Technical consultation to update the WHO Malaria microscopy quality assurance manual

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

Presentations 8–20
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8 - Overview of malaria microscopy QA manual

**WHO EQA Manual and ECA programme**

**Background and aims**

**Aims of the QA manual**

- Stimulate a process of re-invigorating microscopy
- Develop global minimum standards
- Improve quality of clinical malaria microscopy
- Emphasis on technician, rather than laboratory, competence
- Provide practical, implementable guidance for national programmes (without being prescriptive)
  - Outline sustainable system for clinical microscopy QA
  - Provide SOPs
  - Provide an EQA standard for national Core Group to standardize ‘expert’ clinical microscopy
  - Leave countries to adapt details to their programme

*i.e. Provide general QA programme structure, and demonstrable level of expertise for reference microscopists, and leave countries to develop their own QA programme internally according to this guidance.*
Process

• 2004: General meeting on microscopy needs (Kuala Lumpur)

• 2004-8: Coord of development at WPRO
  (in parallel to revision of Training Manuals and Bench Aids)
  – 3 small expert consultations on aspects of manual (Manila, Geneva)
  – Trials of ECA programme (WPRO/SEARO)
  – Statistical review
  – Review of existing SOPs and EQA programmes
    • (esp. KEMRI, MSF, EMRO, NICD, PAHO)
  – Development of manual (Co-authors and reviewers)

• 2009: Publication (as ‘Version One’)

QA Manual Structure

Chap 1: Intro and need
Chaps 2-4: National QA programmes
• Essential functions and roles
• Elements of programme structure
  – Emphasis on regular testing/accreditation and re-training
  – Supervision
  – Limited cross-checking to detect very poor performance

Chap 5: ECA and national core group
Chap 6: Training, retraining, refresher training
Chap 7: Supervision
Chap 8: Cross-checking
  – Structure that limits slide numbers but provides acceptable sensitivity

Chap 9: Developing a national slide bank
Chap 10: IQA
Annexes: SOPs, equipment lists and check-lists for above
What the manual (and ECA) is not intended for

- Training microscopists
- Setting research standards
- Fixing a structure that national programmes must comply with
- Providing a QA structure that is too detailed and cumbersome to be implementable
- Replacing national SOPs
- Origami
- Market gardening

Current WHO Manual

ACTMalaria & the World Health Organization certifies that achieved LEVEL 1 MALARIA MICROSCOPIST according to the WHO Interim Standard* for competency certification in the External Assessment of Malaria Microscopy.

__________________
DATE

Mr Ken Lilley
Training Facilitator

__________________
Co-ordinating Country Director
ACTMalaria
ECA and ‘National Core Group’

ECA:
- Demonstrate level of expertise of reference microscopists in the national programme
- Provide evidence of competency to legitimize their role in training and cross-checking
- Provide limited practical support to improve their standards

National Core Group:
- Provide expertise in clinical microscopy
- Train within programme
- Cross-check slides
- (Provide ECA facilitators)

WHO manual on microscopy QA
External accreditation of national core group
Improvement of ECA participants

Improvements in Species Identification

Improvements in Parasite Counting
(within 25% of correct count)

Why external (and internal) national accreditation?

- Build confidence in quality of diagnosis
- Give legitimacy to ‘expertise’ of higher-level microscopists (trust and authority)
- Establish performance benchmarks for technicians to aim for (encourage self-improvement)
- Establish basis for career structure

Only makes sense if:
- Good performance is used in the national system
- Poor performance is addressed – support to improve
- Microscopists can see a clear gain, not just a threat
  – eg. career structure, remuneration, legitimacy
- National programme has a structure to use the Core group’s skills.

Role of national expert (‘core’) group

- Oversee re-training programme and standards in national slide bank / training sets
- Final referral level for cross-checking programme
- Core of national supervisory programme
- Group with proven expertise to ensure strong local, independent capacity for research
How far should microscopy extend within the programme?

Restricted to central facilities, for severe malaria management, drug-efficacy monitoring, RDT-quality monitoring?

Microscopy in sub-district clinics

Community microscopy

Review (WPRO) of Microscopy ECA programme, 2008

<table>
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<tr>
<th>Countries</th>
<th>Crosschecking</th>
<th>On site Evaluation</th>
<th>SOPs</th>
<th>Competency Assessments</th>
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8 countries assessed

Clear utilization/role for ECA ‘expertise’ within programme 3

Clear hierarchical structure that might accommodate expert core group 6

WPRO/Sania Ahraf
Way forward...

• We need to lift microscopy standards to an acceptable level, not dumb down standards to make them acceptable.
  • *Grandma Brown, Kitchen Living, 1873*

• Providing standards that are impractical to implement is like providing toothpaste to an amoeba.
  • *Plato, ‘Thoughts I Should Have Had, Vol 3’.*
9 - Feedback on MMQAM from technical experts

Feedback of Technical Experts on WHO Malaria Microscopy Quality Assurance Manual (MMQAM)

Ken Lilley

Background to WHO MMQAM (1)

- MMQAM Version 1, 2009
- Lead author Peter Trigg
- Co-authors: Derryck Klarkowski, Ken Lilley, John Storey
- Support received in various kind from many institutions, including:
  - ACTMalaria (Asian Collaborative Training Network for Malaria)
  - AMI (Australian Army Malaria Institute)
  - AMREF (African Medical and Research Foundation)
  - KEMRI (Kenya Medical Research Institute)
  - MSF (Medecins Sans Frontieres)
  - NICD (National Institute for Communicable Diseases)
  - RITM (Research Institute for Tropical Medicine)
  - US CDC (United States Centers for Disease Control and Prevention)
  - WRAIR (Walter Reed Army Institute of Research)
Background to WHO MMQAM (2)

- The Manual is based on the recommendations of a series of informal consultations organised by WHO, particularly a bi-regional meeting by the WHO Regional Offices for the Western Pacific and South-East Asia from 18 to 21 April 2005 in Kuala Lumpur, Malaysia.

- Another meeting was held on 3 March 2006 in Geneva, Switzerland. An informal consultation took place in Geneva from 7 to 8 February 2008, as well as extensive consultations with international malaria experts.

- The Manual is designed primarily to assist managers of national malaria control programmes and general laboratory services who are responsible for malaria control. It should also be of interest to those non-governmental organizations and funding agencies that are involved in the support of malaria disease management and malaria diagnosis in particular.

- It is not designed for the quality assurance of microscopy used in research situations, such as clinical trials of new drugs and vaccines and the monitoring of parasite drug resistance.

- It forms part of a series of WHO documents that are designed to assist countries in improving the quality of malaria diagnosis. These include the revised WHO Training Manuals, Basic Malaria Microscopy Part I. Learner’s Guide and Basic Malaria Microscopy Part II. Tutor’s Guide and the revised WHO Bench Aids for the diagnosis of malaria infections.

Update Process

- Feedback from ‘technical experts’, requests commenced from 23 July 2013

- Wide and varied list of ‘contributors’: from all WHO regions, many institutes and individuals

  - 31 contacted – 6 responded

- Much feedback from Harare meeting (2-4 Sep 13)

- Also feedback from ‘end users’ via on-line survey of Alison Crawshaw

  - 22 respondents

123 comments/suggested changes – some already covered, some contradictory, some requiring discussion/decision

Come back to discussing the required changes after Alison Crawshaw presents feedback from the end-users of the Manual
Future plans

- Decide/harmonise/standardise changes
- Re-write of the draft continues
- Disseminate draft with proposed changes – obtain more feedback
- Need your input – writing or reviewing/correcting sections
- Make final changes
- Publication
- Timeline?

Comments – General/Structure (1)

- Should have better access and dissemination
- Difficult to comply with Manual guidelines due to expense and lack of resources
- Important to standardise but one size will not fit all
- The Manual should have a holistic approach for ensuring effective QA program
- A manual for the establishment of slide banks should be developed and stand separately from the MMQAM and then should detail all important steps which also depicts pictorially and include all supportive documents.
- QA is a function of IQC, EQA and continuous quality/process improvement. Ensuring continuous improvement includes internal audit/assessment, client management, customer service, occurrence management and taking corrective actions.
- Needs to flow better, from plan of QA, though stages to completion
- Most consider order of chapters appropriate
- Remain in A4 format
- Should include a comprehensive section on RDTs in the Manual – most disagree
- Need a brief description of RDTs but defer to their dedicated documents for detail
Comments – General/Structure (2)

- Need to have a contact person listed for comments/changes required
- The Manual should revolve around organisation of QA programs, establishing core group of expert microscopists, training, competency assessment, EQA, supervision, slide bank establishment, and equipment and supplies.
- Better to organise the Manual in a way that is easily understood and implemented by clinical and public health laboratories at all levels.
- The QA cycle is broadly divided into three – pre analytical, analytical and post analytical. The flow should be organised to address these elements in that flow.
- To include the road to a QMS, for example ISO 15189
- A step by step process to obtain a QMS. For example, 3 prioritised steps (short, medium and long term) to achieve the optimal QA programme (also consider costs for each step)
- Should link in and refer to the Universal Access document
- Should mention the follow-up steps for the QA system after the ECA activity

Comments – General/Structure (3)

- Needs to include staff training and competency - What is covered in training. Ways to assess competency. Minimum frequency for training and ECA.
- It no longer fulfils its original objective/s, i.e. of being a tool, or working aid, with which to effectively monitor the quality and progress of a Unit, or units, (at whatever level, national or international) to accurately diagnose in the National Malaria Control Programme setting, malaria in patient’s by parasite stage, species, sometimes density and to correctly report, sometimes treat, and monitor patient’s and their subsequent progress
- The senior-most levels that have received the greatest attention over the past few years and we now have a very good idea of the quality of their diagnostic competence – but not the qualities of their leadership, analytical, supervisory and teaching or training skills or of their accuracy of knowledge.
- The outcome of a QA of a NMCP reflects not only individual and collective competence and reliability but also the quality of training, programme implementation, supervision, indicated retraining needs and the availability of a malaria slide bank (MSB). Need to have a
Comments – General/Structure (4)

- Need to have a contact person listed for comments/changes required

- Besides WHO can only set the standards (through discussion and agreement) and then advise national programmes on the best policy to follow. NMCPs often have their own, or a different agenda and are not forced to follow internationally recommended standards. There are many examples where this is happening.

- The QA Manual is important but I believe it should remain just that – a QA manual. To address the issues you raise I believe the QA Manual needs to be supported by other WHO guidelines – at the very least a ‘Blood film preparation, staining and reading’ manual and a ‘Slide Bank’ manual. I have separated the Slide Bank because I have written such a manual for our programme and it’s 84 pages, so it’s a manual in itself.

- Much more than just training, re-training and QC - Microscopy requires good equipment, good stain, correct pH control, and good workload management, and yes training and QC. And also critically important malaria microscopy doesn’t need a laboratory technician.

- The manual should be able to establish the need for a reachable minimum entry level that is achievable by each programme. Without that, some at least in theory will not exist because they do not meet current ‘international’ standards.

