Technical consultation to update the WHO Malaria microscopy quality assurance manual

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

Presentations 21–29
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CRITICAL AND NON-CRITICAL STEPS IN SOP PROCEDURES FOR DEVELOPING MSB

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

Chloé Masetti
Malaria Unit WHO IST ESA

Outline

• Background: Development of the AFRO regional initiatives

• The AFRO Regional Malaria Slide Bank

• Standard Operating Procedures comparison

• Next steps
Development of the AFRO regional initiatives

- Regional Coordination Workshop on strengthening Quality Management Systems for the Parasitological Diagnosis of Malaria (2-4th September 2013 Zimbabwe)

- Participating partners: CDC-Atlanta, PMI, MalariaCare PATH, MCDI, AMREF, ICAP Ethiopia, NICD/NHLS South Africa, MoH of Zanzibar and Malawi, and WHO

- Goal: Strengthen the Quality Assurance of Malaria Microscopy (QAMM) in the African Region

- Objectives:
  - Discuss experiences on quality assurance of malaria microscopy;
  - Share experiences with the WHO external competency assessment programme;
  - Discuss setting up a regional network for external competency assessment of malaria diagnosis;
  - Review experiences on the establishment of malaria slide banks and discuss setting up Regional Slide Banks in Africa;
  - Lay the foundation to review the Malaria Microscopy Quality Assurance Manual Version 1;
  - Discuss the agenda and participation to WHO meeting on quality management systems of malaria diagnostics to be held in March 2014.

Two Regional initiatives were identified:

- The expansion of External Competency Assessment (ECA) for malaria reference microscopists;

- The creation of a Regional (AFRO) Malaria Slide Bank;
Map of the research institutes participating

Regional Malaria Slide Bank (MSB)

- Participating Research Centres shared their MSB SOPs;

- Review of existing SOPs for MSP in 7 Research Centres (RITM*, EPHI, University of Lagos, NICD, KHRC, AMREF, UCAD);

- Identify the critical steps that would affect the final quality of the Malaria Slide Bank;
Donor screening and selection

Table 1

<table>
<thead>
<tr>
<th>Critical steps</th>
<th>Degree of variability</th>
<th>NC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen by RDT</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Inclusion criteria</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Only critical factor is the intake of antimalarials from the patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample collection (e.g. finger prick, venous)</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Staining procedure</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Competency of the reader(s)</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Only critical factor is the intake of antimalarials from the patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample characterization</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Parasite quantification</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>National protocol with ethics approval</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Informed consent form</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Donor information sheet</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

Low (0-1 centre report variations); Medium (2-3 report variations); High (4≥ report variation)

Venous Blood Sample collection and batch preparation

Table 2

<table>
<thead>
<tr>
<th>Critical steps</th>
<th>Degree of variability</th>
<th>NC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Label for samples</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Amount of blood collected per donor</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>C – volume of sample to anticoagulant should comply with the recommendation form the manufacturer (cells shrink)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticoagulant used in the venepuncture tube(s)</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>C – Heparin would affect the final staining result and platelets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommended time between collection and slide preparation</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Transport and storage conditions of the samples between laboratories (when applicable)</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Availability of slides templates</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Recommended no. of staff to prepare the slides</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Volume of blood for thick film</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Diameter of the thick film</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Volume of blood for the thin film</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Ensure even distribution of parasites</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Quality control slides</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Drying time</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

Low (0-1 centre report variations); Medium (2-3 report variations); High (4≥ report variation)
Batch staining of malaria blood films with Giemsa Stain

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Degree of variability</th>
<th>Critical steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to fix the thin film in methanol</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Time needed and drying position after fixation</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Buffered water</td>
<td>Low</td>
<td>C – standardise phosphate buffer yielding pH 7.2</td>
</tr>
<tr>
<td>Stain dilution used</td>
<td>Low</td>
<td>C</td>
</tr>
<tr>
<td>Time of staining process</td>
<td>High</td>
<td>C - optimum staining time should be assessed in country (depending on water used for the staining)</td>
</tr>
<tr>
<td>Quality Control slides</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Quality control of stain under microscope</td>
<td>High</td>
<td>C</td>
</tr>
</tbody>
</table>

Low (0-1 centre report variations); Medium (2-3 report variations); High (4≥ report variation)

Examination of Giemsa-stained films

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Degree of variability</th>
<th>Critical steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microscope objective lenses</td>
<td>Low</td>
<td>NC</td>
</tr>
<tr>
<td>Microscope oculars (eyepieces)</td>
<td>Low</td>
<td>NC</td>
</tr>
<tr>
<td>Scan for other blood parasites</td>
<td>Low</td>
<td>C</td>
</tr>
<tr>
<td>Satisfactory film thickness for exam</td>
<td>Medium</td>
<td>C – however the volume and template will ensure the right thickness</td>
</tr>
<tr>
<td>No. of HPFs read to declare a Thick film is negative</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>No. of HPFs read to declare a Thin film is negative</td>
<td>High</td>
<td>NC</td>
</tr>
<tr>
<td>Method to determine the type of parasite (i.e. no. HPF, thin vs thick film)</td>
<td>Low</td>
<td>C</td>
</tr>
<tr>
<td>Parasite density (thin vs thick, WBCs)</td>
<td>Low</td>
<td>C</td>
</tr>
<tr>
<td>Parasites per WBCs</td>
<td>Medium</td>
<td>C</td>
</tr>
</tbody>
</table>

Low (0-1 centre report variations); Medium (2-3 report variations); High (4≥ report variation)
Mounting and labelling films

<table>
<thead>
<tr>
<th>Table 5</th>
<th>Degree of variability</th>
<th>Critical steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mounting media</td>
<td>Low</td>
<td>C</td>
</tr>
<tr>
<td>Volume of medium per slide</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Coverslip</td>
<td>Medium</td>
<td>C</td>
</tr>
<tr>
<td>Standardized labelling system</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Bar coding</td>
<td>Medium</td>
<td>C</td>
</tr>
</tbody>
</table>

Low (0-1 centre report variations); Medium (2-3 report variations); High (4≥ report variation)

Validation Process

<table>
<thead>
<tr>
<th>Table 6</th>
<th>Degree of variability</th>
<th>Critical steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of microscopists performing the validation</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Number of WHO certified Level 1 validators</td>
<td>High</td>
<td>C – Level 1 microscopists may be recruited internally and/or externally</td>
</tr>
<tr>
<td>Number of slides read blindly by each validator per batch</td>
<td>Medium</td>
<td>C</td>
</tr>
<tr>
<td>Method to obtain reference parasite density (mean vs average)</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Validation of positivity (microscopy, NAT)</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Validation of species (microscopy, NAT)</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Type of samples confirmed by NAT</td>
<td>High</td>
<td>C</td>
</tr>
<tr>
<td>Method of NAT used</td>
<td>(Not enough information)</td>
<td>NC</td>
</tr>
</tbody>
</table>

Low (0-1 centre report variations); Medium (2-3 report variations); High (4≥ report variation)
Related Procedures

<table>
<thead>
<tr>
<th>Table 7</th>
<th>Degree of variability</th>
<th>Critical steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of Giemsa Stock</td>
<td></td>
<td>C</td>
</tr>
<tr>
<td>Giemsa powder</td>
<td>(Not enough information)</td>
<td>C</td>
</tr>
<tr>
<td>Preparation of Venous Blood Spots on filter paper</td>
<td></td>
<td>C</td>
</tr>
<tr>
<td>Dried Blood Spot card</td>
<td>Medium</td>
<td>C</td>
</tr>
<tr>
<td>Volume of blood per DBS</td>
<td>Medium</td>
<td>C</td>
</tr>
<tr>
<td>Number spots per donor</td>
<td>Low</td>
<td>C</td>
</tr>
<tr>
<td>Drying time of DBS</td>
<td>Low</td>
<td>C</td>
</tr>
<tr>
<td>Storage of DBS</td>
<td>Low</td>
<td>C</td>
</tr>
<tr>
<td>Dilution of blood samples to desired parasitaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume of blood obtained from negative donor</td>
<td>High</td>
<td>NC</td>
</tr>
<tr>
<td>Cell clumping (agglutination) test</td>
<td>Low</td>
<td>C</td>
</tr>
</tbody>
</table>

Low (0-1 centre report variations); Medium (2-3 report variations); High (4≥ report variation)

Regional MSB – next steps

- Harmonization of the MSB SOPs;
- Carry out an independent evaluation and needs assessment of selected centres;
- Reach a consensus on which centres would collect samples and be the repository of the Regional MSB;
- Establish MoU between the collaborating centres;
- Proceed to establish the MSB and modality of use;
- Put in place QA/QC mechanisms to maintain the high standards of the MSB.
Acknowledgements

- African Medical and Research Foundation (AMREF), Kenya
- Ethiopian Public Health Research Institute (EPHI), Ethiopia
- Research Institute for Tropical Medicine (RITM), Philippines
- Kintampo Health Research Centre (KHRC), Ghana
- National Institute for Communicable Diseases (NICD), South Africa
- Université Cheikh Anta Diop (UCAD), Senegal
- University College of Lagos, Nigeria
- Partners involved in the Regional Working Group initiative

Thank you!
22 - Blood sampling for PCR

DNA recovery from Blood collected in tubes vs. dried blood spots

Michael Aidoo.

