



MALARIA LIGHT MICROSCOPY
CREATING A CULTURE OF QUALITY

REPORT OF WHO SEARO/WPRO WORKSHOP ON
QUALITY ASSURANCE FOR MALARIA MICROSCOPY

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The views expressed in this report are those of the participants in the WHO Informal Consultation on Laboratory Methods for Quality Assurance of Malaria Rapid Diagnostic Tests and do not necessarily reflect the policies of the Organization.

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ABBREVIATIONS

ACT	Artemisinin-based Combination Therapy
ACTMalaria	Asian Collaborative Training Network for Malaria
AusAID	Australian Agency for International Development
CDC	United States Centers for Disease Control and Prevention
EMRO	WHO Regional Office for the Eastern Mediterranean
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
LQAS	Lot Quality Assurance System
MR4	Malaria Research and Reference Reagent Resource Center (NIH, USA)
MSF	Médecines Sans Frontières
NAMRU2	US Naval Medical Research Unit No. 2 (Jakarta, Indonesia)
NGO	Nongovernmental organization
PAHO	Pan American Health Organization (WHO Regional Office for the Americas)
PCR	Polymerase chain reaction
QA	Quality assurance
QC	Quality control
RBM	Roll Back Malaria
RDT	Rapid diagnostic test
SEARO	WHO–South-East Asian Regional Office
SOP	Standard operating procedure
SPR	Slide positive rate
WHO	World Health Organization
WPRO	WHO–Regional Office for the Western Pacific

EXECUTIVE SUMMARY

With the spread of drug-resistant and multidrug-resistant species of malaria, particularly *Plasmodium falciparum*, accurate microscopical diagnosis is acutely needed today. In response, the World Health Organization (WHO) has recommended that countries experiencing resistance to monotherapies for falciparum malaria use combination therapies, preferably those containing artemisinin-based combination therapy (ACT), as a first line of treatment. However, ACTs cost at least 10 times more than chloroquine, amodiaquine or sulfadoxine/pyrimethamine. In light of these escalating costs, as well as the inaccuracy of clinical diagnoses, the demand is increasing for confirmation of the presence of a parasite before treatment. While microscopy remains the mainstay of parasite-based diagnosis in health clinics and hospitals, laboratory services are generally inadequate due to years of neglect, lack of financial investment, insufficient infrastructure, and poorly trained and overworked personnel. Therefore, improvement in the accuracy and reliability of light microscopy at all levels of health services, though particularly on the periphery where most patients are treated for malaria, is clearly and urgently needed.

Good microscopical services are cost-effective, and provide results that are consistently accurate and timely enough to impact the treatment of a patient directly. These standards can be achieved only by developing and implementing effective quality assurance (QA) programmes. Everyone involved in the QA of light microscopy—from senior administrators and decision-makers to microscopists and clinicians working at the periphery of the health services—must make a commitment to achieve this objective. Allocating a small percentage of the malaria control budget (1–5% of the national budget for malaria) in this area would yield large benefits through improved use of expensive drugs.

This report details the conclusions and recommendations from a workshop on QA of malaria light microscopy organized by WHO's Regional Office for the Western Pacific (WPRO) and Regional Office for South-East Asia (SEARO). The workshop in Kuala Lumpur was part of a bi-regional project, funded by the Australian Agency for International Development (AusAID) through WHO's Roll Back Malaria Department in Geneva.

The workshop reviewed the need for QA of malaria light microscopy, the status of laboratory diagnosis of malaria QA in the two regions, and recent initiatives by other WHO regions. It also identified the constraints to improving the quality of malaria microscopy. Based on this situational analysis, the report provides guidance to national programmes on:

- planning and organizing QA programmes;
- improving the competence and performance of microscopists;
- identifying the materials and networks needed to support national QA programmes;
- scaling up malaria QA;
- integrating malaria QA with other diseases; and
- increasing the commitment to a culture of quality.

Specifically, the report provides details on:

- the definition of standards that microscopists should achieve at each level of the QA system;
- a model for developing proposals for funding the development, implementation and scaling up of a national QA system;
- a tool for costing QA programmes for malaria laboratory diagnosis; and
- a proposal for a joint SEARO–WPRO project for a network to support QA of malaria microscopy.

Without external assistance, many national programmes will be unable to initiate QA programmes. WHO should take the lead in increasing this commitment by:

- recommending QA to policy-makers and stakeholders as part of a global strategy, demonstrating the potential it offers for major health and financial benefits to health services and patients;
- developing and endorsing a “personal certification” system for malaria microscopists;
- developing and refining the materials for training malaria microscopists; and
- developing a comprehensive and internationally recognized set of guidelines on all aspects of QA of malaria microscopy, taking into consideration initiatives being undertaken in other regions.

The report aims to provide a basis for addressing these proposals, leading to improved national and international support networks to enhance and maintain the quality of malaria microscopy. In turn, malaria case management in endemic countries could be improved.

1. INTRODUCTION

Improvement in the quality and accuracy of microscopical diagnosis of malaria is urgently needed. Early diagnosis, followed by prompt and effective treatment, are the basic elements of malaria control today, as well as the keys to reducing malaria mortality and morbidity (WHO, 1993a, 2000, 2004a). Rising drug costs in the face of the increasing resistance of *Plasmodium falciparum* to traditional monotherapies, combined with the recognition that clinical diagnoses often are inaccurate, are increasing the demand for the confirmation of parasites in the blood before therapy. While microscopy still is the mainstay of parasite-based diagnosis in health clinics and hospitals, laboratory services are generally inadequate to meet the needs of malaria control today. Years of neglect, lack of financial investment, insufficient infrastructure, and poorly trained and overworked personnel make it difficult for health services to maintain the high quality of malaria microscopy that is needed to target therapy to those in need. This is particularly true at the periphery of the health services, where most of the patients are treated.

A reliable microscopical service is one that:

- is cost-effective;
- provides results that are consistently accurate; and
- generates findings that have a direct impact on the treatment of a patient.

These demands can be met only through a commitment to quality assurance (QA) that ensures competent and motivated staff handle the microscopical services, supported by effective training and supervision. QA also requires a logistics system that provides an adequate and continual supply of reagents, microscope slides, microscopes and other essential equipment. Further, the equipment must be maintained in working order.

The problems facing the development and implementation of effective QA programmes are similar in practically all malaria-endemic countries of the World Health Organization's (WHO) Regional Office for South-East Asian (SEARO) and Regional Office for the Western Pacific (WPRO). All of these countries had eradication programmes in which extensive cross-checking of slides taken for routine surveillance assured the quality of microscopy facilities. However, such a system has proven unsustainable in the context of malaria control today. As a result, most countries have abandoned extensive cross-checking and only pay lip service to QA implementation. This has occurred when countries need to implement policies for malaria disease management based on the use of expensive combination therapies.

To address these urgent needs and constraints, WPRO in collaboration with the SEARO initiated a joint programme on QA of malaria light microscopy in 2004. The Australian Agency for International Development (AusAID) funded the joint programme through WHO's Roll Back Malaria Department in Geneva.

This report highlights the results and recommendations from a joint Workshop in Kuala Lumpur, Malaysia organized as part of this programme. It is aimed at managers of malaria control programmes and national health laboratory services, as well as nongovernmental and funding agencies involved in the support of malaria disease management and malaria diagnosis in particular.

2. OBJECTIVES OF THE WORKSHOP

The objectives of this workshop were to:

- provide guidance to countries for the development and planning of national QA programmes for malaria microscopy;
- identify needs for the provision of materials and networks to support training and QA in malaria microscopy;
- develop tools for costing the implementation of national programmes for the QA of malaria microscopy;
- develop templates to assist countries in preparing proposals to external agencies to strengthen laboratory services for diagnosis of malaria;
- improve coordination/cooperation within WHO, and with other organizations/institutions involved in QA of laboratory services; and
- develop a pilot interregional scheme to support QA in selected countries of WPRO and SEARO (details are in Annex 2).

A review of published and unpublished documents related to QA of malaria microscopy, including guidelines,¹ teaching modules and aids, bench aids and slide banks preceded the workshop. External experts unable to attend the workshop also were canvassed for their views on issues to be discussed at the workshop. The results of this review were made available to the participants (Trigg, 2005).

¹ WHO's Regions for the Americas and the Eastern Mediterranean also have developed draft guidelines for the QA of malaria light microscopy, as has Médecines Sans Frontières-Holland. Details of these were presented at the workshop, and are summarized in Annex 2.

3. WHY QUALITY ASSURANCE IS IMPORTANT

3.1 The role of light microscopy in malaria control today

The first suspicion of malaria is almost always based on clinical criteria. In many situations, symptom-based diagnosis is the sole basis for treatment in areas where malaria is endemic. This usually results in all patients with fever—and no other apparent causes of disease—being treated for malaria. Although this approach can identify most patients that need malaria treatment, it also is likely to misclassify many who do not, resulting in patients with other diseases receiving malaria treatment. While this might have been acceptable in the past when malaria was treatable with affordable and relatively safe drugs, it is not acceptable today.

A diagnosis based on clinical symptoms alone has very low specificity. As a result, malaria can be over-diagnosed considerably, while other diseases are overlooked and not treated in a timely manner. This contributes to the misuse of antimalarial drugs, increased costs to the health services and patient dissatisfaction.

Good clinical practice dictates that a laboratory should confirm the presence of parasites in most epidemiological situations.² However, if this is not logistically possible for all suspected cases of malaria, laboratory diagnosis to confirm the presence of parasites is particularly desirable in all suspected cases of treatment failures and severe disease, as well as for diagnosing uncomplicated malaria during low transmission seasons (WHO, 2000).

Laboratory diagnosis by microscopical examination of stained blood smears continues to be the method of choice—the gold standard—for confirming a clinical diagnosis of malaria and epidemiological studies (WHO, 2000a, 2004a).³ Parasite diagnosis also is essential during clinical and field trials of antimalarial drugs and vaccines, and for the QA of other forms of malaria diagnosis.

The method has many advantages. For example, laboratory diagnosis:

- has low direct costs if the infrastructure to maintain the service is already available;
- can be sensitive if the quality of microscopy is high;
- can be used to differentiate between malaria species;
- can determine parasite densities; and
- can be used to diagnose many other diseases.

² A laboratory diagnosis is recommended in patients of all age groups in areas of low and moderate transmission, and in children over 5 years old and adults in areas of high transmission. One possible exception might be children under 5 years old in areas of high transmission, where parasite confirmation of fever might have limited value due to the high prevalence of asymptomatic infections (WHO, 2004a and 2005).

³ Rapid diagnostic tests, another important component of a diagnostic strategy for malaria, can be used to confirm the presence of parasites in certain circumstances (WHO, 2000b, 2003a, 2005). However, they cannot yet be considered a gold standard.

3.2 Current limitations of microscopy for malaria

Microscopical services, specifically for malaria, were well-developed and relatively efficient during the malaria eradication era of the 1950s and 1960s. A vertical health programme implemented the services, which were supported by a QA system, a supply network with supervision, and training of laboratory staff. As such, they were the main tool for malaria surveillance and detection of malaria cases (Pampana, 1963). They were effective for several reasons:

- They were funded and staffed more or less adequately.
- The results were not needed immediately, as presumptive treatment had been given to patients in need.
- The initial impact of the eradication measures in many areas ensured that the number of slides for rechecking was relatively low and could be dealt with adequately by the existing system.

With the abandonment of the eradication campaign in the mid-1960s, antimalarial activities were gradually incorporated into the general health services, and WHO changed its policy to reducing mortality and morbidity due to the disease (WHO, 1984, 1993a, 2000a, 2004a). Early diagnosis and prompt treatment are fundamental to reaching this goal, which can be achieved only if the results of laboratory diagnosis are reliable, accurate and available to the clinical staff as quickly as possible, so that the appropriate treatment can be given (WHO, 1993, 2004a). This has put a greater strain on the laboratory services than during the eradication era, because:

- general health service staff, who have other tasks to perform, carry out the diagnosis;
- the results of the diagnosis need to be available as quickly as possible;
- frequently many more slides than in the eradication era require examination; and
- the general health services usually have not received additional funds to support the implementation of malaria diagnosis.

As a result, even though the importance of light microscopy is well-recognized, the maintenance of good light microscopy has been difficult, especially at the periphery of the health services where most patients are treated.

The current limitations of microscopy for malaria, which are well-recognized and documented (Durrheim *et al.* 1996; Payne, 1988; WHO, 1988a; 1993b), include the:

- lack of political commitment to support the development of laboratory services;
- lack of funds to support the integration of malaria diagnosis into the general laboratory services;
- poor quality of microscopy, particularly at the periphery;
- difficulties in maintaining microscopy facilities in good order;

- logistical problems and high costs of maintaining adequate supplies and equipment;
- lack of adequate training and retraining of laboratory staff;
- delays in providing results to clinical staff; and
- lack of QA and supervision of laboratory services.

