Improving quality of Malaria Diagnosis

Malaria Case Management Working Group Meeting
A. Chinorumba, E. Juma

7 February 2018
Outline

• Policy recommendation
• Challenges
• QA/QC Guidelines Development
• QA/QC for Malaria Microscopy
• Quality assurance for malaria RDTs
Policy Recommendation

• All cases of suspected malaria should have a parasitological test (microscopy or RDT) to confirm the diagnosis.

• Both microscopy and RDTs should be supported by a **quality assurance programme**

• *The results of parasitological diagnosis should be available within less than two hours of the patient presenting. In the absence or delay, patients with suspected severe malaria, and other high risk groups, should be treated on clinical grounds.*
Determinants of diagnostic quality

<table>
<thead>
<tr>
<th>Manufacturer &amp; Product</th>
<th>National Level</th>
<th>Regional Level</th>
<th>Health Facility Level (HF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Selection</td>
<td>Lot Quality</td>
<td>Transport to HFs</td>
<td>Storage at HFs</td>
</tr>
<tr>
<td>Performance of the test by Health Worker</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Microscopy

RDT

Requalification and Evaluation by WHO  Lot Testing
Challenges with Diagnosis /Diagnostics QA and QC
QA/QC Coordination

- Poor coordination of malaria diagnosis QA/QC activities
- Poor communication between laboratory departments and NMCPs
  - Poor implementation of QA activities
  - Duplication of roles
  - Lack of partner coordination
Policy and Regulations

- Lack of control and/or monitoring of the importation of diagnostic products by private sector and lack of compliance with NMCP guidelines on test methods and recommended products.
  - Poor quality RDTs and diagnostic reagents in the private sector
  - Use of different SOPs and reagents making implementation of training and EQA activities difficult
  - Non adherence to diagnostic and treatment algorithms and guidelines
Policy and Regulations

• Regulators lack capacity to enforce regulations and policies on Quality Assurance Requirements (EQA) and reporting mechanisms

• Weak QA/QC structures to support/supervise/monitor the quality of diagnostic services
  • Non participation in QA activities by private sector
  • Non implementation of QA activities by private sector
Manpower and Financial services

- Lack of manpower and financial resources to run comprehensive malaria quality assurance program
- Lack of dedicated manpower from laboratory department to support NMCPs
  - Non-implementation of planned activities
  - Understaffing of laboratories
Post market surveillance

• Non-existent post market surveillance of diagnostic reagents and RDT kits in many developing countries
  • No monitoring mechanisms for tests once deployed in the market
Training and Competency Assessments

- Inadequate training programmes that are not able to train and assess competency of each laboratory technologist once in 3 years as required
- Lack of a defined training schedule for each laboratory technologist
Infrastructure

- Barriers to performing RDTs in non-laboratory sites
  - Lack of waste management systems
  - Most non laboratory sites were not designed to accommodate malaria RDT testing
  - Poor infrastructure (space, lighting, flat table surface etc)
Strengthening QA/QC for Malaria Diagnosis and Diagnostics
Goal of Malaria QA/QC Programme

Availability of Quality assured malaria diagnostic services that detect all malaria cases with:

- Proof that diagnostic tests are performed by trained and certified personnel who are continuously being educated and regularly assessed to be competent.
- Proof that the right test methods are performed correctly under the right environmental conditions and are quality controlled
  - RDT –quality assured RDT kits are procured, lot tested and transported and stored under right conditions
  - Microscopy – Right reagents/equipment, right test method, with IQC and supported by a programme for regular equipment maintenance
- Proof that reporting is accurate, regular and complete and good record keeping.
Malaria Diagnosis QA/QC Guidelines

Support is available to develop QA/QC guidelines for malaria diagnosis.

The document outlines the country’s malaria Quality Assurance and Control activities, for all diagnostic methods including RDTs and microscopy and primarily:

• Defines the QA organizational structure.
• Defines roles and responsibilities of key personnel, committees, departments and stakeholders.
• Defines recommended standard operating procedures for malaria diagnosis.
Malaria Diagnosis QA/QC Guidelines

- Sets best practices for the internal quality control during malaria diagnosis.
- Defines best practices for external quality assurance including proficiency testing, on site supportive supervision and blinded cross checking of slides.
- Defines processes for the procurement, storage and distribution of equipment and supplies.
- Defines process for malaria RDT and microcopy trainings and competency assessments.
External Competency Assessment for Malaria Microscopists (ECAMM)

- WHO supports the training and external competency assessments of key malaria microscopists from countries:

- These are key personnel involved in:
  - Conducting microscopy Trainings
  - Establishing national malaria slide banks
  - Conducting EQA activities

- Total 75 ECAMM courses conducted in the AFRO region
  - 64 by Amref & 11 by UCAD
  - 837 microscopists in AFRO: 711 assessed by Amref, 126 by UCAD
  - These microscopists have come from 51 countries: Africa, Netherlands, Peru, USA
Malaria Slide Banks

- Countries need National Malaria Slide Banks to support Training and EQA programs
- WHO trained laboratory personnel from national malaria programmes and research institutions on how to develop, run and maintain malaria slide banks using WHO recommended Standard Operating Procedures.
- With support from E8 secretariat, NICD was supported to develop a regional malaria slide bank for E8 countries, but funding has ended and efforts are underway to mobilize resources to support this function
Quality Assurance for RDTs

- Procurement of quality products
- Pre-shipment and post-shipment Lot Testing
  - Pre and post shipment lot testing can be done through the WHO collaborating centres in the Philippines.
- Transportation and storage under right environmental conditions
- Training of health care workers
- On site support supervision
- Post Market Surveillance – see lot testing
- Positive control wells for point of care or IQC did not do well in operational tests
WHO-FIND strategy for QA of RDT-based diagnosis

Supply chain management  Transport and storage

Manufacture
Product development
Availability of common reference standards

Stage 1: Product testing
Evaluate product performance

Stage 2: Lot testing
Confirm product quality on arrival in country before dissemination to the field

Stage 3: QC in country: On site support
Supervision, Good transportation and storage, Training of rdt performers

End users
Appropriate training and instructions
Management of positive and negative results
Monitoring of commodity supply and disease rates

Before purchase
Before distribution
Thank you