CDC/PMI
Division of Parasitic Diseases,
Centers for Disease Control and Prevention,
Atlanta.
March 27, 2014

The need for well-characterized samples for slide Banks

Slides to be used for training and proficiency testing

- PCR confirmation
  
  (PCR more sensitive than microscopy - LOD 1 vs. 50 p/µl)

- no ambiguity in true nature of samples
The need for well-characterized samples for slide Banks

PCR better suited for characterization but requires attention to:

- DNA extraction method
- PCR methodology

Advantages of using DBS

Dried blood spots as a source for DNA

- minimally-invasive sample collection method
- ease of collection from remote settings
- room temperature storage (no Freezing short-term)
- ease of transport and storage (less bulky)
- low sample processing cost
Challenges to using DBS

Dried blood spots as a source for DNA

- Subject to quality of paper
- DNA target (host genes vs microbe)
- DNA degradation
- Small sample volume translates to low quantity of target DNA

Systematic review

**HIV viral Load in 100 μL**

- Lower LOD DBS: 2.9 to 3.3 log_{10} RNA copies/mL (four studies)
- Correlation with liquid plasma: 0.72 to 0.99 log_{10} (eight studies)

**Resistance Genotyping**

- DBS amplification success rates: 58% to 95% (eight studies)*

*amplification success rates higher when VL > 3 log_{10} RNA copies/mL

Hamers RL et al. 2009
**DRIED BLOOD SPOT/VENOUS BLOOD COMPARISON**

The comparison of DBS-based assay results with those from matched, simultaneously collected plasma samples using a previously established, “gold standard”

A reasonable analysis can be achieved with 40 or more samples, although 100 or so would be preferable.

It is important to have sufficient numbers of samples that cover the entire range of likely values


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**CDC Study on DBS vs whole blood**

Serially diluted parasite positive blood split into:

- DBS
- Tubes

Monitored overtime using same extraction methods and PCR procedures
Will the use of DBS compromise sample characterization?

Thank You
23 - Proficiency testing for malaria – NICD

Profiency Testing for Malaria Microscopy: Experience from NICD, South Africa

Bhavani Poonsamy
Centre for Opportunistic, Tropical and Hospital Infections – Parasitology Reference Laboratory
National Institute for Communicable Diseases

Outline

• Background
• NICD, NHLS malaria/ blood parasite PT schemes
• Planning a PT scheme
  • Aims of the scheme
  • Challenge schedule and number of blood films needed
  • Budget (Personnel, equipment, reagents and consumables)
  • Referee laboratories
  • Reliable efficient method of distribution
  • SOPs and forms for standardised procedures
  • Determining the true results (identification and parasite counts)
  • Scoring system
  • Assessment software/ programmes
  • Standardised reporting
• Planned improvements
• Summary
Background

- Malaria PT schemes form a crucial part of the QA system, as it external and unbiased.

- The National Institute for Communicable Diseases (NICD) have coordinated five Parasitology EQA Programmes/ PT Schemes over the last ~30 years. Four are malaria/blood parasite schemes.

- Each is different and designed around the aims as set by the funder/ requestor.

- In 2007, we became ISO 15189 (medical laboratories) accredited and in 2013 we accredited our PT Schemes to ISO 17043. This has ensured that meet the requirements of two stringent quality systems.

<table>
<thead>
<tr>
<th>PT Scheme</th>
<th>Year established</th>
<th>Funder</th>
<th>Participants*</th>
<th>Structure of scheme</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NHLS Blood Parasites</td>
<td>1986</td>
<td>NHLS/ NICD</td>
<td>254 laboratories</td>
<td>5 challenges/ survey</td>
<td>3 surveys/ year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(±3500 slides/ year)</td>
<td></td>
</tr>
<tr>
<td>WHO/NICD Malaria</td>
<td>2005</td>
<td>WHO Afro</td>
<td>75 laboratories</td>
<td>10 challenges/ survey</td>
<td>3 surveys/ year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(±2600 slides/ year)</td>
<td></td>
</tr>
<tr>
<td>GSK/ NICD Malaria</td>
<td>2006</td>
<td>GSK</td>
<td>~136 microscopists</td>
<td>20 challenges/ survey</td>
<td>3 surveys/ year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(±900 slides/ year)</td>
<td></td>
</tr>
<tr>
<td>BARC/ NICD Malaria</td>
<td>2009</td>
<td>Pfizer</td>
<td>7 laboratories</td>
<td>~35 microscopists</td>
<td>10 challenges/ survey</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(±160 slides/ year)</td>
<td>1-2 surveys/ year</td>
</tr>
</tbody>
</table>

*Including referee laboratories
Guidelines

• There is no guideline for coordinating malaria PT schemes!
  Should there be?
  What should be included?

• Guidelines could state basic requirements for coordinating a PT scheme, such as:
  • A well established slide bank and a contract with the funder*
  • Aims of the scheme
  • Challenge schedule and number of blood films needed
  • *Budget (personnel, equipment, reagents and consumables)
  • Referee laboratories
  • Reliable efficient method of distribution
  • SOPs and forms for standardised procedures
  • Determining the true results (identification and parasite counts)
  • Scoring system
  • Assessment software/ programmes
  • Standardised reporting, with corrective actions

---

PT Schemes coordinated by NICD

<table>
<thead>
<tr>
<th>PT Scheme</th>
<th>Year established</th>
<th>Funder</th>
<th>Participants*</th>
<th>Structure of scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHLS Blood Parasites</td>
<td>1986</td>
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</tr>
<tr>
<td>WHO/NICD Malaria</td>
<td>2005</td>
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<td>75 laboratories</td>
<td>10 challenges/ survey 3 surveys/ year (±2600 slides/ year)</td>
</tr>
<tr>
<td>GSK/ NICD Malaria</td>
<td>2006</td>
<td>GSK</td>
<td>~136 microscopists</td>
<td>20 challenges/ survey 3 surveys/ year (±900 slides/ year)</td>
</tr>
</tbody>
</table>
Aims of the PT Scheme

- Each scheme design varies depending on the aims of the scheme as provided by the funder.

Consider the following:
- External Quality Assessment or External Quality Assurance?
- Does the PTS need to assess:
  - a laboratory or individual microscopists?
  - microscopy and/or technique?
  - identification of malaria or all blood parasites?
  - identification and/or quantitation?
  - accuracy and/or consistency of parasite counts
- Language

NICD PT Schemes – aims and design

<table>
<thead>
<tr>
<th>PT Scheme</th>
<th>Participants</th>
<th>Assessment criteria</th>
<th>Quantitation assessment</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHLS Blood Parasites</td>
<td>Laboratories</td>
<td>Microscopy (identification and quantitation)</td>
<td>Accuracy of thin film counts (%)</td>
<td>English</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Technique (staining, RDT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO/ NICD Malaria</td>
<td>Laboratories</td>
<td>Microscopy (identification and quantitation)</td>
<td>Accuracy and consistency of thick film counts (p/μl)</td>
<td>English, French (Portuguese)</td>
</tr>
<tr>
<td>GSK/ NICD Malaria</td>
<td>Microscopists</td>
<td>Microscopy (identification and quantitation)</td>
<td>Accuracy and consistency of thick film counts (p/μl)</td>
<td>English</td>
</tr>
</tbody>
</table>
Challenge design and schedule

Budget

- Costs for slide preparation, PCR are minimal.
- Couriering and personnel are costly.

<table>
<thead>
<tr>
<th>Cost per lab/ year</th>
<th>Should be</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHLS Blood Parasites PT Scheme</td>
<td>R 1 700</td>
</tr>
<tr>
<td>WHO Malaria PT Scheme*</td>
<td>R 2 500</td>
</tr>
<tr>
<td>GSK Malaria PT Scheme*</td>
<td>R 20 000</td>
</tr>
</tbody>
</table>

*excluding couriering
Referee laboratories

- To ensure the quality of material sent out for each survey and the standard of assessment, the model (expected) results are compared against the referee laboratories. These can either be selected from the participants or be independent.

