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CDC

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The Global Fund To Fight AIDS, Tuberculosis and Malaria

IMaD Improving Malaria Diagnostics

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

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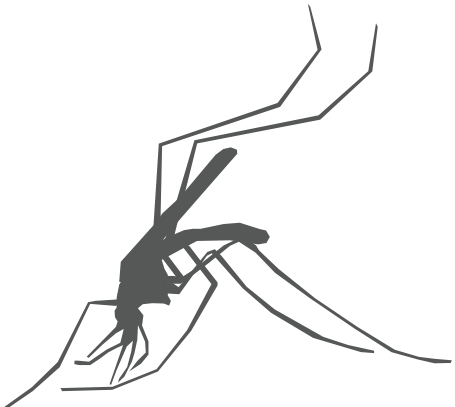
UNIVERSAL ACCESS TO MALARIA DIAGNOSTIC TESTING

AN OPERATIONAL MANUAL



Universal access to malaria diagnostic testing

AN OPERATIONAL MANUAL

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Foreword

The last decade has witnessed an unprecedented increase in funding for malaria control efforts, which has resulted in a massive scale up of malaria prevention efforts, primarily through the use of long lasting insecticide treated bednets and indoor residual spraying with insecticides. These measures (along with intermittent preventive treatment in pregnancy) are estimated to have saved more than 735,000 lives in 34 African countries over the past 10 years. Yet malaria remains an enormous public health problem, responsible for 781,000 deaths a year, most of those among African children less than five years of age. Given that malaria is now an entirely preventable and treatable disease, this represents a senseless tragedy.

One of the reasons for this continued burden is that improvements in access to prompt diagnostic testing and effective treatment of confirmed malaria have lagged behind prevention efforts. Last year, the WHO Global Malaria Programme issued revised guidelines for the treatment of malaria in which it was recommended that all suspected cases of malaria receive a diagnostic test prior to treatment.

In many settings, especially in Africa, this represents a real paradigm change. For far too long, fever has been equated with malaria throughout most of the continent. Now, for the first time, that is changing in many places. With effective and widely deployed prevention measures, the proportion of fevers due to malaria is falling rapidly. The availability of inexpensive, quality-assured rapid diagnostic tests for malaria means that parasite-based diagnosis is now not only achievable at peripheral health care facilities, but also at the community level.

Despite scattered data (and innumerable anecdotes) to suggest that health workers (and patients) will not pay attention to the results of such tests, and that they want antimalarial treatment for every fever, the truth is that most people do want to know what is wrong with them, and that health workers want to provide the best care they can for their patients. Ultimately, providing an antimalarial medicine to someone who has pneumonia, or a urinary tract infection as the source of their fever, is both bad medicine, and bad public health. The indiscriminate use of artemisinin-based combination therapies risks fostering the spread of *Plasmodium* resistance, especially to medicines partnered with the artemisinins.

The scale up of diagnostic testing offers unprecedented opportunities to strengthen health systems in several ways. First, timely and accurate surveillance based on confirmed, rather than suspected cases, is now possible. As malaria transmission continues to fall, such local data are essential to appropriate and effective malaria programme management. Second, the introduction of diagnostic testing allows for improved treatment of the many non-malarial febrile illnesses that are consequently "unmasked" at both facility and community level. For this reason, close collaboration with Maternal and Child Health services in the scale up of malaria diagnostic testing is essential, especially through integrated management of childhood illnesses (at the facility level) as well as integrated community case management.

While achieving universal access to malaria diagnostic testing will not be easy, some countries have already shown that is can be done. In Senegal, following the introduction of malaria RDTs in 2007, malaria diagnostic testing rates rose rapidly from 4% to 86% (by 2009); the prescription

of ACT dropped throughout this period from 73% of malaria-like febrile illness to 32%, reaching close equivalence to confirmed malaria (30% of 585,000 suspected fever cases). More than 500,000 courses of inappropriate ACT prescription were averted.

This operational manual is the result of the work of many people across diverse agencies and organization, a testimony to the importance of diagnostic testing in overall malaria control efforts. We hope that this manual will provide critically useful information to National Malaria Control Programmes and their partners as we work together to reach the health-related Millennium Development Goals, as well as our ambitious goal of near-zero deaths from malaria by the end of 2015.

Robert D. Newman, MD, MPH
Director, Global Malaria Programme
World Health Organization

Abbreviations

ACT	artemisinin-based combination therapy
PCR	polymerase chain reaction
RDT	rapid diagnostic test
WHO	World Health Organization

Acknowledgements

The manual has been developed from a draft framework document jointly prepared by the WHO Global Malaria Programme (WHO/GMP) and the US Centers for Disease Control and Prevention (CDC) in 2009, named "Malaria Diagnosis: An Operational Guideline for Strengthening Malaria Diagnostic Services". This document was shared in March 2010 with the members of the diagnostic work-stream of the Roll Back Malaria Case Management Working Group, to serve as a basis for further development into a new inter-agency manual on universal access to diagnostic testing of malaria. The initial group involved M. Aidoo (CDC Atlanta, USA), L. Barat (USPMI, USA), D. Bell (WHO/GMP), L. Benavente (MCDI, USA), A. Bosman (WHO/GMP), V. D'Acremont (Swiss TPH); P. Hamade (MC, UK), J-M. Kindermans (MSF, Belgium), S. Meek (MC, UK); M. Montague (MC, UK), B. Moonen (CHAI, Kenya), D. Orozco (MSF, Netherlands), D. Schellenberg (LSTMH), M. de Smet (MSF, Belgium), E. Streat (MC, Uganda), J. Van Erps (RBM), and D. Zurovac (KEMRI, Kenya). It was agreed to create a common repository of existing recent operational manuals developed by different agencies, and all agencies/interested groups were invited to upload – to a common WHO sharepoint – documents developed to support the large scale implementation of malaria microscopy and RDTs. As a result, the initial repository included 5 national diagnostic guidelines from Sub-Saharan African countries, 27 WHO technical documents, manuals and training materials, 10 WHO/FIND reports, manuals and training materials, as well as 30 working documents, SOPs, EQA guidelines from Ministries of Health of endemic countries, international NGOs and academic institutions. The full list of resource materials, including additional which were identified during the process of development, is provided at the end of the text. V. D'Acremont, WHO/GMP Consultant based at Swiss Tropical and Public Health Institute, was nominated as the main writer of the document. She identified 6 major areas of work for a drafting committee to convene and work on the framework document on the basis of the additional resource materials identified: A) Policies, regulations and levels of use; B) Algorithm for malaria testing and treatment; C) Quality control/assurance at point of use (emphasis on RDTs); D) Planning and organisation of training; E) Monitoring and evaluation of program outcomes; and F) Methods of RDT quantification and stock management. The drafting committee was convened by WHO/GMP on 6–7 July 2010, and attended by the following resource persons which worked on each of the themes defined above: A): C. Asiimwe (FIND, Uganda), J. Carter (AMREF, Kenya), K. Sim (NMCP, Cambodia), and S. Thiam (NMCP, Senegal); B): L. Barat (USPMI, USA), V. D'Acremont (WHO/GMP), and L. Muhe (WHO/CAH); C): D. Bell (WHO/GMP), L. Benavente, B. Hailgeorgis (ICAP, Ethiopia), and E. Streat (MC, Uganda); D): W.A. Butt (WHO, Afghanistan), J. Luchavez (RITM, Philippines), S. Mkude (NMCP, Tanzania), and S. Schwarte (WHO/GMP); E): J-O. Guintram (WHO/IST, Burkina Faso), Prudence Hamade (MC, UK), B. Hamainza (NMCP, Zambia), and M. Msellem (NMCP, Zanzibar); F): A. Bosman (WHO/GMP) and D. Orozco (MSF, The Netherlands). Based on the inputs received by the drafting committee, V. D'Acremont prepared the first draft of the WHO inter-agency manual on universal access to diagnostic testing of malaria and this was shared with a larger review group 3 weeks before a WHO Technical Consultation to finalize the "Inter-Agency operational manual for universal access to malaria diagnostics", held in Geneva on 25–26 October 2010. In addition to the members of the writing committee the following reviewers were invited to provide comments: J. Carter (AMREF, Kenya), J-P. Clark (World

Bank), S. Cognat (LQMS, WHO Lyon Office), A. Goliusov (World Bank), A. Kabalo (DHMT, Zambia), M. Khalid (NMCP Sudan), D. Klarkowski (WRAIR consultant), S. Logez (Global Fund); M. McMorrow (CDC Atlanta, US), J. Namboze (WHO/AFRO), N. Ngongo (UNICEF, NY), C. Perez Casas (Global Fund), H. Reyburn (LSTMH), S. Schwarte (WHO/GMP), J. Sillah (WHO/AFRO), P. Stannard (JSI Inc, USA), M. Trudeau (Shell foundation, Philippines), and N. Whitehurst (MCD, USA). This review meeting provided extensive inputs to the first draft, and, as a result, V. D'Acremont prepared the second draft of the manual. This second draft was shared by email on 25 January 2011 to all members of the drafting committee and of the review group and, in addition, was sent for comments to all WHO Regional Advisers for Malaria. Additional suggestions for improvement were received by the following resource persons, whose constructive contributions are gratefully acknowledged: M. Aidoo, C. Asiimwe, L. Barat, D. Bell L. Benavente, A. Bosman, J. Carter, S. Cognat, J-O. Guintram, R. Newman (Director WHO/GMP), W. Kazadi (WHO, Solomon Island), D. Klarkowski, C. Ohrt (WRAIR), P. Rogers (WPRO), S. Schwarte, J. Storey (former WHO staff), E. Streat, S. Top (WHO, Cambodia) and M. Trudeau.

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Glossary

Accreditation: Procedure by which an authoritative body formally recognizes that a body or person is competent to carry out specific tasks.

Certification: Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements.

Competence: Knowledge, skills, abilities and attitudes at a level of expertise sufficient to perform in an appropriate work setting; this should be a measurable standard.[1]

Combination rapid diagnostic test: Malaria rapid diagnostic test with more than one test line, detecting *P. falciparum* as well as other malaria species (in different combinations).

Diagnosis: The process of establishing the cause of an illness (for example, a febrile episode), including clinical assessment and diagnostic tests.

Diagnostic test: Diagnostic tool (technique) used to confirm or exclude the presence of a disease

Diagnostic test performance: Capacity of a test to confirm or exclude a disease; a combination of the sensitivity and the specificity of a test that by definition does not depend on the prevalence of the disease in the population tested.

Internal audits: Set of activities organized by a laboratory or health facility staff to effectively and systematically monitor work carried out internally.

External quality assessment: Set of activities organized outside a laboratory or health facility (by external supervisors or an external quality provider) to effectively and systematically monitor work carried out, including not only proficiency testing but also validation of the results of routine blood slide and on-site supervision.

Laboratory: A place where technicians are equipped to perform medical tests on clinical specimens, not including health workers in a health facility or community health workers performing rapid diagnostic tests only.

Level of health-care system: Level of administrative decision-making in a health-care system, not the hierarchical organization of health facilities (primary, secondary or tertiary) or the geographical distribution (central, peripheral).