The current limitations can be overcome only by political commitment that acknowledges the importance of developing laboratory services, the need for adequate funding, and the implementation of a QA system that ensures that:

- training and supervision of staff, and quality control (QC) of their tasks, is constant;
- slide collection, staining and reading are accurate, timely and linked to clinical diagnosis;
- results are provided to the clinicians quickly;
- clinicians can trust the results; and
- logistical support is in place to provide quality supplies and equipment.

3.3 The need for accurate microscopic diagnosis

The need and the importance of accurate microscopical diagnosis have become acute with the spread of antimalarial drug resistance, particularly of multidrug-resistant *Plasmodium falciparum*.

To address antimalarial drug resistance, WHO now recommends that countries experiencing resistance to monotherapies, such as chloroquine, sulfadoxine/pyrimethamine and amodiaquine, use combination therapies as a first line of treatment for falciparum malaria. These combination therapies preferably should contain an artemisinin derivative, known as artemisinin-based combination therapy (ACT)⁴ (WHO, 2003b, 2004a, b, c). An effective first-line antimalarial treatment is considered to have a greater impact on reducing mortality than merely improving the second-line treatment or the management of severe malaria.

ACT is used increasingly in countries of SEAR and WPR. Bangladesh, Bhutan, India, Indonesia, Myanmar and Thailand in SEAR, and eight of the 10 malaria-endemic countries of WPR (Cambodia, Papua New Guinea, People's Republic of China, the Philippines, Solomon Islands, Timor-Leste, Vanuatu and Viet Nam), use ACTs as first- or second-line drugs for the treatment of uncomplicated falciparum malaria.

ACTs cost at least 10 times more than chloroquine, amodiaquine or sulfadoxine/pyrimethamine (Figure 1). The costs of implementing drug policies based on combination therapy could be reduced considerably by improving the accuracy of malaria diagnosis, which would target ACT treatment at those who need it and reduce over-consumption

⁴ The use of ACTs is based on several advantages of artemisinin derivatives: rapid reduction of parasite densities, rapid resolution of clinical symptoms, effective action against multidrug-resistant falciparum malaria, few clinical adverse reactions and reduction of gametocyte carrier rates, which might reduce transmission (WHO, 2001).

of antimalarial drugs by those who do not. Therefore, the need for extending laboratory diagnostic services to the periphery of the health services is self-evident (WHO, 1993b).

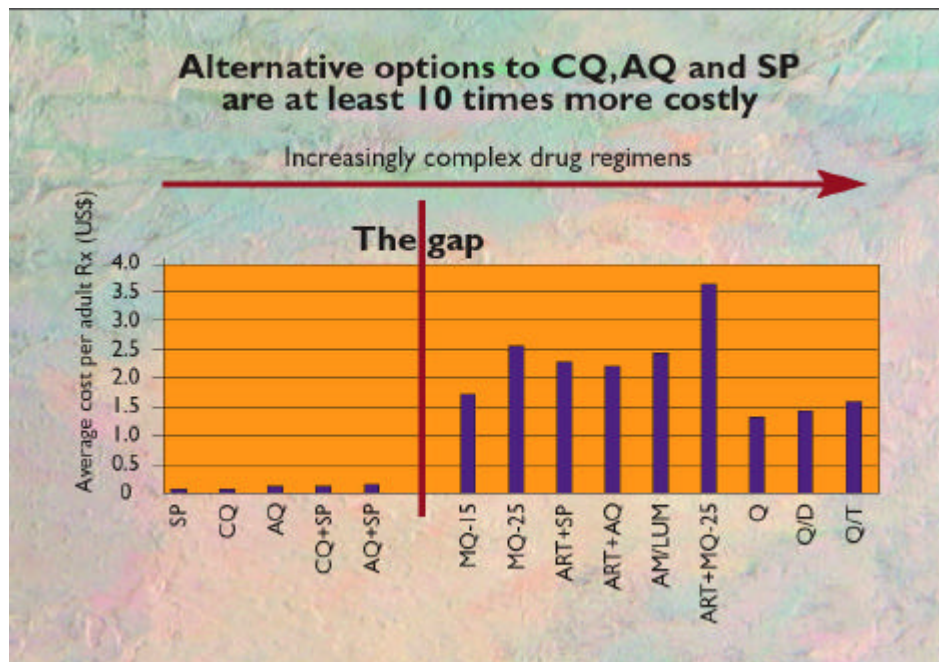


Figure 1. Current costs of antimalarial drugs⁵

CQ, chloroquine; AQ, amodiaquine; SP, sulphadoxine-pyrimethamine; MQ, mefloquine; ART, artemisinin; AM, artemether; Q, quinine; D, Doxycyclin; T: tetracycline.

Adapted from *Improving the affordability and financing of artemisinin-based combination therapies* (WHO, unpublished, 2003).

⁵ The prices of artesunate +SP, artesunate+amodiaquine and artemether/lumefantrine might fall as demand increases.

4. THE CONTEXT FOR IMPROVING QUALITY ASSURANCE IN THE WHO WESTERN PACIFIC AND SOUTH-EAST ASIAN REGIONS

4.1 Regional policies for malaria laboratory diagnosis

Most malaria-endemic countries of WHO's SEAR and WPR have introduced ACTs into their national antimalarial policies. WHO recommends that this be combined with high-quality laboratory diagnosis by using good quality light microscopy or rapid diagnostic tests (WHO, 2004a, c).

This has led both Regions to propose the following strategy for laboratory diagnosis of malaria that would:

- continue to support, expand and ensure the quality of national networks where microscopy already exists;
- expand microscope networks, where possible, down to the grass-roots level, i.e., develop community microscopists; and
- consider the use of rapid diagnostic tests (RDT) instead of starting up new microscopical networks, particularly in remote areas among ethnic minorities.

Expansion of microscopy at the community level has been initiated successfully in the Solomon Islands, where microscopy is a recognized and respected profession. About 150 community microscopists now work in communities with microscopes fitted with solar-powered lights. Although this strategy has increased the microscopists at the periphery, implementation has faced major problems, such as:

- poor working conditions;
- increased turnover of "volunteer" microscopists;
- increased difficulties in maintaining adequate supervision;
- lack of feedback from the central/regional laboratories to the periphery; and
- lack of QC of slide preparation and staining procedures, and poor quality of the glass slides.

4.2 Current status of QA programmes

Countries of the two Regions are decentralizing their health programmes. Malaria control is moving away from vertical structures towards integration with the general health services. Public and private sectors, as well as nongovernmental and bilateral agencies, are becoming increasingly involved. Microscopical facilities exist in all countries with the exception of

Papua New Guinea,⁶ which abandoned light microscopy to confirm the presence of parasites due to increased financial and logistical difficulties in maintaining the facilities in the areas where they are needed most.

Established QA programmes exist in some countries, such as Bhutan, India, Indonesia, Myanmar, the Philippines, Solomon Islands, Thailand and Viet Nam. In India, Indonesia and Myanmar, these continue to be based on the monthly cross-checking by a reference laboratory of all positive and 5–10% of negative slides routinely examined. Thailand abandoned this level of cross-checking by 1989, and now randomly selects 5–10% of all slides (positive and negative) for blind cross-checking. In other countries of the two Regions, QA programmes have been abandoned or are only now being re-established.

In general, QA of malaria microscopy in the two Regions is characterized by:

- incomplete coverage;
- insufficient financial and human resources to ensure effective supervision and corrective measures;
- biases in the selection of slides for evaluation (where cross-checking exists), and poor compliance in the shipment of these slides from the periphery; and
- low cost-effectiveness.

Therefore, QA programmes need to be developed in a variety of contexts, ranging from relatively advanced countries with established infrastructures and access to trained laboratory technicians to countries with poor infrastructures and very limited access to trained personnel.

⁶ Papua New Guinea is deciding whether to re-establish microscopy or to introduce RDTs.

5. PLANNING QUALITY ASSURANCE PROGRAMMES

The plan of action for QA programmes should be realistic and feasible, based on a situational analysis. They should be implemented in phases, according to the financial, organizational and human resources available to each country.

5.1 Objectives

QA programmes have to be:

- feasible and sustainable;
- compatible with the different needs and goals of each country; and
- a catalyst for change, while promoting the highest quality under the prevailing circumstances.

In view of the varied state of laboratory services in the two Regions, the goals of each national QA programme will have to be adapted to the contexts in which they are being developed. For example:

- In countries that have functioning QA systems with trained personnel and some form of infrastructure, the long-term goal should be to benchmark all laboratories to the highest standard. This could provide a management tool to improve the cost-effectiveness of these systems.
- In countries with limited infrastructures and poorly performing laboratory services, a more minimalist approach might be more appropriate and feasible, at least in the short to medium term. This approach might aim to identify poorly performing laboratories and personnel, based on training and less stringent criteria for evaluation.
- In countries lacking infrastructure and adequately trained staff, an evaluation of laboratory services might not be feasible. Hence, the training of microscopists and development of the necessary infrastructure for them to carry out their tasks effectively should be prioritized.

Irrespective of the context, the objectives of all QA programmes should be to:

- improve the overall performance of microscopists at each level of the laboratory services;
- sustain the highest level of accuracy (in sensitivity and specificity) in confirming the presence of parasites; and
- monitor systematically laboratory procedures, reagents and equipment.

5.2 Organizational structure

The hierarchical organization of microscopy services into national, regional/provincial and peripheral levels was considered logical and sound for the management and operation of the QA system. The corresponding elevated standards and responsibilities at each level also have the potential for the development of a career structure for microscopists. Such a career structure was considered extremely important since it will make microscopy more attractive for those entering the service and give incentives for those already in service.

5.2.1 National level

The national level should be responsible for planning, budgeting, implementing and monitoring the QA network. It should include a national QA co-coordinator, who should be a senior laboratory technologist working within the central offices of Ministry of Health, as a focal point for malaria QA. However, this co-coordinator also should be responsible for expanding the service to include other diseases.

5.2.2 Regional level

At this level, laboratory technologists would be responsible for supervising and monitoring activities to maintain the quality of the district and peripheral laboratories. They would externally cross-check slides and be responsible for (a) feedback of results; (b) planning and implementation of training and retraining activities; and (c) ensuring that equipment is maintained in good working order, and that the supply chain does not break down.

5.2.3 Peripheral level

In the context of this report, the peripheral level of the laboratory services comprises (a) the village or community level, where volunteers carry out tests in their own homes; (b) primary diagnostic facilities, which are small, fixed-site facilities dealing mainly with outpatients; and (c) secondary diagnostic facilities, such as laboratories within a hospital or health posts that deal with inpatients and outpatients.

Staff at all levels must be given post descriptions that indicate clearly their responsibilities, and define the tasks that they have to carry out.

5.3 Essential elements of the QA programmes

The essential elements of each QA programme are:

- a realistic costing of the plan of action developed according to a situational analysis;
- adequate funding at all levels of the QA programme;
- a national reference centre/laboratory for the production of standard operating procedures (SOPs), and training and reference materials, such as slide banks etc;
- a selection, training/retraining and assessment programme that ensures a competent workforce of microscopists and trainers;

- a support network that ensures that the performance of microscopists is maintained at the required standards. This includes:
 - consultative visits from higher level staff;
 - cross-checking of slides;
 - an effective logistics system to supply and maintain the essential reagents and equipment;
 - a system to maintain equipment, particularly microscopes, in working order;
 - a working environment that allows competent microscopists to perform at the required levels; and
- Development of a culture of quality throughout the QA programme.

6. IMPROVING COMPETENCY AND PERFORMANCE OF MICROSCOPISTS

6.1 What is competency and performance?

Competency in microscopy is the skill of a microscopist to perform an accurate examination and report of a malaria blood film.

Measuring competency requires:

- defining the specific skills that are required at each level of the QA system;
- setting standards of competency;
- defining the minimum requirements for training in microscopy;
- standardizing training materials and courses; and
- standardizing assessments at the end of training.

Performance of the microscopist refers to his/her accuracy in examining malaria slides in routine practice.

Measuring the performance of a microscopist requires:

- setting performance standards;
- standardizing unbiased cross-checking of slides routinely examined by the microscopist; and
- monitoring performance.

Performance can be improved through:

- effective response to problems;
- consultation visits by supervisors;
- retraining; and
- personal certification.

The relationship between competence and performance is illustrated in Figure 2.