- **NHLS Blood Parasites PT Scheme** selected from top participants
- **WHO Malaria PT Scheme** independent laboratories
  (Philippines, Oman, London, Peru, Honduras)
- **GSK Malaria PT Scheme** independent laboratories
  (Philippines, Oman)

Reliable efficient method of distribution

- Courier system which allows you to track package until delivery.
- Need to be cognizant of custom delays, which may affect result deadlines.
- Sharing this cost with other NICD PT schemes has reduced costs considerably.*

- *NHLS Blood Parasites PT Scheme* local courier + DHL for Africa
- *WHO Malaria PT Scheme* DHL for Africa
- *GSK Malaria PT Scheme* DHL & World Courier for Africa
SOPs and forms for standardisation

For example the NHLS Blood Parasites PT Scheme:

1. Plan surveys for the year, place orders, select referees QASP0013/17/19
2. Prepare surveys 2-3 weeks before shipping date QASP0001/4/8
   [Blood films prepared mostly during malaria season Dec-Mar]
3. Send participants survey with instructions QASP0019
4. Receive results by fax, post and email QASP0002
5. Send provisional results QASP0009
6. Analyse referee responses QASP0010
7. Design marking schedule QASP0012
8. Mark participants results QASP0012
9. Capture data, and retrieve stats QASP0018
10. Design commentary QASP0015
11. Print and post individual results and commentary QASP0019
12. Prepare summary report for the survey QASP0019

Determining the true results

- Validation of true result in reference/ sending laboratory (MSB):
  - Consensus of multiple microscopy readers
  - PCR

- For scoring use:
  - Result of reference/ sending laboratory
  - Referee laboratory consensus
  - Participant consensus
  - Referee laboratory and participant consensus

- NHLS Blood Parasites PT Scheme 70% referee (or participant) consensus
- WHO Malaria PT Scheme NICD and referee consensus
- GSK Malaria PT Scheme NICD and referee consensus
Scoring system

<table>
<thead>
<tr>
<th>Score</th>
<th>Result</th>
<th>Definition</th>
<th>Performance assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Completely correct result</td>
<td>A result accepted as the most correct and clinically relevant result.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td>Almost completely correct result</td>
<td>A result not entirely correct but having little or no clinical impact; a deviation from what is considered the most clinically relevant result.</td>
<td>Acceptable</td>
</tr>
<tr>
<td></td>
<td>Separator</td>
<td>To divide the acceptable from unacceptable responses.</td>
<td>N/A</td>
</tr>
<tr>
<td>1</td>
<td>A significantly incorrect result</td>
<td>A clinically relevant result that could lead to a minor diagnosis or treatment error.</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>0</td>
<td>Completely incorrect result</td>
<td>A clinically relevant result that could lead to a major diagnosis or treatment error.</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>0</td>
<td>No result</td>
<td>No result submitted by participant.</td>
<td>Unacceptable</td>
</tr>
</tbody>
</table>

Assessment software/ programmes

- Microsoft Access or Excel
- Special PTS software
- Consider validation of software
- NHLS Blood Parasites PT Scheme: Microsoft Access
- WHO Malaria PT Scheme: Microsoft Excel + Access
- GSK Malaria PT Scheme: Microsoft Excel

Planned improvement: we will be introducing an online entry system for the WHO/NICD Malaria PT Scheme.
Standardised reporting

- Provisional/interim? and final individual results, with CA and commentary?
- Executive summary reports for the funders
- Post/email reports

- **NHLS Blood Parasites PT Scheme**
  - Provisional results emailed
  - Post individual reports, CAs and commentaries
  - Regional and executive reports sent to NHLS

- **WHO Malaria PT Scheme**
  - Provisional results emailed
  - Post individual reports, CAs and commentaries
  - Executive summary report sent to WHO Afro

- **GSK Malaria PT Scheme**
  - Provisional results emailed
  - Email individual reports and commentaries
  - GSK sent all results

Summary

- PT schemes require a lot of coordination and planning; standardisation of procedures is very important. It is critical that the aims of the scheme be clear as this will guide the coordination. NICD has coordinated basic, intermediate and advanced malaria PT schemes.

- The guidelines on MSB development are very useful as this is one of the main pre-requisites to running a malaria PT scheme, but no other guidance for malaria PT scheme coordination is given.

- Other schemes that offer malaria/blood parasite PT schemes is UKNEQAs and CAP.
  - They sometimes send thick or thin films only for some challenges
  - Paper challenges are becoming more common
  - *Both use thin film (%) counts – consider adding to QA manual*
Acknowledgements

- NICD, NHLS
  - Parasitology Reference Laboratory for maintaining slide bank and coordinating PT schemes
  - Microbiology External Quality Assessment Reference Laboratory for coordinating couriering of the NHLS and WHO PT schemes.
- Our sample providers
  - NHLS laboratories
- Our funders
  - World Health Organization for the African region
  - GlaxoSmithKline
- Our referee laboratories
- Our participating laboratories

24 - Regional scheme for proficiency testing – AMREF

East African Regional External Quality Assessment Scheme (EA-REQAS)

Improving the quality of essential diagnostic services in peripheral health facilities in East Africa
Background

- **2001 - 2003:** MoH Kenya, Mainland Tanzania, Zanzibar & Uganda established the pilot *East African Regional External Quality Assessment Scheme (EA-REQAS)*

- **Major regional meetings** (Arusha, Tanzania, 2003; Zanzibar 2006; Kampala 2009; Nairobi 2010) critical resolutions & recommendations made:
  - Sharing *standards & materials*
  - Strengthening *national QA bodies*
  - *East African Regional External Quality Assurance Committee (EA-REQAC) formed*
  - Determining *critical tests* to be assessed
  - Selecting *reference laboratories* for material preparation
  - Development of *Standard Operating Procedures (SOPs)*
  - Processes for review & reporting of *scheme activities* and *laboratory performance*
  - AMREF appointed as the *Regional Coordinating Centre (RCC)*

**EA-REQAS**

**Goal:** Improve the quality of diagnostic services in peripheral health facilities through regular submission of proficiency testing materials & provision of health learning materials and advice on corrective actions

**Objectives:**

1. Establish an External Quality Assessment Scheme (EQAS) to enhance the performance of *essential diagnostic services in health facilities at peripheral level*
2. Implement mechanisms for *monitoring & enhancing the quality of essential diagnostic services*
3. Use evidence and performance to *influence policy and practice*

**Multiple partners and donors:** MoHs, EAC, WHO, Izumi Foundation, USAID, CDC
Geographical Coverage: current

Total 477 facilities
2 surveys/year

157 Tanzania
112 Uganda
178 Kenya
21 Zanzibar
9 Burundi

5 – 8 facilities per district
District hospital
Sub-district hospital
2-3 health centres (government)
1-2 faith-based
1-2 private

Basic tests: clinical & public health importance

<table>
<thead>
<tr>
<th>Country of production</th>
<th>Materials</th>
</tr>
</thead>
</table>
| Mainland Tanzania     | • Blood slides for malaria parasites  
                       | • Blood slides for *Borrelia*     
                       | • HIV serology                 
                       | • Syphilis serology            |
| Kenya                 | • Peripheral blood films        
                       | • Preserved blood lysate        
                       | • Haemoglobinocyanide standard  
                       | • Smears for Gram stain        |
| Uganda                | • Sputum smears for AFB         
                       | • Blood films for trypanosomes  |
| Zanzibar              | • Stool and urine helminth ova  
                       | • Blood films for microfilariae |
**EA-REQAS activities**

- **Survey / questionnaire preparation**
  - Assess laboratory technical expertise
  - Measure level of cooperation between clinical, laboratory & public health staff
- **Slide / test material preparation (7)**
  Every survey includes:
  - *thick & thin blood films for parasites*
  - *Hb lysate*
  - *TB smear*
  - *HIV serology*
  - *Plus 3 others*
- **Preparing marking keys**
- **Packaging materials**
- **Sending materials + questionnaires by EMS**
- **Telephone follow up**
- **Marking responses and preparing reports**

**Comprehensive, automated data base: analysis, report generation**

---

**Clinical scenarios**

<table>
<thead>
<tr>
<th>Clinical scenario</th>
<th>Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey 4</td>
<td></td>
</tr>
<tr>
<td>IDA in an adult</td>
<td>1 stained thin blood film</td>
</tr>
<tr>
<td></td>
<td>1 preserved stool</td>
</tr>
<tr>
<td></td>
<td>1 Hb lysate</td>
</tr>
<tr>
<td>STI in a neonate</td>
<td>1 serum for HIV</td>
</tr>
<tr>
<td></td>
<td>1 fixed, unstained smear for Gram stain</td>
</tr>
<tr>
<td>Malaria in a non-immune individual</td>
<td>1 stained thick &amp; thin blood film</td>
</tr>
<tr>
<td>Pulmonary TB</td>
<td>1 stained (ZN) sputum smear</td>
</tr>
<tr>
<td>Survey 10</td>
<td></td>
</tr>
<tr>
<td>Anaemia &amp; diarrhoea in a child</td>
<td>1 Hb lysate</td>
</tr>
<tr>
<td></td>
<td>1 preserved stool</td>
</tr>
<tr>
<td>Routine ANC attendance</td>
<td>1 serum for HIV</td>
</tr>
<tr>
<td></td>
<td>1 serum for syphilis</td>
</tr>
<tr>
<td>Persistent cough in an adult male</td>
<td>1 fixed, unstained (ZN) sputum smear</td>
</tr>
<tr>
<td>Fever with another obvious cause of fever</td>
<td>1 stained thick &amp; thin blood film</td>
</tr>
<tr>
<td></td>
<td>Gram stain of pus smear</td>
</tr>
</tbody>
</table>
### Setting target values