Comments – General/Structure (5)

- Need to improve the flow of the current manual

- Competency assessments on yearly basis

- Preventive maintenance

- Quality Policy statement

- Reference to SOPs – and to other manuals

- Frequency on when the manual should be reviewed and responsibilities – contact person

- Coordination, technical working groups

- Safety and security

- Review terminology

- Ask to participants to provide input for technical sides
Comments – General/Structure (6)

- Clear directions on how to get quality results: addressing all aspects – chart on all the aspects that can go wrong and how to resolve/address them
- Summary of key steps in the process – demanded by countries – follow a similar structure to SLIMTA process
- If not achieved universal access should they go into QC/QA – but which components are key (resource constraints)

Comments – General/Structure (7)

- Relate to the 12 pillars of QMS – link to ISO standards (ISO:15189) – structured approach (more user friendly)
- How do we guide countries:
  - Turnover time
  - Stock-outs
  - Workload
- Pre-analytical, Analytical, Post-analytical
- Importance of documentation
- Supply issues
- Customer service/ satisfaction
- Internal Audit
- Cover all Quality Essential issues
Comments – General/Structure (8)

Going through the Manual:
- Contact person
- Amendment table
- Acknowledgement
- Preface: state what it addresses and the specific intended public
- Glossary: too short, abbreviations and definition

- Annexes:
  - 1, 2 should be covered in other documents
  - Either detail in the main body of the text or the annexes

Comments – Technical (1)

- Replace ‘technician’ with microscopist
- Delete reference to ‘PCR’, use NAT
- Differentiate use of EQA from ECA
- Stress ECA is not primarily training
- ECA is aimed at National Core Group
- Need to consider the number of slides required for effective cross-checking
- Changes to the Manual must be based on “evidence”
- Discuss possibility of blinded limited slide checking during supervisory visits – as alternative to often poorly conducted cross-checking exercises
- Consider two levels of assessment slides sets – one for ECA and one for NCA
- Emphasis should be given to ‘Documents and records’ in malaria microscopy that includes all the necessary SOPs, formats, log sheets, etc.
- Should discuss issues of the purchase and inventory of the required supplies and consumables and safety in malaria microscopy.
- Discuss the 3 methods for EQA – 1, blinded slide re-checking, 2, panel testing, and 3, on-site supervision/evaluation. Detail the advantages and limitations of the 3 methods.
- Grading of the microscopists in ECA should maintain ‘parasite detection’ (that includes a set of negative slides) as it stands now in the Manual. This enables the calculation of FPR and then the Sensitivity of the participants individually and aggregated to the group in the training session.
Comments – Technical (2)

- We need to re-visit the range of parasite counts used in the ECA courses. Is it valid to use a slide with a count of 107 P/µL? Are we satisfied that stochastic influence plus inherent variability do not influence the results? What is the value of using a slide with a count of around 100,000 P/µL or 263,000 P/µL? Do we really expect microscopists to be able to count the parasites to within 25% of the true count with such high counts? How much confidence do we have in the true count?

Comments – Technical (3)

- We should consider increasing the minimum number of oil immersion high power fields required to be examined before declaring the film NMPS. Currently WHO recommends 100, but it should be increased to 200, particularly as part of elimination strategies. With the reduction in malaria cases we are seeing more slides with lower densities and increasing the number of fields to 200 will increase the chances of finding these parasites. As the microscopist’s case load is decreasing in many countries there is now more time available to examine the slides for longer, i.e. 200 fields before declaring NMPS

- Is it reasonable to expect microscopists to achieve counts within 25% of the true count irrespective of the parasite density? For example, should we have a ‘sliding scale’ of acceptable limits? For example, something like:

  - Counts of less than 100, plus or minus 50%
  - Counts of 100-500, plus or minus 40%
  - Counts of 500-1,000, plus or minus 30%
  - Counts of 1,000-5,000, plus or minus 25%
  - Counts of 5,000-10,000, plus or minus 30%
  - Counts of 10,000-40,000, plus or minus 40%
  - Counts of greater than 40,000, plus or minus 50%
Comments – Technical (4)

- Is the new method of counting (200 WBC, then decision point of 100 MP, leading to calculation or count to 500 WBC then do calculation) resulting in more accurate ID and counting? Feedback required, including from African countries.

- The MMQAM gives the option of waiting until we find a parasite before counting or starting the count straight away. Should we remove this variability in the procedure? Are we introducing a positive bias when we wait till we find a parasite before starting to count? - yes we are

- Should WHO go one step beyond ‘not recommending’ the Plus System of counting and state that it should not be used?

- The use of the term Expert to describe WHO Level 1 Competency should cease. The term is misleading and probably undeserved for achieving a Level 1 result in a single ECA course. It is also being used uncontrolled in published papers and by other training/competency assessment groups with lower standards than the WHO ECA course. My recommendation is that the term Expert should not be used when referring to Level 1 microscopists, or if it is to be used then perhaps it should be reserved for microscopist that have shown (by assessment) to have achieved very high skill levels (i.e. Level 1) on at least 3 separate assessments. For most microscopists this would take approximately ten years of exhibiting high competency levels.

Comments – Technical (5)

The number of the slides in the Slide Sets is working well, however it would be easier to calculate a 50% result if the counting slides were an even number. Currently 5 slides are used (and it is not possible for a participant to achieve 50%). The cut-off for Level 1 unless otherwise stated is the second decision point of 100 MP. It is not desirable to reduce the number of microscopists to 50% and then on to 25% for Level 1. The time limit for counting and/or identification slides. Time limit: 10 minutes per slide. Suggested changes below, including slight changes to the composition and counts:

The WHO Standard Slide Panel consists of 55 slides divided into two slide sets:

**Slide Set 1 (40-42 slides): Assessment of presence/absence of parasites, and species identification**
- 20 Negative slides ('clean' - not 'spiked' negatives)
- 20 2+ Positive slides of low density (80-200 parasites/L)
- 10 Plasmodium falciparum slides
- 4 mixed (2) species slides (Include P. falciparum. Each species >40 parasites/µL, co-infecting species according to local prevalence)
- 6 Plasmodium malariae, Plasmodium vivax, and/or Plasmodium ovale slides (include at least 1 of each species, ratio according to local prevalence)

**Slide Set 2 (15-14 positive slides): Assessment of quantitation (counting)**
- 6-3 P. falciparum (200-500 parasites/µL)
- 4.6 P. falciparum (500-2000 parasites/µL)
- 2 P. falciparum (>100,000-100,000 parasites/µL)

A third set, **Slide Set 3**: is used for the pre-ECA practice test on Day 1. It contains an approximately 30% sub-set (16-18 slides) of the slides from Slide Sets 1 & 2. For example:
- 5 Negative slides from Slide Set 1
- 6-8 Low positive slides from Slide Set 1 (2-1:2 - Pf, 1:2-Pv, 1-mixed Pf/Pv, 1-Pm, 1-Po)
- 5 For counting, from Slide Set 2 (2-Pf 200-500 parasites/µL)
- 2 Pf 500-2,000 parasites/µL, 1-Pf>100,000 parasites/µL
Comments – Technical (6)

What should be included in the MMQAM:
- Staff training and competency – what is covered, ways to assess competency, and minimum frequency for training.
- Equipment maintenance – microscope care, routine maintenance, & service requirements.
- Reagent QC and control (including consumables) – ordering reagents, and consumables, inspection on receipt, ensuring ample stock.
- Internal QC – QC slide to ensure stain is working.
- External QA – registration/participation in suitable program, corrective action for errors.
- Document control – SOPs for all procedures.
- Leaves many questions unanswered in spite of the considerable accruing literature. Thus questions such as: ‘How long should a thick blood film be examined for before it is pronounced negative for malaria parasites – in time or in oil-immersion fields?’ (Negative for MPs in a 10 minute oil immersion examination); or in the NMCP setting ‘When, and why and how frequently should a parasite count be done on a malaria positive patient?’ and ‘What range of agreement on the density count can be accepted between two workers?’ or ‘what is the maximum number of thick films that can be examined in a day’s work?’ And ETC..

Comments – Technical (7)

- Is the new method of counting (200 WBC, then decision point of 100 MP, leading to calculation or count to 500 WBC then do calculation) resulting in more accurate ID and counting? Feedback required, including from African countries.
- We have to break the paradigm that blood films must be examined for 5 minutes – that is intense reading for 5 minutes or 100 fields. This is impractical. I visit many routine laboratories and when I’m there the laboratory technician duly reads the slides for 5 minutes (because I’m there) and I see the patient queue getting longer and longer. So I have to tell the technician that I have to go somewhere for 15 mins and I deliberately leave the laboratory because my presence is causing a problem. When I get back all the patients have been given their results and have gone. Reading for 5 minutes is not practical, and trying to implement an impractical strategy is a recipe for failure.
Comments – Technical (8)

• Many points for discussion such as: the National Registration of Microscopists following successful completion of their training; the possible use of alternative diagnosis under certain conditions such as PCR and LAMP (down the road but not too far possibly for LAMP); problems associated with drug resistance, G6PD deficiency or with other species (*P.knowlesi*) or the fact that a number of programmes continue using as routine x5 or x6 oculars with daylight; or x6 or x7 monoculars also with daylight; or of the training that continues in an apprenticeship style, running into months and based on no real syllabus.

Comments – Technical (9)

• Leaves many questions unanswered in spite of the considerable accruing literature. Thus questions such as: ‘How long should a thick blood film be examined for before it is pronounced negative for malaria parasites – in time or in oil-immersion fields?’ (Negative for MPs in a 10 minute oil immersion examination); or in the NMCP setting ‘When, and why and how frequently should a parasite count be done on a malaria positive patient?’ and ‘What range of agreement on the density count can be accepted between two workers?’ or ‘what is the maximum number of thick films that can be examined in a day’s work?’ And ETC.

• Essential that SOPs are both available and approvable both before and at the very start of this exercise. This has not been the case in many programmes and so, in theory at least, it has often not been possible to carry out a true QA of a particular situation.

• It will be necessary to establish both guidelines and SOPs on the appropriate use of RDTs which at the time the module was originally written played little part in the global programme.
Comments – Technical (10)

- Take out the portion on picking microscopists to be trained (avoid change standards across the health pyramid)
- Focus on how training should done, frequency
- Lab techs and microscopists will have competency in other disciplines
- Countries policies are going towards qualified technicians that can perform a number of tests - movement from malaria diagnosis to fever diagnosis
- Pre-training and Medical schools – Zanzibar experience: revised the content of malaria course, 1-2 weeks training in the NMCP
- Malawi experience: microscopists picked to perform malaria diagnosis in HF, what is the recommendation? Observation of trend, not a recommendation

Comments – Technical - ECA (11)

- Grading system: parasite detection (sensitivity) should be included (on top of specificity and quantification)
- Consider false positive and false negative results
- +/- 25% limits
- Evidence in making standards more loose or stringent
- Little scientific evidence
- Experience from Dr. Yamo: +/- 30% - try to improve the capacity and not lower thresholds
- Follow-up of participants
- Define generally role of accredited microscopists
Comments – Technical (12)

- For EQA:
  - IQC, EQA, continuous improvement
- EQA: PT, supervision, cross-checking
- Develop PT guidelines
- Supply chain and stock management
  - Stock control and inventory
  - Zanzibar experience: essential drug list, but no essential diagnostic lists? Dependence on vertical programmes for supplies

Comments – Technical (13)

- Cross-checking – Need to review from country experience: Limitations in low transmission (statistical expertise), percentages
- Slide Bank – Should be in a separate document. SOPs. Ethical clearance.
- External inputs:
  - Remove/assess material i.e. SOPs
  - Does not answer technical Qs; i.e. how long do we look at a slide before declared neg – but group agrees not so many details
  - Accreditation of microscopists
  - Different countries will have different systems of regulations i.e. Kenya need to be registered with relevant authority
  - Drug resistance associated problems
  - G6PD deficiency
  - P. knowlesi
Comments – Technical (14)

- Stop referring to ‘Expert’ microscopists. This not specific and can be misleading. Instead say, for example, a highly competent microscopist (e.g. WHO Level 1)
- To avoid confusion, non-WHO accreditation systems or national competency assessment systems should avoid using Level 1 to Level 4 competency levels
- We need to clarify the terminology accredited vs certified (or another term)

Thank You!
10 - Feedback on MMQAM from end-users

Results: End-user questionnaire for *Malaria microscopy quality assurance manual*

March, 2014

Demographics

- Questionnaire sent to 75 potential respondents:
  - WHO regional malaria advisers (6), WHO professionals at AFRO inter-country support team (3), WHO national professional officers in AFRO region (19) and PAHO region (12)
  - CDC resident advisers in malaria endemic countries (20)
  - Representatives of multiple agencies participating in Africa coordination network to strengthen malaria microscopy (25)

- Response statistics:
  - 22 respondents
  - 29% response rate (10% RR considered good)
Demographics

- 16 countries
- 3 WHO regions: AFRO (8), PAHO (5), WPRO (3)
- Most respondents from Philippines (27.3%)
- Majority use English for work (64%); 12% use Spanish, 4% French, 4% Mandarin (16% use non-UN languages)

Role/ function of respondents

- Microscopist/ Technologist/ Lab assistant: 54%
- MM trainer/ Slide validator/ QA officer: 32%
- National guideline and QA programme developers/ National lab coordinators and managers/ Diagnostic experts/ Senior coordinators: 14%
Reasons for using QA manual

- Development & maintenance of a suitable MMQA programme: 38%
- Advocacy: 11%
- Training: 42%
- Other: 2%
- N/A: 7%

Multiple selections allowed

General feedback

- Majority (77.3%) considered writing used in manual to be clear
- Majority (72.8%) considered length of manual to be appropriate
- Majority (77.3%) considered the visual aids used in the manual to be useful
- Majority (≥77%) considered each chapter of manual to be “very important” (scale: not important, somewhat important, very important)
Format and presentation

- Majority (78.9%) of respondents preferred manual to be in A4 format

- Slightly greater preference for document >100 pages (compared to <100 pages), however emphasis should be on communicating all key information

- Colour, graphs, images, booklets and algorithms most popular design features (see next slide)

Desirable design features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>63.6</td>
</tr>
<tr>
<td>Graphs &amp; images</td>
<td>27.3</td>
</tr>
<tr>
<td>Booklets</td>
<td>27.3</td>
</tr>
<tr>
<td>Algorithms</td>
<td>27.3</td>
</tr>
<tr>
<td>Flipcharts</td>
<td>22.7</td>
</tr>
<tr>
<td>Posters</td>
<td>13.6</td>
</tr>
<tr>
<td>Removable inserts</td>
<td>4.50</td>
</tr>
</tbody>
</table>

Multiple selections allowed
Format and presentation

- Majority of respondents* considered current order of sequence of chapters (100%) and annexes (88.9%) to be appropriate and should be maintained.

