

Report on the

**Regional workshop on strengthening quality
management systems for parasitological
diagnosis of malaria**

Muscat, Oman
17–21 September 2011



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Organization**

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1. INTRODUCTION

Malaria diagnosis is important for case management and malaria surveillance. Lack or poor quality of parasitological diagnosis represents a big challenge for malaria surveillance in high burden countries of the WHO Eastern Mediterranean Region. It is a major obstacle that hinders having reliable malaria incidence data for proper evaluation of interventions. For this reason, the WHO Regional Office for the Eastern Mediterranean held a workshop on strengthening quality management systems for parasitological diagnosis of malaria in Muscat, Oman, on 17–21 September 2011. The objectives of the workshop were to:

- review status of access to parasitological diagnosis of malaria and develop strategies for reaching universal coverage of confirmation;
- review country experiences on quality assurance for microscopy and rapid diagnostic tests (RDTs);
- update the countries on development of WHO manual for quality assurance, Guidelines on PSM, RDTs, etc.;
- discuss current experience on microscopy accreditation programme and development of a regional system for external competency assessment of malaria; and
- review experience on and discuss establishment of regional malaria slide bank.

The workshop was inaugurated by Dr Ali Jaffar Mohamed, Ministry of Health, Oman. Dr Jihane Tawilah, WHO Representative for Oman, delivered a message from Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean, in which he emphasized that parasitological diagnosis of malaria was the foundation of effective case management. He reminded participants of the recent WHO guidelines for the treatment of malaria, which strongly recommended confirmation of diagnosis of malaria in all suspected cases before administration with high-quality microscopy or, if not available, quality-assured RDTs. He closed by requesting participants to develop comprehensive plans of action to strengthen the quality management system for parasitological diagnosis that addressed the key components of good laboratory facilities, training, supervision, slide validation and standard operating procedures.

The programme and list of participants are attached as Annexes 1 and 2.

2. TECHNICAL PRESENTATIONS

2.1 Universal access to malaria diagnostic testing

Dr Andrea Bosman, WHO headquarters

WHO is placing major emphasis on the need to ensure universal access to malaria diagnostic testing and a recent inter-agency manual has been released (available at http://whqlibdoc.who.int/publications/2011/9789241502092_eng.pdf). The proportion of reported malaria cases which are tested is increasing in recent years in the Eastern Mediterranean Region, yet the in the proportion of unconfirmed malaria cases which are treated only on the basis of a clinical diagnosis still remains high, particularly in some high-burden countries. The new WHO manual recommends the large-scale use of both microscopy

and RDTs, with clear indication of comparative and complementary roles between the two. It builds on all existing up-to-date WHO documents and resources of collaborating institutions, and includes in the annexes several useful tools which can be adapted for use at country level. The importance of diagnosing malaria in the context of integrated management of febrile illness is stressed, as well as the need to closely collaborate with the general laboratory services and using common approaches for quality management systems. A set of practical planning and budgeting templates are provided for costing the activities which are specific to malaria microscopy, those which are specific for RDTs and those which are important for appropriate management of non-malaria fevers.

All programmes need to define operational clinical criteria for suspected malaria cases, generally based on fever in areas of high malaria risk and “fever without obvious causes of illness” in areas of low malaria risk. Proper criteria are needed for areas of low malaria risk as, the more the clinical criteria are restrictive to limit diagnostic testing to only specific groups of patients, the more probably is to miss some “true malaria cases” if febrile patients are not tested for malaria. In all countries moving towards pre-elimination and elimination the investments required for testing tend to increase over the financial requirements for antimalarial medicines.

Both RDTs and microscopy can be used at hospital/referral levels, and RDTs have comparative advantage for use in health facilities without laboratory and at community level. Low volume, high quality microscopy may have advantages over RDTs in the diagnosis and follow-up of patients with severe malaria following admission, as well as for the investigation of suspected treatment failures for patients which have taken a full antimalarial treatment in the previous 2 weeks.

Strengthening/expansion of malaria microscopy and implementation of RDTs, both require a robust quality management system in place, coordinated at central level and integrated/consolidated with the general laboratory services. A phased approach is needed with strong emphasis on monitoring, with supportive supervision as the key component of quality management systems. Slide proficiency testing should be considered for testing sites only (for example subnational reference laboratories or centres for therapeutic efficacy monitoring). Slide validation (cross-checking) has some limitation in areas of low transmission, and it should also included emphasis on quality of slide preparation and staining. Validation of RDT performance through direct comparison with microscopy slides is problematic as results never correlate perfectly. quality management system for RDTs should focus on competence to prepare and read RDTs correctly and correct storage conditions, both assessed through supervision. Training and supervision need accreditation of trainers and supervisors and trainees. Rapid scale-up with good compliance to test results is feasible as shown by the RDT implementation plan in Senegal from 2007 to 2009.

2.2 Briefing on the WHO manual for quality assurance

Dr Hoda Atta, WHO Regional Office for the Eastern Mediterranean

Microscopy remains the gold standard for species diagnosis, parasite quantification, management of severe cases and monitoring drug efficacy. The most common form of quality control is the cross-checking of routine blood slides to monitor the accuracy of examination, done by a supervisor or the regional/national laboratories. Quality control may also encompass external quality control and reagent quality control. Malaria microscopy quality assurance addresses all factors that affect laboratory performance including test performance (quality control, internal and external), equipment and reagent quality, workload, workplace conditions and laboratory staff training and support

There are a few examples of good quality of malaria microscopy in countries of the Region, but inadequate quality of malaria diagnosis in the general health services is common in many endemic countries and also in malaria free countries. Many programmes are grossly under-resourced for quality assurance of diagnostics, resulting in poor microscopy performance and failure of health workers to use diagnostic tests or to adhere to test results. Current quality control in the Region is focused only on slide rechecking (validation) with weak or no monitoring systems for staff competence, equipment, reagents, stock control, workload, registration and reporting with weak or no supervision. Lack of political commitment to support the development and expansion of laboratory services is a key challenge. The Regional Office has been supporting this area in collaboration with the centre of excellence in Oman to conduct a four-week training course in advanced malaria microscopy and quality assurance.

The quality management system for malaria microscopy has several components: a central coordinator(s) for quality management system, a reference (core) group of microscopists at the head of a hierarchical structure, an external quality management system programme for overseeing programme training and validation standards with good initial training with competency standards and regular retraining and assessment/grading of competency; reference slide set (slide bank); a sustainable cross-checking (validation) system with good feedback; periodic supportive supervision at all levels; good logistical management including supply of consumables and maintenance of microscopes; clear standard operating procedures at all levels of the system; accreditation/competency assessment of microscopists; and adequate budget for funding the quality management system.