<table>
<thead>
<tr>
<th>Reference laboratory</th>
<th>Date sent</th>
<th>Lysate</th>
<th>Lysate</th>
<th>Blood slide</th>
<th>Blood slide</th>
<th>HIV screening</th>
<th>Gram stain</th>
<th>Ziehl Neelsen</th>
<th>Ziehl Neelsen</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAB 1</td>
<td>10-03-08</td>
<td>9.5g/dl</td>
<td>11.7g/dl</td>
<td>60/200WBC</td>
<td><em>P. falciparum</em></td>
<td>Negative</td>
<td>+ve diplococci pus cells 2+</td>
<td>AFB 3+</td>
<td>AFB 1+</td>
</tr>
<tr>
<td>LAB 2</td>
<td>10-03-08</td>
<td>9.9g/dl</td>
<td>12.2g/dl</td>
<td>55/200WBC</td>
<td><em>P. falciparum</em></td>
<td>Negative</td>
<td>+ve diplococci few pus cells</td>
<td>AFB 3+</td>
<td>AFB 1+</td>
</tr>
<tr>
<td>LAB 3</td>
<td>10-03-08</td>
<td>9.3g/dl</td>
<td>11.1g/dl</td>
<td>68/200WBC</td>
<td><em>P. falciparum</em></td>
<td>Negative</td>
<td>+ve diplococci few pus cells</td>
<td>AFB 3+</td>
<td>AFB 1+</td>
</tr>
<tr>
<td>LAB 4</td>
<td>10-03-08</td>
<td>-</td>
<td>-</td>
<td>70/200WBC</td>
<td><em>P. falciparum</em></td>
<td>Negative</td>
<td>+ve diplococci and pus cells</td>
<td>AFB 3+</td>
<td>AFB 1+</td>
</tr>
<tr>
<td>LAB 5</td>
<td>10-03-08</td>
<td>9.4g/dl</td>
<td>10.8g/dl</td>
<td>62/200WBC</td>
<td><em>P. falciparum</em></td>
<td>Negative</td>
<td>+ve diplococci few pus cells</td>
<td>AFB 3+</td>
<td>AFB1+</td>
</tr>
<tr>
<td>Means/consensus</td>
<td></td>
<td>9.5 g/dl</td>
<td>11.3 g/dl</td>
<td>62/200WBC</td>
<td><em>P. falciparum</em></td>
<td>Negative</td>
<td>+ve diplococci few pus cells</td>
<td>AFB 3+</td>
<td>AFB1+</td>
</tr>
</tbody>
</table>

### Quantitative, semi-quantitative answers: marking keys

#### Malaria parasite detection and parasite count

- **Malaria parasites seen, correct species**
  - If *P. falciparum*: ±25% of correct count/200 or 500 WBC
  - 3 marks

- **Malaria parasites seen**
  - If *P. falciparum*: ± >25% ≤ 50% of correct count/200 or 500 WBC
  - 2 marks

- **Malaria parasites seen**
  - Wrong species (if *P. vivax, P. ovale, P. malariae* missed)
  - If *P. falciparum*: ± >50% of correct count/200 WBC or no count
  - 1 mark

- **False positive, no species**
  - 0 mark

- **No answer**
  - 00 mark

- **False negative, wrong species (if *P. falciparum* missed)**
  - -1 mark
### Qualitative answers: coded answer sheet

#### LABORATORY

<table>
<thead>
<tr>
<th>Blood parasites</th>
<th>Treatment of parasitic infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>LBP001 <em>Borrelia</em> spp</td>
<td>CTP001 Albenzol 200 mg stat</td>
</tr>
<tr>
<td>LBP002 <em>Leishmania donovani</em></td>
<td>CTP002 Amodiaquine 3 tablets daily x 3 days</td>
</tr>
<tr>
<td>LBP003 Loa loa</td>
<td>CTP003 Artemether - Lumefantrine (AL) 6 doses over 3 days by body weight</td>
</tr>
<tr>
<td>LBP004 Malaria parasites seen</td>
<td>CTP004 Artesunate - Amodiaquine 3 doses over 3 days by body weight</td>
</tr>
<tr>
<td>LBP005 Microfilaria</td>
<td>CTP005 Choroquine 600 mg (base), 300 mg 6 hours later, then 300 mg daily x 2 days</td>
</tr>
<tr>
<td>LBP006 <em>Plasmodium falciparum</em></td>
<td>CTP006 Ivermectin 150 - 200 µg/kg single dose</td>
</tr>
<tr>
<td>LBP007 <em>Plasmodium malariae</em></td>
<td>CTP007 Levamisole 2.5 mg/kg stat</td>
</tr>
<tr>
<td>LBP008 <em>Plasmodium ovale</em></td>
<td>CTP008 Mebendazole 100 mg bd x 3 days</td>
</tr>
<tr>
<td>LBP009 <em>Plasmodium vivax</em></td>
<td>CTP009 Quinine tablets (600 mg salt) every 8 hours x 7 days</td>
</tr>
<tr>
<td>LBP011 <em>Frypanosoma</em></td>
<td>CTP10 Sulphadoxine-pyrimethamine (SP) 3 tablets stat</td>
</tr>
<tr>
<td>LBP012 <em>Wuchereria bancrofti</em></td>
<td></td>
</tr>
<tr>
<td>LBP013 No malaria parasites seen</td>
<td></td>
</tr>
<tr>
<td>LBP014 No blood parasites seen</td>
<td></td>
</tr>
</tbody>
</table>

#### PUBLIC HEALTH

| PH001 Encourage contacts to go for screening         |                                  |
| PH002 Advice on coughing/sneezing                   |                                  |
| PH003 Advice concerning public transport            |                                  |
| PH004 Mass screening and treatment                  |                                  |
| PH005 Mass drug administration                      |                                  |
| PH006 Use of insecticide treated bednets (ITNs) or long- lasting insecticide treated bednets (LLINs) |                                  |
| PH007 Insecticides: sprays, coils, repellants       |                                  |

### Response rate

**Response rate per survey**

<table>
<thead>
<tr>
<th>Survey</th>
<th>Response Rate %</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>55%</td>
</tr>
<tr>
<td>S2</td>
<td>56%</td>
</tr>
<tr>
<td>S3</td>
<td>56%</td>
</tr>
<tr>
<td>S4</td>
<td>49%</td>
</tr>
<tr>
<td>S5</td>
<td>48%</td>
</tr>
<tr>
<td>S6</td>
<td>48%</td>
</tr>
<tr>
<td>S7</td>
<td>41%</td>
</tr>
<tr>
<td>S8</td>
<td>41%</td>
</tr>
<tr>
<td>S9</td>
<td>40%</td>
</tr>
<tr>
<td>S10</td>
<td>40%</td>
</tr>
<tr>
<td>S11</td>
<td>43%</td>
</tr>
<tr>
<td>S12</td>
<td>43%</td>
</tr>
</tbody>
</table>
**Turnaround time**

![Turnaround time graph]

**Performance**

![Performance graph]
Performance in malaria microscopy

**Malaria parasites seen, correct species**
- If *P. falciparum*: ±25% of correct count/200 or 500 WBC
- Correct negative result: 3 marks, Good

**Malaria parasites seen**
- If *P. falciparum*: >25% ≤ 50% of correct count/200 or 500 WBC
- 2 marks, Fair

**Malaria parasites seen**
- Wrong species (if *P. vivax*, *P. ovale*, or *P. malariae* missed)
  - If *P. falciparum*: >50% of correct count/200 WBC or no count
  - 1 mark, Fair
- False positive, no species
  - 0 mark, Poor
- False negative, wrong species (if *P. falciparum* missed)
  - -1 mark, Poor

---

**EA-REQAS website**

*Select Your Country for Questionnaire Distribution 5S12-2013*

**Resources**
- About the EA-REQAS
- EA-REQAS Contacts
- Partners and Donors
- Participating Labs
- Reports and Publications
- Learning Materials
- EA-REQAS Calendar
- Check Mail
- EA-REQAS Contact Form
- EA-REQAS Participating
- Facilities Map

---

Survey 5S12-2013 closes on 15.12.2013 3:00 PM

Select your country to begin the survey 5S12-2013.
Learning Materials

Reports and Publications
Way Forward & Challenges

- ISO 17043 in process
- Decentralising data entry to Tanzania, Uganda
- Rapid scale up

- Unreliable material production by reference laboratories
- Remoteness of health facilities targeted
- No/incomplete responses:
  - Shortages of qualified and motivated health workers
  - High staff turnover
  - Shortages of supplies, equipment maintenance
  - Working with different levels of the health system

Contacts

For further information on the East African Regional External Quality Assessment Scheme (EA-REQAS), please visit the website www.eareqas.org or contact:

Stephen Munene
AMREF HQ Clinical & Diagnostics Programme
P. O. Box 30125 – 00100, Nairobi
Tel +256 20 6994000; Fax +254 20 6002191
kenya.lab@amref.org

For further information on AMREF, please visit: www.amref.org
25 - Slide validation for malaria in India

**Malaria Microscopy - Quality Assurance in India**

Suman Lata Wattal
Deputy Director(Malaria)

National Vector Borne Disease Control Programme (Dte. General of Health Services)
Ministry of Health and Family Welfare
Delhi, India

**Malaria situation in India**

<table>
<thead>
<tr>
<th>API</th>
<th>2000</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of districts</td>
<td>%</td>
<td>No. of districts</td>
</tr>
<tr>
<td>&gt;10</td>
<td>59</td>
<td>10</td>
</tr>
<tr>
<td>&gt;5-10</td>
<td>22</td>
<td>3.7</td>
</tr>
<tr>
<td>&gt;2-5</td>
<td>65</td>
<td>11.14</td>
</tr>
<tr>
<td>1-2</td>
<td>72</td>
<td>12.2</td>
</tr>
<tr>
<td>&lt;1</td>
<td>370</td>
<td>63</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>API</th>
<th>Stratification of Districts based on API</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>0-1 districts</td>
</tr>
<tr>
<td>&gt;1-2</td>
<td>1-2 districts</td>
</tr>
<tr>
<td>&gt;2-5</td>
<td>2-5 districts</td>
</tr>
<tr>
<td>&gt;5-10</td>
<td>5-10 districts</td>
</tr>
<tr>
<td>&gt;10</td>
<td>&gt;10 districts</td>
</tr>
</tbody>
</table>

API - 2000/2012
Districts in brackets indicate API 0
Magnitude of Malaria Burden in States

- Malaria is a public health problem in 16 states which includes:
  - 7 North Eastern states and 9 Other states - Orissa, Jharkhand, Chhattisgarh, MP, Andhra Pradesh, Maharashtra, Gujarat, Karnataka & West Bengal.