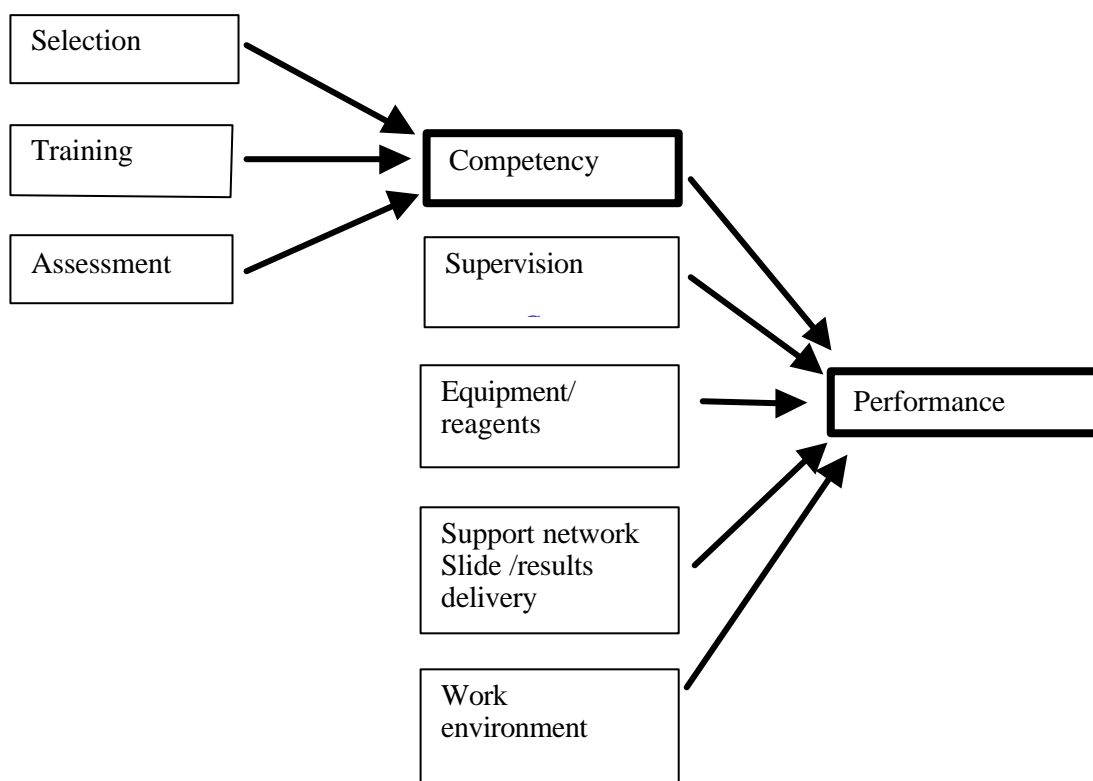


Figure 2. Ensuring and demonstrating good performance in malaria microscopy services

Sections 6.2 and 6.3 provide draft lists of the minimum levels of competency and performance that should be achieved at the five levels of a national QA Programme. The actual levels within a programme will vary according to programme needs and the resources available. WHO will recommend the final levels for national and interregional assessments based on further review and expert opinions.

6.2 Assessment of competence

6.2.1 Defining specific tasks required at each level of the laboratory services

Various tasks should be assigned at different levels of a national QA system (Table 1).

Table 1. Essential microscopy tasks at each organizational level of the national QA system^a

Activity	Village	Primary	Secondary	Region
<i>Blood film preparation</i>				
Collection	+	+	+	+
How to clean slides	+	+	+	+
How to store slides	+	+	+	+
Prepare a thick film	+	+	+	+
Prepare a thin film	+	+	+	+
<i>Staining</i>				
Correct dilution and use of prepared stock of Giemsa stain	+	+	+	+
Prepare stock of Giemsa stain	–	–	–	+
Troubleshoot staining problems	–	–	–	+
<i>Microscope</i>				
Basic cleaning/maintenance	+	+	+	+
Correctly set up a microscope (correct illumination)	+	+	+	+
Correctly use a microscope	+	+	+	+
Troubleshoot microscope problems	–	–	+	+
Perform repairs	–	–	–	+
<i>Slide reading</i>				
Accurately identify trophozoites	+	+	+	+
Accurately differentiate between Pf and non-Pf	+	+	+	+
Identify the species present in the local region	–	+	+	+
Identify all 4 species	–	–	–	+
Identify gametes	–	+	+	+
Identify schizonts	–	+	+	+
Quantify	–	+	+	+
Perform a partial differential count on the thick film—neutrophils, lymphocytes, eosinophils, monocytes and basophils	–	–	+	+
Identify other pathogens	+	+	+	+
Cross-check slides for QC	–	–	+	+
<i>Data</i>				
Record results in a lab register	+	+	+	+
Data analysis	–	–	–	+
<i>Other</i>				
Complete a course in “How to train others”	–	–	+	+
Inventory control—stock management	+	+	+	+
General lab management skills	–	–	+	+
Training in QC—Basic	+	+	+	+
Training in QC/QA—Basic	–	–	+	+
Training in QC/QA—Advanced	–	–	–	+
Computer skills	–	–	–	+
Biosafety/Waste Management	+	+	+	+
Use of referral system	+	+	+	+

Pf, *Plasmodium falciparum*; QA, quality assurance; QC, quality control. N, national level; P, primary diagnostic facility;

Pf, *Plasmodium falciparum*; QA, quality assurance; QC, quality control; R, regional level; S, secondary diagnostic facility; V, village level.

^a As outlined in Section 5.2

6.2.2 Setting competency standards

Table 2. The minimum competency levels that should be achieved at the five levels of a national QA programme

Microscopy Skill	V	P	S	R	N
<i>Sensitivity—trophozoite detection</i>	75%	80%	80%	90%	95%
Specificity—trophozoite detection	80%	85%	85%	95%	>95% ^a
Accuracy of reporting Pf when present	80%	85%	90%	95%	>95% ^a
Quantitation—accurately distinguishing Pf at < 10/field and >10/field	80%	85%	90%	95%	>95% ^a

^aCountry to decide

N, national level; P, primary diagnostic facility; Pf, *Plasmodium falciparum*; R, regional level; S, secondary diagnostic facility; V, village level.

6.2.3 Selection of microscopists

6.2.3.1 Peripheral-level microscopists

Training as peripheral-level malaria microscopists should have two levels, i.e., candidates with no experience and laboratory technicians.

WHO has carried out basic training in malaria microscopy continually since the eradication era. This long experience has shown that health workers from a range of educational backgrounds can be accepted for training as peripheral-level microscopists, and can achieve adequate standards in this field, provided the candidate is interested in the job, and is effectively literate and numerate.

In the past, colour-blindness would exclude candidates from training as malaria microscopists. However, the meeting concluded that no data supported the theory underlying this exclusion. In these circumstances, eyes tests were recommended for trainees only if they experienced difficulties during training.

Table 3. Summary of selection criteria for microscopists and the recommended length of training

Previous qualification	Selection Criteria	Training
Persons with no experience	<ul style="list-style-type: none"> - Literate, numerate (can read/write at a basic level) - If experience difficulties with training, test eyesight 	<ul style="list-style-type: none"> - Minimum 5-weeks training at a level at least equal to the WHO training course - Practical and theoretical examination
Laboratory technicians	None	<ul style="list-style-type: none"> - Minimum 2-week training course - Practical and theoretical examination

6.2.3.2 Trainers

The training of trainers generally has been carried out at the national level, though it also could be an intercountry activity when national capabilities and resources are limited.

Previous training of trainers has concentrated on building a core group of national experts with the skills for training and assessing the competence of laboratory technicians in the basic issues of preparation, staining and examination of blood smears.

In the past, the selection of personnel for training was based on experience working in a malaria diagnostic laboratory and recommendations of the candidates' supervisor. Courses have been 1–2 weeks long. Specific guidelines have not been published for conducting courses to train trainers, which usually have been based on the WHO's basic malaria microscopy manual, particularly the tutors guide.

Details of the recommended practical examinations for potential trainers at the regional and national levels, and their expected performance levels, are in Section 6.2.5.3 and 6.3.1, respectively.

6.2.4 Designing training courses

The workshop recommended that training courses for basic malaria microscopists be based on the manuals produced by WHO (Section 7.2), which also contain suggestions for written examinations. In addition to a written examination, these courses should include a practical examination tailored to the level in the system that the candidate would work following successful completion of training.

6.2.5 Practical examinations

The following practical examinations were recommended:

6.2.5.1 Village level

- Collection of a blood sample, preparation of a slide, preparation of a dilute stain from stock solution and staining of the blood slide.
- Examination of 20 prepared and stained slides for a maximum of 10 minutes per slide. The 20 slides should comprise:
 - 5 negative slides;
 - 8 *P. falciparum* slides with a minimum density of 200 parasites/mm³; and
 - 7 non-falciparum species.

6.2.5.2 Primary and secondary levels

- Collection of a blood sample, preparation of a slide, preparation of a dilute stain from stock solution and staining of the blood slide.
- Examination of 20 prepared and stained slides for a maximum of 10 minutes per slide. The 20 slides should comprise:
 - 5 negative slides;
 - 8 *P. falciparum* slides with a minimum density of 100 parasites/mm³;
 - 6 *P. vivax* slides;
 - 1 *P. malariae* slide; and
 - 1 mixed slide containing *P. vivax* trophozoites and *P. falciparum* gametes.

6.2.5.3 Regional/national levels

- Examination of 20 prepared and stained slides for a maximum of 10 minutes per slide. The 20 slides should comprise:
 - 5 negative slides;
 - 1 slide of an unusual presentation;
 - 1 *P. falciparum* slide with a minimum density of 20 parasites/mm³;
 - 1 *P. falciparum* slide with a minimum density of >50 parasites/mm³;
 - 4 *P. vivax* slides;
 - 2 *P. malariae* slide;

- 1 P. ovale slide; and
- 1 mixed slide.

(Drug pressure effects on parasites will be covered in training, but not in the examination.)

Trainees at this level would be expected to quantitate the presence of parasites according to the following systems:

- 1+/4+ system with an allowable error +/- 1 grade;
- number per white blood cell with an allowable error +/- 50%; and
- number per field with an allowable error +/- 50%.

6.2.5.4 Competency standards for practical examinations

For all these practical examinations, participants would be assessed using the competency standards outlined in Table 2 for the following:

- sensitivity;
- specificity; and
- accuracy, specifically:
 - combination of correctly identifying *P. falciparum* and grading <10 and >10 trophozoites/field for village-, primary- and secondary-level diagnostic facilities; and.
 - combination of correctly identifying *P. falciparum* and grading parasite density for regional and national levels.

(Accuracy in quantitation is assessed for microscopists at the regional/national levels only.)

6.3 Assessment of performance

6.3.1 Defining performance levels

Table4. Draft list of the minimum levels of performance that should be achieved at the five levels of a national malaria microscopy QA programme

Microscopy Skill	V	P	S	R	N
<i>Sensitivity—trophozoite detection</i>	75%	80%	80%	90%	95%
Specificity—trophozoite detection	80%	85%	85%	95%	>95% ^a
Accuracy of reporting Pf when present	80%	85%	90%	95%	>95% ^a
Quantitation—accurately distinguishing Pf at <10/field and >10/field	80%	85%	90%	95%	>95% ^a

^a Country to decide

N, national level; P, primary diagnostic facility; Pf, *Plasmodium falciparum*; R, regional level; S, secondary diagnostic facility; V, village level.

6.3.2 Consultative visits.

6.3.2.1 Importance of consultative visits.

Staff competence is only one of many factors than can affect performance. For example, the majority of poor examination results do not always relate directly to the diagnostic ability of the microscopist. Rather, poor results are often due to:

- personal problems (e.g., family, sickness, etc.);
- poor motivation for a variety of reasons;
- a defectively maintained microscope;
- badly prepared, stored or transported blood slides;
- badly stained blood slides;
- poorly labelled blood slides; and
- an unsustainable workload.

These deficiencies have to be dealt with at the source.

Although on-site evaluations are time-consuming and costly, they are essential to the operation of all QA programmes, because they enable the supervisor to:

- correct incorrect procedures on site;
- relate the conditions of work to the performance of the staff that have been assessed by external cross-checking of slides;
- assess the internal quality-control procedures and the logistical procedures for maintaining equipment and supplies;

- discuss with the technicians and the laboratory management the problems encountered by the laboratory and make improvements on the spot;
- make decisions on training and retraining; and
- build communication with the staff in the routine laboratories.

Because consultative visits are considered so important, malarial microscopy should not be performed at any location where, for whatever reason, such visits are not possible.

While consultation visits are considered the most effective form of continuous monitoring of performance, some issues can reduce their optimal frequency and/or their effectiveness, including:

- cost;
- practicality in certain regions or countries (i.e., remoteness, availability of staff, etc.);
- the skills of the person conducting the consultation visit, which can produce different levels of effectiveness, because not all people have the same interpersonal skills; and
- other factors that can undermine the authority of the consultant in some circumstances, including gender, age, and internal country tensions between different groups.

For these reasons, QC of performance by slide cross-checking remains essential, even with a system of consultation visits (Section 6.4).

6.3.2.2 Frequency

Consultative visits should be:

- conducted at least twice a year;
- conducted more frequently during the first year;
- supplemented with special visits as soon as possible if any problems arise; and
- announced (though depending on conventions in individual countries, consultation visits can be conducted unannounced).

6.3.2.3 Consultants

Staff from at least the next higher level should perform these visits. Staff from the national/regional levels also should periodically visit all levels.

6.3.2.4 What should be done at these visits?

At a minimum:

- The supervisor should complete a checklist of the activities monitored during the visit. (It is recommended that WHO develop, from existing models, a standard generic format for these visits).