It is essential that funding for microscopy services and RDT procurement be accompanied by funding for comprehensive quality management system (budget may be at least 20% of cost of goods). Funding is also necessary at regional/intercountry level for structures and services (external quality assurance, accreditation slide banks, performance testing) to support national level diagnostic programmes. The principles and concepts of quality management system for malaria are similar to those for microscopic diagnosis of other communicable diseases; integration, where feasible and cost-effective, is recommended. Where malaria microscopy is carried out by the general health services, the quality

management system is the responsibility of the national laboratory services, with the technical support of national malaria control programme, in collaboration with other institutions in the country carrying out quality management system, such as universities and nongovernmental .

2.3 Preliminary report: survey on malaria confirmation

Dr Ghasem Zamani, WHO Regional Office for the Eastern Mediterranean

A survey was conducted in all countries of the Region on the situation of malaria confirmation using a questionnaire on malaria diagnostic services. The questionnaire was sent in June 2011. A database was developed for the Region and first stage of analysis was done on the questionnaires received from 13 countries. This database will provide up-to-date information for planning for strengthening malaria confirmation in the Region, particularly in priority countries.

Results of the questionnaire showed that most countries had a quality control/quality assurance system, mostly vertical, with responsibility in the specific malaria laboratory services (7/12). In some countries, quality assurance is the responsibility of the public health or other laboratories. The most common method of slide validation is by rechecking of 10% of negatives and all positives. A few countries (5/13) have a slide bank. All countries have national core trainers/microscopists qualified to train, with numbers ranging from 3 to 21. Supervision is a component in most countries, but it is infrequent and not standardized.

Common challenges for quality management systems in countries of the Region are lack of budget, high staff turnover/limited motivation, insecurity, difficulty in enforcing standard operating procedures, inadequate infrastructure in border areas, inadequate cooperation and non harmonized activities between private and public laboratory systems.

2.4 Lessons learnt from previous regional courses on advanced malaria microscopy and quality assurance in Oman

John Sotry, Dr Majed Al-Zedjali, WHO Temporary Advisers

The course is a four-week theoretical and practical course. Its syllabus focuses on improving leadership and participatory skills; promoting attitudinal change to standard operating procedure use and standards; raising diagnostic competence to 95% and above; teaching and communications skills as a part of supervision; laboratory management and routine quality assurance and monitoring and reporting. Participants are expected to reach levels of 95% diagnostic accuracy, and over, in order to graduate as ‘core trainer’. If not, they may still meet requirements as national validators. Competence should be re-evaluated at 3 year intervals. Core trainer certification should be recognized within national malaria control programmes, ministries of health and internationally. The certificate of competence is signed by the Government of Oman and WHO Representative. During 2007–2011, four international courses were conducted, 61 trainees graduated with certification of achievement as “core trainer in malaria microscopy”. Priority was given to malaria endemic countries. For future courses, more careful pre-selection of candidates is needed based on core function.

2.5 Experiences with the WHO external competency assessment course for malaria microscopists in WPRO and SEARO

Dr Ken Lilley, WHO Temporary Adviser

WPRO and SEARO, in concert with ACT Malaria, have collaborated to develop a bi-regional network to support external competency assessment (ECA) and quality assurance for malaria microscopy. They are based on the ECA courses started in the Philippines in 2002. Duration is five days with no training included, only competency assessment, with focused revision. The pre-course theory test includes 25 general malaria microscopy questions. Pre-course practical test use 14 slides for species identification and counts. Both pre-tests do not count towards the final grading. Competency level is based on species identification and parasite counting (Table 1). The course includes morning presentations (primarily a review) of main aspects of malaria microscopic diagnosis; from specimen collection to diagnostic reporting. Practical sessions include 55 test slides over three afternoons from WHO slide bank (RITM, Philippines). 57 ECA courses have been conducted in 16 different countries: Australia (6), Bangladesh (2), Cambodia (3), China (2), Indonesia (3), Kenya (1), Lao People's Democratic Republic (3), Malaysia (3), Myanmar (3), Philippines (9), PNG (4), Solomon Islands (6), Thailand (4), Timor Leste (2), Vanuatu (4) and Viet Nam (2).

Some challenges noted include: participants from previous ECA courses not transferring new knowledge and skills to others; ECA results not used as per WHO manual on quality assurance; and quality assurance issues are highlighted, but are often not being addressed. Future plans are to continue ECA courses in member countries, linked to 3 year expiry of accreditation, expansion of WHO ECA courses to other regions, harmonization of competency assessment and production of WHO-authorized standard operating procedures and other related documents.

Table 1. Competency level of malaria microscopist

Competency level	Species identification (accuracy)	Parasite counting (+ 25% of true count)
Level 1 ('expert')	≥ 90%	≥ 50%
Level 2	≥ 80%	≥ 40%
Level 3	≥ 70%	≥ 30%
Level 4	< 70%	< 30%

2.6 External competency assessment of malaria microscopists in the African Region

Dr Jane Carter, WHO Temporary Adviser

Assessments of malaria microscopy in 9 countries indicated serious challenges in laboratory staff performance. The WHO Regional Office for Africa, African Medical and Research Foundation (AMREF) and Improving Malaria Diagnostics (IMaD) have collaborated to develop a competency assessment programme in malaria microscopy for the African Region.

Assessment overview, methods and grading schemes proposed by WHO the WHO Regional Office for the Western Pacific were endorsed as the WHO model at the malaria microscopy quality assurance meeting in Geneva (February 2008). Assessments are made of parasite detection, species identification and malaria parasite counting (*P. falciparum*). Certificates with grade achieved are issued to all workshop participants.

The 5-day course includes pre-test theory, pre-workshop practical slide reading test (16 slides), examination of 55 slides under “examination” conditions, presentations and revision on all aspects of malaria microscopic diagnosis and reporting; review of test slides throughout, preparation of thick and thin blood films, provision of the WHO Malaria Microscopy quality assurance manual to all participants and presentations of action plans from each country. Nine external competency assessment courses were conducted in 24 months with 101 participants from 14 countries.

Lack of slide sets, participants with various levels of qualification, no recent refresher training no follow up of participants, lack of financial support for participants and lack of support from national governments are main constraints. Development of local slide banks, regular refresher training courses in all aspects of malaria microscopy including practical sessions, advocacy to increase a wider acceptance and more support to competency assessment, better selection of participants are among the main activities for future. Scoring and grading needs to be revisited and standardized with an automated grading system. Refresher training in malaria microscopy courses should be offered more widely with more emphasis on selection of appropriate participants. Slide banks should be developed at selected sites using standard protocols.