The central level generally corresponds to the national level; however, in some (often big) countries with a federal system, many central decisions are taken at state level rather than at federal level.

The subnational level is any level between the central and the point-of-care level; countries may have multiple administrative structures at this level (governorates, regions, provinces, districts, counties).

[1] Adapted from Harvey L. Analytic Quality Glossary, Quality Research International, 2011. Available at: http://www.qualityresearchinternational.com/glossary/competence.htm

The point-of-care level corresponds to the places at which medical care is delivered to patients; it includes all health facilities (from referral hospitals to the smallest peripheral health facilities) as well as community health workers.

Lot (of rapid diagnostic tests): A lot (or batch) is defined as a production run in which particular batches of monoclonal antibodies and nitrocellulose were used. Each lot is usually identified by a number by the manufacturer and usually consists of 40 000–80 000 tests.

Lot testing: Quality control testing of a product lot (batch) after release from the manufacturing site.

Malaria: Disease caused by infection of red blood cells with *Plasmodium* parasites, with fever as the commonest presenting sign.

Malaria infection: Presence of *Plasmodium* parasites in blood or tissues, confirmed by the presence of parasites in peripheral blood by microscopy, malaria antigenaemia by rapid diagnostic testing or parasite DNA or RNA by polymerase chain reaction (PCR).

Malaria test: For the purposes of this manual, a rapid diagnostic test (RDT) for malaria or microscopic examination of a blood slide (thick or thin smear) for malaria parasites; PCR is not included, as this manual focuses on tests used for the management of patients.

Panel detection score: Main measure (score between 0 and 100) of performance used in WHO product testing of malaria RDTs, corresponding to the percentage of times a malaria RDT gives a positive result on all tests from both lots tested against samples of parasite panels at a specific parasite density (i.e. four tests at 200 parasites per microlitre, two at 2000 parasites per microlitre). It is not a direct measure of RDT sensitivity or specificity.

Parasite density: Number of asexual parasites per microlitre of blood, detected by microscopic examination of peripheral blood films. Any level of parasite density can lead to clinical illness.

Plasmodium antigens: Antigens produced by malaria parasites and detected with RDTs; the antigen concentration depends on the parasite density in peripheral blood and the total parasite load (including sequestered parasites); may also vary with parasite species, stage of parasite life cycle, duration of infection, host immunity and other factors.

Proficiency testing: Inter-laboratory comparisons organized regularly to assess the performance of analytical laboratories and the competence of the personnel. In such programmes, multiple samples are periodically sent to laboratories for analysis or identification, and each laboratory's results are compared with those of other laboratories, with an assigned value and reported to the participating laboratories and others.

Quality assurance: All processes involved in ensuring that results obtained with a tool are as accurate as the tool is designed to be (all diagnostic tools have limitations). Addresses all factors that affect diagnostic performance, including test performance by health staff, internal audits, external quality assessment, microscopy equipment and reagent quality, quality of RDT devices, storage and transport of RDTs, use of test results by clinicians, workload, workplace conditions, training and staff support and community perception.

Quality management system: System to direct and control an organization with regard to quality.

Quality monitoring: All activities involved in ensuring that the diagnostic tests continue to conform with established specifications during storage, distribution and use; part of quality assurance.

Quantification: Estimation of the quantities and frequencies of supplies necessary to meet demand in a specific area, avoiding stock-outs and over-stocking.

Sensitivity: For diagnostic tests, proportion of patients with the disease who have a positive result in the test being evaluated, determined from the results of the reference or 'gold standard' test; ranges from 0% (bad performance) to 100% (optimal performance).

Specificity: For diagnostic tests, proportion of patients without the disease who have a negative result in the test being evaluated, determined from the results of the reference or 'gold standard' test; ranges from 0% (bad performance) to 100% (optimal performance).

Testing site: Any place in which malaria tests (RDTs or microscopy) are performed in the context of the clinical management of patients.

Test performer: Health worker or laboratory technician performing and interpreting an RDT or preparing, staining and examining a blood slide by microscopy.

Universal access: For malaria diagnostic tests, all sick people who fulfil the definition of a suspected malaria case have access to a reliable malaria test, administered by a trained health worker at a health facility or community health centre. Does not include asymptomatic people in the context of strategies for eliminating malaria.

Preamble

The aim of this interagency manual is to provide policy, strategy, technical and operational guidance to countries wishing to strengthen or set up routine malaria diagnostic services. These services include the use of both microscopy and rapid diagnostic tests (RDTs) at all levels for the management of febrile patients by health workers and are integrated within other national programmes for strengthening laboratory services.

This operational guide is primarily for national, provincial and district health and laboratory managers in ministries of health and malaria control programme and for the managers of other health agencies, nongovernmental organizations and faith-based organizations working with national health authorities to strengthen malaria diagnostic services.

The manual starts with a section on programme aspects (section 1), followed by descriptions of the policies and guidelines that are needed in a programme to strengthen malaria diagnostic testing (section 2). The various activities are then described (sections 3–7), with the different aspects of monitoring and surveillance (sections 8 and 9). Strategies for particular settings are briefly proposed in section 10.

Although the general approach is directed to programme management, some sections and tools might be useful for designing training materials and standard operating procedures for health professionals (doctors, nurses and health officers) and laboratory staff (scientists, technicians and microscopists) working in programmes for the diagnosis and treatment of patients with malaria. Most of the tools are described in the annexes to this manual.

This manual is a synthesis of important issues published previously, presented in an accessible format, and is intended to give a practical approach to establishing a reliable system for malaria diagnostic testing. References to WHO publications available online, which provide more detailed information, are listed throughout this manual and in the annexes. The manual is intended to provide general guidance, which may help countries to prepare or revise their operational manuals by involving national health authorities and technical partners active in this area of work. For example, the manual makes reference to health facility support to community health workers in conducting malaria diagnostic testing at community level. These sections might not be relevant to all countries.

The aim of the manual is to stimulate the development of malaria diagnostic testing and management, not as a vertical programme but integrated with activities at various levels of the health system. A key condition for its success is that malaria diagnostic testing not be practised on its own but as one component of the management of febrile patients, including causes of fever other than malaria.

Experience in several countries (Burkina Faso, Ghana, Nigeria, Papua New Guinea, Uganda, the United Republic of Tanzania (including Zanzibar) and Zambia) has shown that, with good training and support, health workers adhere to the results of malaria tests and treat only positive patients. This manual provides technical guidance on who should be tested for malaria and how. This is a major shift from other criteria for deciding who should be treated for malaria. It aligns the management of malaria with that of any other disease for which a reliable diagnostic test is

available. When the terms 'RDT' and 'microscopy' are used in a recommendation, it is considered as implicit that the tests are quality assured and therefore that they provide reliable, reproducible results in line with their technical characteristics.

When not explicitly mentioned, the statements in the manual apply to all *Plasmodium* species (*falciparum* and non-*falciparum*).

This manual is intended to be read comprehensively, although some sections and tools given in the annexes can stand alone.

Introduction

Why is parasitological diagnosis of malaria necessary?

An essential component of malaria control and elimination strategies is prompt, accurate diagnosis and treatment (within 24 hours of onset of illness) of patients with an effective medicine. The process of diagnosis is initiated by a suspicion of malaria on the basis of a defined set of clinical criteria, which may vary with the level of malaria endemicity and the types of non-malaria fevers in the area. Diagnosis is then confirmed by a laboratory test: either a blood film for microscopy or a rapid diagnostic test (RDT).[1]

The clinical presentation of malaria is one of the least specific of all the major diseases. The causes of fever can range from non-serious viral infections to serious, life-threatening conditions that require immediate, appropriate treatment. Malaria infection can coexist with other life-threatening conditions, such as pneumonia, which also require urgent, appropriate treatment, especially in young children. When managing a febrile patient, it is therefore impossible to know if the condition is due to malaria or another disease solely on the basis of the clinical presentation. For optimal treatment and to save lives, an accurate diagnosis is therefore essential. Confirmatory malaria diagnosis is even more vital in areas with successful malaria control programmes, where the malaria incidence is declining and the likelihood that malaria is the cause of fever is reduced, to make sure that antimalarial medicines are not used inappropriately and that other conditions receive the correct management.

Parasitological testing is the only way to diagnose malaria accurately in febrile patients. Treatment based on diagnostic testing is good clinical practice and has many advantages over presumptive treatment of all fever episodes:

- improved care of parasite-positive patients because of confirmation of infection;
- identification of parasite-negative patients, in whom another diagnosis must be sought and treated accordingly;
- avoidance of antimalarial medicine use in parasite-negative patients, which reduces side-effects, drug interactions and selection pressure for drug resistance, potentially resulting in financial savings;
- better public trust in the efficacy of artemisinin-based combination therapy (ACT) when it is used only to treat confirmed malaria cases; and
- better public trust in diagnosis and treatment of non-malaria causes of febrile illness.

Since early 2010, WHO has recommended prompt parasitological confirmation by microscopy or an RDT for all patients suspected of having malaria, before treatment is started. Treatment solely on the basis of clinical suspicion should be considered only where parasitological diagnosis is not accessible.[2]

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[1] *Guidelines for the treatment of malaria, second edition*. Geneva, World Health Organization, 2010. Available at: **http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf**

[2] Not available within 2 hours of the patient presenting at a point of care.

The prevalence of malaria in a wide range of settings, its aspecific clinical presentation, which overlaps with that of many other diseases, and the acute and life-threatening nature of the disease require universal access to parasitological diagnosis, i.e. extension of malaria diagnostic services to all levels, up to the community. The aim of testing a sick person for malaria is not just to confirm the presence of an infection with *Plasmodium* but to decide on the appropriate treatment: a positive result indicates that an antimalarial medicine should be given, and a negative result indicates that no antimalarial medicine should be given. As a general principle (valid for any laboratory diagnostic test), the benefit of testing is lost if clinicians decide not to use a test result as a basis for treatment.

Accurate malaria diagnosis can also greatly improve the reliability of surveillance data. With the progressive deployment of diagnostic testing, the number of recorded malaria cases is changing dramatically: in places where the majority of reported malaria cases had been diagnosed only on the basis of clinical suspicion, there is an apparent decrease in the number of cases because an increasing proportion of reported cases are accurately diagnosed. In many places, these trends are combined with a real decrease in malaria incidence due to effective control efforts, as in Senegal.[1]

New momentum in malaria diagnosis with the availability of RDTs

High-quality microscopy services for the diagnosis of malaria are not widely available, especially at the community level, where access to malaria diagnosis and treatment is needed. Microscopy requires trained staff, well-maintained equipment, a regular supply of reliable reagents, clean water and electricity, and a well-executed quality management system. Where the training of microscopists, equipment and reagents are substandard, the microscopy services are almost always of poor quality. In many countries, ensuring quality management of microscopy at all levels of the health-care system has not been feasible.