- 47.5% of respondents considered the **hard copy of the entire manual** to be the most useful format.

- 35% considered the **electronic copy of the entire manual** to be the most useful; a minority expressed a preference for other formats (e.g. electronic copy of specific “core” sections of the manual).

*who expressed an opinion (n=9)

Other features and output

- 68.2% of respondents requested the following existing core documents be distributed along with the QA manual, if possible:
  - WHO Basic Malaria Microscopy, Part I; WHO Basic Malaria Microscopy, Part II; Tutor’s Guide; Learner’s Guide; WHO Bench Aids for Malaria Microscopy (2009)

- Rationale:
  - These documents are lacking in most districts
  - These are essential documents that serve as the basis for the entire QA programme
  - Their availability will enhance skills during and after training
  - Currently limited access due to lack of funds at peripheral level
Access and dissemination

• Half (50%) of respondents are currently notified about the manual through conferences, meetings or contact with their Ministry of Health

• However, majority (70.9%) stated they would prefer to be notified about the manual via email or WHO website

• Majority (72.7%) stated they had no difficulty in obtaining an electronic copy of the manual; 4% did encounter difficulties

• 50% of respondents stated they had no difficulty in obtaining a hard copy of the manual, 18.2% did encounter difficulties

Access and dissemination

Difficulties encountered in obtaining electronic copy of manual

Difficulties encountered in obtaining hard copy of manual
Difficulties in obtaining hard copy

- Not easily available
- Difficult to order
- Didn’t know where to obtain
- Need to establish a link between HQ and WHO offices/collaborating partners to make hard copy easily accessible and available for distribution

Suggestions for improving scope

- Use generic models which can be easily adapted to national protocol
- Provide practical examples for cross-checking and validation of slides: selection methodology, calculation of degree of detection agreement, calculation of degree of errors
- Include a section on basic statistics for malaria QA to guide decision-making
- Include mean and reference range determination formula for parasite count in the slide validation section (for clarity and validation of training slides)
Suggestions for improving scope

• Include table of reference ranges for a given mean parasite count at a given error limit at the required sensitivity and specificity

• Expand content on panel elaboration and evaluation

• Have a specific QA system under each phase (control/pre-elimination/elimination/maintenance)

• Tease out relevant portions and develop as bench aids, e.g. current treatment trends of the different species at various developmental stages

• Include country experiences

Suggestions for new SOPs

Respondents suggested including new SOPs on the following topics:

• Conducting external competency assessments
• Conducting basic, refresher and proficiency training of microscopists and refresher training of slide validators
• Specifications for supplies for malaria microscopy
• Laboratory protocol, reagent preparation and microscope maintenance
• Parasite counting in thick and thin film
11 - Experience with ECAMM in WPR and SEAR

Experiences with Implementation of External Competency Assessment in WPR/SEAR

Ken Lilley

The only WHO-Authorised ECA Course for Malaria Microscopists (WPRO, SEARO & AFRO)
Background (1)

- From 2002/3 external competency assessment (ECA) courses were trialed in the Philippines and the assessment model and grading schemes developed.
- Bi-Regional Workshop for Malaria Microscopy QA, Kuala Lumpur, Apr 05, formally agreed to the plans for the network. Agreed that ACTMalaria coordinate the network.
- WPRO and SEARO, in concert with ACTMalaria, have collaborated to develop a bi-regional network to support ECA and QA for malaria microscopy.
- The KL workshop recommended that ECA courses be commenced at a national level for senior ‘National Core Group’ (NCG) microscopists in cooperation with national Ministries of Health.

Background (2)

- Informal Consultation on QA of Microscopy - Microscopists and Slide Validation Schemes Meeting, Geneva, 3 Mar 06. Assessment methods and grading schemes were endorsed as the WHO model and were utilised in competency assessment courses until October 2008.
- Malaria Microscopy QA Meeting, Geneva, Feb 08. Continued to endorse the current model and also defined changes to the assessment model which were implemented in 2009 – harmonisation, including changing the composition of slides and increasing the number of slides assessed.
- ECA discussed at other meetings but no formal update meeting until now.
ECA Details (1)

- Duration - five days. NOT training – is Competency Assessment, with 'focused revision'. Important to increase competency, not just measure it.
- Pre-course theory test - 25 general malaria microscopy questions. Does not count towards the competency level
- Pre-course practical test – 16 slides, species identification and counts. Does not count towards the competency levels
- Morning presentations (primarily a review) of all aspects of malaria microscopic diagnosis, from specimen collection to diagnostic reporting. No 'wet' practical sessions.
- 55 test slides over three afternoons – competency level

ECA Details (2)

- Test slides of the four human malaria species (including mixed infections) and various malaria parasite densities. All slides utilised are provided by the WHO Slide Bank (RITM, Manila, Philippines).
- Assessments performed under examination conditions. Ten minutes to examine each slide for either parasites species identification or parasite counting.
- The mornings following assessment slides commence with a review of the slides examined the previous day.
- During the ECA week the Country/VBDC programme QA situation is assessed – try to visit lab/clinic, also talk to supervisors and microscopists
WHO Competency Levels

<table>
<thead>
<tr>
<th>Competency Level</th>
<th>Species Identification (accuracy)</th>
<th>Parasite Counting (within 25% of the true count)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1 (Expert)</td>
<td>≥ 90%</td>
<td>≥ 50%</td>
</tr>
<tr>
<td>Level 2</td>
<td>≥ 80%</td>
<td>≥ 40%</td>
</tr>
<tr>
<td>Level 3</td>
<td>≥ 70%</td>
<td>≥ 30%</td>
</tr>
<tr>
<td>Level 4</td>
<td>&lt; 70%</td>
<td>&lt; 30%</td>
</tr>
</tbody>
</table>

Progress (1)

- Model for competency assessment of malaria microscopists used successfully over the last twelve years in selected WPRO, SEARO and AFRO countries.
- 83 ECA courses in 16 different countries:
  - Australia (9), Bangladesh (3), Cambodia (5), China (3), Indonesia (4), Kenya (1), Lao PDR (4), Malaysia (5), Myanmar (4), Philippines (11), PNG (10), Solomon Islands (7), Thailand (6), Timor Leste (2), Vanuatu (5), Vietnam (4)
- ECA expanded to AFRO in 2009
  - Dr Jane Carter and Yamo Ouma at AMREF
  - ~ 23 ECA courses
Progress (2)

- Very useful tool for assessing competency
- Published data:
  - Almost all microscopists have shown significant increases in performance (species identification accuracy and counting accuracy) during the ECA and when tested prior to the next ECA.
  - Countries data also shows significant improvement in species identification and counting accuracy from pre to post assessment.
- ECA in high demand from WHO countries and the non-government sector

Challenges

- Still many microscopists that have not been competency assessed.
- Some participants not prepared, ie. Inadequate access to regular refresher training.
- Participants from previous ECA courses not transferring new knowledge and skills to microscopist colleagues.
- ECA results not used as per WHO QA Manual (eg. Should not have L4 supervisors).
- QA issues are highlighted, but are often not being addressed, year after year.
Future

- Overdue for update and standardisation decisions
- Need more Facilitators and Lead Facilitators
- Planned continued expansion of ECA needs to be carefully controlled and monitored
- Continuous improvement and quality assurance:
  - Finalise ECA SOP
  - Regular meetings of stakeholders
  - Control and monitor future expansion
  - Other languages, eg. Francophile?

Improvement of ECA participants

Angie Kao, Sania Ashraf.
Improvement of ECA participants

Improvements in Parasite Counting
(within 25% of correct count)

Countries

Angie Kao, Sania Ashraf

Acknowledgement

• Dr Eva Christophel – WHO WPRO
• Dr David Bell – Prev. WHO
• Ms Cecil Hugo – ACTMalaria
• WHO Malaria Slide Bank Team – Ms Jenny Luchavez
Background

- A study done in Kenya to evaluate the accuracy of routine malaria microscopy showed a sensitivity and specificity of 68.6% and 61.5%, respectively (Zurovac et al., 2006).

- Assessments in 9 IMaD countries indicated serious challenges to laboratory staff performance in malaria microscopy.

- A model for competency assessment of malaria microscopists was developed and tried successfully over the last 12 years by WHO WPRO in selected WPRO and SEARO countries.

- WHO AFRO and AMREF are collaborating on implementing a competency assessment programme in malaria microscopy for the AFRO region.
Purpose of the Assessment

• To improve quality of malaria diagnosis in Africa to:
  – Improve case management
  – Mitigate High cost of anti malarial drugs and
  – preserve efficacious life span of AL

• To standardise malaria diagnosis in Africa

• Poor use of laboratory results by clinicians linked to poor laboratory performance

• National core teams require accurate microscopy skills to support national QA programmes

Assessment overview

• Assessment methods and grading schemes proposed by WHO WPRO were endorsed as the WHO model at the Malaria Microscopy Quality Assurance meeting in Geneva (February 2008)

• Assessments of:
  – Parasite detection
  – Species identification
  – Malaria parasite counting (P. falciparum)

• Certificates issued to all workshop participants according to grading scheme

• Twenty two assessments conducted so far:
  – WHO and AMREF
    • Facilitated by AMREF
Course structure

5-day course:
- Pre-workshop theory
- Pre-workshop practical slide reading test (16 slides)
- Presentations/revision on all aspects of malaria microscopic diagnosis and reporting
- Examination of 55 slides under "examination" conditions — 10 minutes per slide
- Review of test slides throughout (opportunity for discussion)
- Preparation of thick and thin blood film
- Provision of WHO Malaria Microscopy QA Manual to all participants
- Presentations of Actions Plan from each country

Malaria Microscopy Quality Assurance Manual Version 1, 2009

WHO Standard Slide Panel

Slide Set 1 (40 slides): Assessment of presence/absence of parasites, and species identification
- 20 negative slides (‘clean’ negatives):
- 20 positive slides of low density (80-200 parasites/µL):
  - 10 *Plasmodium falciparum* slides
  - 4 mixed (2) species slides (include *P. falciparum*. Each species >40 parasites/µL, co-infecting species according to local prevalence)
  - 6 *Plasmodium malariae*, *Plasmodium vivax*, and/or *Plasmodium ovale* slides (include at least 1 of each species, ratio according to local prevalence)

Slide Set 2 (15 positive slides): Assessment of quantitation
- 3-5 *P. falciparum* (200-500 parasites/µL)
- 9-10 *P. falciparum* (500-2000 parasites/µL)
- 2 *P. falciparum* (>100 000 parasites/µL)

Malaria Microscopy Quality Assurance Manual Version 1, 2009
WHO Accreditation Grades