2.7 Experience with establishment of malaria slide bank, PCR validation and operational aspects from the Western Pacific Region

Dr Jenny Luchavez, WHO Temporary Adviser

The 12 key steps and main procedures of development of the malaria slide bank are as follows: 1) establish need and secure funding; 2) identify laboratory/institution-NRL, university/research institution; 3) identify focal person(s) and staff (at least 2), ideally with training or awareness on quality assurance and quality management systems; 4) develop country-specific standard operating procedures, tools and database-parasite species, density, others-collection sites/methods (hospital, clinic or community), donor criteria (age, sex, consent); 5) obtain ethical clearance; 6) purchase supplies/equipment-prepare checklist based on standard operating procedures; 7) train staff on standard operating procedures; 8) implement collection, adherence to standard operating procedures and quality control; 9) organize collection in slide boxes or in cabinets; 10) conduct validation microscopy and PCR; 11) develop database entry standard operating procedures; 12) and develop operation and maintenance, manual of operations and procedures.

The slide validation procedure is complex involving 6 microscopists (level 1), each reading 2 slides per case/sample (=12 slide readings) at 500 WBC to detect difference in mean parasite counts + 5%. Latest collection is 6000 slides, with all species except *P. ovale*.

A malaria slide bank database is available, slide set can be given on loan for 2 months and tracked by borrowers' log. The approximate budget needed to establish the malaria slide bank is US\$ 30 000–50 000 (excluding PCR).

There are some challenges as follows: validation problems as some slides have more parasite counts than the valuations reported; some slides have parasites but PCR result is negative; some slides have mixed species but identified as mono-infection by PCR; difficulty of finding acute and appropriate cases in the field due to declining number of cases; compensation for lost/damaged slides; funding and staffing.

2.8 Lessons learnt in strengthening quality management of malaria diagnosis in Médecins Sans Frontières, Afghanistan and the United Republic of Tanzania

Dr Derryck Klarkowski, WHO Temporary Adviser

Quality 'starts at the top' – quality will not work unless the policy-makers are genuinely committed to quality and therefore critically allocate funding for quality assurance and quality control. All programmes should have minimum performance standards for microscopy and mRDT testing. These should be quantifiable and monitored, and there should be pre-planned corrective action strategies in place if quality standards are not met. Quality improvement should focus on the core essentials – too broad an approach dilutes critical information. Infrastructure and performance should be addressed as separate entities. Infrastructure is a programme responsibility, performance is a tester responsibility. Training is not the solution to every problem. Appropriate infrastructure, minimum performance standards, training and support, supervision, monitoring and evaluation are the main requirements for functional quality assurance and quality control. In addition to microscopy there must be quality equipment, reagents and supplies, for mRDTs, storage temperature management. There need to be commitment and budget allocation for infrastructure in place before engaging consultants to work on performance. For performance, focus should be on the core activities that directly affect testing accuracy.

2.9 Supportive supervision: core component of quality management systems

Dr L. Benavente, Medical Care Development International

Biannual, full assessment is needed with at least one full day in each health facility, including accreditation/training of supervisors and interpersonal skills. In low-resource settings if slide validation is not feasible, a few slides should be re-read by an "expert" microscopist during routine supervisory visits. Or, if no experts are available, the supervisor can still cross-check a few slides and send to the reference laboratory those slides with discordant results. Monthly cross-checking of slides between health facilities by peer-review approach could be a different modality of supervision.

2.10 Approaches for training and preparation of effective training tools for malaria microscopy

Dr Earl Long, WHO Temporary Adviser

The rapid increase of resistance to cheap reliable antimalarials, the increasing cost of effective drugs, and the low specificity of clinical diagnosis have increased the need for more reliable diagnostic methods for malaria. The classic and most commonly used technology remains microscopic examination of stained blood smears, but this method requires skilled, experienced personnel, precision instruments and an adequate source of illumination. An alternative to microscopy is the RDT, which detects circulating parasite antigens, but is not quantitative, does not identify parasite stages, remains positive for several days after cure, is susceptible to high temperatures and humidity and does not yet have positive-control reagents. In situations with minimally trained staff and without electricity, the RDT may be a more practical diagnostic method.

The essential training tool is a good microscope. The instrument should be robust, with precise optics. A good choice is the Olympus CX-21 binocular microscope with plan-achromat objectives of $\times 10$, $\times 40$ and $\times 100$ magnifications and $\times 10$ oculars. These microscopes are specially treated to resist fungal contamination.

A multiple headed teaching microscope, such as the Olympus CX-41, with multiple viewing ports (five is commonly used) is an invaluable teaching aid because it saves time, and enables trainees to see exactly what the trainer sees without having to change places. A more expensive teaching aid is an imaging system with microscope, digital camera, computer and monitor, such as the Olympus BX-41. This enables an entire class to view the same field as and instructor. The teaching microscopes are best suited for permanent installation in a central training facility.

Ideally, trainees in microscopy would be able to study a collection of Giemsa-stained slides with the four principal species of human malaria, each showing the four life stages of the parasites. Many teaching slide sets demonstrate exemplary views of the malaria parasites: well stained, text-book presentations that are seldom seen in clinical situations. Teaching slides should include archived slides made from positive and negative patient specimens, collected from trainees' geographic area. All trainees should be encouraged to assemble their own slide collections because it is becoming increasingly difficult and expensive to purchase teaching slides.

A good introduction to parasite morphology, and for reference, is the CD-ROM addition to the WHO Learner's Guide, Part 1. This contains several hundred images of parasite stages, host-cell morphological changes, parasites in various hosts and organs, rarely seen parasite stages, quizzes at increasing levels of difficulty, views of other pathogens that can be seen in stained blood smears, and explanations of staining artifacts.

Finally, effective training must continue beyond the classroom. It is a continuous learning experience, requires repeated supervision, insistence on regular quality control,

ready access to standard operating procedures, and reliable supplies of clean glass slides and high-quality Giemsa stain. Good microscopy is more than understanding how to do microscopy. It is an art that requires constant practice and long experience.

2.11 Key programmatic indicators for monitoring and evaluation of malaria confirmation and reporting/recording tools

Dr Ghasem Zamani, WHO Regional Office for the Eastern Mediterranean

Classification of malaria is as follows: suspected cases = tested cases + unconfirmed cases; treated cases = total reported cases = confirmed cases + unconfirmed cases. Generally, treatment and diagnostic data are not linked in the health management information system. Data should be available in patient registries at health facility level. Aggregated data can only be used if stock-outs of RDTs or ACTs are uncommon.

Common problems in malaria diagnosis detected by the monitoring and evaluation system were discussed as outlined in the guideline for monitoring and evaluation and malaria surveillance.

