Technical consultation to update the WHO Malaria microscopy quality assurance manual

26–28 March 2014, Geneva, Switzerland
Meeting Report | Global Malaria Programme

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1 - QA practices for malaria microscopy_AFRO

Current QA practices for malaria microscopy and questions from the field

Dr Josephine Namboze
IST/MAL/AFRO - ESA

Outline of the presentation

• Background
• Current status of implementation of malaria diagnosis in ESA countries
• Malaria QA in countries
• AFRO initiatives
• Country experiences
• Challenges
• Questions from the field
Mandate for AFR Lab strengthening

- At its forty-eighth session, the WHO Regional Committee for Africa passed Resolution AFR/RC48/R2 (Sept 1998) urging Member States to evaluate the laboratory component of disease control programmes as the first step towards strengthening disease surveillance.

- The fifty-eighth session (Yaounde, Sept 2008) re-affirmed Regional commitment to Lab strengthening (AFR/RC58/R6)

- The Maputo declaration (Jan 2008)

- ASLM-ministerial call for action (Dec 2012)

Proportion of suspected malaria cases attending public health facilities receiving a diagnostic test

Source: NMCP reports
No of countries that rolled out use of RDTs in health facilities from 2001 to 2012 in ESA region

Status on the indicators - Percentage of all suspected malaria cases that receive parasitological test

<table>
<thead>
<tr>
<th>Countries &gt;80% testing</th>
<th>60-80% Testing</th>
<th>&lt;30% or not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana - 90%</td>
<td>Comoros – ??</td>
<td>South Sudan – 20% of the 40% cases that are reported</td>
</tr>
<tr>
<td>Eritrea - &gt;95%</td>
<td>Swaziland – 75%</td>
<td></td>
</tr>
<tr>
<td>Kenya – 85%</td>
<td>Namibia – 78%</td>
<td></td>
</tr>
<tr>
<td>Rwanda - &gt;99%</td>
<td>Malawi - 68%</td>
<td></td>
</tr>
<tr>
<td>Zanzibar - &gt;95%</td>
<td>Madagascar – 68%</td>
<td></td>
</tr>
<tr>
<td>Ethiopia - &gt;85%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Africa - &gt;95%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zimbabwe – 81.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 - &lt;60% tested</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uganda - 60%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mozambique- ??</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zambia – 52% or higher</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tanzania - ??</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

78% are RDTs and about 20% microscopy
### Malaria Microscopy QA

#### Examples of Areas covered by each programme before the development of the QA Guideline

<table>
<thead>
<tr>
<th>Country</th>
<th>Area Implemented</th>
<th>Partners involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>On site Supervision, Microscopy Trainings; <strong>Proficiency Testing</strong></td>
<td>Government, CDC</td>
</tr>
<tr>
<td>Comoros</td>
<td>Appointment of core group microscopists; Start of cross-checking activities</td>
<td>GFATM</td>
</tr>
<tr>
<td>Eritrea</td>
<td>Appointment of key responsibilities; Malaria QA Manual drafted; <strong>cross-checking</strong></td>
<td></td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Appointment of core microscopist group; WHO accreditation for CG; <strong>Cross checking</strong>; in the process of building a Slide Bank;</td>
<td></td>
</tr>
<tr>
<td>Kenya</td>
<td>Finalization of the QA/QC Manual; WHO accreditation of the CG; PT organized by AMREF;</td>
<td>AMREF</td>
</tr>
<tr>
<td>Madagascar</td>
<td>Recruitment of a core group of microscopists; development of a malaria QA manual; <strong>cross-checking</strong>; CTSS (ImAD);</td>
<td>GFATM, ImAD, PMI</td>
</tr>
<tr>
<td>Malawi</td>
<td>On site Support; supervision, Slide bank development;</td>
<td>IMAD/Malaria Care</td>
</tr>
</tbody>
</table>
Building capacity at National Level:

- 11/17 countries have a Core Microscopy Group:
  - Botswana, Ethiopia, Kenya, Madagascar, Malawi, Mozambique, RSA, Uganda, Zambia, Zanzibar, Comoros

- All countries in the IST ESA region have at least one lab participating to the Malaria Microscopy EQAP AFRO/NICD
QA/QC Guidelines and frameworks:


- Finalized: Zambia (2008), Swaziland (2009), Mozambique (2011), Eritrea (2012), Malawi

Experiences in countries

- Most countries start activities long before development of comprehensive QA/QC guidelines; absent phased costed implementation plans;
- Procedures vary (no standardization) especially when it is not Government initiated (e.g. Uganda);
- Often poor consideration of workload involved in QMS leading to loss of staff motivation and finally failure of the activity;
- Not integrated with other laboratory QMS;
- Logistical challenges including transport of samples between laboratories at various levels and resources (human and financial) to supervise in the field;
Experiences in countries

• Competing sources of funding leading to decision for either vertical or cross-cutting development of laboratory QMS;

• Inadequate coordination of all QMS components especially when malaria programme leads the process;
  – Various QMS activities within the region not harnessed for results;

• Competing activities for laboratory QMS - ISO15189 Accreditation, SLMTA/SLIPTA which focuses on all lab tests takes priority off from malaria QA/QC

• No dedicated personnel/core group for malaria diagnosis at national level – often no malaria reference labs in some countries.