<table>
<thead>
<tr>
<th>Accreditation Level (Based on lowest grade achieved)</th>
<th>Detection of parasitaemia</th>
<th>Species Identification</th>
<th>Parasite Quantitation (± 25% of true count)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1 (Expert)</strong></td>
<td>≥ 90%</td>
<td>≥ 90%</td>
<td>≥ 50%</td>
</tr>
<tr>
<td><strong>Level 2</strong></td>
<td>80 – &lt; 90%</td>
<td>80 – &lt; 90%</td>
<td>40 – &lt; 50%</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
<td>70 – &lt; 80%</td>
<td>70 – &lt; 80%</td>
<td>30 – &lt; 40%</td>
</tr>
<tr>
<td><strong>Level 4</strong></td>
<td>&lt; 70%</td>
<td>&lt; 70%</td>
<td>&lt; 30%</td>
</tr>
</tbody>
</table>

Participation in ECAMM by Country
Performance during ECAMM all courses

Levels Attained by Participants
Post course evaluation: Participation in MMRT

- None: 70%
- One: 20%
- Two: 10%
- Three: 0%

Post course evaluation: Areas where participants require more info

- Species ID: 60%
- Parasite counting: 80%
- Preparation of films: 10%
- Malaria QA: 30%
Slide Preparation

Achievements

- Successfully conducted twenty two External Competency Assessments in Malaria Microscopy
  - 239 participants

- Purchased high quality microscopes for the course
  - Multi head Teaching Microscope
  - 12 CX 31 microscopes
**Constraints**

- Lack of slide sets
- Participants with varied backgrounds, no recent refresher training
- No follow up of participants
- Financial support for participants
- Lack of support from national governments

**Way Forward**

- Development of a local slide bank:
  - Development of slide banks in progress – AMREF, Ghana, Ethiopia, Nigeria
  - Collaboration with partners: HWH
- Provide training courses in all aspects of malaria microscopy, including wet practical sessions
- Offer more malaria microscopy refresher courses:
  - Different sites in Africa
  - Offer the course regularly at least twice annually
- Advocacy to increase a wider acceptance and more support
- Better selection of participants
Acknowledgements

- World Health Organization:
  - African Regional Office
  - Western Pacific Regional Office
- Research Institute for tropical Medicine (Philippines)
- National Malaria Control Programmes
- Presidents’ Malaria Initiative
- Improving Malaria Diagnostics project
- Ministries of Health

www.amref.org
Background

- Model for competency assessment of malaria microscopists used successfully over the last twelve years in selected WPRO, SEARO and AFRO countries.
- 83 ECA courses in 16 different WPRO & SEARO countries:
  - ECA expanded to AFRO in 2009
    - Dr Jane Carter and Yamo Ouma at AMREF
    - ~ 23 ECA courses
    - Expanded by running an ECA in Nairobi – to gain L1 facilitators and to instruct on some aspects of running the ECA. AMREF then ran own ECA with some guidance on data analysis and report writing. Then AMREF operated independently.
- Learned lessons such as inadequate support and guidance (although we covered some issues by email) and requirement for regular discussions on ECA process/suggested changes.
- Always a goal to expand the ECA programme - Identified need for SOP on how to run and expand
ECA SOP

- Production of SOP driven by increasing demand for ECA in all WHO regions and the need to maintain the quality and high standard achieved
- Ken Lilley and David Bell – Draft delivered to WPRO 29 Nov 13
- Really a Manual of Operation, rather than an SOP
- Aims of the SOP/Manual:
  - To support the identification, assessment and accreditation of clinical microscopists within national malaria programmes, thereby facilitating the improvement and maintenance of high quality malaria diagnosis.
  - To set out the basic principles and structure of the programme in a manual, to facilitate this assessment/accreditation whilst ensuring the quality of the programme is maintained.

What does the SOP/Manual do?

- The Manual aims to standardise the function of external competency assessments for clinical microscopists, and the bi-Regional slide bank operated by the WHO Regional Office for the Western Pacific and the WHO Regional Office for South-East Asia to support these assessments.
- Standardising of procedures, and committing existing procedures to text in a Manual, will facilitate expansion of the network to other Regions and entities that wish to assess high-level clinical microscopists, and put in place the structures necessary to support such assessments.
What does the SOP/Manual not do?

- The Manual does not provide a basis for training or for slide preparation or other essential elements necessary to support clinical microscopy. Further, it does not recommend how to run a microscopy QA programme, or provide detail on how an accredited national reference group should be used within a national programme. Existing documents for this purpose are listed in Essential Guidance on page 6. It is intended to support these existing manuals.

- The Manual does not intend to specify competency assessment for research microscopy. The needs of research sometimes differ from clinical diagnostic requirements, and assessment of competency of microscopists for research purposes needs to be structured accordingly.

Major Components

- WHO WPRO
- WHO SEARO
- WHO AFRO
- WHO MSB
- Regional/National MSB
- Coordinating agencies (eg. ACTMalaria)
- WHO Collaborating Centres
- Lead Facilitator/s
- Facilitators
Other important aspects

- Monitoring of the Programme quality
  - 3 yearly QA assessment by WHO and Coordinating agency
  - Assessed against 7 Key Performance Indicators
- Selection, designation and further recruitment of ECA Facilitators
  - Mandatory and desirable qualifications/attributes
- Selection, designation and further recruitment of ECA Lead Facilitators
  - Mandatory and desirable qualifications/attributes
- Borrowing from the WHO Bi-Regional Slide Bank
  - Principles for use
  - Approval for borrowing
- Recommendations on the process for expansion of the programme and inclusion of other regions
- Assessment of prospective region/country/institute for ECA programme expansion
- Principles of financial arrangements
- Standardise the ECA format, certificates, reports and associated SOPs

Plan/Next steps?

- Up to WPRO/WHO now
  - Disseminate and seek feedback
  - Reach harmonisation and agreement
  - Promulgate widely
  - Document control and monitor SOP
14 - Experience of RIRM with WHO SOP for MSB

Establishing a malaria slide bank using the WHO SOPs: Challenges and lessons

Research Institute for Tropical Medicine
Manila, Philippines

(Regional) Malaria Slide Bank

**How it started?**
- 2004 WHO consultation on malaria microscopy QA - slide banks identified as priority for national and regional malaria programmes
- 2007 - WPRO, ACTMalaria and RITM initiated the MSB

**For what?**
- To support malaria programmes QA in the WPR, SEA countries
  - (mainly) Competency assessment programs (WPRO’s External Competency Assessment)
  - Training (national)

**Tasks?**
- Collection and prep’n of high quality and standardized malaria positive and negative blood films
- Validation (microscopy and PCR)
- Proper storage and maintenance of the collection
- Lending and retrieval of slides from borrowers
How did we do it?

Key steps

1. Established need and secured funding
   - WPRO and ACTMalaria provided funding for the regional bank
2. Identified lab/institution
   - RITM as National Reference Lab for malaria in the Philippines;
     with ongoing field-based therapeutic surveillance and other malaria projects
   - later on designated as WHOCC for malaria diagnosis in 2011; maintaining the MSB
     included in the TORs
3. Identified focal person(s) and staff
   - at least 2 who will do the actual work of recruiting/selecting donors, preparing
     and staining the slides
4. Developed country-specific protocol, SOPs and forms
   - determined required parasite species, density, others
   - identified collection sites/methods (hospital/clinic or community)
   - defined donor criteria (age, sex, consent, treatment history)

Key steps ...con’t

5. Obtained ethical clearance (national and in WPRO)
   - at least 3 months!
6. Purchase supplies/equipment
   - prepared checklist based on SOPs
   - ensured good quality slides and stains
7. Trained staff on SOPs
8. Implemented collection
   - at least 30 working days in the field for 50 samples
     (facility-based collection)
9. Organized the collection
   - in slide boxes or in cabinets
10. Validated collection
    - microscopy and PCR
11. Database entry
12. Operation and maintenance
    - lending and retrieval of slides to/from borrowers
Funding ...

1. Determine composition/magnitude
   - How many cases/copies? Species? Other blood-borne parasites? Regional/national?

2. Approximate cost: -$40,000-50,000 (initial)
   - Lab supplies: good quality glass slides, cover slips, stains, mounting media, FTA filter paper, slide boxes, etc.
   - Equipments: pipettors (one for each species), pH meter, tube mixer, slide cabinets, computer
   - Collection activities: staff perdiems, travel, local transportation
   - Validation: PCR, microscopy (honoraria/fees for validators)
   - Operation/maintenance: data management/analysis, software, communication, institutional running costs, shipping

* Succeeding years: ~$15,000 mainly for sample collection, personnel (1) and validation

Procedures (detailed in SOPs or work instructions)

1. Pre-cleaning glass slides
2. Donor recruitment and samples collection

   a) Informed consent
   b) Case Report Form
   c) Venipuncture
   d) Transfer into EDTA
   e) Blood films (initial)
   f) Blood spots for PCR
3. Preparing thick and thin blood films

a) Mix blood gently.
b) Lay-out the paper templates.
c) Pipette 6µl blood for the thick smears.
d) Prepare the thick smears.
e) Pipette 2µl blood for the thin smears.
f) Prepare the thin smears.

* With gentle mixing of blood in-between

4. Drying smears overnight

Cover smears and dry overnight.

5. Preparing stains

Check pH of water used for prep’n of Giemsa stain.
6. Staining

- a) Fix thin smears w/ methanol.
- b) Assign QC slides.
- c) Arrange slides in staining rack.
- d) Stain with 3% Giemsa for 45 min.

7. Washing and drying smears overnight
   - *pH of water for washing also important*

- Cover and dry stained slides overnight

8. Mounting
9. Organizing the collection

10. Database - 2 main sections
   - Filemaker Software
   - SOP developed

- Slide inventory section
- Documents section
Procedures (detailed instructions) … con’t

- Slide inventory section
  - contents and physical organization of each cabinet
  - identity and exact location of every single slide in each rack and shelf

- Documents section
  - Donor information
  - Individual validation results
  - Borrower’s log
  - Final validation results
11. Validation

a. By Microscopy

- Pre-qualified validators; all ECA “Level 1” microscopists
- Initially, 6 validators only (3 from Philippines and 3 from other countries) - observed high variation in counts
- Increased to 12 validators in succeeding collections (6 from the Philippines and 6 from other countries)
- 2 slides per case/sample read all validators = total of 24 readings per case
  - Validation procedure - number of parasites against 500WBCs

b. By PCR - for 5 species

Validation stats

*Species diagnosis*

83% of slides (176/211) - at least 70% of the microscopists/validators (or 16/24 readings) agree on species and with PCR

*Inter- and Intra-rater variability in counts*

<table>
<thead>
<tr>
<th></th>
<th>Total number of slides (positives)</th>
<th>Total number of slides with sig. &lt;0.05</th>
<th>% slides with sig. &lt; 0.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inter-rater</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(between readers/microscopists)</td>
<td>191</td>
<td>41</td>
<td>21</td>
</tr>
<tr>
<td>Intra-rater</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(between slides*)</td>
<td>191</td>
<td>34</td>
<td>18</td>
</tr>
</tbody>
</table>

* 2 slides per case were used for validation
- All outlier counts removed for the analysis
Current composition of the slide bank

<table>
<thead>
<tr>
<th>Species</th>
<th>Parasite Count (p/µl)</th>
<th>0</th>
<th>&lt;200</th>
<th>201-500</th>
<th>501-2000</th>
<th>2001-10000</th>
<th>&gt;10000</th>
<th>Total cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Malaria Parasites Seen</td>
<td></td>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20</td>
</tr>
<tr>
<td>P. falciparum</td>
<td></td>
<td>13</td>
<td>17</td>
<td>21</td>
<td>23</td>
<td>31</td>
<td>105</td>
<td></td>
</tr>
<tr>
<td>P. vivax</td>
<td></td>
<td>6</td>
<td>7</td>
<td>13</td>
<td>25</td>
<td>12</td>
<td>63</td>
<td></td>
</tr>
<tr>
<td>P. malariae</td>
<td></td>
<td>1</td>
<td>2</td>
<td></td>
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<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>P. knowlesi</td>
<td></td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>7</td>
<td></td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>P. ovale</td>
<td></td>
<td>1</td>
<td>3</td>
<td></td>
<td></td>
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<td>4</td>
<td></td>
</tr>
<tr>
<td>Mixed Infections</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pv/Pf</td>
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<td>2</td>
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<td></td>
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<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Po/Pf</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td>20</td>
<td>21</td>
<td>27</td>
<td>39</td>
<td>60</td>
<td>44</td>
<td>211</td>
</tr>
</tbody>
</table>

Current composition of the slide bank

- Often requested (counts below 5000p/µL)
- Rarely requested

Procedures for borrowing and returning slides

**Borrowing**
- Fill-up loan request form with:
  - Species and (range of) parasite count required
  - Quantity to be borrowed
  - Intended use and date(s)
- MSB will decide on the request within 5 working days (to check for slides availability).
- Borrowers will cover all shipment and customs charges through their designated courier.