For these reasons, the development, in the early 1990s, of a simple immunochromatographic test to detect malaria parasite antigens in a fingerprick blood sample was a major advance. RDTs do not require water, electricity or laboratory facilities and can easily be performed in remote rural settings. Although training and regular supervision is as essential for RDT as it is for microscopy, the performance of RDTs and interpretation of their results require less training and experience than microscopy, and diagnostic performance does not depend on the availability of trained laboratory technicians. This new tool allows widescale access to diagnostic testing, which could not be done with microscopy alone. The use of RDTs, with treatment given only to parasite-positive patients, has shown to be safe in recent studies, including for febrile children under 5 years of age living in remote, highly endemic areas.[2] RDTs thus provide an opportunity for accurately diagnosing malaria even in this vulnerable group.

When well-trained and supervised health workers use RDTs of high quality, clinicians can be confident about the reliability of the test result and the safety of withholding antimalarial treatment in test-negative patients,[2,3] thus reducing unnecessary consumption of antimalarial medicines. Health authorities must therefore select RDTs with high diagnostic performance, as assessed in product testing by WHO and the Foundation for Innovative New Diagnostics, which are appropriate for local conditions. Health authorities must also ensure correct management of the supply chain, including transport and storage, effective training of health workers and regular on-site supervision of both clinical and laboratory staff.

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[1] *World malaria report 2010*. Geneva, World Health Organization, 2010. Available at: **http://www.who.int/malaria/world_malaria_report_2010/worldmalariareport2010.pdf**

[2] D'Acremont V et al. Withholding antimalarials in febrile Children who have a negative result for a Rapid Diagnostic Test. *Clinical Infectious Diseases*, 2010, 51:506–11.

[3] Njama-Meya D et al. Treatment of malaria restricted to laboratory-confirmed cases: a prospective cohort study in Ugandan children. *Malaria Journal*, 2007, 6:7.

The availability of RDTs should also be used as an opportunity to improve the quality and availability, where needed, of microscopy; they should not replace microscopy. It is therefore essential that both decision-makers and health workers clearly understand the indications for use of each type of test.

Integration of diagnostic testing for malaria with laboratory services

In most malaria-endemic countries, malaria diagnostic services are part of the general healthcare system. Therefore, strengthening parasitological diagnosis of malaria is an opportunity for strengthening the national laboratory services, in close cooperation with the national coordinating body for all laboratory services in the country.

Integration of diagnostic testing for malaria into the general management of fever

A diagnosis of malaria is only one possibility in the management of a patient presenting with fever. To really improve the quality of care of these patients, WHO promotes an integrated approach.

One of the greatest challenges for a clinician working in a malaria-endemic area is managing a febrile patient who does not have malaria. Clinicians are more likely to adhere to the results of a malaria test when they can perform a comprehensive assessment of the patient to identify and treat other diseases. For this to be effective, additional diagnostic tools must be available to health workers, which are appropriate to the setting, including clinical diagnostic equipment and additional laboratory tests such as urine dipsticks. The appropriate medicines for treating common causes of fever (e.g. antibiotics for pneumonia, oral rehydration salts and zinc for diarrhoea) should also be available.

The training of health workers should include not only malaria diagnosis but also the overall management of fevers on the basis of the range and frequency of other causes of fever in the area. When available, training should include all nationally approved clinical and laboratory decision algorithms for the management of diseases other than malaria. As universal access to parasitological diagnosis of malaria is scaled-up, close coordination with programmes for patient management, such as Integrated Management of Childhood Illness (IMCI), Integrated Management of Adolescent and Adult Illness (IMAI) and integrated Community Case Management, are essential, so that algorithms are appropriately modified for quantification of medicines and supplies. Training health workers in non-malaria febrile illnesses is especially important to avoid unnecessary prescription of antibiotics, which leads to the development of bacterial resistance.

Use of RDTs or microscopy should therefore not be planned as a separate activity run by the national malaria control programme but should be fully integrated into case management programmes, as part of overall efforts to strengthen laboratory services. At central level, the national malaria control programme and the general laboratory services should work in close collaboration, as many activities, such as quantification, procurement, training, supervision, quality management, monitoring and maintenance, require close coordination. Communication and coordination between different focal points are also important at subnational and point-of-care levels.

Types of tests appropriate for parasitological diagnosis of malaria

Routine parasitological confirmation of malaria is based on either identification of parasites in blood films examined by light microscopy or detection of parasite antigens with RDTs. Other diagnostic tests, such as polymerase chain reaction (PCR), may be used in certain situations, such as for identifying morphologically similar species (*Plasmodium malariae* and *P. knowlesi*),

for efficacy testing to distinguish new infections from relapses and recrudescences and in specific elimination and containment projects, but these tests are presently not indicated for the case management of fever. Serological tests for malaria have no place in the management of febrile patients.

Microscopy and RDTs both show adequate performance in the diagnosis of malaria in febrile patients.[1,2] Each test has characteristics that make it useful in particular clinical situations or settings. Therefore, in most countries, both are needed. In all circumstances, setting up an effective quality management system for both microscopy and RDTs should be considered indispensable to ensure the accuracy and reliability of the programme. The introduction of RDTs is thus an opportunity to review and strengthen the entire system for managing the quality of general laboratory services, of which malaria diagnosis is a significant part.

[1] Ochola L.B et al. The reliability of diagnostic techniques in the diagnosis and management of malaria in the absence of a gold standard. *The Lancet Infectious Diseases*, 2006, 6:582–588.

[2] *WHO technical consultation: Parasitological confirmation of malaria diagnosis, 6–8 October 2009.* Geneva, World Health Organization, 2009. Available at: **http://whqlibdoc.who.int/publications/2010/9789241599412_eng.pdf**

1. Programme planning and management

The ultimate goal of a national malaria control programme is to provide universal access to accurate malaria diagnostic testing for all patients suspected of having malaria. In most countries, this will not be possible in a single step, and a careful plan should be established, with strategies and timelines to reach full coverage and priorities set by region, health-care level (e.g. health facility, then community level) and sector (e.g. public sector, then private sector). The plan must subsequently be adapted to the results of monitoring and evaluation.

Strengthening parasitological diagnosis of malaria might be an opportunity to strengthen the existing national laboratory services. An integrated approach should be encouraged, and both the national malaria control programme and other relevant public health programmes should contribute to strengthening the health-care delivery system, coordinated through the structure for coordinating laboratory services in the ministry of health.

1.1 Terms of reference for the national coordination group on malaria diagnosis

The role of the national programme is to coordinate the planning, implementation, monitoring and evaluation of malaria diagnostic services. This should ideally be done by a national diagnostic committee, led by the national laboratory services. The programme should therefore establish such a committee and prepare its terms of reference.

The national diagnostic committee (or an already established group or committee could be used) should comprise the main groups involved in strengthening malaria laboratory diagnosis, including the national reference laboratory, relevant disease control programmes (e.g. national programmes for malaria, tuberculosis and HIV/AIDS), the relevant public health programmes (e.g. Integrated Management of Childhood Illness (IMCI), Integrated Management of Adolescent and Adult Illness (IMAI), integrated Community Case Management), local health authorities, academic and research institutions with expertise in malaria diagnosis, funding, procurement and implementing agencies involved in malaria diagnosis, and the national regulatory authority for assessing diagnostic devices. This committee should ensure the coordination of all malaria diagnostic activities, including both strengthening malaria microscopy and introducing and deploying RDTs.

Terms of reference for the national diagnostic committee should be prepared, for defining the roles and responsibilities of each stakeholder in:

- reviewing and updating policies and guidelines;
- preparing and overseeing implementation plans;
- coordinating the activities of multiple partners;
- regularly reviewing progress and monitoring activities; and
- resource mobilization, partner coordination and preparation of a budget.

1.2 Situation analysis and gap identification

One of the first steps is to conduct a situation analysis, focusing on the status of malaria diagnostic testing and existing barriers to setting up a diagnosis programme and implementing activities. This step is useful not only for gathering information but also for promoting interactions and exchange of information among different stakeholders. The analysis should address the following:

Epidemiology and infrastructure

- malaria mapping and stratification: type of parasite species present in the country, level of endemicity by province or district, epidemic-prone zones, non-endemic areas and areas at risk for reintroduction of malaria;
- health system organization and mapping, including the number and level of laboratories in the public and private sectors;
- laboratory infrastructure, staffing and management;[1]
- number and type of reference laboratories (including research institutions);
- health facility infrastructure, staffing and management;
- community health workers: organization of work, activities, referral and supervisory structures, resources and other support systems;
- common practices of use of diagnostic tests: recent data on diagnostic use in the public and private sectors and community level, if available; and
- access to care: cost, distance, availability, access, vulnerable groups, cultural and religious factors

Policies and regulations

- current policies, regulations and practices, with specific attention to blood-testing devices;
- malaria case definitions, clinical algorithms and treatment guidelines;
- laboratory quality management system status;
- medical equipment management practices and policies: equipment and equipment maintenance, spare parts, maintenance tools; and
- health technology assessment practices and procedures

Training and supervision

- levels of training and career structure of clinical and laboratory staff; numbers of staff trained; training resources;
- quality of pre-service training curricula for health workers and community health workers;
- supervision of clinical and laboratory staff: ongoing activities and available resources; and
- in-service training programmes for health workers and community health workers

Logistics and documentation

- supply chain management and logistics information system;
- safety and waste management;

[1] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009. Table 3, page 21. Available at: **http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf**

- health management information system;
- malaria surveillance system, reporting and data management;
- health system communication and networking;
- health development partners and focus of activities; and
- available resources, including all health development partners, and resource mobilization plans.

Information collected during the situation analysis and the gaps that are identified should be compiled into a report that can be referred to when evaluating the outputs of the diagnosis strengthening programme.[1]

- Identify gaps and constraints in all the above aspects of malaria diagnostic services and the need for strategic and policy changes and new regulations.
- Identify national targets and priorities, in particular regarding malaria diagnostic testing.
- Map resources and time requirements for addressing all priority gaps and bottlenecks in scaling-up. If relevant activities such as malaria programme reviews have been completed recently, the information can be used to identify resource requirements.
- Use all this information to prepare a plan of action (see section 2.4).

1.3 Roles and responsibilities

This section defines roles and responsibilities at different levels in a country (as defined in the glossary): central (national), subnational (provincial or district) and point-of-care (health facilities or community). Issues relating to the private sector are discussed under the subnational level.

The focal points for malaria diagnosis at each level should oversee both microscopy and RDT activities. They should work closely with the person in charge of managing the laboratory services and coordinate their activities with the people responsible for training clinicians in the management of malaria and of fever in general.

Table 1 gives general indications of areas of responsibility. These may vary in some countries. As part of the rapid assessment of roles and responsibilities in the situation analysis, it is important to identify those that are specific for the context of each country.

1.3.1 Central level (national)

The activities described below are generally under the responsibility of departments or agencies at national level and should be coordinated through the national laboratory services. Depending on the health system of the country, however, some of these roles will be filled partially by entities at provincial or even district level.

A focal person responsible for malaria diagnosis should be identified within the national malaria control programme, in close coordination with the national laboratory services. The roles and responsibilities of the focal person should be clearly defined. He or she should facilitate a funded national coordinating mechanism through the national committee on malaria diagnosis to promote integration of activities, including those conducted by the national malaria control programme, the national reference laboratory and key stakeholders, and to facilitate information-sharing and overseeing of the activities of the different partners.