- Corrective training should be undertaken, as appropriate.
- Each location visited should have a log book to record all activities carried out. The supervisor should enter details of the visit and comments into this log.
- In addition to completing the log book, the supervisor should provide verbal feedback to the staff on the day of the visit, as well as written reports to appropriate authorities, as soon as possible after the visit.
- Each microscopist should be required to keep all slides for at least 1 month after examination. This allows the supervisor to look at previous slides.

6.4 Cross-checking of routine slides

QC by the cross-checking of slides taken routinely by the laboratory services can be highly demanding on human and financial resources, and requires the establishment of an efficient logistics network.

Implementation of good quality assurance also requires that:

- technicians and the supervisors are motivated, well-organized and well-trained;
- budgeting and availability of funds are adequate to implement the system;
- technicians send the slides to the supervisory laboratory at the designated times, and understand the reasons for sending them;
- the supervisor and the technicians communicate well;
- the supervisor provides prompt feedback of results, so that action can be taken to correct errors (and late reporting loses impact and discourages the technicians); and
- an efficient postal system, or its alternative, is in place to send the samples that should be dispatched according to the national safety guidelines for the transport of blood products.

A system based on the eradication criteria of cross-checking all positive and 10–15% of all negative slides is widely known to create huge workloads for validators, and is unsustainable for most, if not all, developing countries. As such, many countries are looking for a simpler and more cost-effective system.

Recognizing the demands that any system of cross-checking will have on a health system, the workshop participants agreed unanimously that cross-checking was an essential element in the evaluation of a microscopist's performance. Further, the workshop agreed on several other issues:

- Independent cross-checking of routinely taken blood slides must be performed.
- Performing detailed cross-checking during consultant visits is not appropriate. Slides should be taken away and examined in detail later.
- A fixed number of slides should be checked.

- The laboratory performing the cross-checking must select slides randomly, e.g., by nominating all slides ending in a particular digit.
- The microscopy centre being evaluated must not select slides for cross-checking.
- Cross-checking must be performed blindly, i.e., the person performing the cross-check must not know the results at the time of slide reading.

The efficiency of cross-checking will depend on the number of people that are able to perform the validation, the number of microscopists to be validated and their respective workloads (Section 6.5). In most situations, this will require only a small sample of 50–100 randomly selected slides, with the capacity of the programme to quality control the slides determining the number.

A small sample size is perfectly acceptable, provided that the limitations and assumptions of a small sample size are clearly understood. Protocols based on Lot Quality Assurance System (LQAS) tables and the Médecines Sans Frontières (MSF) protocol⁷ offer the possibilities of using small sample sizes. With these approaches, the QC analysis can be performed in a way that allows the reliability of the analysis (confidence in the results) to be expressed statistically. Given the importance of QC, the workshop considered it essential that the accuracy and limitations of these methods are demonstrated. For example, the LQAS table-based method being adopted in the Philippines (Annex 3) aims to detect very poorly performing microscopists for immediate remedial training, while avoiding overloading a limited pool of available validators. This forms part the QA system, alongside periodic refresher training and assessment all microscopists.

Since this process will have a major impact on the microscopist's career, each microscopist should:

- have confidence in the system;
- understand the reasons and the scientific basis for such a method of QC; and
- be able to question the reasonableness of the QC analysis that has been used to assess his/her performance.

6.5 Workload

Excessive workloads are a major contributor to poor performance. As microscopy is tedious and monotonous, the sensitivity of a microscopist decreases when large numbers of samples are processed due to the time-consuming nature of the work. Even highly competent microscopists cannot perform to their best if they do not have the time to correctly examine malaria slides. This problem is compounded where microscopists have responsibilities for diagnosing other diseases.

The workshop reached a consensus that the current WHO recommendation that a person can read satisfactory 60–75 slides per day (Pampana, 1963) is unrealistic today, and fewer slides per day should be recommended. Choosing a number of slides that represents a reasonable

⁷ Médecines Sans Frontières, Holland Quality Control Protocol. See Annex 1.3 for details.

workload for all situations is difficult. The workload capacity of an individual microscopist depends on many factors, including:

- the slide positivity rate;
- the time allocated to reading positive and negative slides, which will be significantly different;
- the balance of accuracy versus efficiency;
- whether the microscopist also collects the samples, and stains and examines slides; and
- other duties besides malaria diagnosis.

For example, if reading a strongly positive malaria slide takes 1 minute, and reading a weakly positive or a negative slide takes 6 minutes, slide-reading capacities can be calculated. (Table 5).

Table 5. Slide -reading capacities, based on a 6-hour working day^a

Slide positivity rate	10%	20%	30%	40%	50%	60%	70%	80%
Slides read/day	7	8	8	8	9	9	10	11
Slides read/hour	44	46	48	50	53	56	59	63

a This does not include the time taken to collect and stain the slides, and report on the results

If the microscopist has to collect and/or stain the slide, the output in slides per day would be reduced significantly. For example, while reading a strong-positive slide might require only 1 minute, the collection and staining of such a slide might require 6 minutes. As a result, the time required to read strongly positive slides will increase to 7 minutes, and for a weak or negative slide the required time will rise to 13 minutes (Table 6).

Table 6. Average slide output of a microscopist if slide preparation and staining is required

Slide positivity rate	10%	20%	30%	40%	50%	60%	70%	80%
Slides read/day	3	4	4	4	4	4	5	5
Slides read/hour	20	21	23	24	25	27	29	31

An acceptable workload, therefore, will vary depending on the context.

The rational requesting of tests by clinical staff is another important issue that affects the operation of laboratory services. Misuse of laboratory services by medical staff wastes scarce resources, and can lead to poor patient care. Guidelines for requesting slides in different epidemiological situations would be useful to improve communication between the clinical and laboratory staff.

6.6 Refresher training

Refresher training was considered essential for maintaining the competency and commitment of microscopists. The workshop made the following recommendations:

⁸ This does not include the time taken to collect and stain the slides, and report on the results

- All persons performing malaria microscopy should have refresher training every 2 years.
- Refresher courses should be at least 1 week long.
- More stringent training on species identification than is taught in basic training courses should be included.
- Depending on the country, refresher courses should include training in quantitation.
- Reassessment of competency by examination every 2 years is extremely important.

6.7 Corrective retraining

If a microscopist's performance is considered poor and proven to be related to unsatisfactory competency (following QC cross-checking and consultative visits when all factors affecting performance have been considered), the following actions should be taken:

- Additional consultation visits should be arranged for corrective training.
- The microscopist should be given 2–3 opportunities to improve.
- As appropriate, formal retraining should be provided (e.g., attending additional training course).
- The microscopist's eyesight should be checked, if possible.

If a microscopist fails to improve after the corrective training, he/she should not be permitted to examine and report on malaria slides.

6.8 Personal certification

Certification has the potential to improve quality assurance, as well as enhance self-esteem and career development, if it is linked to a defined career structure with pay upgrades. However, few country programmes appear to have systems that:

- formally recognize the skill levels of individual microscopists;
- monitor continuing competency; and
- provide a career path.

At best, malaria microscopists seem to receive initial training and are then assumed to be competent for the remainder of their careers. Refresher and more advanced courses are seen as a reward rather than continuing education. At worst, malaria microscopists receive no formal training—they simply learn from others on the job.

Workshop participants unanimously approved the personal certification system that has been implemented in the Philippines and Solomon Islands. In these countries, basic microscopists and supervisory officers are assessed by written examinations after training. Those who score 80% or better are certified as Licensees for Microscopy Practice in the country. They

receive a Malaria Microscopists Registration Booklet, signed by their respective supervisors, which records the history of their training.

A similar system should be developed in other countries, and WHO should assist in this and in the development of clear recommendations.

6.9 How to get clinicians to use laboratory services effectively

The time required for the laboratory to provide the clinician with accurate results of a blood slide examination is crucial to effective treatment, as well as to instilling in patients confidence and satisfaction with the health system. For malaria, providing results within 30–60 minutes is considered satisfactory (Institutes of Medicine, 1991). This not only requires an improvement in laboratory services, but also that clinicians and laboratory personnel work as a team with mutual benefit and respect.

Unfortunately, this mutual respect and confidence often is not evident. The workshop agreed that clinicians frequently misuse malaria microscopic diagnosis by proceeding with treatment despite negative results. This is probably caused in large part by clinicians lacking confidence in the slide results.

Certain measures could improve the situation:

- **Advocacy.** The importance of malaria slide examination for correct diagnosis should be emphasized.
- **Training.** Clinicians should be provided with training and support literature regarding the clinical importance of malaria microscopy examination, and guidelines for their use in different epidemiological situations.
- **Training certificates.** Microscopists should be strongly encouraged to frame these certificates and display them prominently in test centres.
- **Log books.** Personal **certification** log books for individual microscopists would certify their competence.
- **Quality control QC should** be maintained to confirm a continuing high standard of performance. This might not be feasible in poorly funded areas and those where transporting slides from the periphery to the regional laboratories for cross-checking is difficult.

7. SUPPORT MATERIALS AND NETWORKS

7.1 National reference centres for laboratory diagnosis

The workshop recommended that each country establish and maintain a national reference centre within the national health service, or at an associated institute that would provide a core of expertise for the planning, implementation and monitoring of the national QA programme. It should be responsible for establishing national standards for:

- training courses;
- preparation/adaptation of training materials according to local situations and languages;
- assessment of competency and performance of microscopists according to international standards;
- accreditation (certification) of microscopists; and
- laboratory procedures and equipment.

This centre would be the focal point for international contacts, and should strive for international and regional recognition as a centre of excellence.

7.2 Training manuals and bench aids

The WHO training manuals *Basic Malaria Microscopy: Part 1 Learner's Guide* and *Part 2 Trainer's Guide* (WHO, 1991) continue to be extremely useful as training tools for basic microscopy (Annex 3).

The workshop recommended that production of these manuals be continued following minor updating. In particular, the sections on cross-checking of slides, and the objectives and implementation of QA, need to be updated to bring them in line with the recommendations of this meeting.

WHO has produced bench aids for the diagnosis of malaria infections since 1988 (WHO, 1988, 2000). Aimed at laboratory workers responsible for diagnosing malaria by microscopic examination of blood smears, these 12 plasticized plates are designed for day-to-day use in the laboratory. They also can be used as teaching materials. They cover the same topics as those in the *Basic Malaria Microscopy Part 1 Learners Guide*.

Although these bench aids have been very useful for training, the workshop noted wide variations in the way that microscopists from different locations performed the procedures detailed in these bench aids. Thus, the workshop recommended that these be revised to prevent misinterpretation.

Bench aids are not a substitute for comprehensive and specific SOPs since they do not provide adequate detail to allow procedures to be performed consistently without undue allowance for subjective interpretation. For example, the section on counting malaria parasites (Plate 8) does not go into enough detail on how to perform the counting, particularly regarding

the distribution of white blood cells/parasites and how to traverse the film. Another area that causes problems is the statement that "all the characteristic morphological stages of trophozoites, schizonts and gametocytes may be found in the peripheral blood." (Plate 4) Although not technically incorrect, this statement often is misinterpreted to mean that all stages of *P. vivax* must be seen for a diagnosis of *P. vivax* to be made (Lilley, 2004).

The WHO training manuals and bench aids should be available on the Internet following their revision.

7.3 Slide banks

Microscopical diagnosis of malaria is best learned by a repetitive examination of well-prepared and stained examples of the human malaria parasites in thick and thin blood slides. Thus, slide banks of unimpeachable quality with their content validated, ideally by malaria polymerase chain reaction (PCR) tests, are essential.

WHO collected in the field and catalogued large libraries (slide banks) of 2,000–3,000 slides positive and negative, thick and thin films of all stages of the four human species for use by trainees. However, this was discontinued due to the lack of funds and administrative problems in maintaining such a facility.

Such vital libraries of training slides can be acquired by contracting the preparation of the slides, according to SOPs, to those malaria control institutions that have access to the required range of *Plasmodium spp* in the numbers required. These institutions should be capable of providing coded and matching negative slides to make standardized and high-quality slide sets that can be used for training. Adequate funds would have to be provided to support a sustainable service, as well as to ensure that the slides would be collected under the highest ethical standards. Experience has shown that these slides must be cross-checked to ensure the accuracy of the original diagnoses.

Slide banks require experienced staff, teamwork, ethical clearance for the collection of the samples, high-quality supplies and reagents, careful slide preparation, excellent logistical and laboratory support, and an efficient archiving system that allows the practical retrieval of data and slides.

The US Naval Medical Research Unit No. 2 (NAMRU-2) in Indonesia and Hydas Inc. in USA recently developed such a slide bank as part of a project funded by the Malaria Research Centre (MR4) of the US National Institutes of Health. These slides have been produced according to SOPs for their collection, staining and storage, with their diagnoses confirmed by a panel of international experts and in accordance with PCR diagnosis by two laboratories. Twelve sets of 100 slides containing *P. falciparum*, *P. vivax* and *P. malariae* have been produced.