**Returning**
- Slides are loaned in a time-restricted basis (maximum 2 months).
- Borrowers are notified of the due date.
- If slides are needed for a longer period, another loan request form has to be filed.
- Borrowers are reminded to take good care of the slides during use and return them in their best possible condition.
Slide loans (2012 to March 2014)

<table>
<thead>
<tr>
<th>Date of Request</th>
<th>Requestor</th>
<th>Country</th>
<th>Purpose</th>
<th>Quantity</th>
<th>Date Sent</th>
<th>Date of Return</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/8/2012</td>
<td>AAMI/Killey</td>
<td>Australia</td>
<td>2012 WHO ECA</td>
<td></td>
<td></td>
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<tr>
<td>3/9/2012</td>
<td>NMCP Vanuatu</td>
<td>Vanuatu</td>
<td>Training, evaluation and validation purpose</td>
<td>150</td>
<td>3/30/2012</td>
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<td>5/11/2012</td>
<td>Malaria Control</td>
<td>Myanmar</td>
<td>Training</td>
<td>38</td>
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<td>AMREF</td>
<td>Kenya</td>
<td>Malaria microscopy accreditation course</td>
<td>852</td>
<td>7/27/2012</td>
<td></td>
</tr>
<tr>
<td>6/26/2012</td>
<td>DOH-MCP</td>
<td>Philippines</td>
<td>Refresher Course</td>
<td>46</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>8/8/2012</td>
<td>National Program</td>
<td>Tehran</td>
<td>ECA/ National Assessment</td>
<td>374</td>
<td>10/1/2012</td>
<td>Jan-13</td>
</tr>
<tr>
<td>9/14/2012</td>
<td>DOH-MCP</td>
<td>Philippines</td>
<td>Refresher training in Thailand</td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>10/20/2012</td>
<td>AAMI/Killey</td>
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<td>ECA</td>
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<td>01/17/2013</td>
<td>Dec-13</td>
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<td>10/5/2013</td>
<td>DOH-MCP</td>
<td>Philippines</td>
<td>Instructional Skills Development</td>
<td>90</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>9/5/2013</td>
<td>FIND/UPCH</td>
<td>Peru</td>
<td>Assessment (National/Internal)</td>
<td>5</td>
<td>9/16/2013</td>
<td>9/23/2013</td>
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<tr>
<td>9/18/2013</td>
<td>WHO/NIMR</td>
<td>India</td>
<td>Assessment (National/Internal)</td>
<td>25</td>
<td>9/19/2013</td>
<td>Nov-13</td>
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<tr>
<td>10/6/2013</td>
<td>RITM</td>
<td>Philippines</td>
<td>Training (National)</td>
<td>18</td>
<td>10/21/2013</td>
<td>10/25/2013</td>
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<td>12/24/2013</td>
<td>AAMI/Killey</td>
<td>Australia</td>
<td>ECA</td>
<td>30</td>
<td>01/29/2014</td>
<td>Apr-2014</td>
</tr>
<tr>
<td>10/4/2014</td>
<td>Int‘l Ventures</td>
<td>Philippines</td>
<td>Training (National)</td>
<td>142</td>
<td>03/19/2014</td>
<td>June-2014</td>
</tr>
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</table>

Challenges

(Initial) comments/feedback from users related to quality and composition:

- Some slides have more or less parasites than the reference count (currently, the median count of validators is taken as the reference count)
- Some slides have parasites detected by the validators but PCR is negative
- Some slides have mixed species but identified as mono-infection by PCR
- Others, but less common: some slides are poorly stained or dirty, cover slip on the wrong side of the slide, slides with air bubbles, thin smears unreadable

To resolve issues on species, we derived a “composite species diagnosis” for each case

- At least 70% complete agreement among all validators and with PCR

To resolve issues on variability of counts, we removed outliers, determined the inter- and intra-rater variability for each case, and excluded those with significant differences

- only slides satisfying both criteria are now loaned for ECA
Challenges ... con’t

- Difficulty of finding acute and appropriate cases due to declining incidence in the Philippines
  - train and collect from other countries in the region and request to “deposit” part of their collection to the regional MSB
  - in Sept 2013, RITM trained NIMPE staff from Vietnam for 1 week (in the PH); in December, they reported to have collected and prepared >100 cases

- Validation - expensive!
  - almost “free” in the beginning (validators read the slides during their “free time” and were given a small honorarium; validation took almost 2 years to be completed for a batch of ~120 cases)
  - later increased to ~$8/slide per validator, and with set turn-around-time of 10-15 working days only, depending on the number of slides
  - + cost of shipping (national and international)

- Borrowers reporting lost/broken slides
  - Request borrower to include the damaged slides when they return the set
  - How to compensate/replace these slides???

- Shipping costs and taxes sometimes charged to RITM; delays return of slides
  - Borrowers are reminded to pay all applicable charges and taxes related to shipment, and tick appropriate box for fees (charge to sender) in the shipping documents.

- Dedicated staff

Lessons

- Important to develop and adhere to SOPs to achieve and maintain high quality of the collection
  - Do initial trouble-shooting in the lab and in the field

- Need to have good network between lab and sites and local staff to assist or do the collection

- Need to have a pool of (pre-qualified) validators, Level 1 or 2 ideally
  - Even with pre-qualified L1 microscopists, variation in species and counts observed
  - Set criteria for selecting slides for ECA, training

- Resources (funds, personnel, collection sites, others) big influence on implementation
15 - EPHI experience of MSBs

National Archive of Malaria Slide development in Ethiopia

Tefsay 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

- Role of Malaria slide bank-(NAMS) in Malaria Laboratory Diagnosis quality assurance
- NAMS development process
- Current status of the NAMS
- Using the NAMS
- NAMS management & sustainability
- Challenges
- Recommendations
- Acknowledgement
ROLE OF MALARIA SLIDE BANK IN MALARIA MICROSCOPY QUALITY ASSURANCE

- Quality Equipment & supplies
- Supportive Supervision & mentorship
- Standard Training
- EQA (PT, Blinded rechecking, Onsite evaluation)
- Malaria Microscopy Quality Assurance

Standardized & validated slides
Malaria slide bank

NAMS DEVELOPMENT PROCESS

Planning
Procurement of supplies
Protocol Development and Ethical clearance
Document (SOPs, log sheets, register) development
Site selection
Training of donor site and slide bank staffs
Donor selection, specimen collection, mass slide production
Slide validation
Database development
Slide archive
Planning, Procurement & Protocol development

- Protocol development
  - IMaD, ICAP & EPHI
- Ethical review and approval
  - CDC and EHNRI
- Implementation work plan
- Procurement of supplies
- Technical Assistance: ICAP, PMI & IMaD
- Finance: PMI/USAID

Documents (SOPs, log sheets) development

- Reviewed existed documents to develop those specific to the slide bank establishment
### List of documents for slide bank establishment

**SOPs**
- 1. SOP for Malaria positive patient donor enrollment
- 2. SOP for Malaria Negative patient donor enrollment
- 3. SOP for onsite blood film slide and storage
- 4. SOP for collecting slides and blood samples from sites
- 5. SOP for archiving of malaria slides collected from sites
- 6. SOP for shipping of blood samples and slides
- etc

**Logs books**
- Laboratory enrollment log book slide bank
- OPD Malaria Positive Patient enrollment log book for slide bank

**Checklists**
- Sample Accession criteria for mass slide production of uniform quality standard
- Supervisory Checklist for Panel slides

**Consent forms**
- 1. Oromiffa consent form-Slide Bank
- 2. Amharic consent form-Slide Bank
- 3. English consent form-Slide Bank

**Action plans and frameworks**
- Framework for slide bank establishment
- Action plan of Ethiopian NAMS Implementation

### Site selection & training

- **Adama Malaria control center**  
  *Positive donors*

- **EPHI malaria reference laboratory**  
  *Negative donors*  
  (Foreign visitors from non malaria country, no history of previous malaria)
Determining optimum Giemsa concentration and time of staining

- Research conducted
  - on the best concentration and
  - time of staining at different scenarios
  - 5 slides in each category

<table>
<thead>
<tr>
<th>Giemsa Conc</th>
<th>Time of staining in minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30</td>
</tr>
<tr>
<td>3%</td>
<td>x</td>
</tr>
</tbody>
</table>

Donor selection

- Patient screened for routine health care services
- Patient assessed for eligibility if found positive for malaria
- Patient consented for donating blood
- Venous blood obtained and patient gets the treatment
- Necessary preparations made for blood film preparation
Smear preparation

Smearing and drying

Batch of Fixed blood films prepared for staining

Fixing blood films
Smear preparation...

Quality checks of smearing

Dried blood specimen (DBS) collection for PCR

Giemsa preparation and staining

Filtration of Giemsa

Batch staining
Mounting and labeling

Drying after staining

Labeling

Slide quality check

- Slides discarded
  - Poor smearing
  - Poor mounting
### CURRENT STATUS OF THE NAMS

**DATA ON MASS SLIDE PRODUCTION, March 2014**

<table>
<thead>
<tr>
<th>Ser no</th>
<th>Species type</th>
<th># of donors</th>
<th># of slides collected/ar chived</th>
<th># of donors validation reading conducted</th>
<th>Validation status</th>
<th># of donors validated</th>
<th># PCR required</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negative</td>
<td>6</td>
<td>1577</td>
<td>6</td>
<td>6 (1577 slides)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td><em>P. falciparum</em></td>
<td>6</td>
<td>1745</td>
<td>2</td>
<td>1 (200 slides)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td><em>P. vivax</em></td>
<td>15</td>
<td>4406</td>
<td>10</td>
<td>4 (897 slides)</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td><em>Pf/Pv</em> mixed</td>
<td>3</td>
<td>850</td>
<td>0</td>
<td>TBD</td>
<td>TBD</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>30</td>
<td>8578</td>
<td>18</td>
<td>11 (2674 sides)</td>
<td>7+</td>
<td></td>
</tr>
</tbody>
</table>
USING THE NAMS

- Training
  - In service trainings & TOTs
  - Pre-service training (Universities)
  - Mentorship visits (on-job training)
- Competency assessment
  - NCAMM
  - ECAMM (WHO)
- EQA
  - PT panels
  - Onsite supervision (slide challenge)
- Slide exchange (planned)

NCAMM

- A 4 days of evaluation using a set of 35 validated slides
- Practical demonstrations, review of test slides & presentations on malaria microscopy quality assurance activities

<table>
<thead>
<tr>
<th>Detection</th>
<th>Quantitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative slides, n=10</td>
<td>Positive slides, n=10</td>
</tr>
<tr>
<td>Positives slides, n=15 (8 pf, 5 PV, 2 mixed)</td>
<td>3 low parasite density slides</td>
</tr>
<tr>
<td></td>
<td>5 medium parasite density slides</td>
</tr>
<tr>
<td></td>
<td>2 high parasite density slides</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Accreditation level</th>
<th>Detection of parasitemia (25 Slides)</th>
<th>Species identification (15 slides)</th>
<th>Parasite quantification (10 slides)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Star 4</td>
<td>90%</td>
<td>90%</td>
<td>50%</td>
</tr>
<tr>
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<td>80%&lt;90%</td>
<td>80%&lt;90%</td>
<td>40%&lt;50%</td>
</tr>
<tr>
<td>Star 2</td>
<td>70%&lt;80%</td>
<td>70%&lt;80%</td>
<td>30%&lt;40%</td>
</tr>
<tr>
<td>Star 1</td>
<td>50%&lt;70%</td>
<td>50%&lt;70%</td>
<td>20%&lt;30%</td>
</tr>
<tr>
<td>Star 0</td>
<td>&lt;50%</td>
<td>&lt;50%</td>
<td>&lt;20%</td>
</tr>
</tbody>
</table>
NAMS Management & sustainability

- **NAMS operational manual** drafted
  - Introduction
  - **Scope and Purpose**
  - **National archive malaria slides development** (Site selection, Donor selection and Ethical considerations, Preparation of Materials and reagents, Specimen Collection, Mass slide Production, Slide Validation)
  - **Archiving and database management** (Core functions of the database, Process of archiving, Handling slide exchange requests, Checking out and in of blood film slides [Slide exchange, Lending of slides for PT, Lending of slides for training, Borrowing of blood film slides, Accessioning of blood film slides, Replenishment of broken or lost slides])
  - **Roles and Responsibilities of NAMS Database users** (Slide bank Manager, Quality manager, Training manager, Borrowers)

---

**Slide exchange**

**Memorandum of Understanding (MOU)**

*Between*

Country Ministry of Health (MOH)
Represented by:
(Agency to be Determined [TBD])

And

Ministry of Health of the Federal Democratic Republic of Ethiopia
Represented by:
Ethiopian Public Health Institute (EPHI)

For
Strengthening the National Malaria Slide Archives
Slide validation

- A set of 20 slides shipped for validation to HWH

- Use 6 reference readers

- Determine if PCR is required or not

- Slide validation activities handled by HWH (for 35 donors)
Archiving of validated slides

- Slide cabinet of 10,000 slide storage capacity

Database and slide archiving

- Developed an access based database jointly with MalariaCare
Database and slide archiving...