2.12 Experience with implementation of EQA in the African Region and potential for extension in the Eastern Mediterranean

Dr Andrea Bosman, WHO headquarters

The global external quality assessment (EQA) scheme is for different diseases and health-related issues including microbiology schemes in the African and Eastern Mediterranean Regions. Malaria microscopy proficiency testing scheme assess ability to accurately diagnose malaria species and ability to accurately and consistently count malaria parasites. The overall results of the WHO/NICD malaria EQA scheme shows that the microscopy results are fairly good. However the results show that participants have difficulty with species identification, particularly with non-falciparum challenges. False negative and false positive results do occur but are within reasonable limits. Parasite counts are performed poorly: counts are not consistent, as seen from the intra- and inter-survey repeats, and some participants even do not perform parasite counts. The last EQA review meeting (December 2009, Cairo) recommended to WHO/EMRO to introduce the EQA programme during the 2010 annual meeting of malaria control programme managers, and plan for the implementation of the malaria EQA component. The malaria eradication department in Oman was expected to build a specimen bank to include malaria in October 2010 microbiology survey that was not materialized due to delay in establishing the slide bank.

2.13 East African regional external quality assessment scheme: a model for enhancing laboratory quality through regional cooperation

Dr Jane Carter, WHO Temporary Adviser

In 2001–2003 the scheme was developed with the ministries of health of Kenya, Tanzania (mainland, Zanzibar) and Uganda. The scheme was coordinated by AMREF and supported by WHO headquarters. A regional meeting was conducted in 2003 in Arusha,

Tanzania. Resolutions and recommendations made to share standards and materials across the East African Region for strengthening national quality assurance bodies and for the establishment of East African Regional Quality Assurance Committee (EA-REQAC). Three EA-REQAC meetings held so far in Zanzibar (2006); Kampala (2009) and Nairobi (2010).

Objectives of EA-REQAS were to: establish an external quality assessment scheme addressing essential diagnostic services in peripheral health facilities in East Africa, establish minimum standards for clinical and laboratory diagnostic services, develop mechanisms for monitoring and maintaining quality of essential diagnostic services, and use evidence from laboratory performance to influence policy and practice.

The regional EQA scheme has the advantages of standardized laboratory procedures, standardized quality of scheme materials, wider range of specimens, sharing resources for material preparation, more national resources spent on remedial action and increased regional cooperation.

Scheme operations included “model” standard operating procedures developed by technical working groups in each Ministry and shared across the Region, pathological materials produced by reference laboratories in each country addressing essential tests of clinical and public health importance, clinical scenarios with questions and making keys established for each survey, target values set by “best” reference laboratories in Nairobi and coded answer sheet prepared for qualitative answers. Immediate feedback reports (within 30 days) are sent to each participating laboratory with copies to district supervisor with suggestions for improving performance along educational materials. Composite reports (within 90 days) sent to each Ministry of Health include the results of laboratories in the country and coded results of laboratories in other countries. Facilities that participated in at least four surveys had a significantly higher mean performance than those that participated in only one.

Constraints are as follows: material production by reference laboratories is slow and sometimes fails; failures in transportation; poor response rates (61%) in first 5 surveys; difficulties with electronic reporting; difficulties in obtaining some supplies locally, e.g. carbon tetrachloride; and irregular, inadequate funding. Future plans are: national units coordinating material production; scaling up to more laboratories (5000 in east Africa); starting a pilot scheme in Rwanda and Burundi; expanding laboratory parameters; expanding electronic reporting; exploring mobile phone reporting platforms; and securing Ministry of Health laboratory financial support.

2.14 Malaria RDT product testing and lot-testing updates

Dr J. Luchavez, WHO Temporary Adviser

The importance of product and lot testing in malaria case management and surveillance is to develop and employ an independent, standardized assessment of malaria RDT performance, and to guide procurement decisions and regulatory mechanisms. The number of products and manufacturers submitted for evaluation are increasing: R1 (2008) 41 products;

R2 (2009) 29 products; R3 (2010) 50 products. Consolidated results of product testing showed that the quality of RDTs that are being manufactured and re-submitted for evaluation is improving.

Lot-testing of malaria RDTs is essential due to variation among lots, to ensure no damage during transport and the need to convince clinicians/users/regulatory authorities that tests are working. Lot testing can be done: 1) before purchase and is directly arranged with manufacturer and lot-testing laboratory; 2) after purchase before distribution to the field (more common) and arranged with WHO; 3) after distribution to health facilities/communities to investigate “unexpected” results.

Since 2007, 2 lot testing centres, RITM (Philippines) and IPC (Cambodia) have been established. Observations from lot-testing of malaria RDTs in RITM (2008– June 2011) showed that parasite strains and cross reaction with other antigens included in product testing might affect the results of RDT. The malaria RDT lot-testing request form and related information are available at: malrdt@wpro.who.int.

The process starts by sending a completed test request form, as described in the relevant website. At least 2 weeks’ notice is required to arrange for testing. Once the lot testing site is allocated, the required number of malaria RDTs must be shipped to the laboratory with the completed test request form, and ideally by including a temperature monitoring device. The designated lot testing laboratory usually provides the report within 5 working days after receipt of the shipment. The RDTs are then followed up with regular quality control testing until expiry. If RDTs fail the lot testing at any stage, confirmatory testing is performed in a second lot testing site, and the final report communicated thereafter. Requesting parties are required only to pay for the shipment of RDTs to the lot testing facility; otherwise the service is free of charge. The number of tests required for lot testing are 100 Pf RDTs and 150 Pf-pan RDTs.

2.15 Good practices for selecting and procuring rapid diagnostic tests for malaria

Dr Andrea Bosman, WHO headquarters

Quantification and forecasting are the most critical aspects of procurement and require a multidisciplinary, multi-stakeholder team that overlaps with the related deployment and use of artemisinin-based combination therapies. The team should be guided by information from a logistics management and information system. Step 2 of the manual elaborates on four different approaches of quantification depending on the availability and reliability of surveillance and consumption data: 1) areas with no malaria surveillance data; 2) areas with unreliable malaria surveillance data; 3) areas with reliable malaria surveillance but no reliable data on RDT consumption; 4) areas with reliable malaria surveillance and RDT consumption data. With any of these scenarios, a safety stock needs to be added before estimated needs can be transferred into orders (regarding aspects such as frequency of requisition and in-country distribution, suppliers’ lead times, available budget).

In areas with reliable malaria surveillance but no reliable data on RDT consumption, the estimation approach relies on a critical variable to be obtained from surveillance data which is the number of malaria cases that were not tested (probable or unconfirmed). RDT requirement will be calculated from both probable and tested cases by RDT with adjustment for completeness of reporting, then addition of safety stock.