Regional initiatives currently implemented

• Coordinated by AFRO
  – EQA (NICD)
  – SLMTA/SLIPTA

• Coordinated by ESA
  – ECAMM
  – Capacity building activities on malaria diagnosis
Take home of these AFRO initiatives

- Most of these are well funded and therefore are prioritized by the laboratory staff/NHL;
- Most address some of the components of the QA thus must be seen as a complimentary to malaria microscopy QA
- Some of these components are **NOT** in the remit of the malaria programme and therefore linkages must be established with the relevant departments
Malaria diagnosis QA/QC challenges

- **Slide Bank** development component:
  - Lack of all the species in-country;
  - Countries going towards elimination low cases reported per year;
  - Technical assistance required by countries including the availability of detailed SOPs;
- **Procurement of equipment** – fragmented and of varying quality – VPP;
- **Capacity of the personnel**: lack of skilled and experienced personnel, most experienced microscopists are at retiring age (pre-elimination countries), weak re-fresher training and supervision availability
- **Implementation of QA/QC**: partial in the majority of the countries, rejected commodities circulated for use
- **Monitoring**: Consumption data and quantification: weak leading to shortages and stock-outs
  - Inadequate provision for reporting of QA/QC indicators in the HMIS system (parallel systems developed)

Specific issues raised by the countries on the use of the manual

- Too many areas without prioritization in case of capacity challenges;
- Request to have joint guide with RDTs;
- Slide bank details are not really practical at their level – can’t they do their own slide banks for PT (less stringent criteria)
- Reference lab – is it in terms of infrastructure only as staff may not necessarily be different?
- What are the linkages with other QMS strategies?
- Too detailed in some cases like training, ECAMM etc which should just be cross referenced to the relevant documents or should be stand alone manuals (a suggestion).
Specific issues raised by the countries on the use of the manual

- To be better guided on the targeting/inclusion of labs in cross checking if too many in the country;
- Models of supervision that will allow reach of all field laboratories in resource constrained settings;
- Emphasis on QC to be on-going to address quality concerns structured with accountability before other components are developed/implemented.
- Can the SOPs be separated so that the document focuses more on the standards;
- Relate the relevance of QA interventions to the epidemiological profile (e.g. elimination countries: PT versus cross-checking).

Conclusions

- There has been overall realization of the need to strengthen QMS in the region;
- This has resulted in good initiatives although sometimes implementation is fragmented;
- Malaria programmes are rapidly scaling up malaria QMS although inadequately coordinated;
- Opportunities are presented with the proposed revisions to the current manual.
Current QA practices for malaria microscopy and questions from the field

TECHNICAL CONSULTATION TO UPDATE THE WHO MALARIA MICROSCOPY QUALITY ASSURANCE MANUAL

Maria de la Paz Ade
PAHO/AMRO Specialist, Malaria Prevention and Control
Washington DC, USA
Malaria situation in the Americas, 2012

21 endemic countries (n=469,371 malaria cases in 2012); 61% case reduction since 2000

- 69% P. vivax; 30% P. falciparum; <1% P. malariae (reported by Brazil, Colombia, F. Guiana, Guyana, Peru, Surinam and Venezuela)

108 reported deaths in 2012; 72% reduction since 2000

27 member states free of local transmission
Tools for malaria diagnosis

- **Microscopy** (gold standard): parasite visualization
- **RDT**: detect specific antigens (proteins) produced by malaria parasites (aldolase, pLDH, HRP2)
- **PCR**: for diagnosis confirmation (elimination phase – asymptomatic)
  ➢ Other methodologies: LAMP, RealAmp……..

QA practices – country level

- **Indirect control (slides for validation)**
  100% (+) slides + 10% (-) slides
- **Direct control/panels**
  From central laboratories to intermediate laboratories
- **Monitoring and supervision**
- **Training/Certification**
External Quality Assurance Program (EQAP)

The objective is to define technical procedure for the organization, design, and evaluation of the performance of the national reference laboratories in the countries of the Region in microscopic malaria diagnosis, with a view to maintain an efficient system of quality control and strengthening the monitoring of malaria diagnosis in the Americas (AMRO).

EQAP: Panels sent to central labs
Round 1 - 2012/12 labs
Round 2 – 2013/19 labs
Round 3 – 2014 (in process)
QA practices – regional level AMRO

- Microscopy training/certification
  *Taller de capacitación y certificación de microscopistas para Mesoamérica y el Caribe.*
  *InDRE, México* (January 27 to February 7, 2014), 21 participants /18 certified.

2nd workshop planned for second semester 2014 for south American laboratories

WHO Training materials used bench aids, basic malaria Microscopy tutors and learner’s manuals.

Achievements

- Supranational reference laboratories (HON & PER) participating in the global EQAP (WHO/GMP/AFRO)
- Regional network for malaria diagnosis QA established
- Protocols, guidelines, manuals standardized and applied
- Web platform to report the EQAP results on real time-NetLab/Peru
Questions from the field/challenges

• How often we need to retrain/certify the personnel?
• Moving towards elimination is key to implement a QA/QC program for malaria diagnosis – do we need to include processes for QA of other diagnostic tools?
• Sustainability of human resources
• The use of electronic tools for training and performance evaluation?
• Sustainability of panels with high quality
• Having other plasmodium species in the EQAP
• Language barriers

Thank you
3 - QA practices for malaria microscopy_WPRO

Current Quality Assurance Practices for Malaria Microscopy
in the WHO Western Pacific Region

Glenda Gonzales
Malaria, other Vectorborne and Parasitic Diseases
26-28 March 2014