Features of the database

- Slide Entry
  - Enter/Edit Donors
  - Initial Slide Scan
  - Edit Slide Information
- Check-in/Check-out Slides
  - Archive Summary
  - ECAMM Slide Set Generator
  - MORT Slide Set Generator
- Contact/User Information
  - List of Contacts
  - Edit Borrower Information
- Database Options
  - Navigation Bar
  - Windows Ribbon
  - MS Access Settings
  - Add or Edit Filter
- Full Slide List

Sustainability

- Currently fully financed by PMI
  - Slide production
  - Validation
  - Policy & procedure development
- EPHI plans to take over technical, logistic and administrative responsibilities of NAMS
  - Part of NSP 2014-2020 (EQA, NCAMM, ECAMM)
CHALLENGES

• Some commodities not readily available in country
  – Poly mount
  – Coverslips (24 x 50)

• Low number of validators in country (ECAMM is expensive to conduct it outside country)

• Delayed External validation process and which is unsustainable

• Unavailability of low parasitemia slide collections

RECOMMENDATIONS

• Build capacity to validate slides in country
  – Increase the number of level 1 experts in countries
  – Strengthen the capacity of PCR lab to validate slides
    • MalariaCare planned to train one EPHI expert in UCAD, Senegal

• Would be good if WHO facilitate develop generic template MOU for slide exchange between countries as part of the slide bank manual

• It would be useful if WHO develops/facilitate development of database of validators (level 1 & 2) and engage them in regional activities

• Introduce/standardize the dilution method of high parasitemia blood to produce low density parasitemia
ACKNOWLEDGMENTS

• Adama Malaria Control center staffs
• Ethiopian Public Health Institute (EPHI)
• Oromia Regional Health Bureaus
• IMaD/MalariaCare
• PMI/USAID

THANK YOU FOR YOUR ATTENTION!!!
16 - University of Lagos experience of MSBs

Malaria diagnosis quality assurance: specimen, slide banking and diagnostic implementation

Wellington Oyibo
ANDI CENTRE OF EXCELLENCE FOR MALARIA DIAGNOSIS
WHO/FIND Malaria Specimen Collection Site
The International Center for Malaria Microscopy and Malaria RDT Quality Assurance Center
College of Medicine
University of Lagos
Lagos – Nigeria
EMAIL: coemalariadx@gmail.com

Institutional Background

- College of Medicine, University of Lagos established in 1962
- Mandate to build capacity of health workers, conduct research and provide service
- One of the most patronized University in the country
- Attached to a tertiary hospital, the Lagos University Teaching Hospital
- Functional Research Ethics Committee

- Over 1,200 staff: academic, technical and administrative
- Host research sponsored by WHO, USAID, PEPFAR/Harvard, German Government, and other International and national organizations
ANDI Centre of Excellence for Malaria Diagnosis

- Started as Tropical Disease Laboratory – malaria, onchocerciasis, schistosomiasis, soil transmitted helminthes
- Designated ANDI CoE for Malaria Diagnosis in 2011
- Platform for malaria research – malaria pathogenesis, case management - diagnosis, drug, vaccine trials and diagnostic implementation
- Capacity building and post-training competency assessment

Quality Assurance for Malaria Rapid Diagnostic Tests (MRDTs)

- Contribute calibrated wild *Plasmodium falciparum* to Global Malaria Specimen bank in CDC, Atlanta, USA
- Involved in 3 rounds of collections (parasite calibration and speciation) – highest in Africa
- QC Panels of collection stored and used for:
  - In-country Pre-procurement testing of RDTs to ensure their suitability for use in health facilities
  - In-country Lot testing
  - Training on MRDTs, supervision and monitoring
- All activities carried out under GCLP/GCP
Contributions to Global Malaria Specimen Bank

60 Wild type Plasmodium falciparum QC samples produced in 2013 from Nigeria's parasites
Deployed parasite calibration and malaria QC sample prep skill to slide banking

Blood mixing at 4°C to dilute to lower parasitaemia

Malaria microscopy: QA and capacity building

- Malaria microscopy curriculum expanded to address local issues: ethics in the laboratory for example
- Certified malaria microscopists and tutors
- Coordinate malaria QA/QC for the country
- Developed Malaria Slide Bank since 2008
- Microscopist trained at NICD, South Africa on slide banking in 2007
- Produced and stained over 5,000 slides in a 5-day period with collaborators from Oman and South Africa
- Linkage to external groups through the WHO/TDR network
Certified Malaria Microscopists

Other microscopists preparing for certification

Response to operational malaria diagnostic challenges

Improvement of blood transfer devices
(accuracy, safety, and ease-of-use)
in collaboration with FIND

Sub-standard Malaria stains

High quality Malaria Stains
produced at our Centre and
supplied to labs and institutions

Heidi Hopkins et al., (2011). Blood transfer devices for malaria rapid diagnostic tests:
evaluation of accuracy, safety and ease of use. Malaria Journal 2011; 10:30
External Competency Assessment Experience

- Worked in collaboration with AMREF/IMCDI in ECA/Accreditation in Lagos, 2011

Trained by our team

<table>
<thead>
<tr>
<th>Name of participant</th>
<th>Parasite detection</th>
<th>Species ID</th>
<th>Parasite quantitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last</td>
<td>First</td>
<td>State</td>
<td>pretest</td>
</tr>
<tr>
<td>Benue</td>
<td>64</td>
<td>38</td>
<td>14</td>
</tr>
<tr>
<td>Benue</td>
<td>55</td>
<td>72</td>
<td>0</td>
</tr>
<tr>
<td>Ebonyi</td>
<td>82</td>
<td>72</td>
<td>14</td>
</tr>
<tr>
<td>Nassa</td>
<td>64</td>
<td>69</td>
<td>57</td>
</tr>
<tr>
<td>Oyo</td>
<td>55</td>
<td>64</td>
<td>14</td>
</tr>
<tr>
<td>Nassa</td>
<td>55</td>
<td>67</td>
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</tr>
<tr>
<td>UoL</td>
<td>82</td>
<td>95</td>
<td>57</td>
</tr>
</tbody>
</table>
Collaboration with NMCP – FMoH, State, and Partners

- Provides platform for QA on malaria diagnosis (RDTs and microscopy) to NMCP and most partners
- Malaria Consortium/SUNMAP/DFID – set up state malaria diagnosis QA team & capacity building
- Society for family Health (SFH) – Capacity building for microscopists from 18 southern states
- MAPS/USAID – capacity building for malaria diagnosis for state QA team
- Lagos State Government – malirometric and epidemiology studies
- To commence Malaria Microscopy QA (PT) in private sector using QC slides in three states of Nigeria (SFH)
Successful Collaboration in slide banking

NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES

Pasteur Institute Cambodia

RIPM, The Philippines

Slide exchange
Plasmodium vivax slides and P. ovale exchange:

Malaria Slide banking at UoL
Malaria diagnostic activities at University of Lagos

- Microscopy and RDT Training
- Certification of Microscopists
- Slide-Banking
- External QA
- QA of RDTs (in-country lot testing, field testing, post-purchase)
- Malaria Indicator Surveys in communities

Opportunities for slide exchange

- No custom challenge as all activities are covered ethically
- Have received slides from Burkina Faso, Uganda (QA for WHO/FIND Malaria in pregnancy studies), Cambodia etc.
- Shipped calibrated QC parasites samples to CDC, Atlanta; HTD, UK; slides to Swaziland; dry blood spots to Australia etc.
Funding

- Activities personally driven due to clear in-country and overseas gap on microscopy QA
- No direct funding on slide banking activities – this limited our expansion
- Generate funds that covers QC slide production activities only – covers field collection, materials and reagents, smear preparation, mounting, validation etc
- Provide slide cross-checking services to top private sector facilities
- Grant for expansion of infrastructure, human resources and coordination critical

QC slide produced/distribution

- Po: 406 slides
- Pf/Po: 720 slides
- Pf/gm: 103 slides Pf ring stages = 500
- Pf/Pm: 359 slides P. vivax = 160 slides
- Total: 2,248 slides (include teaching slides that have been used repeatedly) – slides produced regularly upon request and need

- Produced new counting slides on 21/03/2014
- High density – 500,000 p/ul of blood (100 slides); approx 250 p/ul of blood (100 slides)
- Low density - 256p/ul of blood (100 slides)
In-country and overseas demand for QC slides from UoL

- Supplied slides to Partners for capacity building in-country – USAID supported Malaria action plan for states (MAPS); SuNMAP/Malaria Consortium
- Currently producing QC slides for proficiency testing in the private sector facilities – implementation in 3 states of Nigeria [Society for Family Health (SFH)]
- On going slide checking and PT test in clinics of multinational companies

- Supplied slides to Swaziland Malaria control programme
- Discussing with contacts in DRC to provide QC slide
- Demand in-country will increase as we commence the operationalization of Microscopy QA and capacity building

Four years Malaria QA plan (1)

- **Overall Goal** – To provide an excellent, effective and efficient platform for quality malaria diagnosis

- Strengthen and expand current infrastructure and capacity to produce, validate, and store QC slides to serve in-country and overseas *needs* *(by end of year 3)*

- **In country:** To provide validated slides for malaria microscopy competency assessments/accreditation, proficiency testing and capacity building in the 36 states of the country including the FCT *(by end of year 2)*

- QA Malaria Microscopy teams are currently being set-up in 40-50% of the states
Four years Malaria QA plan (2)

• Each state has between 10 – 44 Local Government Areas (LGAs) where real-time supervised PT testing would have to be done frequently to improve quality of malaria diagnosis in facilities

• Plasmodium culture would established to provide ready parasite resource for QC slide production \( \text{by end of year 4} \)

• Strengthen slide storage and replenishment system \( \text{by end of year 2} \)

• Develop a strong in-country coordination platform to address malaria microscopy challenges – ICT, e-learning, virtual slide reading, setting up of databases etc \( \text{by end of year 3} \)

Four years Malaria QA plan (3)

• Strengthen nucleic acid-based slide validation system \( \text{by end of year 2} \)

• Build a critical mass of National, State and LGA Microscopists with strong competency across the country (public and private sectors – increased human resources \( \text{by end of year 4} \))

- Overseas

• Support NMCPs with QC slides, capacity building and undertake External competency assessment \( \text{all years} \)

• Collaborate with other centres to strengthen and promote QA on malaria diagnosis \( \text{all years} \)
Resource requirements