[1] *Malaria programme reviews: a manual for reviewing the performance of malaria control and elimination programmes, trial edition, March 2010.* Geneva, World Health Organization, 2010; Annex 5.6. Available at: **http://www.who.int/malaria/publications/atoz/whomprmalariaprogramperformancemanual.pdf**

Table 1. Areas of responsibility by level of the health system

Area of responsibility	Central (national)	Subnational	Point-of-care: health facilities	Point-of-care: community
Planning	Annual national operational plan of activities	Regional plan of activities	Plan for internal quality assurance and community health worker supervision	
Policy development and dissemination	Updating and harmonizing policies			
Product selection and procurement	Selection of RDTs, microscopes, stains and related supplies; quantification	Compilation of requests for supplies from local quantification	Quantification and requests for supplies	Quantification and requests for supplies
Transport	From central store to regional warehouses	From regional warehouse to health facility	From health facility to community health workers	
Storage and stock management	Central warehouse	Regional warehouse	At health facility	Appropriate storage place
Maintenance	Medical equipment management policy and maintenance tools	Medical equipment maintenance	Medical equipment maintenance	
Quality management system	National reference laboratory, training in quality management, monitoring of subnational reference laboratories, accreditation schemes for microscopists, proficiency testing and/or slide validation, request for lot-testing of RDTs	Regional reference laboratory, slide validation, visits to malaria testing sites, direct observation of microscopists and health workers performing RDTs	Internal audits of laboratories Internal audits of RDT performance	
Training (pre- and in-service)	National standards, training curricula, training materials, planning, funding, coordination and facilitation of courses	Facilitation of training courses	Selection of health workers, community health workers and other staff for microscopy and/or RDT training	
Testing			Performance of RDTs and/or microscopy	Performance of RDTs
Advocacy, communication and social mobilization	Strategy development, production of materials and messages adapted to local context	Planning and implementation of community sensitization activities at district level	Sensitization of patients in health facility and dissemination of health education materials for use by community health workers	Sensitization of patients and community members
Supervision	Standard tools and reporting format, evaluation of supervisory system and overall performance	Planning and implementation of on-site supervisory visits of health facility and community health workers and feed-back	Supervision of community health workers (when relevant)	
Private sector	Licensing and monitoring of private health facilities and private laboratories, quality control of private suppliers	Inspection, supervision and training of private health facilities and laboratories, quality control of private suppliers	Procurement, testing, storage of commodities and internal quality control	

Table 1. Continued

Area of responsibility	Central (national)	Subnational	Point-of-care: health facilities	Point-of-care: community
Monitoring and evaluation	Choice of indicators, tools for data collection, data management, analysis and use for programme implementation	Data management, analysis, feed-back and use for remedial action at health facility level	Data recording, feed-back and use for remedial action at community health worker level (when relevant)	Data recording, action on feed-back
Budgeting and resource mobilization	Resource mobilization and preparation of full national budget to cover all activities	Resource mobilization, compilation of regional or district budget requirements for all activities	Compilation of budget requirements for health facility activities	

Policy development

The role of the national level is to devise malaria diagnostic policies that are integrated into national and treatment policy and regulations, as the basis for practical guidelines for health workers. The malaria diagnostic policy should be reviewed and updated regularly in the light of new developments and changing malaria endemicity, harmonized with other relevant, approved policies and regulations related to malaria control, integrated case management, community health care, laboratory services, private health care and disease surveillance systems.

The review and elaboration of a malaria diagnosis and treatment policy will reveal issues requiring harmonization and updating in different policy documents. It must therefore be conducted in an inclusive national coordinating mechanism. The role of the national or central level is therefore to ensure that policies and guidelines are up to date, available and followed. The full aspects of policy, regulation and technical guidelines are addressed in section 2.

Planning

At national level, annual plans of action should be prepared, with clear objectives for activities based on policy direction and the national strategic plan, responsible partners, timelines, budgets, staff resources, sources of funding and monitoring indicators. The national strategic plan for malaria control should include the components needed to achieve universal access to diagnostic testing. If the strategic plan already exists and does not include these components, a working group or task force should be identified to prepare this component.

Strengthening of malaria diagnostic capacity must be linked to the health sector development plan, especially regarding health infrastructure and distribution of laboratory services, human resources and systems for quality management of laboratories. The national plan of action will be strongly influenced by the availability of human, material and financial resources. A phased approach, depending on the priorities of the government and the availability of resources, is recommended. The phases should be defined and articulated; for example, first, all health facilities in priority districts; then, all health facilities in the remaining districts; then, the community level. Phased implementation will also allow expansion of activities on the basis of local experience and identified solutions.

For elaboration of the national plan for strengthening malaria diagnosis, one or more workshops should be held. In some countries, the national malaria control programme has strengthened the involvement of various partners through technical working groups by including some of the following technical areas within the plan of action:

- regulatory requirements and diagnostic services;
- resource mobilization, partner coordination and budget;

- procurement and supply;
- malaria diagnosis in the context of the management of fever;
- promotion of good diagnostic practices in the private sector;
- training, supervision and a quality management system;
- safe disposal of waste and sharps;
- advocacy, communication and social mobilization;
- monitoring and evaluation; and
- operational research for updating country-specific regulations, policies and practices, e.g. use of RDTs by medicine vendors, incentives or user fees and waste disposal at community level. However, local field studies to specifically assess the sensitivity and specificity of RDTs should be discouraged (see section 3.1.1).

Once these components have been elaborated in detail, a plan of action, timelines and budget requirements can be prepared. An example of an implementation plan with detailed activities is given in section 2.4.1.

1.3.2 Subnational level

Depending on the country, the subnational level will correspond to provincial and district levels, or, in some countries, further administrative units. The role of the subnational level may be similar to that of the national level, except for policy updating and procurement, which, for the public sector, are generally centralized.

The specific role of the subnational level is to provide:

- regional reference laboratory services to laboratories and RDT testing sites in a designated area;
- supervision and external quality assessment of public and private health institutions and providers in the designated provinces or districts;
- training and remedial action in the designated provinces or districts;
- laboratory support services for outbreak investigation; and
- advocacy to the central level for budget support.

Although responsibilities vary from country to country, the subnational level should also provide:

- appropriate storage facilities for laboratory and RDT supplies and supply chain management;
- transport, handling and distribution of the supplies;
- cool chain distribution of temperature-sensitive products (RDTs);
- contingency response to stock-outs;
- maintenance of laboratory equipment and replacement of spare parts;
- a regional or district plan for safe disposal of waste and sharps;
- coordination with national-level staff to schedule training, such as workshops, for health workers;
- a locally appropriate advocacy, communication and social mobilization plan for community sensitization and education;
- data management for monitoring and evaluation for the designated province or district; and
- financial planning and management for the designated province or district.

The subnational level should also ensure that private hospitals and clinics, faith-based organizations, nongovermental organizations and private medicine vendors:

- are trained according to national requirements and guidelines;
- adhere to national guidelines (in particular, treatment based on the malaria test result);
- procure and use approved equipment, reagents and RDTs according to national regulations;
- monitor that consumers have access to affordable, appropriate RDTs, ACT and medicines to treat non-malaria fevers;
- are regularly inspected by the appropriate health authorities;
- complete and submit data for malaria surveillance according to procedures recommended by the health authorities;
- participate in national external quality assessment programmes for malaria testing; and
- safely dispose of infectious waste and sharps.

1.3.3 Point-of-care level: health facilities

The role of health facilities is to:

- provide malaria microscopy and RDT diagnostic services;
- provide supplies and support supervision and monitoring of lower-level facilities; and
- ensure disease surveillance and participate in outbreak investigations.

In health facilities with a significant number of health workers but no functioning laboratory service, it may be appropriate to nominate a focal point for RDTs (who could for example be also the focal point for other rapid diagnostic tests, such as for pregnancy, HIV and syphilis) to ensure good follow-up and continuous internal monitoring of staff performing RDTs or using RDT results.

The role of the point-of-care level is to:

- ensure that malaria testing, patient management and follow-up adhere to national guidelines (in particular that results are used to guide patient treatment);
- ensure that malaria test results and treatment are recorded in patient registers and reported to a higher level as part of an appropriate surveillance system;
- keep laboratory supplies in appropriate storage conditions with temperature monitoring (where possible) and recording;
- maintain all medical equipment according to national guidelines;
- quantify the supply needs for the health facility to cover a specified period (including safety stock requirements) and for community health workers served by the health facility;
- if microscopy is done, keep a predetermined number of blood slides for quality management (validation of routine slide results);
- ensure self-monitoring of laboratory and clinical performance through internal audits;
- ensure that clinicians and laboratory personnel are encouraged to work as a team, with mutual benefit for the patient and professional respect;
- ensure adherence to biosafety guidelines and proper disposal of sharps and waste; and
- ensure that locally appropriate health education messages on the need for and benefits of a malaria test before treatment are widely disseminated to community members.

In countries where community case management is available, health facility personnel have the following additional tasks:

- train, regularly supervise and oversee the work of community health workers;
- provide them with the required RDT kits and medicines; and
- collect from community health workers the data required for the health information management system.

1.3.4 Point of care level: community

Community health workers are an integral part of the health system and provide a link between the community and the formal health system; they liaise regularly with health workers in the formal health system. Community health workers are especially important in providing care to vulnerable groups in remote areas with little access to health facilities.

In some countries, these workers do not provide patient care and mainly undertake preventive activities (health education, distribution of insecticide-treated nets). In countries where they do provide patient care, they should:

- refill their RDT and medicine kit orders at appropriate times, to avoid under- and over-stocking;
- receive appropriate stocks in a timely manner and be provided with storage conditions for RDTs to avoid exposure to high temperatures;
- perform the tests correctly according to the guidelines;
- refer patients elsewhere when appropriate;
- provide appropriate treatment for malaria and non-malaria cases on the basis of test results and guidelines;
- advise patients on adherence to treatment and when to return if still sick;
- record test results and treatment appropriately, and submit the information as part of the health information management system;
- follow-up patients after treatment; and
- deliver health education message to the community about prevention, early treatment-seeking and the need for a malaria test before taking treatment.

Community leaders and other key people should:

- educate communities about the benefits of testing for malaria before treatment;
- encourage community members to seek early diagnosis and effective treatment without delay when they have fever or suspected malaria; and
- ensure that community members are aware of where they can get a malaria diagnostic test and receive treatment.

KEY MESSAGES OF SECTION 1

- Each level of the health system has a role in implementing and maintaining the national treatment guidelines on fever case management and malaria diagnostic testing, although the levels of responsibility will differ.
- A national malaria coordination group on malaria diagnosis should be established that includes representatives of the national laboratory services and relevant technical programmes.
- Policies and strategies should be revised on the basis of all available information, including the results of a situation analysis.
- Technical working groups might be required to address specific tasks, such as policy and regulatory review, technical guidelines, supply management, partner coordination and resource mobilization.
- Monitoring and evaluation and regular feedback are essential components of implementation and improvement of the programme at all levels.