The Centers for Disease Control and Prevention (CDC) in USA also developed a CD-ROM-based virtual teaching/slide bank. It contains slides of the four human species of malaria parasites in thick and thin smears, mixed infections, negative slides, and placental smears, as well as *Babesia spp* and other pathological states, such as sickle-cell anaemia, ovalocytosis and malaria-like artefacts. Although the slides do not show perfect textbook specimens, they represent slides that are typical of those seen in field laboratories. PCR has been used to confirm mixed infections.

The format is:

- more than 200 slides with viewer-controlled captions; and
- virtual microscope slides that can be manipulated in three dimensions by a mouse, which can be used to move the slide and focus the view.

The workshop concluded that:

- slide banks were an essential need;
- slide banks for training should be maintained in each country as part of the national QA programme;
- these national slide banks should be prepared and defined according to national SOPs;
- a validated slide bank maintained at an international level was essential to support assessment of microscopists and to provide well-documented standards;
- electronic slide banks, with their potential for virtual microscopy, were a very useful adjunct to training programmes;
- further development of electronic slide banks and teaching aids should be a high priority for development by WHO; and
- when development of these new aids is completed, they should be available to all interested parties through WHO.

7.4 Equipment and supplies

7.4.1 Standardized lists

The ability to perform high-quality work depends directly on the quality of the equipment and reagents available. The type and standards of equipment and reagents used by countries of SEAR and WPR vary greatly, resulting in many countries needing guidance. Major problems also exist in operating an effective logistics system that can maintain adequate supplies and the equipment in working order.

The workshop, therefore, recommended that WHO develop and endorse guidelines on the equipment and reagents needed to perform malaria microscopy. These should include:

- a list of the minimum quality standards for equipment and supplies;
- specific recommendations for the selection of microscopes; and
- guidelines for assessing the microscopes used in the field to ensure that they are operating correctly.

These guidelines also should consider the different contexts in which national programmes operate.

All equipment and supplies should match nationally or internationally recognized standards. When this is not immediately possible, the equipment should be standardized as soon as possible. The standardization of microscopes (binocular microscopes should be used wherever electricity supplies permit) is essential as this simplifies maintenance, as well as the acquisition and supply of spare parts. Where artificial illumination is difficult, satisfactory blood slide examinations can be made using good monocular microscopes. However, microscopists might not be able to sustain long periods of slide examination due to the eye-fatigue associated with monocular microscopes.

7.4.2 Establishment of a supply chain

The establishment of an effective supply chain is essential to foresee and provide all the equipment and supplies that are needed to sustain an uninterrupted flow of reliable malaria diagnoses. To facilitate this, standard establishment and replenishment lists of equipment should be created. Equipment should be replenished as and when required. However, if rapid replenishment of consumable items cannot be assured, buffer stocks equal to the operational requirements for at least 6 months should be maintained at all levels.

7.4.3 Routine maintenance of microscopes

If the manufacturer's agents are not available to conduct routine microscope maintenance, an in-house staff member should be trained and supplied with ample spare parts. In principle, the spares inventory should include about 50% of the required number of spare oil immersion objectives and 10% of all other replacement parts. In continual and careful daily use, the reasonable life of an oil immersion lens is only 1–2 years, and other parts of the microscope often show marked wear before 10 years. Only premium grade immersion oil—as recommended by the manufacturer of the microscope—should be used. A light administration of xylene should be used to remove excess immersion oil.

7.4.4 Stains and other reagents

Giemsa stain is the most commonly used stain, and the best for routine diagnosis due to its applicability to thick and thin blood. In view of its critical importance in producing high-quality staining, Giemsa stain stock solutions should be bought from a reputable supplier. If this is not possible, the Giemsa stain stock solution should be made up centrally in quality-controlled batches and distributed in-house to the users. One of the critical variables in staining is the pH of the staining solution. Simple handheld pH meters exist and should be available to peripheral laboratories, where more sophisticated equipment is unavailable.

7.5 Standard operating procedures

SOPs are essential for the day-to-day running of all aspects QA process.

Several institutions have published detailed operating procedures for the preparation, staining and examination (WHO, 1988, 1991, 2000; UK General Haematology Task Force, 1997). These can be found on the Internet, for example, on the web sites of CDC and the Royal Perth Hospital (<http://www.dpd.cdc.gov/dpdx/HTML/DiagnosticProcedures.htm> <http://rph.wa.gov.au/labs/haem/malaria>).

While principles of these procedures are similar, some of the details differ. For example:

- Times and methods for drying the slides before staining might differ.

- Giemsa stain is recommended by all sources. However, the British also recommend Field's Stain as an alternative for staining thick smears, as it is more rapid and can produce excellent results if the staining procedure is followed carefully (Gilles and Warrell, 1993). Jaswant Singh Battacharya (JSB) stain is widely used in India.
- The formulae and sometimes the process for making up the buffer solutions might differ, although the correct end points might be achieved. Buffer tablets are widely used in some programmes.
- The concentration of Giemsa stain and the staining times might vary.
- Some sources recommend washing stained slides in tap water, while others wash with the same buffer used for staining.
- The number of microscope fields that should be examined before a slide is designated as negative might vary.

These observations clearly illustrate the need for standardized and unambiguous procedures.

Standardized procedures for all aspects of QA of malaria microscopy do not exist, although the Pan-American Health Organization (PAHO) recommends that a national handbook of procedures be developed (PAHO, 2004).

8. SCALING UP QUALITY ASSURANCE

8.1 The need

Scaling up of malaria QA has become a priority with the increasing use of high-cost antimalarial drugs. Today, QA is linked specifically to the use of ACT, because ideally this combination therapy should be given only to patients in whom malaria has been validated by a laboratory diagnosis that confirms the presence of parasites.

In many countries, QA programmes will have to be rebuilt due to the reduction and, in many cases, the demise of quality microscopy. This rebuilding cannot be achieved without increased investments in financial and human resources. Some countries might be able to provide these resources nationally. However, many others where ACT is an integral part of their antimalarial drug policies will require external assistance from the international community.

8.2 How to proceed with scaling up

Irrespective of the source of these new investments, national programmes will need to develop realistic proposals with credible budgets to convince decision-makers that the benefits to be gained by investing in rebuilding the infrastructures and human resources required to ensure quality malaria microscopy are worth the money.

The rebuilding effort must be based on a phased plan of action, covering at least 5 years and taking into consideration the Millennium Development Goals set for 2015.⁹ The first step of such a plan should be a situational analysis, based on the use of a checklist and a costing tool with specific items related to QA, to determine the status of QA in the country.

Such a checklist might include:

- the objectives of the malaria control programme;
- organization of laboratory services for malaria (e.g., types of laboratories that perform malaria diagnosis, number of microscopists, etc.);
- the status and/or feasibility of integration with other disease programmes, which will depend on the specific objectives of the malaria control programme;
- the role and importance of the private sector in malaria diagnosis and treatment;
- the existence and capabilities of a national reference laboratory;
- capabilities of infrastructure and staff for training and assessing the competence and performance of the laboratory services;

⁹ See <http://www.un.org/millenniumgoals/>

- availability of reagents and equipment;
- capabilities of logistics systems to provide the necessary reagents and equipment regularly, and maintain the latter in working order;
- availability and use of guidelines and SOPs for all activities related to ensuring high-quality malaria microscopy;
- reporting mechanisms;
- organization, status and performance of QA; and
- levels of financial support and their origins.

The importance of malaria QA should be linked to cost savings, as well as case management, showing that improved QA will save costs and lives, while reducing morbidity from other diseases. Such links are extremely important to partners and donors, not least the Global Fund for AIDS, Tuberculosis and Malaria.

8.3 Essential elements for a proposal for funding malaria QA

Continuous interaction between national laboratory experts, clinicians and epidemiologists is essential to the planning, implementation and monitoring of all proposals for improving the QA of malaria microscopy. It should be developed based on a situational analysis as described above.

The essential elements of a proposal are the:

- context;
- objectives;
- constraints to meet these objectives;
- activities to address these constraints;
- timetable of activities;
- budget;
- indicators for measuring progress, outcomes and impact; and
- expected outcomes.

The following is an outline of a hypothetical proposal, which is provided as a guide to countries that wish to develop their own proposals. Some comments are common to all proposals, while others will vary depending on a country's specific situation and objectives.

8.3.1 The context

Descriptions of the:

- national malaria control strategy;
- national antimalarial treatment policy as an essential part of the national drug policy;
- national strategy for malaria diagnosis, i.e., use of microscopy and/or RDTs;
- status of laboratory diagnosis and its QA;
- constraints to implementing quality light microscopy;
- expected contribution of improving QA of malaria microscopy to the goals of the malaria programme and its impact on the current malaria situation; and
- links with other interventions, control programmes and QA systems.

8.3.2 The objectives

A clear and concise statement of the proposal's objective(s) is essential. Here is one possible example: "To establish a national QA scheme for malaria diagnosis that covers at least x%¹⁰ of public and private health care facilities after 5 years."

8.3.3 Requirements to meet these objectives

The proposal should describe the constraints that will be addressed to reach the objectives. These might include the need for:

- strengthening/establishing a national reference centre;
- improving staff competence and performance at regional and peripheral levels;
- external technical assistance;
- developing locally appropriate training materials;
- creating or improving the system for cross-checking routine blood slides;
- improving the motivation of staff;
- improving the quality of reagents and equipment; and
- improving the quality of equipment maintenance.

¹⁰ The percentage will vary depending on the local situation.

8.3.4 Planned activities in support of the objectives

Activities should be feasible and achievable within the time period of the proposal, and are likely to include many essential items in the following lists.

8.3.4.1 National reference centre's infrastructure requirements are likely to include:

- upgrading structural facilities to meet increased requirements and standards for quality assurance;
- developing national pre-service and in-service training programmes;
- developing national slide bank;
- translating, adapting and distributing WHO manuals and guidelines into local languages; and
- developing and distributing national SOPs.

8.3.4.2 Human resources

To increase the number, competence and performance of microscopists, the following details should be provided:

- the number of microscopists and supervisors to be trained each year;
- the methods and length of training; and
- how they will be evaluated.

At the periphery, one multitask-oriented microscopist per 10,000 people should be assumed. This microscopist should read a maximum of 30 slides per day. Additional technicians might be required in areas with many malaria cases.

8.3.4.3 Technical assistance

External expert(s) will be recruited to assist in the:

- development of national SOPs;
- design and implementation of training courses; and
- evaluation of microscopists and their supervisors.

Details of the required skills and tasks to be carried out should be provided.

8.3.4.4 Improving staff motivation

A certification scheme for microscopists and supervisors will be developed. Details of how this scheme will work and be managed should be given.

8.3.4.5 Improving quality and maintenance of reagents and equipment

To improve the quality and maintenance of reagents and equipment, the following steps should be taken:

- A standard checklist of essential equipment and supplies will be developed.
- Logistics systems will be improved to provide the necessary reagents and equipment, and maintain the latter in working order.
- Training in microscope maintenance will be incorporated into basic training for microscopy.

Details on how these activities will be carried out should be provided.

8.3.4.6 Timetable

A timetable should be provided, indicating when each activity will be initiated and completed during the period of the proposal.

8.3.5 Budget

Budgets should be realistic and commensurate with the activities to be carried out within the project period. For details of costing activities see Annex 4 and the WHO's Roll Back Malaria Department (RBM) costing tool (http://rbm.who.int/docs/costing_tool.zip).

8.3.6 Indicators for monitoring progress

Process, outcome and cost indicators should be developed that are linked to each activity/intervention. These should be measurable and achievable and targets set against the Millennium Development Goals for 2015.

8.3.6.1 **Process indicators** can be developed from baseline data obtained from the situational analysis. Key indicators include the:

- number of microscopists/supervisors needed versus actual;
- number of microscopists/supervisors trained or retrained, evaluated and certified as competent;
- number of adequately staffed and equipped health centres; and
- number of microscopists whose performance is judged satisfactory by cross-checking and supervisory visits.

8.3.6.2 **Outcome indicators** could include:

- improvement in microscopists' competency to achieve at least 80–90% microscopic accuracy;
- increase in performance levels, such as a reduced discrepancy rate between microscopist and supervisor following cross-checking;
- increase in the number of patients treated based on confirmed diagnosis versus clinical diagnosis alone (cost-benefit); and

- reduction in the use of ACT in relation to positive and negative patients (taking first year as baseline), as more patients are accurately treated, with a consequent impact on the use of drugs.

8.3.6.3 **Cost indicators** should be used to demonstrate value for money that donors have invested. For example, these might include:

- the cost per correct slide/diagnostic accuracy (unit cost) as a reflection of performance;
- the reduction in the cost of drugs used to treat malaria per patient, and cost of additional drugs due to clinical misdiagnosis; and
- a regular comparison of costs during the project with the costing made during the situational analysis.

8.4 Costing QA programmes

8.4.1 What tools are required for costing QA programmes?

Unfortunately, studies to determine the costs of implementing a malaria QA programme are limited. No studies have been conducted to determine cost-effectiveness and cost-benefits of such schemes. However, the costs of implementing a national QA programme clearly will vary greatly between countries due to a variety of factors, such as:

- specific goals of each country, i.e., malaria control or elimination;
- seriousness of the malaria situation;
- status and effectiveness of the present system; and
- each country's implementation capabilities.