2.16 Approaches for training and effective training tools for malaria RDTs

Dr J. Luchavez, WHO Temporary Adviser

Preparatory activities before implementing RDT training include: adaptation of WHO training guide and materials to suit local situation; translation to the local language if needed; selection and training of potential trainers/facilitators; conduction of facilitators, meeting/workshop; and prioritizing areas where RDTs will be deployed and used immediately; and arranging for logistics, resources and venue for training. Trainees should be identified with a set of criteria, e.g. residing in endemic areas, respected member of community, able to read and write, willing to accept additional responsibility, conduct pilot training and evaluate and modify/improve materials, as needed. Several materials are available for training: A guide for training community health workers and other health workers, job aid and rapid diagnostic test, and a tutor's manual developed for training of trainers.

2.17 Calculation of parasite density from the ratio of parasites to white blood cells on thick blood film

Dr Andrea Bosman, WHO headquarters

The old method is to count up to 200 WBCs. If ≥ 10 parasites: stop and record. If < 10 parasites: count parasites up to 500+ WBCs. The new method is to count up to 200 WBCs. If ≥ 100 parasites: stop and record. If < 100 parasites: count parasites up to 500+ WBCs.

Parasite counting is more important in hospital and efficacy studies and not in the periphery dealing with uncomplicated malaria; however microscopists should be trained and able to count. Using actual number of WBC of the patient, if possible, is preferred.

2.18 Possible methods for the evaluation of malaria microscopy and RDT testing performance at point of care

Derryck Klarkowski, WHO Temporary Adviser

Programmes should focus heavily on blood film preparation and staining quality control. If the blood film is poor everything that follows will also be poor. EQA (known slides sent to laboratories for blinded reading) should be implemented as soon as possible. The WHO crosschecking quality control protocol was not designed for low prevalence settings – it doesn't work for pre-elimination or at prevalence $< 20\%$. For low prevalence settings, it is recommended to use a competence/performance protocol. There is not currently an established field quality control for mRDT testing protocols. It is recommended to implement crosschecking quality control and to use maximum–minimum thermometers at

each testing site to monitor storage temperature. The storage temperature of mRDT transport should also be monitored. It is recommended to use a competence/performance protocol for mRDT testing.

2.19 Improving malaria diagnostics in Ghana

Dr Luis Benavente, Medical Care Development International

Improving malaria diagnostics (IMaD) is a partnership composed of multi-stakeholder involving the private sector, the government and communities of Ghana, civil society organizations, and research institutions.

The baseline assessment showed that less than one quarter of laboratories harvested rain water; none of these were in government hospitals. Half of government health centre laboratories were staffed by one or more laboratory technicians; none had a biomedical scientist and only one out of four had laboratory assistants. Three-quarters of laboratories re-read slides as internal quality assurance; an EQA scheme was used in less than 10%. Only 5% of laboratories saved slides for EQA because slides were usually recycled. Standard operating procedures for film preparation and reading were available in six out of ten facilities visited; despite this, less than half of blood films viewed were rated as “good”. There was stock-out of essential supplies in 2 of 15 categories: government health centres and government hospitals. The ratio of overall cases diagnosed to positive test results was too high in all health facilities and highest in health centres. This indicates a very high level of clinical diagnosis and treatment of patients with negative test results.

Competence of the supervisors improved in post-test in all parameters (sensitivity, specificity, species ID and counting). Adherence to negative tests has increased since the beginning of the initiative.

2.20 Software for monitoring quality management of malaria diagnosis confirmation

Derryck Klarkowski, WHO Temporary Adviser

Data have no value unless they are accessible and able to be meaningfully analysed. Simple Excel charts can be highly effective. Checklists should be developed that are quantitative, and the data should be analysed by user-friendly software. This software should provide summary analytical data in both chart and table format. ‘Single page’ reports (one parameter only, e.g. false positive rate, number of *P. vivax* cases etc) generated by software are highly effective. They should be linked with conditional formatting to highlight data of key importance (e.g. all false positive rates >10% highlighted in red). It is recommended that common software should be used in countries of the Region. This reduces costs, enhances IT support and enables comparison between countries.

Counting precision is dependent on the number of WBCs counted and the parasite density. At low parasite density there is low precision and this must be taken into account when interpreting results. The limitations of counting precision is a critical consideration in assessing the competence of a microscopist (such as in training, certification etc). A model

was presented to quantify this imprecision. Grading parasitaemia using the 1+ to 4+ system can be more practical than counting against leucocytes. However it must be performed on a correctly prepared blood film and using correct technique to be reliable.

3. COUNTRY PRESENTATIONS

3.1 Afghanistan

A quality assurance system exists wherein the reference laboratories cross-check all positive slides and 10% of negative slides randomly on monthly basis from selected peripheral laboratories. Slides are sent in packs of 5–10 each in white paper with label (name of clinic and microscopist, slide results and date). If some health facilities could not send their slides for cross check, they keep them for 3 months). Slides are sent to national malaria leishmaniasis control programme by post office, public transport or provincial laboratory supervisor.

The main activity of quality assurance is collection of 3-month activity reports and on-site evaluation for assessment of (laboratory, designing, safety, equipment and reagents). Priority is given to strengthening the quality control centres in Nangarhar, Kandahar, Helmand, Takhar, Laghman, Kunar, Herat, Balkh, Laghman, Kunduz.

Use of RDTs was piloted in 4 provinces in the northeast region, including 150 health posts, 350 community health workers and 31 trained community health supervisors. Lack of incentives for community health workers who work as volunteer, cold chain management (central to community level), supervision of community health workers, weak feedback system, security situation in some districts for following up the community health workers' activity, low literacy rate and lack solar support for microscopes are among the main challenges for a functional quality assurance system.

Future needs include: standardized data collection and registration forms, training of young microscopists, support of laboratories with equipment, reagents and other materials, quarterly review meetings to collect data and slides for cross check, supervisory checklists, preparing of standard operating procedures with WHO standard bench aids for malaria microscopy laboratories, training on repair of microscopes, slide bank from different types of malarial parasites at central and provincial levels.

3.2 Djibouti

The number of health facilities performing malaria microscopic diagnosis is 17 out of 23 facilities (74%). The number of hospitals that perform malaria microscopic diagnosis is 8/9 (89%). The number of community health facilities that perform malaria microscopic diagnosis is 9/14 (64%). Quality assurance is not a key activity in the national malaria control programme. Challenges are very limited budget, no maintenance programme in place, lack of reagents (Giemsa, slides, and gloves) and limited workforce.

In 2010, the number of RDTs procured was 10 500, while 7100 were used. The national programme does not know at which level RDTs were used because the supply management system does not keep records. The health facilities do not report the number of RDTs used. Key challenges are very weak supply management system, lack of confidence in results, no lot testing and storage limitation.