Malaria in the WPR

10 endemic countries:
- Republic of Korea: elimination phase
- Malaysia: pre-elimination phase
- 8 countries (KHM, CHN, LAO, PHL, PNG, SOL, VAN, VTN): control phase
Malaria in the WPR

- 8 countries: achieved > 75% decrease in confirmed malaria cases (2000-2012)
- LAO: projected to achieve 75% decrease in 2015
- PNG: progress is slower

Malaria Microscopy QA: Regional Activities

1. Planning, coordination, policies and guidelines
2. QA systems/ laboratory capacity assessment
3. Support to QA implementation
4. Laboratory strengthening
1. Planning, coordination, policies and guidelines (1/2)

- Regional coordination (workshops, regional QA plan)
- Support to in-country workshops on QA planning

1. Planning, coordination, policies and guidelines (2/2)

- Development of generic SOPs/ guidelines
  - SOPs for all aspects of malaria microscopy
  - SOPs for malaria slide bank (RITM)
  - SOP for external competency assessment of malaria microscopists (draft)
- Provide policy support when needed
2. QA systems/ lab capacity assessment

- In-country visits to assess QA systems (Cambodia, Laos, Viet Nam).
- IDENTIFY laboratory assessment tool – included in the external quality assessment programme (Mekong + Malaysia and Philippines)
- ECA reports from countries

3. Support to QA implementation (1/4)

- Internal QA
  - Technically supports establishment of national slide bank
  - Supports training where needed
  - Procurement of lab supplies (e.g. insecticide resistance of malaria vectors)
3. Support to QA implementation (2/4)

- External QA
  - External competency assessment (ECA) of malaria microscopists
  - Maintenance of regional malaria slide bank
  - External quality assessment programme for malaria laboratories

3. Support to QA implementation (3/4)

- External QA
  - External competency assessment (ECA) of malaria microscopists
  - Maintenance of regional malaria slide bank
  - External quality assessment programme for malaria laboratories
3. Support to QA implementation (4/4)

- External QA
  - External competency assessment (ECA) of malaria microscopists
  - Maintenance of regional malaria slide bank
  - External quality assessment programme for malaria laboratories

4. Laboratory strengthening

- Human resource trainings
  - Instructional skills development
  - Microscopy refresher trainings
  - Microscope maintenance
- Supervision and evaluation
- Identification of a possible regional malaria PCR reference laboratory for Plasmodium knowlesi
Challenges

1. Competency of microscopists in diagnosing malaria needs to be sustained especially in areas where malaria cases is decreasing.
2. No regular access to refresher courses
3. Level 1s mostly engaged in research.
4. Supervisory visits are done intermittently which is related to workload and funding
5. No microscope maintenance programme present in most countries

6. NCG not functional in some countries
7. Performance and training needs are not monitored
8. SOPs – not strictly followed, standardized or detailed
9. Cross-checking of slides not done regularly and feedback of results take too long
10. Supplies and reagents and limited due to financial constraints
WHO Partners

- National malaria control programmes
- ACTMalaria
- Research Institute for Tropical Medicine
- Institute Pasteur in Cambodia
- Australia Army Malaria Institute
- USAID PMI
- USAID IDENTIFY
- ERAR (B&MGF, AusAID)
4 - QMS for malaria microscopy in Honduras

Honduras experiences in quality management systems (QMS) for malaria microscopy (MM)

Dra. María Luisa Matute
Chief of the National Surveillance Laboratory Department
March 26, 2014

ORGANIZATION CHART NATIONAL LABORATORY
Quality Assurance: Concepts

- Proper treatment of patients with malaria depends on access to timely and reliable diagnosis laboratory that can be offered by health services.

- The establishment and maintenance of a reliable diagnosis is managed through a series of actions of quality assurance.

Objectives of the Quality Assurance System (QAS) of the microscopic diagnosis of malaria:

1. Improve the work performed by laboratory personnel at each level of health services through standard operating procedures for the microscopic diagnosis of malaria.

2. Systematically monitor, through direct and indirect assessments, installations and units of diagnostic procedures, reagents and equipment used by laboratory personnel across the network diagnostic units.

3. Establish a training program and corrective measures based on the results of the evaluation to the staff and diagnostic units.

4. Maintain the highest level of professional competence (knowledge and performance) in the staff working in the network of diagnostic units, which perform laboratory diagnosis of malaria.
**Elements of QAS**

- **Standard Operating Procedures (SOPs)** that unify staff performance.
- **Technical standard** that provides guidelines and regulate performance.
- **Forms and information system** to assess and monitor performance.
- **Training program** based on the results of evaluations and monitoring.

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**Malaria in Honduras**

- **Standard Operating Procedures (SOPs)** that unify staff performance. They describe the microscopic diagnosis procedures in sufficient detail to be reproduced in a standardized manner by staff.
Coordination between National Malaria Programs and reference laboratories

• **Technical norm**

Provide technical guidelines which regulate the exercise of the microscopic diagnosis of malaria, from the selection and training of personnel, structure and workings of the diagnostic units, the reading of the samples to the registration and channeling of information.

Coordination between National Malaria Programs and reference laboratories

• **Information System**

Which allows to assess and monitor the timely and effective surveillance for prevention and effective control of malaria.
Coordination between National Malaria Programs and reference laboratories

Training Manual.
Training for staff, working to correct the deficiencies found through the assessment of professional competence: supervision, accreditation, diagnosed blood film review and performance evaluation.