While the capital cost of QA programmes will be high in countries where they do not exist, preliminary studies in Thailand suggest that the implementation costs will be low in others with existing infrastructure and trained staff (Indaratna and Plasai, 2005).

Simple costing tools for malaria need to be developed to confirm this observation and to enhance its political impact with decision-makers. These costing tools (e.g., a spreadsheet template) should be linked to all health care levels to identify a true picture of costs and to identify gaps in knowledge. Guidelines for their use will need to be developed. As this costing tool is used, documented case studies can be developed and publicized to increase the evidence base. Health economists should be involved to enhance the validity.

The WHO Lyon Office for National Epidemic Preparedness and Response Laboratory Strengthening Team is developing such a costing tool and guidelines for its use (Annex 4). The workshop recommended that WHO support these studies, so that the tool can be widely applicable to malaria QA programmes.

8.4.2 What are the expected cost implications of implementing effective malaria QA?

Preliminary evidence from Thailand (Indaratna and Plasai, 2005) indicates that the marginal costs of a QA programme are 1%–5% of the overall national budget for malaria. This

cost seems small for the expected benefits. For countries that need to scale up their QA programmes, short-term costs will be higher. These countries will have to procure and refurbish equipment, and train or retrain microscopists and supervisors. However, this investment should be followed by a significant cost-benefit over the medium to long term as:

- fewer drugs will be used, because treatment will targeted at those in need;
- fewer drugs will be wasted;
- malaria morbidity and mortality will decrease;
- other diseases will be recognized better; and
- health service costs will decrease.

With a modest investment, the potential gains might be substantial.

9. INTEGRATION OF MALARIA QUALITY ASSURANCE WITH OTHER DISEASES

For many years, WHO has recommended the integration of malaria microscopy and its QA with that for other microscopically diagnosed communicable diseases (WHO, 1993, 2000). However, progress has been very limited. While integration potentially has many advantages, it also could encounter many constraints. Thus, the feasibility of integrating malaria QA with QA of other diseases will depend on many factors.

9.1 Potential added value of integration

A single QA system could:

- simplify the administration, logistics of supply of reagents and equipment, reporting and evaluation of the performance of microscopy;
- be less resource-intensive as QA for malaria could "piggyback" on other QA schemes, using existing resources and infrastructures;
- improve other laboratory sectors, including the use of new tests and the supply chain for reagents and equipment, as well as the maintenance of microscopes and other equipment in working order;
- optimize the use of microscopes and other equipment in laboratories with low work loads;
- maintain general proficiency when the workload is low;
- generate more interest for the laboratory technicians, thereby increasing staff commitment;
- provide the same approach and grading for measuring the competence and performance of microscopists, making implementation of a career structure easier;
- require only one budget;
- be easier to monitor and evaluate, making the system more transparent;
- increase attractiveness to donors; and
- save money through reduction of duplication.

9.2 Constraints

Integration of laboratory services, therefore, is an attractive strategy, though one with immediate and practical implementation problems. The constraints include the following:

- Integration must be proven to be necessary and cost-effective, leading to health and financial benefits.

- Implementation requires an integrated management system, including expert advisers in more than one disease, long-term support and commitment from all parties involved.
- Other QA schemes must be persuaded to integrate and work with malaria QA, and vice versa.
- Trained “polyvalent” QA staff who are capable of supervising and evaluating a multidisease QA programme are limited.
- Multidisease supervisors might have problems attaining and maintaining their skills for all diseases, becoming too generalist in their performance.
- Integration might not be feasible in countries with vertical disease-orientated programmes whose objectives are elimination of disease.
- Maintaining high standards across all disciplines and at all levels could be harder than in a system oriented toward a single disease.
- Confusion could be created over the standards required for different disciplines, especially between malaria and tuberculosis.

9.3 Determining the feasibility of integration

The capacity of a country to overcome these constraints will depend on the current objectives of the national disease programmes, the infrastructure, the activities being carried out and the levels of funding of the respective programmes. The feasibility of integration should be determined as part of a thorough situational analysis for scaling up QA (Section 8.2). The following is a guide to the major issues that should be considered in this analysis.

9.3.1 Country-specific objectives and programme organizational factors

9.3.1.1 Are the objectives of the national malaria programme control or elimination of malaria disease?

If the objectives are to control malaria, and if disease surveillance is integrated, integration of QA laboratory services should be considered seriously. However, if the objective is the elimination of disease by a vertical disease-specific programme, integration will be difficult and might not be recommended. Since the goals to be achieved are "absolute," this situation might not be conducive to sharing resources between programmes.

9.3.1.2 Does a laboratory coordination office/group exist at the national level?

If such a coordination office does exist, this implies use of common procedures for laboratories, such as common operating procedures, common methods of supervision and common training of staff. Further, this implies that a common QA programme is ongoing or planned. In this case, malaria will need to fit into this existing system by integrating all of its activities.

If a laboratory coordination office does not exist, specific malaria programmes could be the initial basis for coordination between communicable disease control programmes, taking into consideration that coordination does not always mean integration.

9.3.1.3 Does the political will exist to integrate laboratory services?

Integration should be promoted if the political will to do so is deemed to exist. If not, the benefits and constraints will have to be balanced to develop a feasible strategy for integration.

9.3.2 Factors related to programme activities

9.3.2.1 Are the targeted diagnostic laboratories multidisciplinary or disease-specific?

In multidisciplinary laboratories (which are the most common at the periphery), the same technician will diagnose tuberculosis, malaria, gastrointestinal parasites and other diseases. A common QA programme is advantageous as it targets the same individual, who could be trained in a common multidisciplinary training programme.

In malaria-specific laboratories, integration is not essential. However, if QA of malaria laboratories is established, it could form the basis of laboratory coordination (9.2.1).

9.3.2.2 Does a laboratory QA programme exist?

If a laboratory QA programme is in place, integration of malaria will be easier and should be promoted. However, if such a programme does not exist, malaria could take the lead in establishing such a QA programme (and might be joined later by other programmes/diseases).

9.3.2.3 Are personnel training programmes and an accreditation process ongoing in the country?

If such schemes are in place, integration of malaria is recommended. Evaluation of competency and performance is the essential part of training and accreditation of all QA schemes.

If training programmes and accreditation schemes do not exist, malaria can take the lead in establishing these as components of a multidisease QA programme. Other disease programmes might join later.

9.3.2.4 How are the operating procedures and/or QA manual organized in the country?

If multidisease SOPs or a national QA manual already exist, those for malaria should be integrated within them.

If disease-specific procedures and a malaria QA manual already exist, integration will be much harder.

9.3.2.5 Are multiskilled staff available who are trained, or could be trained, as supervisors of peripheral laboratory technicians as part of an integrated programme?

If multiskilled staff are available, supervision and follow-up will not be a problem. If not, supervision might become quite problematic.

9.3.3 Partnership and funding factors

9.3.3.1 What funds are available for QA in the country?

If substantial funding is available for QA, financing QA of disease-specific programmes is possible. If funds are limited, however, integration will allow economies of scale and joint activities.

9.3.3.2 What are the wishes of the partners/funding agencies?

If the partners and/or funding agencies have a strictly disease-specific focus, integration will be difficult to implement. However, if they are nonspecific or multidisease-based, integration is recommended.

10. IMPROVING COMMITMENT - TOWARDS A CULTURE OF QUALITY

A culture of quality cannot be achieved without a commitment from all those involved in the QA process of malaria microscopy. This ranges from senior administrators and decision-makers in international and nongovernmental organizations (NGO) to national control programmes to the microscopists and clinicians working at the periphery of health services. WHO needs to take a leadership role by recommending QA to policy-makers as part of a global strategy. The culture of quality should start from the top.

Decision-makers need to be given options. However, a small percentage of the malaria control budget (1%–5% of the overall national budget for malaria) appears likely to generate large benefits through improved use of expensive drugs. Evidence-based cost analyses need to be carried out to confirm this observation, and to demonstrate that implementing effective QA schemes for malaria microscopy can yield substantial and real cost savings and health benefits in the medium term.

In addition to highlighting the benefits of a QA programme, managers need demonstrate to decision-makers their capacity for delivering a cost-effective programme by developing realistic budgets commensurate with the activities to be carried out within a feasible time frame. These are the seeds from which a culture of quality can grow.

QA activities must be part of the whole programme (these are well-known mantras of management). Commitment to QA includes explicit elements, such as:

- training and career development;
- recognition and encouragement;
- feedback and better communication for good performance;
- wise use of corrective actions;
- sense of ownership and responsibility;
- teamwork between the laboratory and clinicians, stressing the importance of the lab in case management; and
- certification and benchmarking.

A culture of quality has been achieved when total quality management is in place, and staff at all levels put into practice what they write and write what they actually practice.

11. SUMMARY OF RECOMMENDATIONS TO WHO

Malaria-endemic countries vary widely in resources, in strength and organization of health systems, and in the epidemiology of malarial disease. The appropriateness of alternative strategies for maintaining microscopy quality, therefore, will vary between countries, and between other organizations involved in the management of malaria. WHO can play a role in setting international standards, and providing advice and support for national malaria control services in setting and maintaining standards appropriate for each country. Clearly, WHO needs to increase its activity in this area. In particular:

- WHO should develop a comprehensive strategy for malaria diagnosis in different epidemiological situations. This should include the role of clinical diagnosis, of parasite confirmation by microscopy and RDTs, and of QA.
- WHO needs to take a leadership role by recommending QA to policy-makers and stakeholders as part of a global strategy, showing that it offers the potential for major health and financial benefits to health services and patients.

To confirm the potential benefits, evidence-based cost analyses need to be carried out to document the impact of QA of light microscopy on malaria diagnosis and on the use of combination therapy.

- WHO should develop a comprehensive set of guidelines for all aspects of the QA of malaria microscopy, taking into consideration initiatives that are being taken in other Regions. This should include:
 - developing and endorsing a checklist to be used for all consultation visits to individual malaria microscopists and malaria microscopy centres;
 - recommending that all malaria slides be kept for at least 1 month after examination to allow slides to be reviewed during consultation visits to testing sites, and to allow for slides to be examined retrospectively if problem solving is needed;
 - developing guidelines on problem solving if the performance of a microscopist is unsatisfactory;
 - developing and endorsing guidelines on the equipment and reagents needed to perform malaria microscopy, including minimum quality standards, specific recommendations for the selection of microscopes, and guidelines for assessing a microscope in the field to ensure that it is operating correctly;
- reaching a consensus on:
 - sample sizes and methods of analysis for QC cross-checking of routinely taken slides, with a view to recommending specific QC protocol (or protocols) for malaria slide microscopy; and
 - parasite density reporting (quantitation) systems, with a view to recommending a standard method for country programmes; and

- updating the WHO training manuals *Basic Malaria Microscopy: Part 1 Learner's Guide* and *Part 2 Trainer's Guide* and bench aids in line with the recommendations of this workshop. Once revised, these materials should be made available on the Internet.

WHO should develop and endorse a personal certification system for malaria microscopists, using the current systems in the Philippines and Solomon Islands as a model.

Electronic slide banks, with their potential for virtual microscopy, are a very useful adjunct to training programmes. WHO should prioritize the further development of electronic slide banks. When development of these new aids is completed, they should be made available to all interested parties through WHO.

ANNEX 1: SEAR/WPR JOINT PROJECT FOR A NETWORK TO SUPPORT QUALITY ASSURANCE OF MALARIA MICROSCOPY

1. Background

The organization and capacity of countries in the World Health Organization's (WHO) Western Pacific Region (WPR) and South-East Asia Region (SEAR) to carry out quality assurance (QA) of malaria microscopy varies widely. Implementation and sustainability have become more difficult with the decentralization of health services and reduction in funding in many countries over the past decades. Support from the Global Fund for Aids, Tuberculosis and Malaria (GFATM) in several countries had expanded diagnostic services, enabling these countries to establish pilot QA programmes or modify existing ones.

WPRO collaborated with the WHO Country Office for the Philippines, the University of the Philippines, the College of Public Health and the Research Institute for Tropical Medicine to develop a training/retraining course with participant assessment for national-level microscopists in 2002–2004. This was initially in response to the need to ensure high microscopy standards for research and testing of malaria rapid diagnostic tests. Later, this aimed to assist in the training of trainers for the QA of malaria microscopy. The success of this programme, as well as discussions with a number of countries and institutions of the two Regions, highlighted the potential for a collaborative network to provide independent assessors and trainers, well-characterized blood slides of malaria parasites, and other materials to increase the skills of microscopists and their trainers.

This workshop in Kuala Lumpur, Malaysia provided a forum for countries to discuss their preferences for the function and structure of such a network, and ways to begin implementing its programmes. The agenda did not cover decisions on formal participation in a support network, which national control services will make at an appropriate time.

Representatives from national malaria control services of the Cambodia, India, Indonesia, Malaysia, Myanmar, People's Republic of China, Philippines and Solomon Islands, together with WHO, ACTMalaria and other workshop participants, discussed the proposed network and its functions.