The national reference laboratory in Djibouti is at the General Hospital of Peltier. There are only 2 staff working with responsibilities to collect data and evaluate performance, identify limitations and causes of problems, validate the results of collected slides, training/retraining workforce of laboratory staff. The quality assurance system consists of visits from the national laboratory team to monitor staff competence, equipment, reagents, stock control, workload, registration and reporting. Key challenges are lack of plan of action, ineffective logistics system to supply and maintain the essential reagents and equipment (particularly microscopes), lack of motivation from the stakeholders, insufficient competent workforce of laboratory staff and trainers and lack of national slide bank. Regular supervisory visits are not yet carried out in Djibouti. The quality assurance team does not have sufficient human and financial resources to carry it out in rural areas and is only carried out in the capital so far. Training resources are very limited. The national school of medicine does the accreditation of microscopists. No training activities were carried out in Djibouti for malaria microscopists in 2009 and 2010.

3.3 Egypt

There are central laboratories in the Ministry of Health which can be used as a reference laboratory. Also, there are many teaching institutes. Resources in the Ministry are limited to conduct extensive training, and there is no slide bank. WHO can provide support for training of personnel to develop a quality assurance and quality control system. The national malaria programme also needs support in securing laboratory equipment and RDTs.

3.4 Islamic Republic of Iran

National guidelines for laboratory diagnosis of malaria were prepared and published after three stakeholders meetings. A baseline laboratory assessment was conducted to design a quality assurance system for malaria microscopy. Retrospective information on the infrastructure, workload and slide positivity were collected by a checklist. Information on staffing and the number of malaria tests conducted were collected from medical laboratories of 3 provinces, where laboratory services are concentrated. The number of microscopists trained and retrained annually is 100. Supervision aims at training of outreach areas. Existing human resources increased with 20 new posts last year. A national malaria slide bank is kept in the School of Public Health.

the main challenges of the national malaria quality assurance programme as a new initiative are inappropriate mechanism to enforce standard operating procedures, inadequate infrastructure and equipment in some border areas, inadequate cooperation and non harmonized activities between private and public laboratory systems.

3.5 Iraq

Access to malaria microscopy is 76% (facilities with functional malaria microscopy are 97 Baghdad + 727 governorates/facilities expected to confirm malaria diagnosis are 100 Baghdad + 1077 governorates). Lack of training slides and some materials and equipment are the key constraints. RDTs were not used in Iraq in 2009 and 2010. The national reference laboratory of malaria undertakes quality assurance. Staff include the malaria manager, one microscopist in Baghdad and 2–5 in governorates. Responsibilities of quality assurance staff are cross-checking of malaria slides (all positive and 20% of negative), organizing training courses, preparation of stains, reporting of monthly statistics.

Primary cross-checking is performed in the malaria laboratory in the sectors belonging to two Baghdad directorates and in malaria laboratory of sectors of each governorate directorates. Slides are associated with form of information including name, sex, age and resident area. Final cross checking is performed in the national reference laboratory in Baghdad and validation result is sent to the national malaria control programme administration. Budget and resources are available from WHO and the Ministry of Health. Validation considers results accuracy and smear quality (type, size, shape, stain quality, colour and clarity). Cross-checking and validation is performed every month.

Supervision is integrated with national laboratory services. It is organized in collaboration with national malaria control programme administration in CDC, two visits a year for each governorate. The visit includes observation on work proceeding, meeting with the staff to discuss challenges, visiting three health clinics and a field visit.

The national reference laboratory has the capacity for training on malaria diagnosis including efficient microscopists, enough microscopes and other training equipment, except training slides. There is no national system for accreditation of microscopists in Iraq, but there are intensive training courses. Two staff previously trained at the regional course on advanced malaria microscopy in Oman. WHO support is needed in training, fellowships and financial support for research.

3.6 Morocco

The malaria reference laboratory is in the department of parasitology located in the national institute of health. Training is organized each year either at the central, regional or provincial level. The aim is improving competencies of microscopists. All microscopists should have refresher training every 2 years. The training is one week long and includes practical sessions on identification of the plasmodia species and on calculation of parasitaemia. Corrective retraining is organized when a microscopist shows weak performance or insufficient competence. It consists of theoretical and practical parasitology and a discussion with the microscopist to determine the professional issue, microscope problem, misuse of technique and other issues.

A national quality control system exists for evaluation of the performance of microscopists at the regional and provincial level three times a year. An evaluation report is

sent after corrections to each candidate. Internal quality control exists. It includes evaluation of the quality of thick and thin smear practice, Giemsa staining and microscopy, evaluation of performance and strategy of the malaria diagnostic test. A slide bank is prepared by the central laboratory according to national standard operating procedures. There is an archiving system allowing the practical retrieval of data and slides. Some regional laboratories prepare their slide bank. PCR identification of species is a new step to perform.

Supervision is done by central service and regional supervisors. The activities of supervision are: supervision of the buildings, checking of the registers and information forms, checking of the various steps of diagnosis (preparation of the smears, staining, dilution of the dye), checking of stocks of the material and the reagents and checking of the defectively maintained material (microscope, distiller). On-site training is conducted to evaluate the competencies by slide examination, correct/incorrect procedures on site, check existence of the reference documents, discuss with the microscopists to know their problems and to try to find solutions. A fixed number of slides are taken out randomly to be re-examined in the central laboratory to make decision of training, assess the workload and communicate the report of the visit.

3.7 Oman

The system includes national malaria office, 11 regional malaria offices and malaria units in *wilayats*. There are 503 private clinics that do not examine malaria. The existing malaria microscopy quality control system in Oman includes slide cross-checking, supervisory visits and training. Slide cross-checking is performed monthly at the regional laboratory and then at the central malaria laboratories for all positive slides and 10% of negative slides. Assessment is done for film preparation, staining, species diagnosis and parasite density counting. Immediate cross-checking is carried out on all doubtful results at notification at the regional and/or central malaria laboratory.

Supervisory visits are annual, without prior notice by the national malaria office (quality control team) for all the health institutes with malaria diagnostic services. Assessment of the quality of malaria diagnostic services includes laboratory management, equipment and reagents, film preparation and staining and competency. Training courses are training of trainers, in-service refresher training and 2-week mandatory training during internship.

3.8 Pakistan

Interventions carried out during flood emergency 2010 were the establishment of 60 new microscopy centres and training of microscopists with provision of new microscopes. Future plans are to ensure early diagnosis and prompt treatment for all positive cases at 504 health facilities, strengthen and increase the number of microscopy centres from 340 to 400 and RDT centres from 63 to 83.