Critical for strengthening, expanding and sustaining current activities

<table>
<thead>
<tr>
<th>S/No.</th>
<th>Description</th>
<th>Estimated Amount (USD)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>Equipment/Materials:</strong> Additional microscopes for ECA, reagents, 1 multi teaching microscope with camera, barcode scanners and labels, vacuutainer tubes, syringes, vacuutainer holders, Whatman filter paper etc</td>
<td>Cost being prepared</td>
<td>Have 70 middle level microscopes and 5 new model microscopes – CX21. Materials could be purchased over time</td>
</tr>
</tbody>
</table>
| 2.    | **Personnel (dedicated and ad hoc):** 2 dedicated lab staff, 4 adhoc lab staff, 1 middle level Admin and 1 junior administrative staff. Postgraduate students and interns provide support regularly. | Cost being prepared    | 2 Lab staff / year = 22,500.00  
2 Admin staff/year = 16,500; Ad hoc staff for slide mounting and other preparatory activities. |
| 3.    | **Lab infrastructure:** slide cabinets, parasite culture system [in the future when clinical samples become scarce], LAMP/Thermocycler for slide validation) | Cost being prepared    | Already have some slide cabinets. More would be required for expansion |
| 4.    | Logistics and Communication                      | Being prepared         |                                                                         |

Closing remarks

- The selection of University of Lagos (UoL) as a collection site for malaria specimen in 2005 for RDTs was a great stimulus to our malaria diagnostic quality assurance activities
- UoL developed great interest in QA for malaria diagnosis but constrained due to limited government funding
- WHO/TDR and other partners – FIND, DFID programmes, USAID etc have been supportive
- We have the capacity, capability and zeal to provide leadership in malaria diagnosis quality assurance (RDTs and microscopy)
- Current intervention by WHO and partners is commendable and should give fillip to Centres to attain clear deliverables
Acknowledgement

- WHO/TDR (Geneva)
- WHO AFRO/Nigeria
- Foundation for Innovative New Diagnostics (FIND), Geneva, Switzerland
- NMCP (Nigeria)
- Society for Family Health (SFH)
- NIMR
- David Bell
- Sebastian Cognant
- Jennifer Luchavez
- Dieder Menard

- EQA programmes in South Africa & Oman
- WHO (Western Pacific) & Philippines MoH
- Dedicated staff
- College of Medicine University of Lagos/LUTH
- Malaria Consortium/SuNMAP/DFID, UK
- USAID/MAPS
- Pasteur Institute, Cambodia
17 - NICD experience of MSBs

Malaria Slide Bank (MSB): Experience from NICD, South Africa

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

Overview

• Background
• Personnel
• Laboratory set-up
• Distribution systems
• MSB procedures: NICD deviations
• Challenges
• Planned improvements
• Summary
Background

• The National Institute for Communicable Diseases (NICD) has coordinated 4 malaria/blood parasite EQA Programmes/PT Schemes over the last ~30 years.

• To sustain the above we established a malaria slide bank (MSB), comprised of stained blood films with:
  • malaria parasites,
  • non-malaria blood parasites, and
  • no parasites i.e. negative.

• We also conduct malaria training courses for staff of the National Health Laboratory Service and the Malaria Control Programme, for which we prepare slide sets from our MSB. Some laboratories do request slide sets/positive controls from us.

• The costs of maintaining the MSB are covered by the PT Scheme budgets.

Personnel

1. Parasitology Reference Laboratory, NICD: we have 1 pathologist, 3 medical scientists and 4 medical technologists.

2. The following number of staff are competent to perform the listed activities:
   • 7 can prepare blood films
   • 3 can mass stain blood films
   • 5 can identify and quantitate malaria

   However, due to other work commitments, 1 staff is responsible for the MSB and performs most tasks.

3. We have no accredited readers as yet.
   • A previous staff member did attend training in RITM, Philippines in May 2006 and implemented techniques learnt.
   • One staff member attended the Malaria Microscopy Training Course conducted by KEMRI Malaria Diagnostic CoE in Kenya, in May 2009.
Laboratory set-up

Accommodation
• Well ventilated, temperature controlled laboratories
• Adequate bench space and two sinks, to prepare and stain up to 800 slides at a time
• Good quality tap water (pH 7.25)
• Efficient waste management system

Equipment, reagents and consumables
• Good microscopes (with camera), shaker, pH meter, pipettes
• PCR equipment (& facilities)
• Good procurement system to order and receive consumable and reagents within ± 1-6 weeks

Quality assurance system
• ISO 15189 and ISO 17043 accredited
• SOPs for all aspects of the MSB, including microscope maintenance and QC forms

Distribution systems
• PT Scheme samples are sent by courier to individual laboratories. This allows for samples to be tracked until receipt.
MSB Procedures

1. Donor screening and selection
2. Venous blood sample collection from blood donors and batch preparation of malaria blood films
3. Batch staining of malaria blood films with Giemsa stain
4. Examination of Giemsa-stained thick and thin malaria blood films by light microscopy
5. Mounting and labelling Giemsa-stained malaria blood films
6. Validation process
7. Preparation of venous blood spots on filter paper
8. Dilution of blood samples to desired parasitaemia

Our slide banks differ slightly from most other MSBs in the following aspects...

Donor screening and selection

- We are not linked to any hospital/clinic i.e. we have no contact with patients.
- We use the NHLS network of laboratories to obtain our samples. Laboratories close to us contact us when they have positive malaria samples and we arrange for the blood to be brought to us.
- We perform the following to determine if we can use the blood:
  - a wet preparation to check for clumping,
  - a *P. falciparum* RDT (if negative, then a combo/PAN is also performed),
  - prepare and stain the blood films with either rapid haematology stain and/or Giemsa (10% for 30 mins), read slides, quantitate if *P. falciparum*.
- For negative blood slides or for dilutions of *P. falciparum*, staff members complete consent forms and donate blood. (no travel to malaria areas in last 3 months)
Venous blood sample collection from blood donors & batch preparation of malaria blood films

- We prepare blood films as per WHO guidelines.
  - Exception: when we have limited blood for non-falciparum blood we use 5µl for the thick film instead of 6µl.
We stain blood films as per WHO guidelines.

Batch staining of blood films with Giemsa stain

- We stain blood films as per WHO guidelines.
Examination of Giemsa-stained thick and thin malaria blood films by light microscopy

- We examine blood films as per WHO guidelines.
Mounting and labelling Giemsa-stained malaria blood films

- Slides are kept in labelled boxes and are only labelled once they are selected for use.
- Slides are mounted if they will be read by multiple readers:
  - PTS which assess microscopists
  - Training slides

Validation procedure

- Each batch is confirmed by PCR (Padley et al.)
Preparation of venous blood spots on filter paper

- Blood aliquot kept (±50µl), if sufficient blood.
- Unmeasured amount of blood used to prepare blood spots.

Dilution of blood samples to desired parasitaemia

- We do blood grouping before selecting a donor.

Challenges

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Reason/root cause</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Films don’t spread well</td>
<td>Poor quality slides (greasy)</td>
<td>Wash/clean slides</td>
</tr>
<tr>
<td>Thick films washing off</td>
<td>Not dried for long enough</td>
<td>Leave to dry for 2-4 nights before staining (no major auto-fixing)</td>
</tr>
<tr>
<td>RBC/WBC clumping</td>
<td>Inherent patient factors</td>
<td>Perform clumping test before using blood</td>
</tr>
<tr>
<td>Small quantity of non-falciparum blood received</td>
<td></td>
<td>Use 5µl instead of 6µl for thick blood films</td>
</tr>
<tr>
<td>Acquiring non-falciparum blood</td>
<td>Low prevalence in SA</td>
<td>Exchange slides with Philippines</td>
</tr>
</tbody>
</table>
| Thin films washing off (thick films fine) |                                                                              | Methanol? Prolonged fixing as temporary solution. Change grade of methanol?
Planned improvements

• We are sending one (possibly two) staff on the August ECA course in Kenya.

• Investigating acetone fixing to improve staining.

• We are willing and able to improve our current procedures should we be required to assist with the WHO Afro MSB. For example,
  • We could be more active in sample collection, by visiting busy sites during malaria season.
  • We could use our PTS courier process to deliver MSB slide sets.
  • The WHO Afro MSB would be very beneficial in providing:
    • Slides for the Afro ECA courses
    • Training slide sets, and
    • Slides for international PT schemes

Summary

• We (NICD) have a well-established MSB, which is funded by our PT scheme contracts.

• There is a definite demand for malaria positive control slide sets from laboratories who want to conduct in-house training, as well as organizations that require malaria PT schemes. We are able to adapt to the needs of the request.

• The biggest endorsement of our slides is that we have distributed them around the world and received back concordant results.
Acknowledgements

For the guidelines (Annex 8) to assist in developing our MSB:
  • WHO

For providing samples to use in our MSB:
  • NHLS laboratories
  • RITM, Philippines
  • OMAN
  • NICD staff

For development and maintenance of the NICD MSB, staff of the Parasitology Ref. Lab.:
  • John Frean, Leigh Dini, Rita van Deventer, Desiree du Plessis, Benjamin Mogoye, Lisa Ming Sun, Ntswaki Seolwanyane, and Nonhlanhla Kamolane
18 - Kintampo experience of MSBs

KHRC Malaria Slide Bank Experiences

Seth Owusu-Agyei, Director
Kintampo Health Research Centre,
Ghana

www.kintampo-hrc.org

RESEARCH CENTRES OF MOH/GHS, GHANA

Navrongo Health Research Centre
(northern belt)

Kintampo Health Research Centre
(middle belt)

Dangbe West Research Centre
(coastal belt)

AMAHDSS
Total Placement in MOH

• We carry out relevant health research that mainly impact on public health
• Authorities in GHS/MOH access us to carry out health research that is deemed relevant
• Participate in Senior Managers meetings where annual reviews of GHS/MOH take place
• On malaria, KHRC tasked to train microscopists in our health facilities

KHRC lab - to support research

Microbiology

Microscopy

Biochemistry/ Hematology

Molecular Biology
Slide bank

- Malaria microscopy continues to be the “gold standard” for malaria diagnosis.
- KHRC is one of the clinical trial sites in Africa, with indepth involvement in Malaria clinical trials.
- Now established a “Centre of Excellence” for malaria microscopy training for clinical trial sites in Africa and training for lab Techs in Ghana.
- We work closely with the Kisumu Malaria Centre of Excellence (Peter and others) in Kenya.

Section of Technicians for Malaria Microscopy
Background (2)

- Capacity built through support from
  - PATH-MVI/GSK RTS,S Malaria Vaccine prog
  - INDEPTH-MCTA prog
- Funding from Gates Foundation

Background (3)

- Standard slide archive is needed for training and objectively assessing proficiency of malaria microscopists.
- KHRC, in collaboration with GHS/MOH and Hydas World Health in 2010 started development of an archive of validated slides to serve primarily as the National Archive of Malaria Slides (NAMS)
- Requests now come from all over the African region (Liberia, DRC, Equatorial Guinea)
Donor Selection

Negative Smears

• Any healthy adult (≥18yrs old) resident of a non-malarious country upon agreement to give informed consent was eligible to provide a negative donation within six days of arrival in country.

Positive Smear

• All adults (≥18yrs old) potential donors deemed positive for malaria by light microscopy or RDT and agreed to give informed consent were eligible for donation.

• Note: There were however, challenges in getting high density parasitaemia in adult donors.

Slide Preparation and Reading

• EDTA anticoagulated blood samples used for preparation of smears.
• Thick and thin smears prepared on same slide using 6µl and 2µl respectively.
• Slides stained using 10% giemsa stain for screening and 3% for archive slides.
• Each donor slide is read on site and independently by 2 microscopists out of 10 expert readers.
• Slides in the archive were validated externally by
  – 14 independent microscopists and
  – PCR method to be used for testing of blood blot samples of discordant slides.
KHRC’S EXPERIENCE IN SLIDE BANKING

• We have built a pool of slides of different species and parasite densities that were prepared and validated for the KHRC/Hydas World Health Project for the KHRC/NAMS slide bank.

• Slides database created for the bank for checking slides in and out.

• 780 slides of different species and parasite densities were created for Equitorial Guinea slide bank project upon request.

Types of slides

- Malaria Status
  - Positive
  - Negative

- Species
  - Pf
  - Pm
  - Po
  - Mixed Infection (Pf/Pm, Pf/Po)

- Densities (para/µl)
  - <100
  - 100-1,000
  - 1001-10,000
  - 10,001-100,000
  - >100,000
Use of Slides from the Bank

• Clinical Laboratory Unit of Ghana Health Service:
  – For malaria microscopy trainings at the national and regional levels.
  – For malaria microscopy proficiency testing.

