TB laboratory performance indicators

to measure the effect of ISO 15189 QMS implementation

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Does a laboratory really improve?

Establishing a QMS costs a lot of resources in terms of time, efforts and money

(quality costs money, but no quality costs a fortune!)

The question is:

- What are the effects of establishment of a QMS on performance of laboratories?
Why measure the effect of QMS implementation?

- Effectiveness of the GLI tool in improving quality in laboratories ("the performance")

- Advocacy purposes
  - Internally (staff motivation, physicians, etc.)
  - Externally (government, sponsors, etc.)

- Research purposes
Methodology

- Two days workshop January 2012 at KIT in Amsterdam, The Netherlands (funded by TB Care)

- The workshop was attended by 12 participants representing SRL (Belgium), NTRL (Benin), CLSI, WHO, GLI, ACILT, CDC, CAREC, KNCV & KIT
Definition of laboratory performance

Laboratory performance is defined by what stakeholders of the laboratory perceive as important.

• Identification of all types of stakeholders of a laboratory.
• Determine for each stakeholder the most important element in laboratory performance.

Examples:
• For sponsor: cost-efficiency is most important aspect in laboratory performance.
• For patient: timeliness and correctness of results is most important aspect in laboratory performance.
• For staff: pleasant and safe working environment may be most important aspect in laboratory performance.
Stakeholders identified

Internal: Technical staff
Management
Support staff

External: Health care workers
Patients
Institutes/owners
Other laboratories
Authorities
Accreditation bodies
Payers & sponsors
Research & education
Industry as supplier
Topics

- Extent of implementing ISO 15189
- Access to adequate and safe facilities
- Ability to comply to regulations
- The analytical performance of the laboratory
- Staff competency
- Error reporting
- Work efficiency
- Guidance and education provided by the laboratory
- Timely and accurate results and reports
- Interruption of service
- Customer satisfaction
Output and outcome indicators

- 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

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

- USER
  - Requirements
    - Care-Provider
    - Patient
  - Request
  - Pre to Post Examination Process
  - Report
  - USER Satisfaction or dissatisfaction
<table>
<thead>
<tr>
<th><strong>Topic</strong></th>
<th><strong>Indicator</strong></th>
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<tbody>
<tr>
<td>Extent of implementing ISO 15189</td>
<td>• Number of GLI tool activities completed versus the number of activities that still need to be completed.</td>
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<tr>
<td>Access to adequate and safe facilities</td>
<td>• The number of deficiencies found during the WHO Biosafety audit (based on checklist in the WHO Laboratory Biosafety Manual, 3rd edition).</td>
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<td>Ability to comply to regulations</td>
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<td>The analytical performance of the laboratory</td>
<td>• Percentage of correct results in proficiency testing (PT)/external quality assessment (EQA), or, if these are not available: inter laboratory testing rounds.</td>
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<td>Staff competency</td>
<td>• Percentage of tests covered by PT/EQA/inter laboratory testing.</td>
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<td>Error reporting</td>
<td>• Percentage of nonconformities in a specific process of the laboratory that have been solved/corrected.</td>
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<td>Work efficiency</td>
<td>• Cultures contaminated vs. total no. of culture samples tested.</td>
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<td>• Stratified nr. of tests done per patient.</td>
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<td>• Nr. of tests done per technical FTEs.</td>
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<td>• Nr. of tests done per staff member (of total staff).</td>
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<td>Guidance and education provided by the laboratory</td>
<td>• Percentage of rejected sputum samples.</td>
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<td>• Percentage of requests for new samples.</td>
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<td>• The percentage of incompletely filled-out request forms.</td>
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<tr>
<td>Timely and accurate results and reports</td>
<td>• Accurateness: laboratory demonstrates constant or increased performance in PT (already included in subject 3).</td>
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<td>Interruption of service</td>
<td>• Timeliness: relative proportion of results reported within established turnaround time (TAT).</td>
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<td>• Percentage of external reports submitted on, or before the deadline.</td>
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<td>Customer satisfaction</td>
<td>• Satisfaction measured with questionnaire (or, when budget is available, by focus group discussions and interviews in certain customer categories).</td>
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Next steps

- Validate indicators for feasibility of measurement
- Adapt indicators if necessary
- Integrate with the GLI tool for use by laboratories themselves
- Measure the effect of introducing a QMS on laboratory performance
- Advocacy

Validation will start Friday in Benin