3.9 Somalia

RDTs tests procured were 60 000 and 200 000 in 2009 and 2010 respectively. In 2010, 200 105 tests were used at health facility and community level. Using RDTs without lot testing, weak supply management system, lack of confidence in RDT negative results, insufficient advocacy to achieve community and health staff acceptance are among the challenges. Coverage by malaria microscopy in 135 health facilities with microscopes is 74% (35/53 northwest, 25/32 northeast zone and 40/50 south/central zone). The quality assurance system composed of four quality control laboratories, two functional (northeast and northwest), two under establishment (south/central zone). The staff are 3 laboratory technicians and 2 supportive laboratory staff responsible for training, supervision, slide validation (cross checking for all positives and 10 % of negative), outbreak response, etc. Financial resources are only from the Global Fund.

Key constraints to scaling up coverage of quality assured malaria microscopy are poor motivation, high staff turnover, lack of conducive working atmosphere, lack of rules and regulation, withdrawal of nongovernmental organization support, infrequent supervision, limited staff who are engaged in other health activities and security issues which restrict movements. Staff previously trained at the regional course on advanced malaria microscopy in Oman are the focal points of the malaria quality control laboratory. Further requirements are continuous support of training, establishment of a slide bank, accreditation of malaria microscopists and national support of RDT lot testing.

3.10 Sudan

The objective related to malaria diagnosis in Sudan is to increase the proportion of malaria cases correctly managed from 68% to 85% by 2015. Access to malaria microscopy is 29% in primary health centres (1413/4912). The number of RDTs used in 2009 was 684 354, which increased to 1 548 329 by 2010. Procurement is made by UNDP/Global Fund and UNICEF. Quality control and quality assurance of RDTs is through local studies to assess RDTs quality and adherence. The main challenges for shifting from clinical to diagnosis through RDTs are lack of trust in RDT results, need for quantification, reporting, monitoring and standard operating procedures, storage at lower level health facilities and needs for refresher training.

The quality control and quality assurance system includes 15 state reference laboratories plus central quality control and quality assurance reference laboratory with 74 personnel (45 laboratory technicians and 29 malaria microscopists). Responsibilities of reference laboratories include (3×3) assessment, intervention package (refresher training) and supervision and evaluation. Main areas for improvement include increasing coverage of high quality microscopy, improving adherence to RDTs, sustaining training activities, maintenance/repair, providing quality supplies and equipment and mobilizing more resources. Strengthening training institutes and school laboratories is also crucial. Sinnar and Blue Nile institutes and the national slide bank (under establishment with a good stock of reference slides) are among valuable available resources.

Accreditation of microscopists is done by the National Council for Medical and Health Professions. Staff previously trained at the regional course on expert malaria microscopy are still working in the malaria control programme, doing different activities. WHO can provide technical assistance, support quality supplies and equipment procurement, support capacity building (more training on quality control and quality assurance system), set standards and monitor partner implementation and advocate for and mobilize more resources

3.11 Yemen

Malaria confirmation by microscopy is provided in only one third of the public health facilities including hospitals and health centres (1031/2818 health facilities) and in nearly half of the private health facilities (2182/3950) including hospitals, health centres, clinics, polyclinics and private laboratories. The main constraints of malaria microscopy are: poor infrastructure, inadequate microscopes and other supplies (e.g. stains and reagents). The national quality assurance and quality control system is still weak with difficulties in implementation of the proposed quality assurance standards. Physician confidence in microscopy results is low, funds are insufficient to support the quality system and there are challenges to incorporate the private sector in the quality system.

Requirements to scale up coverage of the quality control system include baseline assessment of the laboratory services and establishment of a national laboratory database, training for the service providers, development of key performance indicators, mobilize resources, plan and implement adequate and regular monitoring and supervision activities and benchmarking for continuous improvement.

RDTs were recently introduced in Yemen (since 2009) which detect *P. falciparum* only. Yemen hosted the first regional training of master trainers course on RDTs in 2009. During the past 3 years, 505 020 cassettes of First Response® and CareStart™ were procured. Lot testing has not been done. Key challenges in RDTs use scale-up are test selection, lot testing, transport and storage, training, supervision and quality assurance and quality control, and expansion of the use RDTs through community involvement projects.

A national quality control/quality assurance plan and standard operating procedures for malaria microscopic diagnosis are in place. The national malaria control programme initiated the process of developing the national standards for malaria microscopy and assignment of malaria quality control focal point to the monitoring and evaluation team. The quality control system is ongoing in Hadramout governorate; however, the current political turmoil hampered the implementation of the planned activities in the rest of the country. Future needs include the establishment of a slide bank and organizing a training course on advanced malaria microscopy and quality assurance and quality control in Arabic for 16 staff from the national malaria control programme and the central laboratory network.

4. CONCLUSIONS

All participating countries of the Region recognize the need to accelerate universal access to malaria diagnostic testing as a key component of national efforts to ensure quality

of care, reduce pressure on antimalarial medicines, improve efficiency and strengthen the malaria surveillance system.

Both microscopy and rapid diagnostic tests have major roles in ensuring that all suspected malaria cases are confirmed: each test has characteristics that make it useful in particular clinical situations. In all settings, both microscopy and rapid diagnostic tests require an effective quality management system in place to ensure the accuracy and reliability of malaria diagnostic testing. For improving access to quality-assured malaria diagnostic testing the workshop made a number of recommendations.

5. RECOMMENDATIONS

Universal coverage

1. Countries should expand access to quality assured malaria diagnostics in a phased manner, according to national priority areas, and progressively scale up in all parts of the countries. The phased expansion takes into account access/security in countries with complex emergencies. Countries with good quality management systems in the public sector should plan for progressive involvement of the private sector. The plans should be aligned with the health sector development plan, especially in relation to anticipated staffing requirements.
2. National policies and strategies for universal coverage of malaria diagnosis should be informed by the results of a national in depth assessment and gap analysis, based on national targets and priorities. The assessment should review the infrastructure requirements (laboratories, equipment, staffing, supply management, cool chain for transport and storage, funding etc.) as well as performance requirements (skills, training, supervision, prescribing practices, consumer education, monitoring and evaluation).
3. National malaria control programmes should promote access to diagnostic testing as much as possible, as part of the integrated management of febrile illnesses, with integrated supervision activities and strong collaboration with the general laboratory services and national reference laboratory.
4. Countries should procure malaria RDTs that have been assessed by the WHO product testing programme, and all procured lots should be tested according to WHO-recommended procurement criteria. From arrival up to point of use, programmes should ensure the cold chain for transport and storage.
5. Countries should consider including support for improvement of the procurement and supply management system, including cold chain for RDTs, in future proposals for funding.

Quality management system

6. A national coordination group on malaria diagnosis should be established as a core requirement of a quality management system with access to a core group of national experts, qualified as national trainers in malaria microscopy and RDTs.