• KHRC:
  – for malaria microscopy trainings at international, national and regional levels.
  – Currently trained microscopists in the region where we are located

Distribution of slides from Bank

• Request for slides are made through formal writing to KHRC Director.

• Upon approval, the name and address of the requester is entered into the slides database

• Condition of the slides, date of check out and due date for submission are entered into the database and slides scanned and checked out.
Retrieval of slides for Bank

- Slides are thoroughly scrutinized upon return for any defects

- Conditions of the slides are entered into the database and the slides scanned and checked in.

- Distribution of slides for proficiency testing surveys is done using courier agents.

Future Plans

- Continue collection of slides for:
  - replacement of broken slides

- setting up of malaria microscopy proficiency testing programme for assessing competency of personnel involved in malaria diagnosis.

- expansion of the slide bank to serve other countries in Africa, especially in areas where specific category of species and density are needed.

- expansion of training programmes.
WHO Certification

- Participation by KHRC microscopists in the WHO malaria microscopy certification processes
- Currently part of the clinical labs in Ghana receiving support from WHO-AFRO, CDC as part of the SLIPTA accreditation process

Resources Required

- Quality, effective and efficient slide banking requires logistics for slide preparation, validation, space for storage and permanent personnel to manage the bank.
- Funding to sustain preparation of slides to replace broken slides and expand bank to meet increasing demands.
- Special slide fireproof cabinets needed for storage of slides.
Challenges

• Delays during distribution of slides by courier agents result in difficulties in meeting timelines for returning slides to the bank.

• Needed financial support to sustain the process and contribute to ensuring malaria quality care
Establishing a malaria slide bank
to support training, competency assessment &
quality assessment in malaria diagnosis
in Africa

**Purpose**

- **Training & Assessment**
  - Refresher Training in Laboratory Diagnosis of Malaria
  - External Competency Assessment of Malaria Microscopists

- **Quality improvement (in discussion)**
  - Maintaining performance of Expert Microscopists (Level 1)
  - As part of structured capacity building/CME /Distance learning (Levels 2, 3, 4)
Current source of validated slides

Slide Bank methodology

- **Proposal** development and ethical approval
- Identification of **hospital sites & authorisation** by Medical Officers in charge
- **Procurement** of consumables & reagents
- **Team leader**
  - Training of assistants
  - Provision of SOPs, Manuals
- **Transport** to sites (air, road)
- **Two surveys** conducted at Siaya District Hospital, Western Kenya
  - June – July 2010
  - August – September 2010
- **Total 19 donors**
### Age groups of donors

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 – 10</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>11 – 20</td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>21 – 30</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>51 – 60</td>
<td>-</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>61 – 70</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>9</td>
<td>10</td>
<td>19</td>
</tr>
</tbody>
</table>

### Species & parasite densities

<table>
<thead>
<tr>
<th>Parasite ranges*</th>
<th>Patients</th>
<th>Pf</th>
<th>%</th>
<th>Age (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>80-200</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>200-500</td>
<td>2</td>
<td>261</td>
<td>7%</td>
<td>11</td>
</tr>
<tr>
<td>500-2,000</td>
<td>4</td>
<td>920</td>
<td>24%</td>
<td>14 – 65</td>
</tr>
<tr>
<td>2,000-100,000</td>
<td>10</td>
<td>2449</td>
<td>63%</td>
<td>7 – 58</td>
</tr>
<tr>
<td>&gt;100,000</td>
<td>1</td>
<td>250</td>
<td>6%</td>
<td>24</td>
</tr>
<tr>
<td><strong>Total slides</strong></td>
<td></td>
<td>3880</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pf/Pm: 1
Negative Slides: 2
Total slides collected: 4657

*Parasite ranges as per accreditation requirements (WHO Malaria Microscopy QA Manual, Version 1, 2009; p37)
Donor database

<table>
<thead>
<tr>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
<th>M</th>
<th>N</th>
</tr>
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<tbody>
<tr>
<td>A1</td>
<td>B1</td>
<td>C1</td>
<td>D1</td>
<td>E1</td>
<td>F1</td>
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<td>J1</td>
<td>K1</td>
<td>L1</td>
<td>M1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Batch No.</th>
<th>Collection Date</th>
<th>Institute</th>
<th>Accession ID</th>
<th>Total Donor Available</th>
<th>Donor No.</th>
<th>Parasite</th>
<th>Age</th>
<th>Sex</th>
<th>Location</th>
<th>Disease History</th>
<th>Medication Used</th>
<th>Prophylaxis Used</th>
<th>Zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>21/6/001</td>
<td>Srimali</td>
<td>XENOYA-01</td>
<td>211</td>
<td>21/6/001-a</td>
<td>pf</td>
<td>563</td>
<td>23 yrs</td>
<td>F</td>
<td>Maha</td>
<td>April</td>
<td>AL</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>21/6/001</td>
<td>Srimali</td>
<td>XENOYA-01</td>
<td>211</td>
<td>21/6/001-b</td>
<td>pf</td>
<td>515</td>
<td>21 yrs</td>
<td>F</td>
<td>Maha</td>
<td>April</td>
<td>AL</td>
<td>No</td>
</tr>
<tr>
<td>10</td>
<td>21/6/001</td>
<td>Srimali</td>
<td>XENOYA-01</td>
<td>211</td>
<td>21/6/001-c</td>
<td>pf</td>
<td>418</td>
<td>21 yrs</td>
<td>F</td>
<td>Maha</td>
<td>April</td>
<td>AL</td>
<td>No</td>
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<tr>
<td>11</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>12</td>
<td>25/8/002</td>
<td>Srimali</td>
<td>XENOYA-02</td>
<td>149</td>
<td>25/8/002-a</td>
<td>pf</td>
<td>14,000</td>
<td>21 yrs</td>
<td>F</td>
<td>S. E. Angola</td>
<td>No</td>
<td>None</td>
<td>No</td>
</tr>
<tr>
<td>13</td>
<td>25/8/002</td>
<td>Srimali</td>
<td>XENOYA-02</td>
<td>149</td>
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<td>pf</td>
<td>38,134</td>
<td>21 yrs</td>
<td>F</td>
<td>S. E. Angola</td>
<td>No</td>
<td>None</td>
<td>No</td>
</tr>
<tr>
<td>14</td>
<td>25/8/002</td>
<td>Srimali</td>
<td>XENOYA-02</td>
<td>149</td>
<td>25/8/002-c</td>
<td>pf</td>
<td>66,507</td>
<td>21 yrs</td>
<td>F</td>
<td>S. E. Angola</td>
<td>No</td>
<td>None</td>
<td>No</td>
</tr>
<tr>
<td>15</td>
<td>25/8/003</td>
<td>Srimali</td>
<td>XENOYA-03</td>
<td>256</td>
<td>25/8/003-a</td>
<td>pf</td>
<td>1,040</td>
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<td>F</td>
<td>Tororo</td>
<td>May</td>
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<td>16</td>
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<td>F</td>
<td>Ndere</td>
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Challenges

- **Pure rare species** & mixed species:
  - Pure Pm, Po, Pv
  - Mixed Pf + Pm; Pf + Po;
- **Timing**: long waiting times to find appropriate donors:
  - parasite species, low density
- **Insufficient donors**:
  - Unwilling subjects
  - Fewer malaria patients seen
  - Children <7 years excluded
- **Dedicated funding**
  - Incorporated in training programme
Way Forward

- **Complete** the malaria slide bank:
  - Target geographic sites in Kenya with required species
  - Trial an alternative system of donor blood collection
  - Slide exchange

- **Molecular confirmation**
  - In process

- WHO accredited **Expert Readers**
  - Agree on protocol: numbers, slide numbers, within & outside Africa

- **Scale up** malaria microscopy refresher training & competency assessment courses

- **Develop** distance training/CME in malaria microscopy

Considerations: staffing, logistical, financial

- **Slide collection**: training, communicating, follow up of laboratory staff in remote sites; slide shipping

- Slide **labelling**, bar coding

- Ongoing **validation**

- Maintaining the **database**

- Organising **slide loans**: shipping, checking, dealing with requests

- **Financial** management: funding, cost recovery
Acknowledgements

• Patients & donors
• Laboratory staff at Siaya DH
• AMREF laboratory staff
• AMREF Laboratory Programme funds
20 - UCAD experience of MSBs

VERY RECENT UCAD SLIDE BANK FOR MALARIA MICROSCOPY TRAININGS

Daouda NDIAYE
Professor of Parasitology-Mycology
Faculty of Medicine and Pharmacy
University Cheikh Anta Diop (UCAD), Senegal

Goal of acquiring in developing MSB

• **Goals:**
  – **Train Microscopists field workers** during Pre and In-service Trainings
  – **Train Research Institutional staff**
  – ? UCAD Accreditation Course

• **Staff involved:** Professor, Assistant Professors, Biologists, Lab technicians, field staffs, Data Manager

• **Many years of Slide preparation for trainings (not SB)**
Senegalese Health Facilities/Institutions involved for Slide Bank creation

- **National, Regional and District Hospitals**
  - Outpatients coming from Senegal, Mali, Mauritania for tracking all species (screening using RDT and or Blood Slide)

- **SLAP Malaria Research Center in Thies**
  - Field site Coordination for slides preparation, staining.

- **UCAD Parasitology Laboratories**
  - SOPs, Bench aids and Protocol Developments
  - Slides ID labeling, Barcoding, Quality Control, Storage

- **Senegal Harvard Malaria Molecular Biology Laboratories**
  - NAT genotyping Quality Control: Ribosomal, Nested and qRTP
    - Ribosomal for Parasite Detection: Negative/Positive
    - Nested for Specie Identification (Pf, Pm, Po, Pv, and mixed)

UCAD Parasitology LeDantec Laboratories Training Center

Lab technician, Doctorate, Master, PhD Trainees from: UCAD, Mali, The Gambia, Guinea, Morocco, Tunisia, Mauritania, Comoros

New from: Ethiopia, DRC
Technical consultation to update the WHO Malaria microscopy quality assurance manual

Presentations 8–20

UCAD, Faculty of Medicine

UCAD Slide Bank Development: Slide ID Preparation (Started 2 weeks ago)
Number and Type of slides produced:

- From previous collections
- ~ 500 *P. falciparum* (renewal each year)
  - 300-500 parasite/µL
  - 2,000-10,000 parasite/µL
  - 100,000-200,000 parasite/µL
- 2 *P. malariae*
- 1 *P. ovale*
- 1 *P. vivax*
- 50 Negatives

Demand for Slides and Plans

- **Ongoing from February 2014 to August 2014**
- **Collection has started:**
  - Screening using RDT and Blood Slide
- **Slides to be prepared including:**
- ~ 6,000 slides for *P. falciparum*:
  - 200-500 parasite/µL
  - 1,000-2,000 parasite/µL
  - 5,000-10,000 parasite/µL
  - 100,000-200,000 parasite/µL
- >200 slides for *P. malariae*
- >200 slides for *P. ovale*
- >200 slides for *P. vivax*
- 200 slides MIXED for *P. f (+ P.v, P. o, P.m)*
- ~ 1,000 Negative

Quality Control: Filter Papers spot and tubes collection for Genotyping
Use/distribution systems

• Trainings at UCAD for
  – UCAD Master, PhD, Graduates Students
  – Labtechnicians from School Pre-Service
  – West African Training

• Request from West Africa

• From the 2014 collection, we will be able to share
  with others countries

Resource requirements
(personnel, lab, running costs)

• **Facilities, Lab and Personnel available:**
  – UCAD Teaching hospital
  – Laboratories at UCAD for blood collection, slides
    preparation, storage, NAT QC

• **Staff:** Clinicians, Lab technicians, Data managers

• **Budget:** $US ???
Challenge and Plan

- Funding mechanism
- Finding Mixed infection and P. ovale, P. vivax
- External Quality Control

THANKS

Harvard School of Public Health

MINISTÈRE DE LA SANTÉ ET DE L’ACTION SOCIALE

THANKS