Direct Evaluation

Includes accreditation, such as a certified Microscopist, which can be done in a workshop, and supervision that is done according to a monthly schedule which evaluates the Microscopist in their work environment, including the assessment of the infrastructure of the diagnostic unit.

Does the Malaria Laboratory Accredits? Yes
Does the Malaria Laboratory Supervises? Yes
### Indirect Evaluation

Includes de Validation of Diagnosed Slides (VDS) and the External Evaluation of Performance (EEP).

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the Malaria Laboratory performs VDS?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does the Malaria Laboratory performs EP?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does the Malaria Laboratory performs EEP?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Performance Evaluation and Quality Control in the National Network of Laboratories

**Corrective Measures**

- Feedback through technical reports
- Retraining
- Training
- Tutorials
- Direct supervision
External Quality Assurance Program (EQAP) for Malaria Microscopy

- **Supported by:**
  - Regional Malaria Program
  - Neglected, Tropical and Vector Borne Diseases
  - Communicable Diseases and Health Analysis
  - Pan American Health Organization

- **Funded by:**
  - U.S. Agency for International Development USAID/PAHO through the agreement No 527 A-00-08-00026-00.
External Quality Assurance Program (EQAP) for Malaria Microscopy

Objective:

Accomplish that the microscopic diagnosis of malaria is executed with quality assurance in the countries of the Region of the Americas.

Methods

• Evaluation of diagnostic concordance with panels of slides
• Positive slides: *P. vivax*, *P. falciparum*, mixed infections
• Negative slides: malaria-free person
• Inclusion of low, medium and high densities
• Coloration: GIEMSA.
Evaluated Parameters

- Result
- Species
- Stage
- Parasitic Density

National Reference Laboratories participants according to rounds
Towards the elimination

To be taken into account:

• 100% of the cases diagnosed by microscopy

• National Programs ensuring the quality of diagnosis established

Conclusions

Strengthen interaction between national and reference laboratories for improving the diagnosis, control and prevention of malaria.

Strengthening capacities in laboratories for microscopic diagnosis of malaria:

– Identification of the parasite species: F, V and Mx
– Identification of parasitic stages: asexual and asexual both *P. vivax* and *P. falciparum*
– Standardize the evaluation criteria of parasitic density in parasites per μl of blood.
Recommendations

- Standardize processes for microscopic diagnosis of malaria in the region.

- Ensuring the quality of diagnosis in all levels of attention of each of the participating countries, if these are endemic or non-endemic.

- Ensure rapid and quality diagnosis for timely treatment in order to shorten the transmission time, and to not reintroducing the disease in areas where it has already been eliminated.

THANK YOU

Yojoa Lake, Honduras
5 - QMS for malaria microscopy in Peru

TECHNICAL CONSULTATION TO UPDATE
THE WHO MALARIA MICROSCOPY QUALITY ASSURANCE
MANUAL,
26-28 MARCH 2014,
GENEVA, SWITZERLAND

Nancy ARROSPIDE VELASCO
malaria@ins.gob.pe
SUPRANACIONAL DE MALARIA
Centro Nacional de Salud Pública
INSTITUTO NACIONAL DE SALUD
MINISTERIO DE SALUD PERU

30,135,875 habitantes de acuerdo al INEI
Technical consultation to update the WHO Malaria microscopy quality assurance manual

Presentations 1–7
Programa de mantenimiento de microscopios

Mantenimiento de microscopios anual.

Se entrena a los microscopistas en manejo y mantenimiento de microscopios.

Aseguramiento de la calidad de la Red de Microscopia Nacional de PERU

a) Control de calidad indirecto: local
   a) Frecuencia 4 veces al año
   b) Evalúa: Condiciones operativas del dx de las redes de Microscopia.
   c) T U C / T P D y T U E
b) Control de calidad directo (paneles) LRN Regional
   Frecuencia de una vez por año.
   Evalúa precisión de diagnostico individual: resultado, especie, estadio y carga parasitaria en p/ul.
c) EJECUCION DE SUPERVISIONES.
CALIDAD TECNICA DE LA GG / CCI

- Tamaño de la muestra
  - GG: 1 cm
  - Frotis: 3 cm
- Ubicación
  - 1.5 - 2 cm del borde

Precipitado
- Tonalidad
- Calidad

Deshemoglobúinización
- Tonalidad
- Precipitado
- Calidad

ASEGURAMIENTO DE LA CALIDAD DE GOTA GRUESA

RESULTADOS CONTROL DE CALIDAD NACIONAL 2012-2013

- CONTROL DE CALIDAD DIRECTO – PANELES

<table>
<thead>
<tr>
<th>Nº LABORATORIOS EVALUADOS</th>
<th>ACEPTABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>12</td>
</tr>
</tbody>
</table>

- CONTROL DE CALIDAD INDIRECTO- OPERATIVO
RESULTADOS DE LA I RONDA PEED DE SUD AMERICA Y CENTRO AMERICA

<table>
<thead>
<tr>
<th>Laboratorio</th>
<th>Año de evaluación</th>
<th>Frecuencia</th>
<th>Resultado (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC</td>
<td>2002</td>
<td>Anual</td>
<td>100% concordancia</td>
</tr>
<tr>
<td>Hospital Pitié Sipétrie- FRANCIA</td>
<td>2004-2005</td>
<td>Anual</td>
<td>100% concordancia</td>
</tr>
<tr>
<td>National Institute for communicable Diseases SUD AFRICA</td>
<td>2013 a la fecha</td>
<td>Tres veces</td>
<td>100% concordancia</td>
</tr>
</tbody>
</table>

09/12 Países diagnostica malaria. Hay mas dificultad en identificación de negativos que positivos.
RESULTADOS DE I Y II RONDA DE SUD AMERICA

Parámetro: Resultado (dx de malaria)

ACEPTABLE 3/6

ACEPTABLE 8/10

Los países evaluados aun no alcanzan ACEPTABILIDAD en los parámetros: especie, estadio y densidad p/ul.