2. Policies and technical guidelines

2.1 Update relevant national policies

Several national policies should be updated in order to implement a strategy for universal access to malaria diagnosis. The national malaria control programme should either amend the policies or ensure that the malaria diagnostic guidelines are included in each relevant policy. The following national documents should be reviewed and updated:

- the national malaria strategic plan (often prepared on a 5-year basis);
- the national malaria control policy;
- the national clinical laboratory policy and guidelines;
- the national malaria treatment guidelines;
- the national laboratory quality management guidelines;
- the national malaria monitoring and evaluation framework and guidelines; and
- other guidelines and regulations, including Integrated Management of Childhood Illness (IMCI), Integrated Management of Adolescent and Adult Illness (IMAI), integrated community case management, use of blood testing in the private sector, safety and waste management, antenatal care guidelines and surveillance guidelines.

The national diagnostic committee should address the following main areas of policy for malaria diagnosis:

- national policies and guidelines and the national strategic plan to include universal access to malaria diagnostic testing;
- regulations on medical devices, blood safety and waste management;
- quality management requirements at multiple levels (including medical equipment management);
- procurement procedures and regulations;
- human resources strengthening (job descriptions, qualifications at various levels, in-service training);
- supervisory support (qualifications, structured checklists and incentives);
- private sector licences (laboratory requirements, reporting, informal sector legislation); and
- the cost of laboratory services to the client. In order to ensure universal access to malaria diagnostic testing, services should be provided free of charge, especially in countries where antimalarial medicines are provided at no cost to the patient.

National malaria diagnostic and treatment guidelines give standards and norms for use of malaria diagnostic testing and treatment, taking into account the following malaria-specific factors:

- malaria endemicity, epidemic-prone zones and malaria-free areas;
- clear definition of suspected malaria on the basis of signs and symptoms relevant to the national context;

- clear criteria for selecting patients for malaria testing (see sections 2.3.3 and 2.3.4);
- clear criteria for treating patients selected for malaria testing (see sections 2.3.3 and 2.3.4);
- type of health facility in which malaria diagnostic tests (microscopy and RDTs) and supplementary tests are deployed (see section 2.3.5);
- selection of type of microscope, laboratory reagents and related equipment (see section3.1);
- selection of type of RDT (see section 3.1);
- selection of supplementary tests for investigating fever and severe malaria;
- positions of staff and workers who are qualified and allowed to perform each type of test;
- degree of involvement of the not-for-profit private sector (faith-based organizations, nongovermental organizations);
- degree of involvement of the formal private sector; and
- degree of involvement (or not) of the informal for-profit private sector.

2.2 Address regulatory issues

2.2.1 Regulation of RDTs

RDTs are blood diagnostic devices and must therefore comply with blood safety procedures (i.e. samples must be treated as a potential biohazard); furthermore, they generate blood-contaminated waste that must be disposed of and destroyed in the same way as other laboratory infectious waste. The national regulations related to blood tests should be reviewed, as they may have major implications for the deployment of RDTs at points of care and their use by community health workers.

The use of RDTs in the private sector should be allowed, provided the health worker has been trained and performs the test him- or herself. Regarding the sale of RDTs to consumers in the private sector (e.g in pharmacies), there is evidence that untrained consumers (e.g. international travellers) do not perform the test correctly. The sale of RDTs should therefore be allowed only if the provider asks the consumer to demonstrate (after oral and written instructions) his or her ability to perform a test and correctly interpret the result.

In countries where diagnostic devices are formally registered, all RDT products used should be registered, as a requirement of procurement. Registration of the products may take several months, and this should be taken into account in selecting, procuring and planning for the introduction of RDTs. In most procurement processes funded by external funding agencies, national registration is a specific requirement, in addition to other requirements such as diagnostic performance and quality certification of manufacturing facilities.

2.2.2 Regulation of personnel

National regulations and procedures established by national laboratory services also define the minimum requirements for personnel to be eligible or authorized to perform a RDT or microscopy, with attention to competence and blood-handling requirements. Specific topics should be addressed in such regulations.

For RDTs:

- appropriate level of literacy of users;
- physical (vision) and mental ability;
- minimum training in which patients should be tested, how to perform the test, how to act on the result of the test, how to record and report the result and how to dispose of waste safely;

- motivation and incentives; and
- regularity of supervision, with on-site check of competence.

The regulation should also cover shifting of tasks, by training other personnel to use RDTs when there is an inadequate number of health workers, to increase access to parasitological diagnostic tests.

For microscopy:

- personnel authorized to be trained for microscopy;
- physical (vision) and mental ability;
- minimum training in which patients should be tested, how to perform the test, how to record and report the result and how to dispose of waste safely;
- initial accreditation;
- regularity of supervision, with on-site check of competence; and
- incentives and career structure.

2.2.3 Safety and waste management

Malaria diagnostic tests generate both infectious waste (blood-contaminated sharps and non-sharps) and general waste. Blood-contaminated sharps include lancets and needles, which should be disposed of in sharps boxes. Blood transfer devices for RDTs (loops, straw pipettes, inverted cups and calibrated pipettes) are infectious waste but are non-sharps (except glass capillary tubes) and should therefore be disposed of separately from sharps, together with used gloves, used cassettes, cotton wool and alcohol swabs. The introduction of RDTs will increase the volume of non-sharps infectious waste substantially: these materials should be handled and destroyed according to national guidelines.

2.2.4 Registration of laboratories

All laboratories in public and private health facilities should be registered or licensed by the appropriate regulatory body in the country for malaria testing by microscopy or RDTs. This will ensure that the laboratories comply with the basic mandatory requirements for malaria testing. In addition to initial licensing, many quality management systems include a requirement for further periodic accreditation, although this is not yet done in most highly endemic countries. Additional mechanisms, such as certification (to national norms or international standards such as ISO 9001) or accreditation (to national standards or international standards such as ISO 15189), may be used, usually on a voluntary basis, under the appropriate authority (certification or accreditation body).

2.3 Prepare national guidelines

2.3.1 Guidelines for managing fever episodes

The incidence of malaria is decreasing in many countries as a result of widescale, effective control interventions. In these countries, most fever episodes seen at health facility or community level are therefore no longer due to malaria. The commonest cause of fever in malaria-negative children is a viral infection. The causes vary from one setting, year or season to another and by age group; however, except in epidemic periods, viral causes (especially of respiratory origin) almost always predominate. Therefore, only a minority of patients who test negative for malaria need antibiotic treatment.

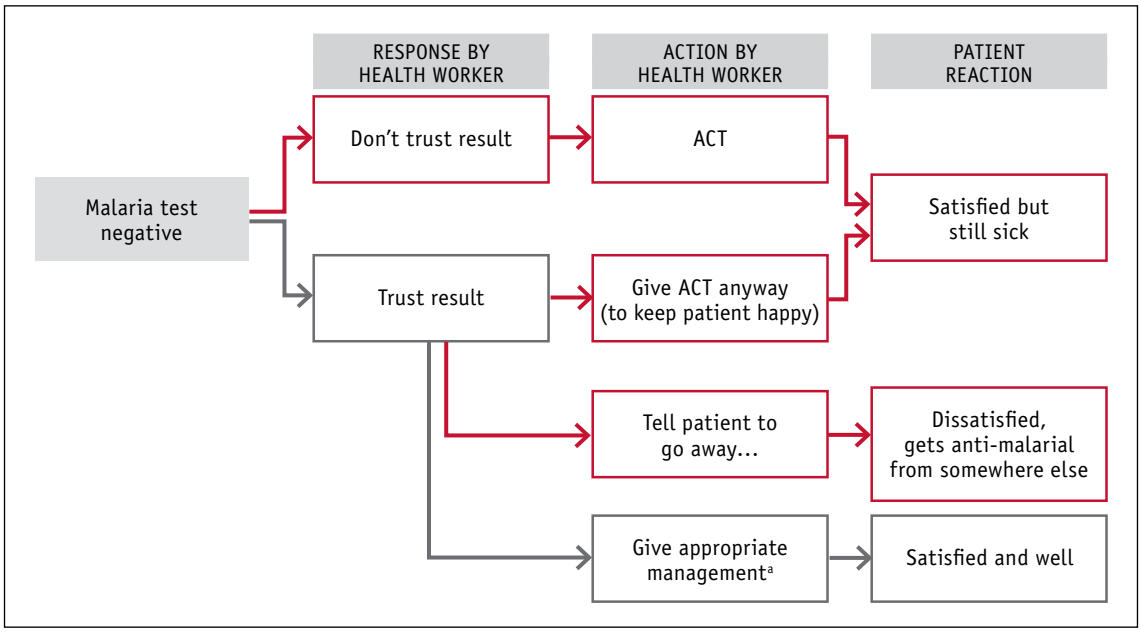
COMMON CAUSES OF ACUTE FEVER IN OUTPATIENT CHILDREN UNDER 5 YEARS OF AGE
(in approximate descending order of frequency)[a]

- Upper respiratory tract infections, including otitis media and tonsillitis (viral origin)
- Other viral diseases (influenza, human herpesvirus 6, parvovirus B19, Epstein-Barr virus, cytomegalovirus)
- Pneumonia
- Malaria
- Gastroenteritis
- Urinary tract infection
- Typhoid fever
- Skin infection (abscess, cellulitis)
- Sepsis due to bacteraemia
- Meningitis

[a] From the 'Study to investigate the causes of fever in children living in urban Dar es Salaam and rural Ifakara', Dar es Salaam City Council, Ifakara Health Institute, United Republic of Tanzania and the Swiss Tropical and Public Health Institute (2011).

There is evidence that, when programmes are not managing non-malaria febrile illnesses properly and only malaria diagnostic tests and treatment are used in the management of fever, health workers still tend to treat patients with a negative test result with antimalarial medicines, thereby undermining the effectiveness of the malaria diagnosis programme (Figure 1). This is especially true in settings where RDTs have been introduced to replace poor-quality microscopy.

FIGURE 1.
Dilemma of health workers facing a negative malaria test result in a febrile patient



Red indicates not recommended actions/behaviours.
[a] Treatment for cause other than malaria; explanation of result of malaria test and final diagnosis; counselling on when to return to health facility.