- These State contribute to the Country:
  - Population-54%
  - Total Malaria->80%
  - Pf. Cases>90%
  - Death due to malaria >90%
### Trend of Malaria Parameters in India (2001 to 2013*)

<table>
<thead>
<tr>
<th>Year</th>
<th>ABER</th>
<th>SPR</th>
<th>SFR</th>
<th>ABER, SPR &amp; SFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>2.00</td>
<td>1.00</td>
<td>0.50</td>
<td>1.00</td>
</tr>
<tr>
<td>2002</td>
<td>1.50</td>
<td>0.80</td>
<td>0.40</td>
<td>0.60</td>
</tr>
<tr>
<td>2003</td>
<td>1.00</td>
<td>0.60</td>
<td>0.30</td>
<td>0.40</td>
</tr>
<tr>
<td>2004</td>
<td>0.50</td>
<td>0.40</td>
<td>0.20</td>
<td>0.30</td>
</tr>
<tr>
<td>2005</td>
<td>0.00</td>
<td>0.20</td>
<td>0.10</td>
<td>0.10</td>
</tr>
<tr>
<td>2006</td>
<td>0.00</td>
<td>0.10</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>2007</td>
<td>0.00</td>
<td>0.05</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>2008</td>
<td>0.00</td>
<td>0.03</td>
<td>0.02</td>
<td>0.02</td>
</tr>
<tr>
<td>2009</td>
<td>0.00</td>
<td>0.02</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>2010</td>
<td>0.00</td>
<td>0.01</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>2011</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>2012</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>2013</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

* Provisional

### Reported & Estimated Malaria cases, Pf Malaria and Malaria Deaths

<table>
<thead>
<tr>
<th>Reported*</th>
<th>Global</th>
<th>SEARO</th>
<th>India</th>
<th>*As per Reported - India is at</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria cases</td>
<td>94.30 Mil.</td>
<td>4.44 Mil.</td>
<td>1.59 Mil.</td>
<td>18th position- total malaria</td>
</tr>
<tr>
<td>Pv cases</td>
<td>16.40. Mil.</td>
<td>3.3 Mil.</td>
<td>0.76 Mil.</td>
<td>21st position deaths.</td>
</tr>
<tr>
<td>Pf cases</td>
<td>77.90 Mil.</td>
<td>1.1 Mil.</td>
<td>0.83 Mil.</td>
<td>*India contributed against world malaria</td>
</tr>
<tr>
<td>Malaria deaths</td>
<td>3,45,960</td>
<td>2,426</td>
<td>1,018</td>
<td>1.7 % to the total Malaria</td>
</tr>
<tr>
<td>Estimated Malaria deaths</td>
<td>6,55,000</td>
<td>38,000</td>
<td></td>
<td>4.6 % to total Pv. Case</td>
</tr>
</tbody>
</table>

*Source: World Malaria Report 2011

- Estimated cases and deaths are approx:
  - Dhingra et al (2010) -- Deaths 125,000-277,000
  - VBCDCP (Padam Singh) Committee- Cases 9.7 mil Deaths 30,000-48,000
  - WHO- Estimated cases 9.0 mil Deaths 15,000-25,000
  - Christopher: (2012) Estimated Deaths due to malaria 46,800

- 7 North Eastern states and 9 Other states Odisha, Jharkhand, Chhattisgarh, MP, AP, Maharashtra, Gujarat, Karnataka & West Bengal. These states contribute to the total of Country Population-54%, Total Malaria->80%, Pf. Cases>90%, and Death due to malaria >90%
Diagnostic tests for Malaria used in NVBDCP

1. Malaria microscopy
2. RDTs (bivalent introduced in 2013)

- Testing by RDT: ~ 20%
- Malaria Microscopy: ~ 80%

*: J.S.B. stain is used.

Training material and networking of Labs

- NVBDCP is the nodal agency for implementation of Malaria programme and has networked the laboratories involving Apex institute, Medical colleges, Regional and State referral Laboratories (SRL), ROHFW and ZMOs for QA MM

- The following SOPs and manuals have been developed:
  - Manual on Quality Assurance of Laboratory Diagnosis of Malaria by Microscopy
  - Manual on Quality Assurance of Laboratory Diagnosis of Malaria by Rapid Diagnostic Tests
  - Manual on Quality Assurance of Laboratory Diagnosis of Malaria: Networking of Laboratories
  - Laboratory Diagnosis of Malaria: Operational Guidelines for Laboratory Technicians
Documents developed by NVBDCP for QA

Roles & responsibilities at each level - Central, Regional, State, district has been well defined in the manuals/SOPs

QA – Malaria Microscopy

- For slide examination 10% ABER is targeted.

- All positives and 5% of the negative slides are cross checked.

- Positive slides are cross-checked on 50:50 sharing basis by Central Malaria Lab of the networked ROHFW/research institute and district/zonal laboratory.

- Negative slides are cross-checked in the proportion of 1.5:8.5 by the ROHFW & networked district/zonal lab/research institute.
Supervision

- Regular monitoring at central level through visits by NVBDCP
- Regular monitoring at state level & district level by visits of Regional Director, DMO and identified expert LTs to randomly selected 2-3 PHC labs to
  - confirm that the LTs are doing their jobs according to their training.
  - assess whether they need re-orientation training/or their performance is satisfactory.
  - suggest necessary corrections to their work as per the requirement.
  - find whether the performance of LT is affected due to faulty equipment or poor quality of logistics supplied.
  - see whether NVBDCP SOPs are followed.
- This also provides opportunity to LTs to discuss the difficulties & rectify mistakes.

Training of Lab Technicians for MM

- 10 days introductory training for newly recruited technicians/existing untrained technicians at well established State level training centres, Research Institutes and Medical colleges.
- 5 days reorientation training for in-service lab. Technicians at the district or state level as per requirement through performance assessment.
- All training labs have their own collection of training slides
Cross checking time line

• QA cell at NVBDCP issues a code by 9th day of each month to the states/ROH&FW & ICMR institutes by email or telephone/fax
• ROH&FW forwards the code by 10th day of each month to the / States/districts by email or telephone/fax
• District forwards the code on the same day or not later than the next day
• On 12th day slides must be dispatched from PHCs to District Malaria Officer(DMO)
• On 13th day DMOs must dispatch the slides to respective labs as networked (under intimation to State Programme Officer)

Results
• By 15th day of succeeding month (copy to State, Dte, NVBDCP)
• DMOs convey the results during the monthly review meetings and prepare the action plan if required to improve the quality under intimation to the State/ ROH&FW)

Cross checking time line

• All slides are preserved at the PHC level laboratory until the crosschecking results are received back.

• In case of high discrepancy rate i.e. 2% or above, the SPO and Regional Director of each ROHFW should take the necessary remedial action like supervision of the concerned laboratory reporting high discrepancy.
### Cross checking parameters

- Quality of blood smear – thick and thin
- Quality of stain used.
- Parasite species and stage.
- Discrepancy of results
  - ✅ Based on the results, feedback for corrective action is suggested to the lab technician
  - ✅ If required lab visit or training is arranged.