RESULTADOS DE I Y II RONDA DE PEED DE LAS AMERICAS

En las Américas los países han mostrado mejor performancia en la II Ronda de evaluación PEED.
REPORTE DE RESULTADOS EN TIEMPO REAL EN SOFTWARE NET LAB DE INS

![Image of Software NET LAB DE INS interface]

La Compañía de Jesús. Cusco, Perú

GRACIAS
6 - AMREF QMS Resources

**AMREF International Training Centre**

- **24 short courses** (2 – 4 weeks) including:
  - Malaria Prevention, Control & Management
- **3 annual (long) courses** (Masters in Public Health, BSc Community Health, Diploma Community Health, Masters in Community Health)
- **3 e-learning nurse/midwifery upgrading courses** to diploma level in Kenya, Tanzania, Uganda
- 2 courses offered by **AMREF Virtual Nursing School** (eLearning BSc Nursing, Diploma in Comprehensive Reproductive Health)

- **Resource Centre** & Library
- **New training building** nearing completion to accommodate 215 students
- Process of conversion to **University status** underway
AMREF Organisational Structure

AMREF Headquarters & European & North American Offices (10)

AMREF Country Offices

AMREF Technical Programme Areas

1. M & RH
2. Child Health
3. HIV/AIDS, TB & Malaria
4. WASH
5. Clinical & Diagnostics

Kenya
Tanzania
Uganda
Ethiopia
South Sudan
South Africa
Senegal

AMREF Clinical & Diagnostics Programme

1. Regional Projects
   - *East African Regional Quality Assessment Scheme (EA-REQAS)*
   - *Regional Laboratory Training*
   - *Community Based Disease Surveillance (CBDS)*

2. Country Specific Projects
   - **Kenya**: Central Laboratory, TB Control, IDSR, Strengthening PH
   - **Tanzania**: Training and capacity building on HIV, TB & others
   - **Uganda**: Training and systems strengthening
AMREF Clinical & Diagnostics Programme

AMREF Diagnostics Programme Regional Office

- ISO 15189 in process
- Expansion of physical facilities

Michael Wood Clinical and Research Centre, Nairobi: 2005
Regional Laboratory Training

Enhancing the diagnostic capacity of laboratory & clinical staff through targeted training

- **Two major annual training courses:**
  - Refresher Course in Essential Laboratory Services (RCELS): 12 weeks
  - Medical Laboratory Practices and Management (MLP&M) – LSTM: 22 weeks
    - *E-learning conversion in process*

- **Short training courses:**
  - Competency Assessment (WHO): 5 days
  - Malaria Microscopy Refresher Training: 5 days
  - Refresher Training in Good Diagnostic Practices for Clinicians & Lab staff: 2 weeks
  - Lab-based Disease Surveillance Training: 2 weeks

- **Multiple collaborating partners:** CDC, USAID, WHO, teaching institutions, MOHs, NRHs, NPHLSs

Human Resources

- **9 experienced** laboratory trainers in AMREF (across EA):
  - 1 level 1 in MM
  - 3 Level 2 in MM

- **3 assessors/mentors** undergoing CDC/AFRO SLIPTA programme

- Dedicated **Laboratory Training Coordinator**

- **Access to trainers** in MOH, NRLs, NPHLS, universities
Training resources

➤ **Training labs** and lecture rooms
  - Clinical Laboratory
  - Microbiology & Parasitology Laboratory
  - Range of laboratory equipment

➤ **High quality microscopes:**
  - 12 CX 31 microscopes
  - Multi-head teaching microscope

Resources & information

- **Reference materials** (SOPS, bench aids and manuals) available

- **Slide-bank** development in-progress

- **Microphotographic slide bank** containing all malaria parasite species & other blood parasites available

- **Prospectus & Information Sheets** on each course available

- Laboratory training courses information available **online** – [www.amref.org](http://www.amref.org)
Data & Documentation

➢ Training data bases:
  o Detailed information on students/courses since 1989
  o Specific ECAMM data base

➢ Detailed reports after each course; standard template

Financial sustainability

➢ All participants’ fees are supported:
  • Large numbers of applicants every year
  • Wide sponsorship from Partners and AMREF Offices in Europe & North America

• Annual Laboratory Training budget: $90,000 – 120,000
Contacts

For further information on the AMREF Laboratory Training Programme, please visit the website [www.amref.org](http://www.amref.org) or contact:

**David Isaboke**  
AMREF HQ Clinical & Diagnostics Programme  
P. O. Box 30125 – 00100, Nairobi  
Tel +256 20 6994000; Fax +254 20 6002191  
[kenya.lab@amref.org](mailto:kenya.lab@amref.org)

For further information on AMREF, please visit: [www.amref.org](http://www.amref.org)
7 - WHO LQM resources

