<th>Occurrence Management &amp; Process Improvement</th>
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</table>

**CLSI Assessments**

**AFRO**

- Organization and Personnel
- Process Control & Internal and External Quality Assessment

- Occurrence/Incidence Management & Process Improvement

**Management Reviews**

**Internal audit**

**Internal & External Quality assessment**

**Corrective action**
## WHO AFRO tiered QM system

<table>
<thead>
<tr>
<th>Category</th>
<th>WHO-AFRO Category</th>
<th>Max. points</th>
<th>Points (%)</th>
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<tbody>
<tr>
<td><strong>Inputs</strong></td>
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</tr>
<tr>
<td></td>
<td>3. Organization &amp; Personnel</td>
<td>20</td>
<td>120 (48)</td>
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<td></td>
<td>5. Equipment</td>
<td>30</td>
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<td></td>
<td>7. Purchasing &amp; inventory</td>
<td>30</td>
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<td>12. Facilities &amp; safety</td>
<td>40</td>
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<tr>
<td><strong>Process</strong></td>
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<td></td>
<td>1. Documents &amp; records</td>
<td>25</td>
<td>82 (33)</td>
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<td>8. Information management</td>
<td>14</td>
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<td></td>
<td>9. Process control &amp; IQA/EQA</td>
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<tr>
<td><strong>Assessment</strong></td>
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<td></td>
<td>2. Management reviews</td>
<td>12</td>
<td>48 (19)</td>
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<td></td>
<td>4. Client management &amp; customer service</td>
<td>8</td>
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<td></td>
<td>6. Internal audit</td>
<td>10</td>
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<td>10. Corrective action</td>
<td>8</td>
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<td></td>
<td>11. Occurrence management &amp; process improvement</td>
<td>10</td>
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We all are most comfortable with own habits
A desired result is achieved more efficiently when activities and related resources are managed as a process.
ISO 9001:2000 System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization’s effectiveness and efficiency in achieving its objectives.
Essential factors in quality management systems according to ISO15189

- ORGANIZATION
  - ORGANIZATIONAL CHART
  - GUIDELINES, PROCEDURES
  - ROLES AND RESPONSIBILITIES

- RESOURCE SYSTEMS
  - PERSONNEL
  - EQUIPMENT
  - SUPPLIES
  - FACILITY
  - FINANCE

- SUPPORT SYSTEMS
  - DOCUMENTS AND RECORDS
  - LAB INFO SYSTEM
  - PURCHASING AND INVENTORY
  - SAFETY

- QUALITY MANAGEMENT SYSTEMS
  - PROCESS CONTROL-IQ
  - OCCURRENCE MANAGEMENT
  - INTERNAL ASSESSMENT
  - EXTERNAL ASSESSMENT
  - EVALUATION AND CONTINUOUS IMPROVEMENT

- USER
  - Requirements
    - Care-Provider
    - Patient
  - Request
  - Pre to Post Examination Process
  - Report
  - Satisfaction or dissatisfaction

Amsterdam, The Netherlands  www.kit.nl
Many documents and tools available

• Roadmaps, guidelines, SOPs formats, training tool kits, roadmaps, checklists, etc.
Many documents and tools available

- Roadmaps, guidelines, SOPs formats, training tool kits, roadmaps, checklists, etc.

BUT:

- Operational translation of guidelines: where to start and how to proceed?
- Little attention to management aspects.
- Shortage of harmonization/standardization.
- Not always addressing TB specific needs.
Continual improvement of the quality management system

Customers (and other interested parties)

- Requirements
- Resource management
- Product realization

Management responsibility

Measurement, analysis and improvement

Product

Satisfaction

Input

Output
The Eight (8) Quality Management Principles

1. A Customer Focused Organization
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continual Improvement
7. Factual Approach to Decision-Making
8. Mutually Beneficial Supplier Relationships

ISO 9001-2000
What is still needed for accreditation of national reference laboratories?

- Coordination / harmonization with existing initiatives

- Defining the quality system elements/framework on basis of existing QS (ISO/CLSI/AFRO/CPA/Other)

- Specific TB guidelines for all elements
  - Translating standards into technical requirements for each category of TB diagnostic tests/service (ZN/FM, culture, DST, new molecular tests ...): most are available.
  - Translating standards into requirements for pre- and post-analytical processes: not all available; need adaptation to local situation.
  - Translating standards into requirements into TB-specific performance indicators and measures for continuous improvement.
What is still needed for accreditation of national reference laboratories? (2)

- Implementation guidelines with templates, formats, etc.
- Complement existing trainings especially with management and leadership training programmes.

In conclusion: making the toolbox complete!

- Define national notifying body endorsed by the MOH or use existing accreditation bodies (SANAS, CAP, etc.).
- Develop and offer a teaching module on laboratory quality for adaptation and implementation in country vocational curricula.
Quality Standards

• The available quality standards (like ISO 15189 or AFRO) are very resource/time demanding and not suited/needed for every level of laboratories in developing countries.

• Developing countries (through WHO/GLI?) should therefore develop minimal quality standards for their health laboratories adapted to their situation.
Certification needed for laboratories in TB laboratory networks: ensuring quality

Requirements specifically targeting the operation of microscopy labs

- Establish requirements for Organization and Management, and for each path of workflow described in detail in a quality manual;
- Format provided, details filled in at local level;
- District lab responsible for providing certification for the three main steps of the workflow (assessments by peer-review/quality circles).
- New test introductions only beneficial if basic Q requirements are met.
Franchising as a means of contracting diagnostic services

• Quality diagnostic services can be defined by objectively verifiable outputs and outcomes, but...
• ...quality systems should be adapted to reality of DC and take into account the role of private labs

• Franchising could offer:
  • Implementation of quality systems
  • Central purchase of (cheap) Dx tests and supplies (and thus prevent entrance of bad quality tests)
  • Central maintenance services
  • Connecting to insurance schemes (opening up new markets for the branded labs)
THANK YOU for your attention