### Supervisory visit by LT - actions taken

- During the visit, the supervising LT also cross checks some of the examined slides and compare with the PHC lab results.
- Observations are reported to respective RDs in the prescribed format.
- The RD in turn are conveyed the observations to SPO/DMO under intimation to QA cell, NVBDCP with suggested remedial measures if any.
- RD/DMO compare the improvement at a regular intervals.
- LTs from Apex Lab - NIMR F/S where ever available also are involved in such supervision, e.g., in Nagaland & Arunachal Pradesh.
### Results of cross checking- RoHFW

<table>
<thead>
<tr>
<th>State/(Year 2010-2012)</th>
<th>-ve Slides</th>
<th>+ ve Slides</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arunachal Pradesh</td>
<td>0</td>
<td>0-18.6</td>
</tr>
<tr>
<td>Bihar</td>
<td>0.88-1.09</td>
<td>8.21-17.09</td>
</tr>
<tr>
<td>Goa</td>
<td>0.01-0.17</td>
<td>0.02-0.13</td>
</tr>
<tr>
<td>Haryana</td>
<td>0.61-0.87</td>
<td>1.18-2.03</td>
</tr>
<tr>
<td>Himachal Pradesh</td>
<td>0.02-0.04</td>
<td>5.19-17.54</td>
</tr>
<tr>
<td>J &amp; K</td>
<td>0.06</td>
<td>4.0</td>
</tr>
<tr>
<td>M.P</td>
<td>0.05-0.28</td>
<td>0.21-1.13</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>0.09-4.69</td>
<td>0-40.65</td>
</tr>
<tr>
<td>Meghalaya</td>
<td>0.29</td>
<td>9.6-27</td>
</tr>
<tr>
<td>Jarkhand</td>
<td>0-0.88-1.08</td>
<td>8.29-17.09</td>
</tr>
<tr>
<td>Kerala</td>
<td>9-25</td>
<td>0</td>
</tr>
<tr>
<td>Tripura</td>
<td>0.03-0.99</td>
<td>0</td>
</tr>
<tr>
<td>Punjab</td>
<td>0.04-0.12</td>
<td>1.46-3.32</td>
</tr>
<tr>
<td>Rajasthan</td>
<td>0.01-0.33</td>
<td>0.14-0.58</td>
</tr>
<tr>
<td>Puducherry</td>
<td>9-40</td>
<td>0</td>
</tr>
</tbody>
</table>

### Challenges

- adhering to Standard Operating Procedures
- Extra burden on lab technician due to integration of all disease control programmes
- ensuring quality of reagents used and calibration of equipment
- adequate training and re-training
- Timely detection of errors in the techniques and taking corrective steps
- Re use of slides leading to quality issues.
- giving timely feedback
- low priority to malaria microscopy vis-à-vis RDTs.
- Remarkable variation of competency of laboratory technicians across different labs at the PHC/peripheral level
Way Forward

Development of an internationally accepted, sustainable QA programme for malaria microscopy.
26 - Slide validation for malaria in Ethiopia

External Quality assessment in Malaria Laboratory diagnosis: Blinded rechecking

Tesfay Abreha
Director, PMI Malaria Laboratory Diagnosis and Monitoring Project
Columbia University - ICAP IN ETHIOPIA

TECHNICAL CONSULTATION TO UPDATE THE WHO MALARIA MICROSCOPY QUALITY ASSURANCE MANUAL
26-28 March 2014, Warwick Hotel, Geneva, Switzerland

Outline of presentation

• Background
• PMI MLDM Project
• Achievement on Malaria EQA program: Blinded rechecking
• Challenges
• Recommendation
• Acknowledgements
BACKGROUND

• Total population ~79.8 million (2010).
• Nine Regional States & 2 city administrations with 817 Districts/16,253 Kebeles/
• ~75% of the country landmass is malarious
• 68% of the total population is at risk (52 million).
• Malaria transmission is seasonal and unstable with P. falciparum -60% [22-89%] and P. vivax -40%[11-67%]
• Major epidemics occur every 5-8 years
• Two transmission seasons
  ✓ Main: September to December
  ✓ Minor: April to and May.

BACKGROUND...

• Health facilities
  – 1 National Reference lab
  – 9 Regional Reference labs
  – 125 Hospitals (129 under construction)
  – 2,999 Health centers
  – 4,144 private health facilities
  – >16,000 Health Posts
BACKGROUND...

National laboratory structure and EQA

EPHI

Federal & uniformed forces Hospital laboratories

Regional referral hospital laboratories

Regional laboratories

Zonal/District hospital laboratories

Sub regional laboratories

Health center laboratories

FMOH

RHB

Zonal Health Office

District Health office

Health post

BACKGROUND...

- Situation of the Malaria laboratory diagnosis of the health facilities, End of 2008
  - No standardized national diagnostic guidelines for malaria
  - No EQA guidelines for malaria diagnosis
  - No EQA program for malaria lab diagnosis across the tier lab system
    - Only the national malaria lab had international EQA program
  - No standardized national training materials for malaria diagnosis & case management
  - No in-service training program on malaria lab diagnosis & fever/malaria case management
  - Most facilities had poor equipment & irregular supplies
  - No regular supportive supervision
PMI MALARIA LABORATORY DIAGNOSIS & MONITORING PROJECT

• Two components:
  – Improving Quality of Malaria Laboratory Diagnosis
  – Improving Quality of Malaria Case Management

<table>
<thead>
<tr>
<th>Year</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
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<tbody>
<tr>
<td># facilities supported</td>
<td>70</td>
<td>114</td>
<td>195</td>
<td>271</td>
<td>372</td>
<td>562</td>
</tr>
<tr>
<td>Regions covered</td>
<td>Oromia</td>
<td>Oromia</td>
<td>Oromia Diredawa</td>
<td>Oromia Diredawa Amhara Tigray SNNPR</td>
<td>Oromia Diredawa Amhara Tigray SNNPR</td>
<td>Oromia Diredawa Amhara Tigray SNNPR</td>
</tr>
</tbody>
</table>

Malaria Laboratory Diagnosis Quality Assurance- Strategies

- Quality Equipment & supplies
- Supportive Supervision & mentorship
- EQA (PT, Blinded rechecking, Onsite evaluation)
- Standard Training
Steps to strengthening malaria laboratory diagnosis quality assurance

- Facilities selected for the PMI support by RHBs
- Conduct baseline assessments
- Provide training on malaria microscopy QA/QC
- Provide microscope and other malaria lab diagnosis commodities
- Provide guideline, SOPs, log sheets, registers
- Engage on EQA (blinded rechecking & onsite evaluation)
- Provide feedback, joint supportive supervision & mentoring

Standardizing trainings

- Production of Standardized microscopic slides

- Produced 1200 quality slides composed of negatives, Pf, Pv, mixed and Borrelia
- Provided to EHNRI to be given to Regional labs and Universities with Medical lab schools (a set of 75 slides each)
Standardizing trainings...

Developed excel based grading tool

Results compared during the training session (Pre & post tests)
Major gaps discussed during each session

Pre test
Post test
**ACHIEVEMENTS ON EQA PROGRAM: BLINDED RECHECKING**

- Blinded rechecking
- Onsite evaluation
- Proficiency testing
  - National & regional reference labs

- 257 health facilities from different regions
  - Oromia
  - Diredawa
  - SNNPR
  - Tigray
  - Amhara regions

**Blinded Rechecking experiences in Oromia**

- Blinded rechecking (REQAS) conducted by regional labs
- Three times a year, random selection of 10 slides/month/facility
Example: Trend of Malaria EQA performance in five zones (n=51 health facilities) of Oromia Region, since 2010

Expansion of Blinded rechecking facilities by regions
Approaches to Scale up of blinded rechecking

• Timely reading of slides became challenging at regional labs
  – Competing activities
  – Staff turnover
  – Increased number of facilities involved in EQA and high number of slide collections

• Developed and introduced a temporary graduation criteria from blinded rechecking

FRAMEWORK FOR STRENGTHENING AND Expansion OF REGIONAL EQA

- Malaria Regional EQA schemes (REQAS)
  - Proficiency test (PT)
  - Onsite evaluation
  - Blinded rechecking
  - Facilities reporting 100% negative malaria laboratory results & having no or low suspected malaria clinical cases
  - Facilities performing ≥95% in blinded rechecking
    - Enroll as many malarious facilities as possible for at least 3 rounds of EQA
    - Facilities performing <95% in blinded rechecking
      - Challenge selected facilities e.g. Regional Labs, referral hospitals
      - Facilities will continue to be engaged in blinded rechecking & evaluated based on the three last EQA performances
      - Facilities maintaining good QA/QC activities
    - Facilities sliding back on QA/QC activities
      - Re-engage facilities in blinded rechecking
      - Facilities will continue on onsite evaluation
      - Facilities will continue to be engaged on onsite evaluation
    - Facilities reporting 100% negative malaria laboratory results & having no or low suspected malaria clinical cases
      - Graduate Facilities from blinded rechecking
      - Facilities will continue to be engaged in blinded rechecking & evaluated based on the three last EQA performances
      - Continue to add new facilities to the EQA scheme

Graduating facilities by results from blinded rechecking

Example: Trend in Malaria EQA (blinded rechecking) activity performance  (n=51 health facilities)

<table>
<thead>
<tr>
<th>Grading on % slide reading agreement</th>
<th>Number of facilities &amp; EQA round</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st</td>
</tr>
<tr>
<td>100% (Excellent)</td>
<td>6</td>
</tr>
<tr>
<td>95&lt;100 % (Very good)</td>
<td>9</td>
</tr>
<tr>
<td>85&lt;95 % (Good)</td>
<td>23</td>
</tr>
<tr>
<td>&lt;85% (poor)</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
</tr>
<tr>
<td>Total graduated facilities (&gt;=95%)</td>
<td>14</td>
</tr>
</tbody>
</table>

Recognition of good performance (graduation)
Feedback of Blinded rechecking

- Feedback is provided to health facilities jointly with regional laboratory and zonal program focal persons
  - Parasite detection (slide reading agreement)
  - Species misdiagnosis
  - False positive rate
  - False negative rate
  - Slide smearing and staining quality
  - Temporary graduation
- The feedback is addressed to
  - Zonal summary
  - Health facility

CHALLENGES

- Work load and delayed rechecking of slides by second and third readers for EQA
- Staff turnover and lack of experienced malaria microscopists in the regional laboratories where the blinded rechecking process is conducted
- Lack of integration of regional level EQA activities of major diseases (TB, HIV and Malaria)
- Poor quality of reagents in the local market
- Lack of logistics to implement EQA regularly by the government system
- Centralized EQA program
RECOMMENDATION

• Support the regional laboratories to integrate EQA activities

• Scale up in-service training

• Strengthen pre-service training at Universities

• Strengthen supervision & mentoring along the tier structure
  – Conduct non blinded rechecking during site visit
  – Onsite training using set of standard slides

RECOMMENDATION ...