WHO resources for Laboratory Quality Management

Dr Katrina Roper, Technical Officer
Laboratory Strengthening & Biorisk Management
WHO Office in Lyon, France

Technical Consultation to Update the WHO Malaria Microscopy Quality Assurance Manual
26-28 March 2014
Geneva, Switzerland

Laboratory Strengthening & Biorisk Management team

Team leader: Sébastien Cognat

Team members:
• Lyon: Chris Oxenford, Katrina Roper and Virginie Dolmazon
• Geneva: Kaz Kojima, and Magdi Samaan
The WHO suite of tools to help you implement a quality management system in your laboratory

The quality manual template provides guidance for public health and clinical laboratories on writing policies and procedures to support a quality management system. It comprises a main document providing information and examples to assist with writing a laboratory quality manual together with 24 appendices. Available in English and Russian (French in progress).

The Laboratory Quality Stepwise Implementation tool is for you. The LQSI translates ISO 15189 requirements into step-by-step activities, structured by an interactive roadmap. It provides additional support material such as document templates. Available in English (French and Russian in progress).

The Laboratory Assessment Tool describes the general process for assessing laboratories and provides two questionnaires to help assess national laboratory systems and individual laboratories. Assessors can use it as is, or customize the available materials to meet local requirements. Available in English, French, Russian and Spanish.

All tools available at: http://www.who.int/ihr/lyon/hls/en/

Quality Norms and Standards

GP26-A4 Quality Management System: A Model for Laboratory Services, fourth edition

ISO 15189:2012 - Medical laboratories – Requirements for quality and competence

ISO 15190:2003 - Medical laboratories – Requirements for safety
The 12 Quality System Essentials

(1) Laboratory Quality Management System (LQMS) Training Toolkit

- Provides comprehensive materials that allow for designing and organizing of training workshops for all stakeholders in health laboratory processes, from management, to administration, to bench technicians.
- Powerpoint presentations for trainers
- Group work and individual exercises for participants
- Test questions for participants
- Additional supporting materials
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Presentations 1–7
Learning Objectives

At the end of this module, participants will be able to:

- relate how facility design impacts the efficiency and safety of laboratory workers
- describe practices to prevent or reduce risks
- list personal protective equipment (PPE) that should be used routinely by laboratory workers
- explain general safety requirements for the laboratory
- describe steps to take in response to emergencies such as biological or chemical spills, or laboratory fires
LQMS Training Toolkit

- **Webpage:** available in English, French and Russian
- **Available at:**
  http://www.who.int/ihr/training/laboratory_quality/doc/en
- **CD-Rom:** available in English and French (Russian version to be produced by EURO)

(2) WHO Laboratory Assessment Tool (LAT)

- The Laboratory Assessment Tool offers guidance for the assessment of laboratories and national laboratory systems.
- It describes a general process for assessing laboratories and provides two questionnaires to help assess national laboratory systems (Annex 1) and individual laboratories (Annex 2).
### Specimen Collection

<table>
<thead>
<tr>
<th>Question</th>
<th>Documents to be collected</th>
<th>Yes</th>
<th>Partial</th>
<th>No</th>
<th>Non applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are written instructions available for patient preparation prior to collection (e.g. glucose tolerance test)?</td>
<td>1, 2, 3, 4</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are collection procedures documented and available to relevant personnel?</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do these include minimum patient identification details?</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Is a standard specimen request form available for those requesting tests?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes or partial, does it include:</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Name of the patient?</td>
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<tr>
<td>Gender?</td>
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<tr>
<td>Date of birth?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Patient identification number (if applicable)?</td>
<td></td>
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</tr>
<tr>
<td>Identification of the prescriber?</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Date of collection?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time of collection?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Type of specimen?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Specimen identification number (if applicable)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Examinations requested?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical information?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Are specimen recorded in a book, worksheet, computer or other comparable system?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes or partial, is there:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A unique identification number?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>The date of receipt?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>The time of receipt?</td>
<td></td>
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</tr>
<tr>
<td>Are specimen portions traceable to the original primary sample (identification number, etc.)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Specimen Handling

<table>
<thead>
<tr>
<th>Question</th>
<th>Documents to be collected</th>
<th>Yes</th>
<th>Partial</th>
<th>No</th>
<th>Non applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the laboratory experience problems with specimens from outside the facility due to (Never, Sometimes, Regularly, Always)?</td>
<td>1, 2, 3, 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No request form</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete request form</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incorrect specimen identification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Transport**

Possible answers (unless otherwise advised): 1. Yes; 2. Partial; 3. No; 4. Non applicable
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Presentations 1–7