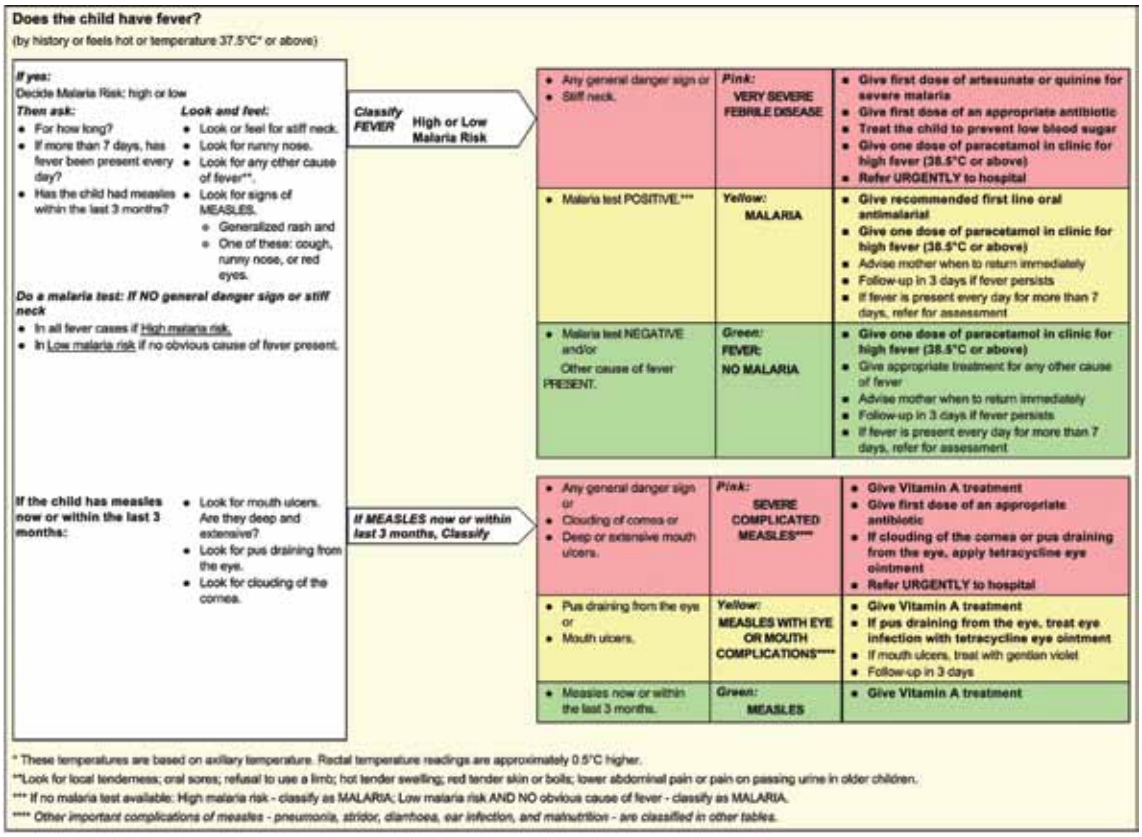
The minimum diagnostic and treatment requirements for the management of a febrile patient should be defined and included in the guidelines and training material. Depending on the diseases prevalent in the area, the availability of appropriate diagnostic tests and medicines should be ensured in parallel with malaria diagnostic tests and medicines.

Four WHO guidelines address the management of malaria and non-malaria fevers: one for district hospitals (the pocket book of *Hospital care for children*), one for children under 5 years of age [Integrated Management of Childhood Illness (IMCI)], one for adults [Integrated Management of Adolescent and Adult Illness (IMAI)] at primary care level and one for community health workers (integrated Community Case Management).

- In the pocket book of *Hospital care for children*,[1] a child referred to the hospital with a history of fever for less than 1 week should be tested for malaria as well as for urinary tract infection. If the child has cough and fast breathing, he or she should be considered as having pneumonia (a chest X-ray is not recommended for the initial diagnosis). The presence of other specific symptoms and signs should prompt additional investigations (e.g. lumbar puncture in case of neck stiffness or bulging fontanel).

FIGURE 2.

Updated part of the algorithm of the Integrated Management of Childhood Illness (IMCI) dealing with fever



Source: *Integrated Management of Childhood Illness*, WHO Department of Child and Adolescent Health and Development, 2010.

[1] *Pocket book of hospital care for children: Guidelines for the management of common illnesses with limited resources.* Geneva, World Health Organization, 2005. Available at: http://whqlibdoc.who.int/publications/2005/9241546700.pdf

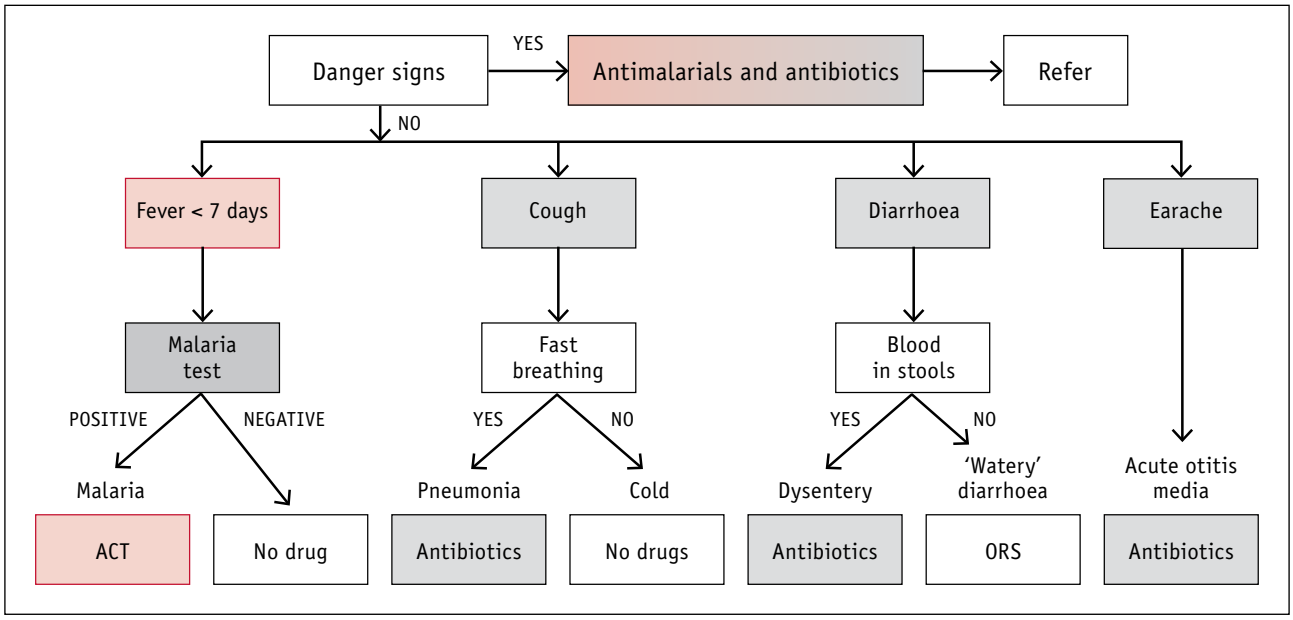
- The updated algorithm for the Integrated Management of Childhood Illness (IMCI)[1] includes the use of malaria diagnostic tests to assess a child who presents with fever (Figure 2). In highly endemic areas, all febrile children should be tested; in low-endemic areas, only children with no obvious cause of fever should be tested for malaria. Only febrile children with a positive malaria test or with danger signs of severe illness should receive antimalarial treatment. Regardless of the result of the diagnostic test for malaria, the patient should always be fully assessed for other conditions.

- In the Integrated Management of Adolescent and Adult Illness (IMAI),[2] a malaria test should be performed for all patients in a malaria-endemic area who complain of fever for less than 7 days. At present, the algorithm does not specify whether the different levels of malaria endemicity or the presence of an obvious cause of fever should influence the decision to test febrile adults for malaria.

- The new WHO/UNICEF strategy for integrated community case management[3] recommends that community health workers perform a malaria RDT for all patients with a history of fever of less than 7 days. In parallel, children should be assessed for acute respiratory infection and diarrhoea (Figure 3).

FIGURE 3.

Summary chart of the WHO/UNICEF strategy for integrated management of childhood illness at health facility level



Adapted from *Integrated management of childhood illness: caring for the sick child at health facility level*, WHO/UNICEF, 2010

[1] *Integrated Management of Childhood Illness for high HIV settings: chart booklet*. Geneva, World Health Organization/UNICEF, 2008. Available at: http://whqlibdoc.who.int/publications/2008/9789241597289_eng.pdf

[2] *Integrated Management of Adolescent and adult Illness: interim guidelines for first-level facility health workers at health centre and district outpatient clinic: acute care*. Geneva, World Health Organization, 2009. Available at: http://www.who.int/hiv/pub/imai/acute_care.pdf

[3] *Integrated Management of Childhood Illness: Caring for Newborns and Children in the Community. Manual for the Community Health Worker*. Geneva, World Health Organization, Unicef 2010. *In press*.

2.3.2 RDTs and microscopy

As a general principle, microscopy and RDTs are both adequate for diagnosing malaria in febrile patients,[1,2] and both are needed in most countries. In situations and settings where both tests can be used, countries must decide which test to use where. The decision should be based on the advantages and disadvantages of each test in each location on the basis of its technical characteristics.

Several factors should be considered in choosing whether RDTs or microscopy should be used for diagnosis in certain settings and clinical situations, including the existence of a laboratory, workload, malaria prevalence, the skill of personnel performing the test and the availability and

Table 2. Technical strengths and constraints of RDTs and microscopy to be taken into account in selecting the best options for different clinical situations and settings

Criterion	Characteristic of diagnostic test	Target cases and clinical setting	Recommended diagnostic test	
			RDT	Microscopy
Parasite density	**RDTs** give only a positive or a negative result, while **Microscopy** can also show parasite density.	Uncomplicated malaria cases	**Yes**	**Yes**
		Severe cases upon admission	Not alone[a]	**Yes**
		Follow-up of admitted patients[b]	No	**Yes**
Antigen persistence	**RDTs** detect persisting antigens after parasite clearance,[c] while **Microscopy** gives negative result as soon as the parasite is cleared from the patient's blood.	Confirmed malaria cases with persisting fever despite antimalarial treatment	No	**Yes**
		Cases of persisting fever not previously tested for malaria	**Yes**	**Yes**
		Cases of persisting fever in people who did not receive antimalarial treatment	**Yes**	**Yes**
Electricity supply	**RDTs** do not require electricity, while **Microscopy** requires a reliable electricity supply.	Health centres and hospitals	**Yes**	**Yes**
		Health workers in the community and at health posts	**Yes**	No
Time for test completion	**RDTs** can be performed comparatively quickly, while **Microscopy** requires more time.	Settings with low work load per health worker, e.g. small health facilities and facilities in areas of low endemicity	**Yes**	**Yes**
		Settings with high work load per health worker, e.g. outpatient departments of hospitals or health centres in areas of high endemicity	**Yes**	Not alone[a]
Competence and training requirements	**RDTs** are comparatively easy to perform, while **Microscopy** is more complex and requires the competence of a trained microscopist.[d]	Health workers with limited training in laboratory skills or settings with limited resources for supervision[d]	**Yes**	No
		Settings where specific training in malaria microscopy is possible and a laboratory quality management system is functioning[e]	**Yes**	**Yes**

[a] This diagnostic test can be used, but not exclusively (the other test is necessary).
[b] Parasite density required to monitor response to treatment.
[c] RDTs to detect pLDH may remain positive up to 5–6 days after disappearance of the parasite, while those to detect HRP2 remain positive up to 2–3 weeks after disappearance of the parasite.
[d] Both diagnostic techniques require minimum specific training.
[e] Both diagnostic techniques require regular supervision support.

