Quality Assurance for Point-of-Care Diagnostics

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Quality Assured Point-of-Care Diagnostics: Framing the discussion

Latest developments and elements of interest for the diagnostics industry

• Quality Assurance (QA) and challenges of QA POC
• External Quality Assurance program
  – EQA scheme and provider support global coverage of quality assured POC testing
• Country QA Experiences (Zimbabwe and Malawi)
  – Connectivity, integrated QA POC/laboratory network, innovative QA solutions
• The value of QA data
What is the cost of 2% compromise in quality?
# The Value of QA

<table>
<thead>
<tr>
<th>POCT with QA</th>
<th>POCT without QA</th>
</tr>
</thead>
<tbody>
<tr>
<td># infants tested</td>
<td># infants tested</td>
</tr>
<tr>
<td>Misdiagnosis rate</td>
<td>Misdiagnosis rate</td>
</tr>
<tr>
<td>False positives</td>
<td>False positives</td>
</tr>
<tr>
<td>False negatives</td>
<td>False negatives</td>
</tr>
<tr>
<td>QA and CA costs</td>
<td>QA and CA costs = 0</td>
</tr>
<tr>
<td>Cost of treating False positives</td>
<td>Cost of treating False +</td>
</tr>
<tr>
<td>DALYs lost by missing HIV+ infants</td>
<td>DALYs lost by missing HIV+ infants</td>
</tr>
</tbody>
</table>

**Programmatic Data:**
- The # infants tested are the same in both scenarios.
- Misdiagnosis rates are estimated based on country situation.

**Quality Assurance Data:**
- Without QA you will see an increase in both false positives and false negatives.
- With no QA, the costs associated with identifying quality issues and addressing these issues becomes 0.
- While no QA program can save some money, this is off-set by significant increases in cost of treating false positive infants and DALYs lost by missing HIV+ infants.
Definitions

**Quality assurance**
The continuous and systematic approach to monitor, evaluate and include actions to improve the quality of testing. The continuous assessment of quality encompasses quality control, external quality assurance, documentation, supervision, safety and inventory management.

**Quality control**
Procedures used routinely to assure that a test run is valid and the test results are reliable. QC include internal kit controls and/or external quality control samples.

**External quality assessment**
Defined as a system for objectively checking the performance of a testing site (including the testers and the system used for testing) using an external agency. EQA is sometimes used interchangeably with proficiency testing; EQA can also be carried out using other processes such as retesting of samples by another accredited facility and site visits.
Quality Assurance: From Laboratories to Point-of-Care Sites

Laboratory Facility
ISO 15189

Staff + Tests

Licensure
External Quality Assessment
Guidelines

Specimen ➔ Accurate Result

Conventional
POC
WHO/CDC Handbook for Improving the Quality of HIV-related Point-of-Care Testing

Phase I: Plan HIV-related POCT Quality System
- Engage leadership
- Establish national QA coordination team
- Define roles and responsibilities
- Define expected quality for POCT
- Conduct situational analysis
- Select and Assess sites
- Develop implementation plan
- Develop policies and incorporate QA into national plan
- Plan financial and human resources

Phase II: Implement QA for POCT
- Develop and implement QA training and certification
- Conduct site supervision and drive accreditation
- Implement process control
- Generate QA-related documentation
- Strengthen logistics for QA

Phase III: Sustain QA
- Plan and allocate resources for the long term
- Encourage social entrepreneurship
- Increase country ownership
- Implement sustainability-focused M&E
- Improve advocacy
- Mobilize the community

Plan
Define
Implement
Monitor
Evaluate
Improve
Quality Assurance Cycle
External Quality Assurance Program

Sites
• Confidence in test results
• Accurate surveillance data
• Lab-clinic strengthening/trust

Programmatic
• Strengthening supply chain
• Compares performance across sites
• Targeted cost-effective interventions

Industry
• Strengthening supply chain
• Maximize potential of assay/improving patient outcome
• Invalid results and errors
• Root cause analysis
Partnership for Global POC External Quality Assurance Program

- Building national and regional EQA centres in Africa in collaboration with LSHTM, CDC, EQAPOL, and ASLM.
- Local/regional proficiency testing production
- Providing critical and sustainable services: affordable EQA, training, technology transfer, corrective action
External Quality Assurance Program

- Well-characterized source material
- Mimics patient specimen
- Robust and cost-effective
- Increase coverage then frequency
  - Start with 2 times per year
- Results reported and analyzed timely
- Immediate root cause analysis and corrective action
National QA/EQA Model
What does it cost to fund a quality assured testing?

Rapid Syphilis Testing Programme:
- Cost/woman tested: $3.33
  - Training: USD 0.24
  - Testing: USD 1.92
  - EQA: USD 0.51 (15%)
  - Staff: USD 0.66

- Transport and storage
- Start-up training and supplies
- Healthcare Provider Training
- Supervision and refresher training
- External quality assurance
- Laboratory monitoring
- Procurement of consumables
- Procurement of cartridges
A National Model for Quality Assured Point-of-Care Testing

- **QMS**: Identify gaps and strengthening systems
- **EQA**: Challenging the testing environment and bringing about corrective actions
- **Connectivity**: Monitoring quality and testing events through connectivity
- **Costing**: Providing a value to quality assured tests
- **Policy**: Sustainability and country ownership
National Quality Assurance Program

Looking to empower countries through a holistic national QA program, that can be leveraged for other diseases and programs.

QA

Disease Control
Eradication
Elimination