Global capacities, alert and response

<table>
<thead>
<tr>
<th>Biorepository management policy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Has a policy concerning the management of laboratory biohazard (biosafety and biosurveillance) been written?</td>
<td>X</td>
</tr>
<tr>
<td>Does this policy clearly state the biosafety management objectives and commitment to improve biosafety management performance?</td>
<td></td>
</tr>
<tr>
<td>Is the policy appropriate to the nature and scale of the risk associated with the facility and associated activities?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Biorisk assessment and control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have the hazards associated with proposed work been identified and documented?</td>
</tr>
<tr>
<td>Have the biorepositories been assessed and categorized?</td>
</tr>
<tr>
<td>Are biohazard control measures described in an action plan?</td>
</tr>
<tr>
<td>Are biohazard control measures documented?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Implementation and operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are roles and responsibilities related to biohazard management defined and documented?</td>
</tr>
<tr>
<td>Is a senior manager designated to oversee the biohazard management system?</td>
</tr>
<tr>
<td>Is there a biohazard management committee?</td>
</tr>
<tr>
<td>Has a biohazard management advisor (or biological safety officer) been designated?</td>
</tr>
<tr>
<td>Is there a Biohazard Management Advisor present?</td>
</tr>
<tr>
<td>Has the laboratory source of the incident been identified?</td>
</tr>
<tr>
<td>Has the laboratory source of the incident been identified?</td>
</tr>
<tr>
<td>Are mechanisms in place to ensure that personnel are competent (e.g., through successful completion of training)?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Global capacities, alert and response</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Organization and management</strong></th>
<th><strong>25%</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td><strong>Documents</strong></td>
<td><strong>31%</strong></td>
</tr>
<tr>
<td>3.</td>
<td><strong>Specimen collection, handling and transport</strong></td>
<td><strong>34%</strong></td>
</tr>
<tr>
<td>4.</td>
<td><strong>Data and information management</strong></td>
<td><strong>42%</strong></td>
</tr>
<tr>
<td>5.</td>
<td><strong>Consumables and reagents</strong></td>
<td><strong>53%</strong></td>
</tr>
<tr>
<td>6.</td>
<td><strong>Equipment</strong></td>
<td><strong>40%</strong></td>
</tr>
<tr>
<td>7.</td>
<td><strong>Laboratory testing performance</strong></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td><strong>Facilities</strong></td>
<td><strong>42%</strong></td>
</tr>
<tr>
<td>9.</td>
<td><strong>Human resources</strong></td>
<td><strong>22%</strong></td>
</tr>
<tr>
<td>10.</td>
<td><strong>Bio risk management</strong></td>
<td><strong>20%</strong></td>
</tr>
<tr>
<td>11.</td>
<td><strong>Public health functions</strong></td>
<td><strong>28%</strong></td>
</tr>
</tbody>
</table>
12. Gap analysis

What are the biggest needs/weaknesses in the laboratory?
Score from 0 (no gap) to 5 (high gap) for the points below and please provide comments for the areas that display the biggest gaps (4 and 5).

- Financial resources for laboratory activities
- Equipment adequacy
- Equipment calibration and maintenance
- Reagent and consumable availability and delivery
- Laboratories collection, standardization and quality
- Guidelines on laboratory practices
- Laboratory organization, service delivery structure
- Regulatory framework
- Data management
- Laboratory safety or security
- Other

Gap analysis, from 0 (no gap) to 5 (high gap)

<table>
<thead>
<tr>
<th>Financial resources for laboratory activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment adequacy</td>
</tr>
<tr>
<td>Equipment calibration and maintenance</td>
</tr>
<tr>
<td>Reagent and consumable availability and delivery</td>
</tr>
<tr>
<td>Laboratories collection, standardization and quality</td>
</tr>
<tr>
<td>Guidelines on laboratory practices</td>
</tr>
<tr>
<td>Laboratory organization, service delivery structure</td>
</tr>
<tr>
<td>Regulatory framework</td>
</tr>
<tr>
<td>Data management</td>
</tr>
<tr>
<td>Laboratory safety or security</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

For other, please specify:

Gap Analysis from Smallest (Score 0) to Biggest (Score 5) Weaknesses.

- Other
- Political commitment
- Quality assurance
- Laboratory safety or security
- Data Management
- Regulatory framework
- Laboratory organization, service delivery structure
- Transportation of specimens
- Guidelines on laboratory practices
- Reagent and consumable availability and delivery
- Reagent and consumable quality
- Equipment calibration and maintenance
- Equipment adequacy
- Human resources- qualifications
- Financial Resources for laboratory activities
WHO Laboratory Assessment Tool

- Available in English, French, Russian and Spanish

Available at:

(3) WHO LQMS Handbook

- Linked to the training toolkit on laboratory quality management system.
- Provides a comprehensive reference on laboratory quality management for all stakeholders in health laboratory processes, from management, to administration, to bench technicians.
- Covers topics essential for quality management of a public health or clinical laboratory, based on both ISO 15189 and CLSI GP26-A3 documents.
Technical consultation to update the WHO Malaria microscopy quality assurance manual

Presentations 1–7
Role in quality management system

Programme considerations

3.1: Overview

Equipment management is one of the essential elements of a quality management system. Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable and timely testing.

The benefits of a good equipment management programme are many:

- helps to maintain a high level of laboratory performance;
- reduces rejection of test results, and improves the technologist’s confidence in the accuracy of testing results;
- lowers repair costs, as fewer repairs will be needed for a well-maintained instrument;
- lower instrument life;
- reduces interruption of services due to breakdowns and failures;
- increases safety for workers;
- produces greater customer satisfaction.

A great deal of thought and planning should go into equipment management. As the laboratory puts an equipment management programme in place, the following elements should be considered:

- Selection and purchasing—When obtaining new equipment, what criteria should be used to select equipment? Should equipment be purchased or would it be better to lease?
- Installation—For new equipment, what are the installation requirements and who will install the new instrument?
- Calibration and performance evaluation—What is needed to calibrate the equipment and validate that it is operating correctly? How will these important elements be maintained?