[1] Ochola L.B et al. The reliability of diagnostic techniques in the diagnosis and management of malaria in the absence of a gold standard. *The Lancet Infectious Diseases*, 2006, 6:582–588.

[2] *WHO technical consultation: Parasitological confirmation of malaria diagnosis, 6–8 October 2009.* Geneva, World Health Organization, 2009. Available at: http://whqlibdoc.who.int/publications/2010/9789241599412_eng.pdf

strength of quality management and supervisory activities. When choosing between microscopy and RDT, each technical strength and constraint should be taken into consideration in selecting the best options for different clinical situations. The list of general considerations in Table 2 should be taken into account in deciding on the optimal use of RDT and microscopy at different levels of the health-care system.

For example, the microscopy services currently used in health services with a high case load per laboratory technician should be reserved for the investigation of treatment failures and for the diagnosis and monitoring of patients admitted for severe malaria (see below). This will enable each microscopist to perform the correct number of slide examinations per day and implementation of a correct quality management system for monitoring laboratory performance in malaria diagnosis.

2.3.3 RDTs and microscopy in clinical management of patients

The considerations below take into account the fact that RDTs, unlike microscopy, detect antigens rather than parasites, which is an advantage for detecting malaria in patients with low parasite densities fluctuating around the level of detection of microscopy (real positive cases), but is a disadvantage when patients have cleared all their parasites after effective antimalarial treatment and have only remaining antigens (false-positive cases). The duration of persistence of antigens after effective treatment depends on the type of antigens detected by the RDT (HRP2 persists longer than pLDH and aldolase) and also varies from one patient to another. For practical purposes, patients who reattend a health facility for febrile illness 2 weeks or more after completing full antimalarial treatment are considered to have a new malaria infection and are managed accordingly.[1] In most people, persisting antigens are cleared after 2 weeks, and reinfection after a malaria episode treated with most antimalarial medicines is plausible after 2 weeks.

Uncomplicated febrile illness

Who should be tested for malaria?

- In highly endemic areas, all patients presenting with a history of fever or elevated temperature should be tested for malaria. In addition, patients under 5 years of age with palmar pallor or anyone with a haemoglobin level < 8 g/dl should also be tested for malaria.
- In low-prevalence areas, it is reasonable to limit testing for malaria to febrile patients with no obvious cause of illness, as is already done in several countries (e.g. India, the highlands of Madagascar and Senegal). The clinical criteria used to restrict testing might be different from one country to another and might vary according to the phase of malaria elimination. The prevalence threshold (malaria test positivity rate among febrile patients presenting at health facilities or parasite prevalence in the general population) at which testing should be restricted depends on local circumstances.
- If malaria testing is performed before the patient is seen by a clinician, the health workers performing the test should be trained to select patients on the basis of the recommended criteria (case definition of a suspected malaria case) in the area or country. This practice is used in some settings to improve the efficiency of patient flow in health facilities with high patient loads.
- A patient presenting with fever in a highly endemic area may have both malaria and another cause of fever. All patients, irrespective of the results of malaria testing, should be fully assessed for other potential causes of fever.

[1] *Guidelines for the treatment of malaria*, second edition. Geneva, World Health Organization, 2010. http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf

CONSIDERATIONS FOR DEFINING AREAS OF HIGH AND LOW MALARIA RISK

In the Integrated Management of Childhood Illness (IMCI), the threshold for areas of high malaria risk is a positivity rate of malaria tests of 5% among febrile children presenting in health facilities. As surveillance of malaria cases is particularly important when the prevalence drops, the threshold chosen by some countries is a positivity rate of 1%, i.e. when 1 per 100 patients or fewer presenting to a health facility with a history of fever is positive by either RDT or microscopy. Each country might choose a different threshold, depending on the acceptable risk of missing a malaria case and on the level of investment in malaria testing they are ready to make.

Once a threshold is chosen, it implies that some parts of the country or some periods of the year (during or between malaria transmission seasons) might have to use a different diagnostic algorithm. The feasibility of using different algorithms in different parts of the country or different seasons should be carefully considered.

Which malaria test should be used?

- For the management of a new fever episode, quality-assured microscopy and RDTs are equivalent in terms of performance for the diagnosis of uncomplicated malaria.[1,2]

Who should be treated for malaria?

- In uncomplicated cases, only patients with a positive diagnostic test for malaria should receive antimalarial treatment. In addition, the patient should be assessed for other causes of fever, and specific treatment should be provided in addition to the antimalarial treatment, if needed.
- In uncomplicated cases, when the diagnostic test for malaria is negative, an antimalarial medicine should not be given. The patient should be assessed for other causes of fever, and specific treatment should be given only for those conditions identified. For example, upper respiratory tract infections do not require antibiotic treatment and are treated symptomatically.
- If both an RDT and microscopy are performed in parallel to assess a new episode of fever and one of the two tests (or both) is positive, the patient should be considered as having malaria.
- If a combination RDT[3] is used, the patient should be treated for *P. falciparum* malaria in two situations: if both test bands appear or if the *P. falciparum* band appears but not the pan band:

Positive for *P. falciparum* and Pan-Plasmodium
(*P. falciparum* or mixed infection)

Positive for *P. falciparum*
(*P. falciparum* infection)

In both situations, the patient should be treated with an antimalarial medicine active on *P. falciparum*, even if he or she has taken an antimalarial treatment recently. As RDTs are

[1] Ochola L.B et al. The reliability of diagnostic techniques in the diagnosis and management of malaria in the absence of a gold standard. *The Lancet Infectious Diseases*, 2006, 6:582–588.

[2] *WHO technical consultation: Parasitological confirmation of malaria diagnosis, 6–8 October 2009.* Geneva, World Health Organization, 2009. Available at: **http://whqlibdoc.who.int/publications/2010/9789241599412_eng.pdf**

[3] A combination RDT is one with three or more test bands. In most of these tests, one band detects HRP2 specific to *P. falciparum*, one band detects pLDH common to all species and one band is a control.

slightly more sensitive in detecting HRP2 than p-LDH or aldolate, the result of the test shown above on the right side could be due to a real infection that requires treatment. The sole appearance of the *P. falciparum* test line does not mean that the test is detecting only persisting antigens.

Who should be referred?

- Any patient with danger signs of severe disease should be referred to an inpatient facility.
- Patients returning for a follow-up visit in which treatment failure is suspected should be referred to a facility where microscopy is performed, if it is not available on site. When referral is not feasible and other causes of fever have been ruled out, second-line antimalarial treatment should be given.

Follow-up of febrile illness

Who should be tested for malaria

- If febrile patients return for a follow-up visit more than 2 weeks after full antimalarial treatment, they should be considered as having a new episode of fever and be tested by RDT or microscopy, beside being assessed for other causes of fever.
- Treatment failure might be suspected when the patient has an initial positive malaria test, took full, effective antimalarial treatment and has persisting fever in the following 2 weeks.

Which malaria test should be used?

- In cases of suspected treatment failure, microscopy is the preferred test; RDTs are not recommended because the parasite antigen persists after parasitaemia has cleared (see comment above).
- Patients who initially test negative for malaria and have no other identified source of illness should be advised to return for repeated testing (by either RDT or microscopy) in 2 days if the fever persists or sooner if the symptoms worsen.

Who should be treated for malaria?

- Patients who initially test positive for malaria and still have a positive blood slide for malaria at follow-up should receive second-line antimalarial treatment.
- Patients who initially test positive for malaria and have a negative blood slide for malaria at follow-up should not be given an antimalarial medicine. The patient should be assessed for other causes of fever, and specific treatment should be provided for the identified conditions. For example, upper respiratory tract infections require symptomatic treatment (to relieve cough and soothe the throat) but not antibiotics.
- Patients with danger signs should be assessed as for a first visit

Who should be referred?

- If the patient is still febrile after 7 days or if the symptoms worsen, he or she should be referred for specific assessment.

Severe febrile illness

Who should be tested for malaria?

- For patients with danger signs seen at peripheral level where no inpatient facility is available (including at community level), priority should be given to immediate administration of pre-referral treatment rather than losing time by testing the patient for malaria.

Which test should be used in which clinical situation?

- In severe cases, microscopy is necessary because parasite density must be assessed for monitoring treatment response. If the patient is in hospital, the use of an RDT is helpful to guide initial emergency treatment and to document malaria in patients who have received pre-referral antimalarial treatment (and might thus have already cleared their parasites).
- For inpatients with fever, when both microscopy and RDT are negative, the diagnosis of malaria has been excluded and no antimalarial treatment is needed.

Who should be treated for malaria?

- In hospitalized patients with danger signs, antimalarial treatment should be started as soon as one malaria test is positive.
- The treatment should include an antibiotic both in malaria-positive and malaria-negative patients, especially children. There is indeed considerable clinical overlap between bacteremia, pneumonia and severe malaria, and these conditions may coexist. It is moreover very difficult to document bacterial infections in a severely ill patient, especially when blood cultures are not available. Even when malaria has been documented, antibiotics should be stopped only if blood cultures are negative and other bacterial infections, such as severe pneumonia, have been ruled out.
- In patients with danger signs who must be referred to a higher-level facility, pre-referral treatment should be provided immediately, before any testing is performed. This treatment should include an antimalarial medicine and an antibiotic, according to national guidelines.

2.3.4 Algorithms for malaria diagnosis and treatment in febrile patients

The generic clinical algorithms discussed below refer to the management of febrile patients during first (Figure 4) and follow-up visits (Figure 5), with regard to malaria diagnosis and treatment in areas of high and low malaria risk. These generic algorithms should be adapted to the situation in each country on the basis of national guidelines for the management of malaria and other febrile illnesses.