7. National reference slide sets should be established in all countries mainly for training purposes. For countries with already available national reference slide banks, a validation system should be established using the standard operating procedures developed by WHO.
8. In all countries the methods for slide cross-checking should comply with international standards. Re-checking of a limited number of slides during the supervision visits can provide complementary and immediate feedback to the microscopy and laboratory technicians. Improvement of the slide preparation and staining, with special emphasis on the quality of thick films, is crucial, along with slide reading and immediate feedback and corrective action by quality training and supportive supervision.
9. Countries should allocate appropriate resources for supervision as a fundamental component of all efforts to implement quality management systems, including training on leadership and supervisory skills, development of appropriate checklists, field operations, problem-solving and management of data and information.
10. Quality of microscopes, Giemsa stains and RDTs are particularly vulnerable to poor procurement practices. In all countries the national malaria control programme should collaborate proactively with national or international procurement management units to prevent the selection of sub-standard or inadequate products. Procurement decisions, particularly for these products, should not be based mainly on unit price of goods.
11. Systems for national external quality assessment should be established as part of the function of the national reference laboratory using validated slides according to international standards. The WHO Regional Office should coordinate the sharing of information.

Training

12. WHO should continue to support the regional microscopy course in Oman. The fifth course is planned for the second week of September 2012.
13. Countries should train clinicians on malaria diagnosis and make sure that new laboratory technicians have a standard basic malaria microscopy course before starting practice in the field.
14. Countries should implement a proper career pathway for trained personnel and plan for better use of their capacity.
15. WHO should support conduct of a training course on maintenance and repair of microscopes.

Monitoring and evaluation

16. Countries should adopt improved appropriate indicators for monitoring and evaluation of coverage of malaria diagnostic testing. In countries where data related to malaria diagnosis are not routinely reported by the health management information system, consideration should be given to retrieving these data from inpatient registries of a representative sample of health facilities.

Collaboration

17. The Regional Office should develop a project document to support the establishment of a regional malaria slide bank in collaboration with the regional centres (Islamic Republic of Iran, Oman, and Sudan) and international foundations.
18. The Regional Office should facilitate networking among countries, other regions and international institutions for sharing experiences and standard operating procedures, guidelines and other relevant documents, especially in the area of slide banks, human resources capacity and competencies.

Annex 1**PROGRAMME****Saturday, 17 September 2011**

08:00–08:30	Registration	
08:30–09:30	Opening Session	
	Message from Dr Hussein A. Gezairy, Regional Director, WHO/EMRO	<i>Dr H. Atta</i>
	Message from H.E. Dr Ahmed bin Mohamed bin Obaid Al Saidi, Minister of Health of Oman	<i>Dr H. Atta</i>
	Nomination of officers	
	Objectives of the workshop and methods of work	
09:30–10:30	Technical update on recent WHO guidelines on malaria parasitological diagnosis	<i>Dr A. Bosman</i> <i>Dr H. Atta</i>
	Briefing on WHO Manual for quality assurance	
11:00–11:30	Overview of the situation in respect to access to malaria confirmation in malaria endemic countries	<i>Dr G. Zamani</i>
11:30–12:00	Discussion	
12:00–13:00	Country presentations on situation/activities for scaling up quality parasitological confirmation for malaria: Afghanistan, Djibouti, Pakistan	<i>Country representatives</i>
13:00–13:30	Discussion	
14:30–15:30	Country presentations on situation/activities for scaling up quality parasitological confirmation for malaria: Somalia, Sudan, Yemen	<i>Country representatives</i>
15:30–15:45	Discussion	
16:00–17:00	Country presentations on situation/activities for scaling up quality parasitological confirmation for malaria (malaria elimination group): Islamic Republic of Iran, Iraq, Saudi Arabia	<i>Country representatives</i>
17:00–18:00	Country presentations on situation/activities for scaling up quality parasitological confirmation for malaria: Egypt, Morocco, Oman, Syrian Arab Republic	<i>Country representatives</i>
18:00–18:30	Discussion and wrap-up	

Sunday, 18 September 2011

08:00–08:30	Summary of the first day presentation and discussion	<i>Dr H. Atta</i>
08:30–09:30	Lessons learnt/Future perspective from past four regional courses on advanced malaria microscopy and quality assurance in Oman	<i>Dr J. Storey, Dr M. El Zadjali</i>
09:30–10:30	Shared experience on microscopy accreditation programmes in the Western Pacific and African regions	<i>Dr K. Lilley, Dr J. Carter</i>

11:00–12:00	Experience with establishment of malaria slide bank, PCR validation and operational aspects from WPRO	<i>Dr J. Luchavez</i>
12:00–13:00	Lessons learnt in strengthening quality management of malaria diagnosis in Medicines Sans Frontiers, Afghanistan and the United Republic of Tanzania	<i>Dr D. Klarkowski</i>
14:00–15:00	Supervision as key components of quality assurance: objectives, tools and operational aspects	<i>Dr M. El Zadjali, Dr L. Benavente</i>
15:00–16:00	Approaches for training and preparation of effective training tools for malaria microscopy	<i>Dr E. Long, Mr J. Storey</i>
16:30–17:15	Key programmatic indicators for monitoring and evaluation of malaria confirmation and reporting/recording tools	<i>Dr G. Zamani</i>
17:15–17:45	Experience with implementation of EQA in the African Region and potential for extension in the Eastern Mediterranean	<i>Dr A. Bosman, Dr J. Carter</i>

Monday, 19 September 2011

08:00–08:30	Summary of 2nd presentation and discussions	<i>Dr A. Bosman</i>
08:30–09:30	Product testing and lot testing of malaria RDTs	<i>Dr J. Luchavez</i>
10:00–11:00	Selection and quantification of RDTs	<i>Dr A. Bosman</i>
11:00–12:30	Practical on selection and estimation of RDT requirements	<i>Working groups</i>
13:30–14:00	Presentation of results and discussion	
14:00–15:00	Approaches for training and effective training tools for malaria RDTs	<i>Dr J. Luchavez</i>
15:30–16:15	Possible methods for the evaluation of malaria microscopy and RDT testing performance at point of care	<i>Dr D. Klarkowski</i>
16:15–16:45	Discussion and wrap-up	

Tuesday, 20 September 2011

08:00–08:30	Summary of 3rd day presentations and discussions	<i>Dr G. Zamani</i>
08:30–09:00	IMaD collaborative project to strengthen malaria laboratory quality management systems in Ghana	<i>Dr L. Benavente</i>
09:00–10:00	Software for monitoring quality management of malaria diagnosis confirmation	<i>Dr D. Klarkowski</i>
10:30–10:45	Introduction to field visit	<i>Dr M. Al Zedjali</i>
10:45–17:30	Field visit	

Wednesday, 21 September 2011

08:00–09:00	Presentations of the group on the lessons learnt during the field work	<i>Country groups</i>
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Annex 2

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