Equipment management. Some criteria to consider when selecting laboratory equipment are listed below:

- Why and how will the equipment be used? The instrument should be matched against the service the laboratory provides.
- What are the performance characteristics of the instrument? Is it sufficiently accurate and reproducible to suit the needs of the testing to be done?
- What are the facility requirements, including the requirements for physical space?
- Will the cost of the equipment be within the laboratory’s budget?
- Will reagents be readily available?
- Will reagents be provided free of charge for a limited period of time? If so, for how long?
- How easy will it be for staff to operate?
- Will instructions be available in a language that is understood?
- Is there a retailer for the equipment in the country, with available services?
- Does the equipment have a warranty?
- Are there any safety issues to consider?

If the decisions about purchasing are made outside the laboratory (e.g. by a central purchasing body), the laboratory manager should provide information that will support selecting equipment that will best serve the needs of the laboratory in areas where there are national programmes for purchasing standard equipment. The laboratories of the country should have some input to decisions. In addition, in areas where donors are likely to provide some of the equipment that is used, laboratory management should have input into the choice of equipment. If this is not possible, management should consider declining equipment if it is inappropriate for laboratory needs.

Is it better to purchase or lease equipment? When making this decision, it is a good idea to factor in repair costs. The manufacturer should provide all of the necessary information to operate and maintain equipment. The initial cost of an instrument may seem reasonable, but it may be expensive to repair. Also consider savings that could be negotiated if the laboratory needs more than one piece of equipment.

Before purchasing ask if:

- wiring diagrams, computer software information, a list of parts needed, and an operator’s manual are provided;
WHO LQMS Handbook

- Available in English, French and Russian
- Printed spiral-bound version
- Available for download as PDF at:
  http://www.who.int/ihr/publications/lqms/en/

(4) WHO Laboratory Quality Stepwise Implementation (LQSI) tool

- A web-based tool that provides a stepwise plan to guide medical laboratories towards implementing a quality management system in accordance with the requirements of ISO 15189.
- Based on the Global Laboratory Initiative (GLI) Stepwise Process towards Tuberculosis Laboratory Accreditation (GLI Tool). See: http://www.gliquality.org/
About the Stepwise tool ...

- Structured according to the CLSI 12 quality system essentials framework
- Uses a 4-phase approach to implementing a quality management system, with checklists for each phase
- Has an interactive roadmap to provide day-to-day guidance
- Provides to links to additional material (standard operating procedures, templates, guidelines on specific topics etc....)
- Can be downloaded for off-line use (no internet required)
The implementation of a quality management system is a helpful assessment to understand the baseline situation of the laboratory. It will provide information on where some elements of a quality system may already be in place and functioning, or may reveal areas that need to be addressed. That is, the strengths and weaknesses of the system can be objectively identified and appropriate action taken. Such assessments are of great assistance when planning for the implementation of a quality system.

The Laboratory Quality Stepwise Implementation Tool, as developed by WHO, is provided to help assess laboratories and laboratory systems. The target audience is any stakeholder performing quality assessments including national health authorities, multilateral agencies, and organizations (WHO’s) and laboratory managers. The main steps for assessing laboratories include:

1. Preparing the assessment team
2. Collecting data
3. Reviewing regulations and standards
4. Scoring and analyzing results
5. Identifying strengths and weaknesses
6. Developing an action plan
7. Monitoring progress
8. Reporting findings

The tool is currently available in English. French and Russian translations will also be prepared this year. Some WHO Country offices are investigating other languages, such as Spanish and French. The tool is available at:

https://extranet.who.int/lqsi/

A download version (for off-line use) can be requested through the webpage and transferred to requesters.
(5) Generic Laboratory Quality Manual

- Provides guidance for public health and clinical laboratories on writing policies and procedures that support a quality management system
- Comprises a main document providing information and examples to assist with writing a laboratory quality manual, together with 24 appendices. These are examples of standard operating procedures, forms and processes.
- All documents are in Word format as they are meant to serve as templates and are thus modifiable. The individual laboratories are required to customize the text of the template to the local situation.

Global capacities, alert and response
1. Introduction to the Quality Manual

1.1 Overview of the organization

As part of the diagnostic services of XXX (if big structure), the Name of the laboratory provides biochemistry, immunology, microbiology, parasitology, toxicology, virology, haematology, and testing and other tests relevant to medicine and disease surveillance to physicians, healthcare providers, and epidemiologists for the benefit of the patient and population.

The laboratory has adopted a quality management system for the purpose of the effective and efficient use of its resources. All employees are committed to the culture of quality and staff shares responsibility for identifying nonconformities or opportunities for improvement to ensure that corrective or preventive actions can be taken to ensure the laboratory meets the needs of its customers.

1.2 Mission statement

Include the organization or laboratory's mission statement here (e.g., a brief description of the laboratory's fundamental purpose for existing). These are usually defined by the laboratory director or senior administrative management.

1.3 Vision statement

Include the organization or laboratory's vision statement here (e.g., a statement of what is possible, the picture of the future laboratory in 5-year time).
Generic Laboratory Quality Manual

- Currently published as annex to chapter 16 of the LQMS Training Toolkit
- Will be moved to own landing page soon
- Available in English and Russian (French version in progress)
- Available at:
  http://www.who.int/ihr/training/laboratory_quality/quality_manual/en/

Thank you!

WHO Lyon Office
Laboratory Strengthening & Biorisk Management team

Visit us at:
http://www.who.int/ihr/lyon/hls/en/

For further information, please contact:
Dr Katrina ROPER - roperk@who.int