2. Role and function of the network

Workshop participants reached a clear consensus that such a network could provide benefits to most countries concerned (Malaysia was uncertain). These benefits, however, will vary depending on each country's needs and capacities.

Two roles for the network were identified clearly. These were to support:

- external assessment and skills training of top national microscopists; and
- management training for the planning and implementation of national microscopy QA schemes.

Most countries' participants identified the need for both components. Some with greater national capacity for peer review and cross-checking of expert microscopists might not require external assistance for assessment and skills training.

The workshop recommended that the network begin on a small scale with limited activities, and build according to need, experience and available funding in the participating countries.

A number of possible activities under the two broad roles were identified:

- formation of a cadre of independent trainers/assessors;
- development of an interregional slide bank for training and evaluations:
 - A biregional slide bank would be relatively expensive to establish. Therefore, its use should be restricted to external evaluations and training for top microscopists.
 - An interregional slide bank also could be a source of slides of less common species for national slide banks.
 - The slide bank of the Malaria Research and Reference Reagent Resource Centre (MR4) of the United States National Institutes of Health is available at no cost, except for temporary borrowing. Its size is limited and availability might be a problem.
- technical support for establishment of national slide banks:
 - Some countries already maintain national banks to support internal QA and training. Standard operating procedures (SOPs) might be needed to guide the preparation and maintenance of such banks, and external support to establish new national banks.
 - The workshop noted that SOPs for the production of the MR4 slide bank, developed by Hydas Inc. and the US Naval Medical Research Unit No. 2 (NAMRU-2), are freely available on the MR4 web site. These might need some modification for local needs.
- development of self-assessment tools/slides for microscopists, including CD-ROM and web-based slides for microscopists (computer access and the suitability of computer-based materials require further exploration);
- development of a slide validation service to include:
 - a database of expert microscopists for referral;
 - assistance to internal peer review-based QA, where results are unclear;
 - validation of slides for national slide banks where local capacity is limited; and

- capacity to transmit slides over the web, which the WHO Lyon Office Laboratory Strengthening Team is using (though this is likely to be expensive and of limited use).
- facilitation of intercountry visits to gain experience of effective QA programmes;
- development of group access to online training courses and electronic material; and .
- curriculum and material support for national microscopists to train trainers.

The appropriateness of extending external QA to include assessment and training of private sector practitioners and laboratories will vary between countries. In some cases, this might be desirable at a national level, but will be an issue for each national control services to consider.

3. Coordination

The workshop reached a general consensus that ACTMalaria would be an appropriate coordinator or facilitator of the network. The board of ACTMalaria has agreed in principle to this role, subject to the details of operation being determined by the ACTMalaria secretariat and WHO. ACTMalaria's coordination of the network will not exclude countries that are not members of ACTMalaria.

Where training and assessment is provided, the coordinator of the network should be a facilitator, rather than a validator. This distinction was considered important to acceptability and sustainability. A form of certification, or evidence of proficiency provided from outside the country, was considered desirable by smaller countries in particular, as this will assist top-level microscopists in maintaining credibility in national validation and certification processes. However, this should arise from a network that is seen to be coordinated and run by the countries concerned, and to which the countries could contribute personnel and materials.

The WHO Lyon Office's cluster of surveillance and response (CSR) has experience in building networks of laboratories for QA, and is planning to include malaria among its target diseases for these activities. It will be an appropriate body to provide technical support and to guide future expansion of activities. Close cooperation between the network coordinator and CSR should be developed. CSR is in a position to set up an Internet portal to facilitate communication within a network of laboratories, though an appropriate moderator will be necessary from the regions.

4. Training and evaluation of the competence of national-level microscopists

The two types of competence necessary at the national level are:

- expertise in malaria microscopy; and
- expertise in training microscopists and running a QA system.

These two competencies can be addressed through separate training and assessment, or through a combined curriculum, depending on country needs.

The majority of country representatives considered refresher training, external assessment and confirmation of competence of top-level microscopists desirable. Some countries, notably

India, have many senior-level personnel and a national peer review scheme might be more appropriate than external assessment.

Confirmation of competency will involve some kind of standardization of notification of results of assessment. Therefore, this will require uniform standards and materials (slides and course curricula) at each national external QA site. The workshop suggested that the recent external assessments of top-level microscopists in the Philippines be used as an initial model for this. The network should aim to become self-sufficient in terms of trainers/assessors for external QA and slide banks. The former will develop when a sufficient pool of microscopists within the network has demonstrated high proficiency.

5 Funding

The workshop recommended that the network start small and prove success before expanding. WHO will seek further funding to sustain the process, while advocating the inclusion of a budget for QA activities in national malaria budgets and GFATM funding proposals. The current Australian Agency for International Development grant to WHO for this activity is available to start the network on a limited scale.

6 Immediate steps and activities

The following actions and activities should be started immediately to initiate the development of the biregional network:

- Country needs assessments should include:
 - current QA structure and the extent of function;
 - capacity for peer versus external assessment and training of “core group” or top-level microscopists;
 - existing slide banks and training materials; and
 - requirements for the involvement of the private sector.
- National representatives who attended the workshop detailed in this report will discuss these issues with national programme managers.
- ACTMalaria will hold further discussions with WHO before approaching countries.

Existing materials will be used, where possible, to initiate/strengthen malaria QA at the country level. They include training manuals, web-based learning, materials, SOPs for developing slide banks, and international slide banks, etc.

ANNEX 2: STATUS OF EXISTING GUIDELINES FOR QUALITY ASSURANCE OF MALARIA MICROSCOPY

1. World Health Organization (WHO) Region of the Americas.

These guidelines were developed for use in countries of the Americas by a technical group meeting in Caracas, Venezuela in July 2004 (WHO/PAHO, 2004).

Quality assurance (QA) of malaria microscopy in the Americas is carried out predominantly through periodic cross-checking of slides sent from peripheral clinics and hospitals to intermediate reference laboratories and, in some cases, to a national reference laboratory. This system is only partially operational since many countries consider the investments in time, money and human resources to be huge without being able to fulfil its objectives.

A. Essential elements of the system

The essential elements of the proposed system are:

- **Assessment of human resources.** All staff in the malaria diagnosis network will be trained properly and certified according to national guidelines. National reference laboratories will carry out grading of competency (certification), though an internationally recognized certification is proposed for the future.
- **Handbook of procedures.** The National Reference Laboratory will prepare a handbook of procedures for microscopical diagnosis of malaria, in compliance with prevailing national standards. These include the processes of preparing, staining, examining blood slides, their transport and handling under nationally approved blood safety recommendations, and all aspects for the implementation of internal and external QA.
- **Internal quality control** All laboratories must carry out internal quality control according to the procedures in the national handbook for procedures. The head of each malaria reference laboratory must ensure systematic compliance with the norms for internal quality control. In peripheral clinics and hospitals, the laboratory technician must assume this responsibility.
- **External quality assurance.** External quality control should be carried out at all levels of the national laboratory network. In turn, the National Reference Laboratory should be subject to external quality control by an international laboratory.

External QA of staff of all intermediate laboratories and those at the peripheral clinics and hospitals will be subject to national assessment by three processes:

- **Performance evaluation.** This will be carried out through their analysis of known, but coded, banks (panels) of high-quality blood slides, representing all species present in the region, different parasite densities, mixed infections and negative slides. The National Reference Laboratory will prepare these according to standardized procedures, and will send them not less than twice a year to each laboratory where microscopists are to be assessed. The results of these tests will be sent to the National Reference Centre for comparison with the known identities of each slide.
- **Cross-checking.** The intermediate or National Reference centres will handle this indirect quality control of the results of slides prepared, stained and analysed by each laboratory. The guidelines propose that laboratories should submit to the higher level all of the slides processed during a fixed evaluation period (e.g., 1 month per year). This period might vary from year to year, depending on the results of a particular laboratory and the number of slides examined. In the checking laboratory, one person will select at random 50 positive and 50 negative slides belonging to the month being

evaluated. If less than 100 slides are being processed in the month, all slides should be evaluated. (It is not clear from the draft if this applies to the laboratory as a whole or to each microscopist.) The evaluation also will include the quality of the slides and their preparation.

- **Supervision.** Based on the results of the external quality assessments, staff from the higher-level laboratories will visit the peripheral and hospital laboratories periodically to correct faults, check on the internal quality control and identify training and retraining needs. Supervision reports will be sent to the laboratories concerned and the National Reference Centre.

B. Implementation

Implementation will be gradual and consensual, taking into account the structure and development of the laboratory and service networks. It will be based on a situational analysis, the proven strengths in each country, and a plan of action based on the principles outlined above.

2. WHO Eastern Mediterranean Region

The WHO Eastern Mediterranean Region (EMR) strategy for laboratory is to:

- ensure QA of microscopy in countries where malaria has been or is being eliminated, as well as in areas where it is less prevalent (low endemic);
- use rapid diagnostic tests in special situations, such as for the screening of travellers and immigrant workers; and
- use light microscopy in countries with moderate and high transmission initially for the confirmation of epidemics, monitoring therapeutic efficacy, following cases of severe malaria in hospitals. Light microscopy also will be used in epidemiological surveys to increase the coverage of laboratory services where feasible, prioritizing areas of moderate transmission and integrating with services for tuberculosis.

An analysis of the status of QA of light microscopy for malaria was carried out in 2001. QA programmes for malaria microscopy are said to exist in 84% of the countries. Despite changing priorities of malaria control, they are still based on the principles of eradication. The responsibilities for such programmes rest with primary health care in some countries, with the malaria control programme in others, and with both services in a third of the countries. Microscopes are available on more than 90% of hospitals and malaria clinics, but only in 30% of primary health care clinics. The private sector is a major source of laboratory diagnosis for malaria in more than 70% of the countries. QA in EMR is generally poor, and has the same shortcomings that are experienced in other regions of WHO.

Guidelines for the QA of malaria microscopy are being developed, following a workshop on QA of laboratory diagnosis of malaria in Teheran in 2001 (WHO/EMRO, 2002). A draft of these guidelines (WHO/EMRO, 2003), which was available to this meeting, proposes a three-tiered administrative system:

- **National QA coordinator.** This person should be a senior laboratory technologist working within the central offices of the ministry of health as a focal point for malaria QA, but also responsible for expanding the service to include a number of other diseases.

- **Regional laboratory technologists.** These persons would be responsible for the supervision and monitoring of activities to maintain the quality of the district and peripheral laboratories.
- **QA team at district and peripheral laboratories.** Wherever possible, this level should include all staff whose work is impacted by the laboratory. Thus, the team should include not only the microscopists, but also the clinical, support and management staff. This team should be responsible for internal quality control of the laboratory operations, and for providing solutions to the day-to-day problems that lead to poor QA. The skills necessary to develop such a QA team will be acquired through in-service training and short 3–5 day training programmes for QA teams from several laboratories, organized at the regional country level.

The guidelines also propose that:

- the private sector, including nongovernmental organizations, should be incorporated into this public sector system;
- a national microscope servicing system is established either within the government system or through private contracts;
- although three monthly evaluation visits by the regional laboratory technologists is a convenient approach for the external assessment of each laboratory, their actual frequency should be tailored to match the ongoing situation; and
- standardized operating procedures should be adopted for all steps of the QA process. To aid countries, the guidelines provide details of the equipment and supplies required for each laboratory and the maintenance of microscopes, as well as procedures for taking, staining, examining, storing and transporting blood smears. These are based on information provided in WHO's *Basic Malaria Microscopy Manuals* (WHO, 1991).

3. Médecines Sans Frontières (MSF) Holland Quality Control Protocol (MSF-Holland, 2004)

Médecines Sans Frontières–Holland operates more than 70 laboratory services in 23 countries. The services provide health care for a wide array of diseases, such as HIV, tuberculosis, malaria, Human African Trypanosomiasis, and kala-azar, as well as general health care.

This scheme is the only one that incorporates QA of malaria microscopy with that for other diseases. The protocol provides uniform methodology for measuring malaria thick blood film sensitivity and malaria parasite identification (based on the presence or absence of *P. falciparum*), the sensitivity of *Mycobacteria* (tuberculosis) quality, the diagnostics of kala-azar (direct agglutination test, spleen and lymph node aspirates), diagnostics for malaria and human immunodeficiency virus (HIV). Further tests are being added progressively to the proposed QA/quality control (QC) package that includes:

- the QA/QC protocol;
- pre- and post-analytical tools;
- laboratory inspection assessment tools;

- standard operating procedures (SOPs);
- laboratory workshops; and
- field communications network.

The objectives of the protocol are to provide a uniform QC guideline, minimize the QC workload, and allow the bench marking of QC performance of all laboratories as a management tool. The guidelines are considered to be the minimum, although MSF encourages missions to perform additional QC provided this does not compromise the quality of the procedures used and affect the stringency of cross-checking the required minimum number of samples.

Under field conditions, compromises have to be made between the feasible and the ideal. The protocol is based on the principle that it is better to perform less QC but perform it well, than perform more frequently but of a poor standard.