- Strengthen the decentralization of EQA program

EPHI

Regional laboratories n>9

Sub regional laboratories

Federal & uniformed forces Hospital laboratories

Regional referral hospital laboratories

Zonal/District hospital laboratories

n>300

Health center laboratories n>3000

Health posts n>16000

Supportive supervision, mentorship & EQA
**RECOMMENDATION....**

- Strengthen onsite evaluation for expansion of EQA programs

*Quality management system: a phased approach is better…*

<table>
<thead>
<tr>
<th>Microscopy</th>
<th>RDT</th>
</tr>
</thead>
<tbody>
<tr>
<td>- First step (At central level)</td>
<td>- competent RDT trainers / supervisors</td>
</tr>
<tr>
<td>- core group of expert microscopists (NRL)</td>
<td></td>
</tr>
</tbody>
</table>

**Take-home messages for program managers:**

- Resources should be put in priority on all other activities of the QMS, rather than on slide/RDT validation
- Strengthening of on-site supervision is mandatory

**Strategies for scale up of Malaria Laboratory Diagnosis Quality Assurance**

**WHO-AFRO Publishes SLIPTA Guidance Document**

- SLIPTA is a framework for improving quality of public health laboratories in developing countries to achieve ISO 15189 standards.
- It is a process that enables laboratories to develop and document their ability to detect, identify and promptly report all diseases of public health significance that may be present in clinical specimens.

**WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region** (with checklist)
Strategies for scale up of malaria lab QA..

- Introducing the Quality Management System Model for Laboratory Services
  - SLMTA/SLIPTA initiatives in the country
    - National, regional and hospital laboratories trained in LQMS
    - Expanding LQMS training to HCs
    - Introducing LQMS with the malaria microscopy training
Strategies for scale up of malaria lab QA..

Supervisory checklist

<table>
<thead>
<tr>
<th>Section</th>
<th>Total Points</th>
<th>Assessed Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1: Documents &amp; Records (5 items)</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Section 2: Management Reviews (2 items)</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Section 3: Organization &amp; Personnel (4 items)</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Section 4: Client Management &amp; Customer Service (2 items)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Section 5: Equipment</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Section 6: Internal Audit (2 items)</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Section 7: Purchasing &amp; Inventory (4 items)</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>Section 8: Information Management (4 items)</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Section 9: Process Control and Internal &amp; External Quality-Assessment (4 items)</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Section 10: Corrective Action (2 items)</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Section 11: Occurrence/Incident Management &amp; Process Improvement (2 items)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Section 12: Facilities and Safety (4 items)</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>TOTAL SCORE</td>
<td>160</td>
<td></td>
</tr>
</tbody>
</table>

- Evaluation and transferring/Graduation criteria
  - receive 4 supervisory visits and focused mentorship
  - achieve >=80% of supervisory checklist score at the 4th visit
  - achieve >=80% of average slide reading agreement on 3 consecutive supervisory visits

ACKNOWLEDGMENTS

- FMOH
- Ethiopian Public Health Institute (EPHI)
- Regional Health Bureau
- Regional Laboratories
- Zonal Health departments
- Health facilities
- PMI/USAID
27 - Outreach Training and Supportive Supervision

**IMPROVING MICROSCOPY with Outreach Training and Support Supervision Program**

**TECHNICAL CONSULTATION TO UPDATE THE WHO MALARIA MICROSCOPY QUALITY ASSURANCE MANUAL**

**26-28 MARCH 2014, GENEVA, SWITZERLAND**

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**About MalariaCare**

- A five-year, multi-country, $50M USD project funded by the PMI through USAID — Oct 2012 – Sept 2017

- Year 2: 11 African countries and Cambodia

- Goal: increase the percentage of suspected malaria cases that are diagnosed with a quality test, and ensure appropriate treatment consistent with the test result (both for malaria and non-malarial fevers)
Current diagnostic activities: Microscopy

- Skills refresher (annual) and supervisor trainings
- Quarterly OTSS visits
- Slide re-checking during OTSS
- On-site proficiency training (PT) using validated slide sets (NAMS)
- Reference lab EQA through UK NEQAS (DRC)
- Support to ECAMM and for National Accreditation programs

Outreach Training and Support Supervision

- Enables on-site support to HW conducting malaria dx and treatment.
- Visits conducted initially every 3-4 months and then bi-annually by national, regional and/or district level laboratory supervisors with known competency (parasite detection = >85%).
Improving microscopy during OTSS visits

Supervisors conduct the following tasks:

• Direct observations against SOPs for making and interpreting slides (CDC).
• Cross-checking of 5 weak positives and 5 negatives
• Provide on site training, corrective action, and troubleshooting.
• Plan to conduct PT panels (using NAMS) to measure individual and HF scores for parasite detection, species ID, and counting.
Aggregate laboratory scores for observed slide preparation and reading as compared to SOP

- Performance improves during initial period and begins to plateau around 85%.
- The project is investigating new ways to maintain microscopy performance (e.g., introduce interactive training methods, opportunities for individual or HF recognition).

Aggregate Laboratory Scores for Slide Re-checking as Compared to Supervisor
Slide re-checking

- Blind slide re-checking has remained high in all countries participating in OTSS.
- Participation/interest dwindling since the introduction of RDTs.

OTSS Lessons Learned Workshops (LLWs)

- Traditionally done annually with the central/provincial/district level OTSS supervisors and NMCP staff, other programs.
- Useful for discussing progress, identifying problems, and making incremental changes.
- Looking at how to leverage these to improve OTSS program
  - link LLW to action plans and responsible parties
  - Sub-national LLW for sub-provincial level supervisors done several times/year
  - Annual national LLW for national/provincial level supervisors
  - Add component of continuing education (e.g. case management updates)
OTSS Major Challenges

• Timely feedback – largely due to data entry.
• Transfer data management to central level due to people leaving (Ghana example).
• Maintaining supervisor competency in between refresher trainings.
• Scale-up in some countries (e.g. Zambia) – expensive, identification of qualified supervisors.
• Supervisors are replaced by MOH before competency can be evaluated.
• Lack of supervisor quality standardization for
  – Mentoring capacity

Annual Malaria Diagnostics Refresher Training (MDRT)

• Targets both health facility laboratory supervisors and bench microscopists.
• MOH use OTSS results to select trainees for MDRTs based on data obtained during OTSS.
• Course size is ~20 participants
• Validated slide set – total of 60 slides are read over 4d.
• Method is similar to ECAMM with daily assessments and slide review.
Annual training in malaria microscopy
reference level (supervisors)

Democratic Republic of Congo
Reference level microscopists

Zambia
Reference level microscopists

Routine training in malaria microscopy

Malawi
Peripheral level microscopists

Ghana, Brong-Ahafo Region
Peripheral level microscopists
MDRT – Lessons and Challenges

• Annual refresher training for supervisors is essential.
• All diagnostic staff require routine training however not always possible.
• Improving scores for species ID is difficult to achieve in a week.
• Regional trainings helpful- can identify regional weaknesses (Ghana BAR example).

Proficiency Testing Panels

• Used to assess the performance of a lab or health worker in slide reading.
• Focuses on the minimum competencies for slide reading –uses WHO reference/peripheral level standards.
• PT panels will be distributed by supervisors during OTSS visits to labs performing microscopy (reference and peripheral level).
Proficiency testing panels composition

• PT panels will occur bi-annually during OTSS visits (total of 30 slides over 1 year)
• Panels currently include:
  – 5 negatives
  – 3 Pf –(2 LD:1 MD)
  – 4 Pf counting slides (2 LD: 1 MD:1 HD)
  – 2Po
  – 1 mixed (Pf/Po)

Support development and implementation of slide banks

Ghana NAMS: Developed by Kintampo Health and Research Centre, Kintampo, Ghana (IMaD/PMI).
Implementation of slide banks

- NAMS use operations manual
- Developed a database/lending library with physical tracking system
- Supervisors currently accessing slide bank for regional trainings in Ghana.
- One goal of NAMS is to establish bi-level accreditation to assure quality of OTSS supervisors:
  - WHO Level 1&2 accreditation requirement for central/provincial core group of laboratory supervisors
  - National Level 1 & 2 accreditation required for sub-provincial level OTSS supervisors

Slide Set Generator Feature

- Can automatically generate the following slide sets at the push of a button:
  - MDRT (routine training slide sets)
  - WHO 55 Sets (used during ECAMM)
  - Proficiency Testing panels
  - Can be customized for NMCP needs
Acknowledgments

- PMI (USAID/CDC)
- AMREF and HWH
- KHRC - MOH Ghana
- EHNRI – MOH Ethiopia
- ICAP – Ethiopia
- MOHs – Malawi, Zambia, Ghana, Mali, Benin, and Liberia