It also depends largely on cross-checking by laboratory staff working in peripheral laboratories, rather than by external reference laboratories. Essentially, this is internal QC, but the proposed checking is performed thoroughly and blindly (i.e., the cross-checkers must not know the reported results of the samples before cross-checking them).

The general procedure is as follows:

- Each month the laboratory supervisor selects an equal number of positive and negative slides for cross-checking. Ten slides is the minimum, but more can be selected provided the capacity to check all slides accurately is available. In situations where fewer than 10 slides are examined per month, all slides should be checked. Negative slides are selected randomly, whereas the positive ones to be checked are randomly selected only from the weekly positive slides (i.e., classified as +/-, 1+ and 2+, according to the WHO recommendations). (WHO, 1991)
- Slides selected for quality control are then cross-checked blindly by the laboratory staff, or externally by a reference laboratory, another laboratory (such as another MSF laboratory), an expatriate laboratory specialist or a national supervisor. Cross-checking should be done as soon as possible after the end of each month, and the results should be available preferably within 2 weeks and not later than 4 weeks after the original diagnosis. Cross-checking should approach the "gold standard" as closely as possible. When a discrepancy is found between the original and cross-checked readings, the discrepant slide should be reread by the cross-checkers. If the original microscopist and the cross-checker disagree, the slide should be read by a third microscopist.
- The results are recorded in a standard manner in a 2x2 table. The percentage agreement is calculated, and the results reported to laboratory staff and users of the laboratory. Using a supplied MSF Excel analysis programme, the lower 95% confidence interval also is calculated and reported to Amsterdam for benchmarking as soon as the results become available.
- Analysis for benchmarking will be performed on the results of the required minimum slides selected each month. If a laboratory performs QC on more than the minimum number of slides, only the results of the minimum are used for benchmarking calculations (to allow uniformity of analysis between all MSF mission sites).

- The aggregated results from all MSF laboratories are returned to participating field laboratories, allowing individual laboratories to assess their performance against all other MSF testing centres. Individual laboratories are not identified in these aggregated results.

SOPs for randomizing the selection and calculation of 95% confidence intervals values are provided in the guidelines. MSF recommends that all QC blood slides are kept for at least 6 months. Ideally, all laboratory slides should be kept for more than 12 months, though fungus in high humidity conditions can reduce the practical storage time for slides. If keeping all slides is impractical, then every attempt should be made to keep QC slides/samples in special conditions for at least 6 months.

These guidelines will be field tested for 6 months and revised accordingly.

ANNEX 3: SLIDE SELECTION FOR VALIDATION BASED ON LOT QUALITY ASSURANCE TABLES

(Philippine Ministry of Health/WHO draft protocol)

The Philippines is facing a rapidly increasing number of microscopists, as well as an overloaded and poorly performing national slide quality assurance (QA) scheme based on extensive slide validation. (Department of Health, Manila, University of the Philippines and WHO/WPRO, 2004) In response, the Philippines is piloting a system based predominantly on periodic assessment and refresher training, supplemented by a validation of a reduced number of slides determined on the principles of the Lot Quality Assurance System (LQAS), which aims to detect major failures for urgent remedial training. This method of selecting slides for validation allows selection of a small number of random or consecutive slides sufficient to detect poor performance with a known degree of probability. Slides are selected irrespective of the initial microscopy result, the total number being determined using LQAS tables according to the prevailing parasite prevalence and the desired power to detect a certain failure rate. Assuming 10% prevalence and aiming to detect failures below 80% sensitivity and 100% specificity for presence of parasites with a 95% confidence interval, 96 (100) randomly selected slides are required annually from a microscopist seeing 1 000 or less negative slides per year, 103 (120) if seeing 1 001 to 5 000 (Table A3.1).

Table A3.1. Slides required for validation based on modified LQAS method

Expected negative slides/year	5%	10%	15%	20%	25%	30%
200	107	72	54	43	36	30
500	154	89	62	48	39	31
1000	180	96	66	49	40	33
5000	208	103	69	50	40	33

Under this method, a peripheral microscopist is no longer required to store positive and negative slides in different boxes. Instead; slides are stored sequentially by laboratory number regardless of positivity. The sample size depends on the slide positive rate (SPR) and the total number of negative slides processed each year (Table A3.2).

Table A3.2. Slides to be validated based on a SPR of 10% in the Philippines.

Slides examined per year	Slides needed to be cross-checked per year
Less than 1 000	100 (2 boxes)
1 001–5 000	120 (3 boxes)

If this method was applied in a country with a national slide positivity rate of 10%, and where the average annual workload for peripheral microscopist is around 2 800 negative slides, only 120 slides would need to be rechecked during the year. These can be selected randomly or consecutively, and may be spread over the 12 months (i.e., 40 every 3 months).

The participants of the workshop agreed that cross-checking slides is an important element of external quality control of peripheral-level microscopy, where the prime objective would be to detect a high number of errors in their routine work. In this case, the LQAS-based method appeared appropriate and less cumbersome to operate compared to conventional earlier procedures. The workshop considered that, at SPR of 10%, it could be expected to yield representative results regarding positive and negative slides. However, it might be less sensitive in the assessment of the accuracy of species diagnosis. The workshop also suggested that the statistical basis of LQAS be explained in an annex to the proposal, because it might not be easy to convince laboratory personnel who do not understand statistics that a few slides are sufficient to indicate the reliability of a microscopist's performance.

Such methods aimed at detecting major failures in a system, rather than grading competence, are appropriate where more stringent cross-checking cannot be maintained. This is the case of many health systems in malaria-endemic countries, where the workload imposed on senior microscopists by more traditional methods of cross-checking is unsustainable. The meeting noted that the method proposed in the Philippines is inadequate for QA in fairly well-established and "resourced" laboratories at the provincial/regional level, and at more peripheral levels of some nongovernmental organization systems, where the criteria for error need to be more stringent. Therefore, a two-tiered QA system has been suggested. Methods that only seek to identify major failures (e.g., LQAS table-based) must be backed by regular supervisory visits and refresher training, as the Philippine scheme proposes.

ANNEX 4: COSTING TOOL FOR QUALITY ASSURANCE OF MALARIA MICROSCOPY

WORKING DRAFT

This draft costing tool has been developed by the World Health Organization (WHO) Lyon Office for National Epidemic Preparedness and Response Laboratory Strengthening Team, in collaboration with the WHO Roll Back Malaria Department in Geneva, taking into consideration the recommendations of this workshop. It is provided as a model to guide national programmes in preparing realistic budgets for the establishment and implementation of quality assurance (QA) programmes for malaria light microscopy. It demonstrates the potential costs of establishing a QA scheme in Malaysia. This is given as a hypothetical example.

Each country will need to produce its own individual "costings" based on a situational analysis. The costs of implementing a national QA programme for malaria microscopy will vary greatly between countries, depending on factors such as the programme's objectives, the epidemiological situation, available infrastructure, and feasibility of implementation.

Further details of the costing tool can be obtained from the WHO/Roll Back Malaria web site at <<http://www.rbm.who.int>>

MALARIA EQA PROGRAMME COST SUMMARY

Considered country:	Malaysia
Date:	24/05/2005

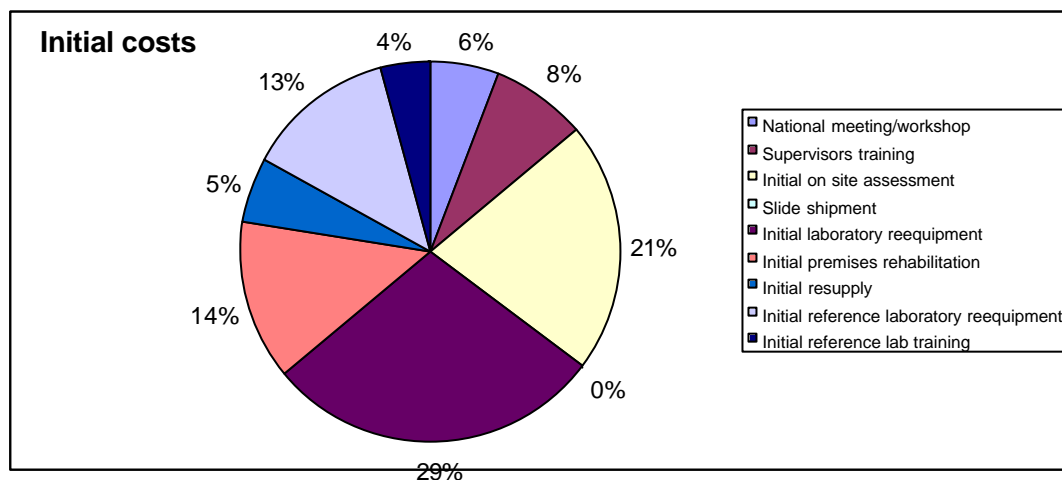
1- Initial costs 295,562 USD

Initial assessments	104,100 USD
National meeting/workshop	17,000 USD
Supervisors training	24,000 USD
Initial on site assessment	63,100 USD
Slide shipment	0 USD

Peripheral laboratory level	141,248 USD
Initial laboratory reequipment	85,120 USD
Initial premises rehabilitation	40,000 USD
Initial resupply	16,128 USD

Reference laboratory level	50,214 USD
Initial reference laboratory reequipment	38,214 USD
Initial reference lab training	12,000 USD

Total initial costs: 295,562 USD

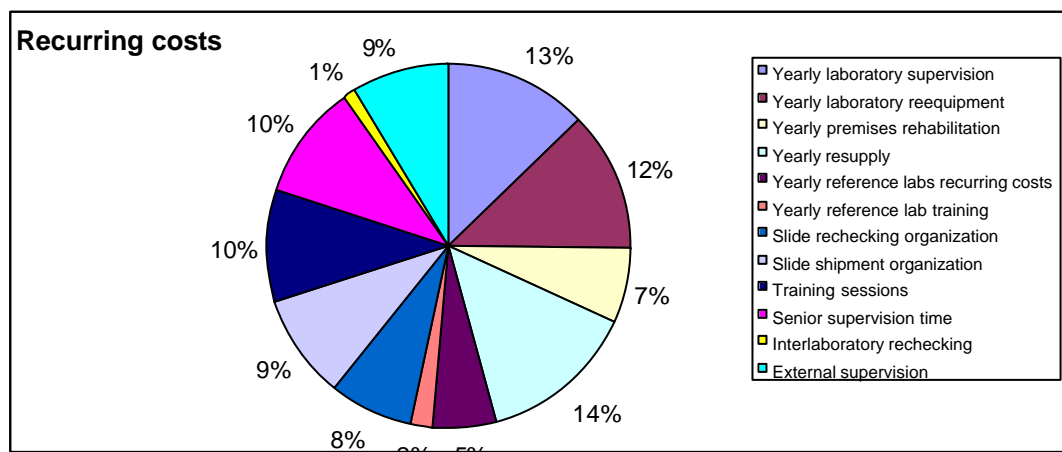


2- Recurring costs 453,565 USD

Peripheral laboratory level	220,184 USD
Yearly laboratory supervision	61,100 USD
Yearly laboratory reequipment	59,584 USD
Yearly premises rehabilitation	32,000 USD
Yearly resupply	67,500 USD

Reference laboratory level	233,381 USD
Yearly reference labs recurring costs	26,202 USD
Yearly reference lab training	10,000 USD
Slide rechecking organization	36,000 USD
Slide shipment organization	44,000 USD
Training sessions	48,000 USD
Senior supervision time	48,404 USD
Interlaboratory rechecking	5,276 USD
External supervision	41,700 USD

Total recurring costs: 453,565 USD



3- Indicators

Total costs per inhabitants under risk

# inhabitants under malaria risk	4,000,000		
	USD	Per inhabitant	Per periph. lab.
First year (initial +recurrent)	749,127 USD	0.19 USD	1,873 USD
Other years	453,565 USD	0.11 USD	1,134 USD

Total costs per slide

total # of slides performed (+15% contingency)	230,000	
		Cost per slide
First year (initial +recurrent)	749,127 USD	3.26 USD
Other years	453,565 USD	1.97 USD

Total training cost

	USD	# week/person
Cost for one supervisor training	1,200 USD	2
Cost for one lab technician training	300 USD	1
Cost for one staff from ref lab training	417 USD	1

Total reference laboratories costs

Initial reference laboratory reequipment	38,214 USD
Initial reference lab training	12,000 USD
Yearly reference labs recurring costs	26,202 USD
Yearly reference lab training	10,000 USD
External supervision	41,700 USD
Total	128,116 USD

per inhabitant*	0.032 USD
per lab	320 USD

Total reference laboratory and supervisors activities

Supervisors training	24,000 USD
Initial on site assessment	63,100 USD
Yearly laboratory supervision	61,100 USD
Slide rechecking organization	36,000 USD
Slide shipment organization	44,000 USD
Training sessions	48,000 USD
Senior supervision time	48,404 USD
Total	324,604 USD

per inhabitant*	0.081 USD
per lab	812 USD

* inhabitant under malaria risk

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