Support laboratory staff to ECAMM

COMPETENCY ASSESSMENT CAN IMPROVE MALARIA
PARASITE DETECTION, SPECIES IDENTIFICATION AND
PARASITE COUNTING

African Society for Laboratory Medicine
First International Conference

1-7 DECEMBER, 2012
CAPE TOWN, SOUTH AFRICA
Dr Jane Carter
Challenges ECAMM

• Identification/promotion of the appropriate candidates. Is there a need for minimum cut-offs for attendance?
• Confusion of what levels mean on the ground. Levels can become - “WHO Certified Microscopist” opposed to 1, 2, 3, and 4.
28 - Rapid assessment of QMS for malaria microscopy in Benin and Ghana

**Rapid Assessment of Malaria Diagnostic Capacity and Quality in Ghana and The Republic of Benin**

Presented by Timothy Finn, MPH
Tulane University - Center for Applied Malaria Research and Evaluation
Technical Consultation To Update the WHO Malaria Microscopy QA Manual
March 28, 2014 - Geneva, Switzerland

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**Background**

- Study initially intended to evaluate Improving Malaria Diagnosis (IMaD) project – but shifted to assessment

- Nationally representative information on coverage, usage, adherence and quality of malaria diagnostics is lacking for much of Africa.
Background - Aim

Primary aim was to assess quality and accuracy of parasitological confirmation for malaria diagnosis and treatment using RDTs and microscopy in diagnostics.

Background – Primary Outcomes

• Proportion of slides and RDTs correctly read and interpreted
• Proportion of malaria cases among children under 5 years old that are laboratory confirmed
• Proportion of malaria cases among patients greater than 5 years old that are laboratory confirmed
Survey Instrument

- Modified Service Provision Assessment questionnaire
  1. Clinic/General Service Provision Assessment
  2. Direct Patient-Clinician Interaction Observation
  3. Laboratory Service Provision Assessment
  4. Patient Exit Interview
  5. Archived Slide Collection for Confirmation
  6. Retrospective Patient Log Book Data (for weighting results)
  7. RDT Observation Form
  8. Microscopy Observation Form
  9. Semi-structured interviews with clinicians/laboratory technicians
  10. Pre-prepared slide banks and RDT interpretation quizzes

Survey Implementation

**Staff 1 – Clinician/ Supervisor**
- Patient Observations
- RDT Observations
- Clinic SPA

**Staff 2 – Lab Tech**
- Microscopy/RDT Observations
- Lab SPA
- Microscopy/RDT Battery Tests
- Archived Slide Collection

**Staff 3 – Interviewer**
- Patient Exit Interviews*
- Patient load data collection*
- Semi-structured Interviews

**Facility Level Sampling**
- 1 outpatient department (SRS)
- 1 clinician for patient observations (SRS within OPD)
- 1 lab and laboratory technician (SRS within facility and within lab)
- 10 patient-clinician observations targeted at each facility
- 10 RDT and/or slide observations targeted at each facility

**Survey Time**
- Approximately 2 days total field work per facility for one team
  - 1 day travel and 1 day survey per facility

*Ghana used 4th person to collect exit interviews and brief data collection activities
Survey Instrument - Diagnostics

• Designed to assess:
  – Access to and administration of parasite testing
  – Technician performance of proper testing protocol
  – Sensitivity and specificity of observed parasite tests (according to expert re-reading for slides and survey worker re-read for RDTs)
  – Technician accuracy for slide/RDT battery tests
  – Lab stock-outs

Survey Instrument - Diagnostics

Malaria P.f Rapid Diagnostic Tests

1  2  3  4  5  6  7  8  9  10
• 16 key RDT process steps identified
• 6 crucial RDT steps:
  – Use sterile lancet
  – Use loop/appropriate instrument to collect blood
  – Use loop/appropriate instrument to add blood to RDT
  – Add correct # of buffer drops
  – Wait appropriate time to read results
  – Read results correctly

• 25 key microscopy process steps identified
• 6 crucial thick film slide steps:
  – Use sterile lancet
  – Apply 2-3 drops blood 1cm from slide center
  – Use corner of 2nd slide to join remaining 2-3 droplets of blood
  – Dry slide for appropriate length of time
  – Stain slide by immersion and wait appropriate length of time to dry
  – Examine min 100 fields using 100x oil immersion (for negative slides)
Methods - Sampling

- SRS of facilities with sub-sampling of clinicians and labs within facilities frame

<table>
<thead>
<tr>
<th>Method</th>
<th>Ghana</th>
<th>Benin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Patients observed</td>
<td>266</td>
<td>272</td>
</tr>
</tbody>
</table>

- Sampling frame (HMIS datasets in Benin; National facilities list in Ghana)
- Alternatives could be cluster sampling using district as first stage

Results - 1

Sensitivity, Specificity and Accuracy of Microscopy

Microscopy Interpretation Quiz
- Ghana – 89% sens, 77% spec, 83% accuracy

RDT Interpretation Quiz
- Benin – 84% of 231 RDT observations matched true result
- Ghana – 77% of 102 RDT observations matched true result
Results - 2

Results for Children Under 5 years

- Ghana: 66.5%±5.9, 55.9-77.0%
- Benin: 49.9%±6.3, 36.3-63.5%

30% of all malaria diagnoses confirmed

Results - 3

Use of antimalarials for patients and diagnostic confirmation of malaria diagnosis

<table>
<thead>
<tr>
<th>Antimalarial Prescriptions:</th>
<th>Ghana</th>
<th>Benin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribed an antimalarial</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Test positive prescribed antimalarial*</td>
<td>64</td>
<td>85.4</td>
</tr>
<tr>
<td>Test negative prescribed antimalarial*</td>
<td>39</td>
<td>30.1</td>
</tr>
</tbody>
</table>

*Restricted to where testing available

Patients with fever tested
- Benin – 89% (80-99%)
- Ghana – 69% (54-84%)

Patients without fever tested
- Benin – 67% (40-94%)
- Ghana – 21% (-11-53%)
Discussion

• Testing scale up is reaching a large proportion of facilities in Ghana and Benin
• But more limited in Ghana (53% of sampled facilities) than Benin
  • Probably due to RDT scale up, not expansion of services
• RDT and microscopy sometimes utilized in same facilities (sometimes on same patients)
• Quality of microscopy still less than ideal, though better than expected
• Performance on RDT test banks good and interpretation good, but tests often read too quickly
• Adherence to negative test results was less than ideal by current WHO guidelines

Discussion - Limitations

• Shoestring budget
  – Small sample sizes, limited time at facilities
  – Limited investment in training and data quality assurance
• Larger investment (even if not tremendous) -> more precise estimates
  – Wide 95% CIs around point estimates
  – Limited ability to conduct in depth analysis of associations with poor quality or absent diagnostics
• Cross-sectional survey may miss seasonality
**Discussion - Challenges**

- Microscopy test results – Not always available same day
  - But clinicians still diagnose and prescribe
- Slides prepared in parallel – challenge for assessing process steps
- Heavy workload for survey supervisors
  - Too many data collection instruments/data needs
- Survey workers must confirm RDT readings on the spot

**Discussion - Challenges**

- Quality of slide bank test readings in facilities can be limited by external factors
  - Lab tech capacity, time pressure, electricity, microscope quality/cleanliness
- Sample frame creation still challenging at national level
- Not representative of private sector
Conclusion

- Inexpensive surveys
- Rapid, nationally representative of public sector
  - 12-15 days total for 30 facilities
- Closer to routine work assessment than a training course or supervisory visits
- Assesses microscopist performance but also malaria diagnostics and protocol as a system at facility level
- Can be standardized to provide platform for national rapid M&E of malaria diagnostic capacity and quality
  - Adapt to PDAs/Tablets

Acknowledgements

- USAID/MCDI funding support
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- Brady Zieman, Keith Esch, Margaret Werner
- DERMED Consult Ltd. - Ghana
- CRE-Institut d'Sciences Biomédicales Appliquées - Benin
29 - SOPs for malaria microscopy collated by WPRO

Standard Operating Procedures (SOPs)

• Part of QA system, should be developed in consultation with microsopists
• Outlines the sequence and procedures for the diagnosis of malaria in patients by light microscopy
• Standardization and compliance are key
• NMCPs have different ideas what SOP should be
SOPs in WPR countries

- Some labs have SOPs but not for all relevant procedures, some not containing adequate detail
- Not standardized
- Not widely disseminated or used

Generic SOPs

1. Cleaning and storing of glass micro slides
2. Making up Giemsa stock solution and pH 7.2 buffer water
   1. Preparation of stock solution of Giemsa stain
   2. Preparation of buffered water
3. Making blood films from patients
4. Staining blood films with Giemsa stain
5. Examining thick films for malaria parasites
Generic SOPs

- No specific format
- Must contain information which is updated each time a change is made in the SOP
  - SOP title and number
  - Who prepared the SOP and when
  - Who cleared/approved the SOP
  - Date of the SOP’s effectivity
  - If there are revisions, date when revised

Other SOPs can be added, e.g.

- Care and maintenance of microscope
- Bio-safety in handling blood specimens and disposal of infectious waste materials
- Parasite counting
- Interpretation, recording and reporting of results
- Validation of malaria blood smears
- Others?