2.3.5 Appropriate levels for different diagnostic methods

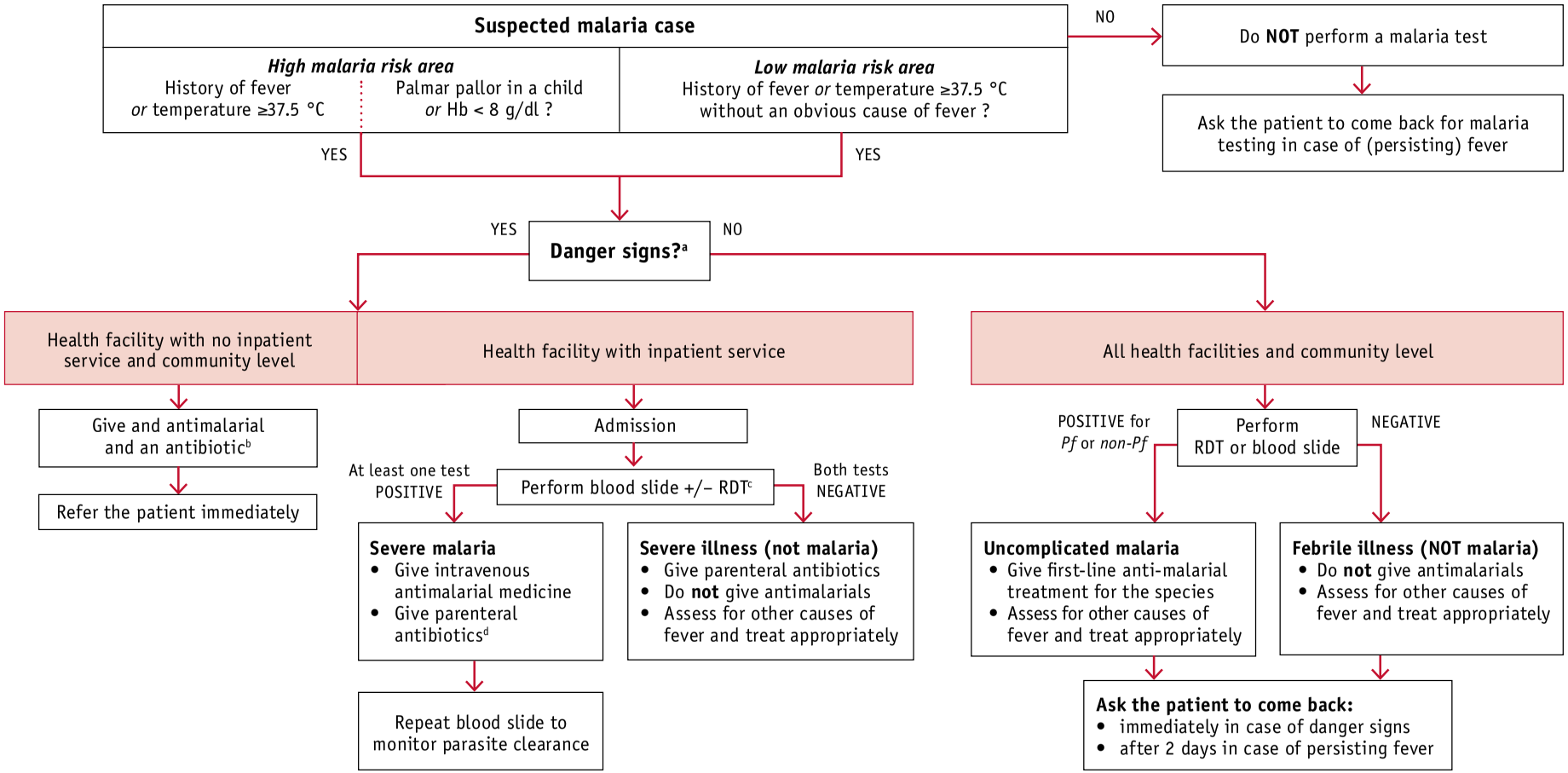
Microscopy

Microscopy may be introduced or strengthened in all public and private health facilities (see Table 3) that have a laboratory which participates in a quality management system for malaria microscopy, which should include the following:

- provision of good-quality equipment and supplies (conforming to minimum standards), especially microscopes, slides and stains;
- access to equipment repair services;
- provision of an alternative power source in areas with no mains electricity or where the power supply is unreliable;
- well-organized laboratory with waste disposal facilities;
- microscopists trained and accredited in line with national standards;
- certification of laboratories in line with national and international standards or at least efforts in that direction;
- participation of laboratories in an external quality assessment programme;

FIGURE 4.

Algorithm for malaria diagnosis and treatment: first visit



[a] The following general danger signs are considered criteria for referral at peripheral level [adapted from Integrated Management of Childhood Illness (IMCI) and Integrated Management of Adolescent and Adult Illness (IMAI)]:
in children: unable to drink or breastfeed, vomit everything, have convulsions, are lethargic or unconscious and present with neck stiffness, chest indrawing or stridor;
in adults: are very weak or unable to stand, are lethargic or unconscious or have neck stiffness, convulsions, respiratory distress or severe abdominal pain

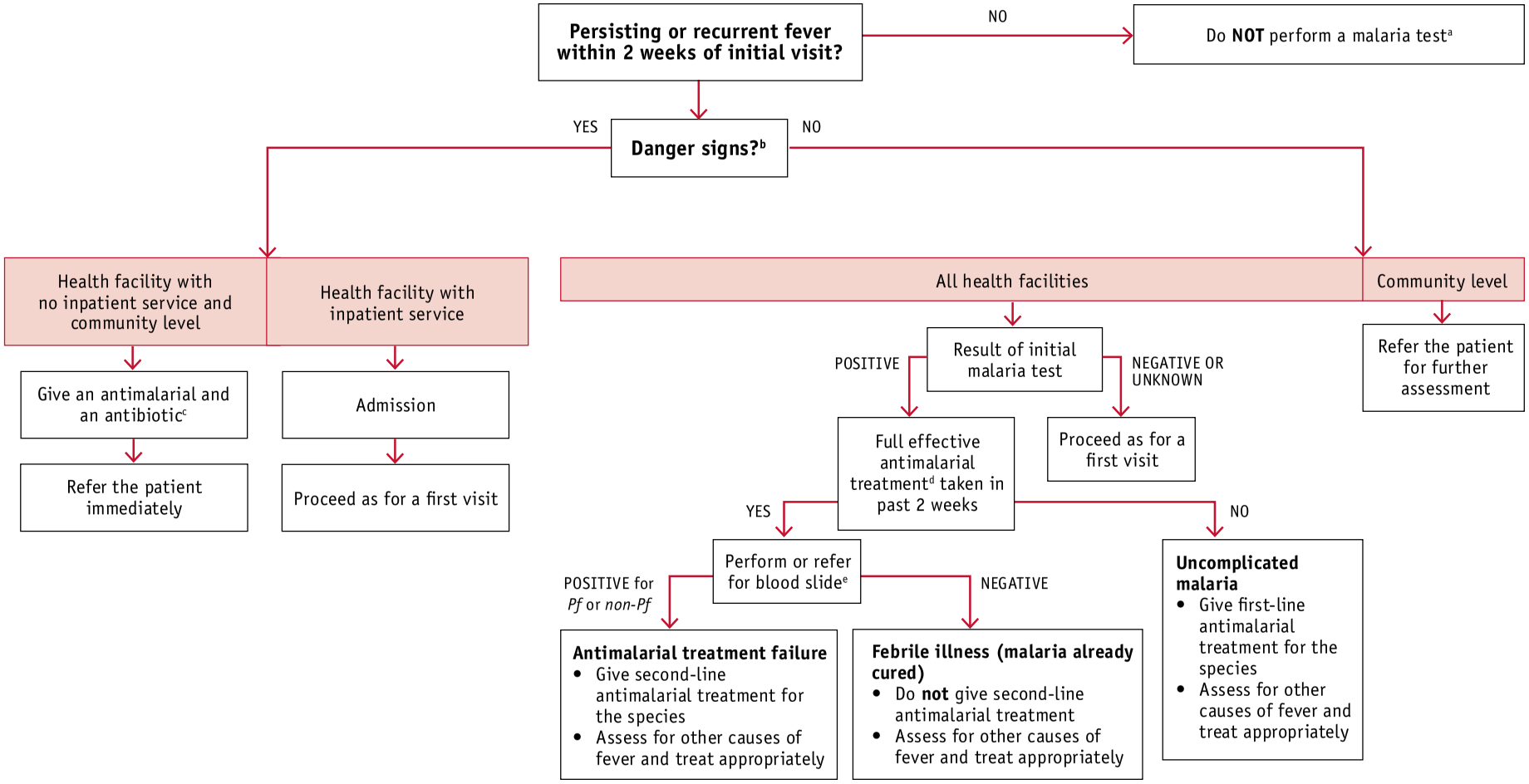
[b] Pre-referral treatment as recommended by WHO 2010 *Guidelines for the treatment of malaria* and by Integrated Management of Childhood Illness (IMCI) and Integrated Management of Adolescent and Adult Illness (IMAI): rectal artesunate or intramuscular quinine, artesunate or artemether and intramuscular ampicillin plus gentamicin or intramuscular ceftriaxone

[c] RDT is performed while waiting for the result of the blood slide to decide earlier on treatment and to document malaria in patients who have received pre-referral antimalarial treatment (and might thus have already cleared their parasites).

[d] Because of the possibility of concomitant bacterial infection in severe malaria patients, especially in children, antibiotics should be given beside antimalarials until bacterial infections have been ruled out (including bacteremia by blood cultures if available).

FIGURE 5.

Algorithm for malaria diagnosis and treatment: follow-up visit



[a] In case of persisting or recurrent fever after two weeks of initial visit, use the algorithm for the first visit (Figure 4).

[b] The following general danger signs are considered criteria for referral at peripheral level [adapted from Integrated Management of Childhood Illness (IMCI) and Integrated Management of Adolescent and Adult Illness (IMAI)]:
in children: unable to drink or breastfeed, vomit everything, have convulsions, are lethargic or unconscious and present with neck stiffness, chest indrawing or stridor;
in adults: are very weak or unable to stand, are lethargic or unconscious or have neck stiffness, convulsions, respiratory distress or severe abdominal pain.

[c] Pre-referral treatment as recommended by WHO 2010 *Guidelines for the treatment of malaria* and by Integrated Management of Childhood Illness (IMCI) and Integrated Management of Adolescent and Adult Illness (IMAI): rectal artesunate or intramsucular quinine, artesunate or artemether and intramsucular ampicillin plus gentamicin or intramuscular ceftriaxone.

[d] A patient is considered to have taken full, effective antimalarial treatment if he or she has taken all the prescribed doses of the recommended first-line drug without vomiting within the hour of intake.

[e] If microscopy is not available, give second-line antimalarial treatment.

Table 3. Appropriate levels of the health system for the use of microscopy and RDTs		
Level of the health system	**Microscopy**	**RDTs**
Tertiary health facilities	✓	✓ [a]
Health facilities with a laboratory service	✓	✓ [a,b]
Health facilities without a laboratory service		✓
Community level (supervised community health workers)		✓
Formal private sector health facilities	✓	✓ [c]
Outbreak investigations and follow-up of the progress of an epidemic response	✓ [d]	✓
Population surveys	✓ [d]	✓

[a] especially in facilities with high outpatient load
[b] particularly after working hours of the laboratory
[c] in a few countries, RDTs have also been deployed in the informal private sector
[d] microscopy slides are taken in the field for later examination in the laboratory by qualified technicians

- regular supervision by on-site visits; and
- an effective documentation system.

Before considering expansion of microscopy to new health facilities, a well-functioning quality management system should be established in order to strengthen the quality of existing microscopy services.

Rapid diagnostic tests

RDTs can be used in all the settings mentioned in Table 3. When using RDTs, the quality management system should include at least:

- selection of a product that fulfils international standards of diagnostic performance;
- testing of all RDT lots procured;
- recommended transport and storage conditions;
- training of health workers in RDT use and management of febrile illnesses according to national guidelines;
- regular supervision by on-site visits; and
- an effective reporting and surveillance system for diagnosis and treatment.

In addition, it is essential that a well functioning supply management system for RDT distribution is in place.

2.3.6 Appropriate diagnostic tests for different levels of the health-care system

A few additional points should be taken into account, depending on the level of the health system considered.

Community level

Community health workers should be trained for and equipped with RDTs (if the policy permits use at this level) and fully supported to confirm malaria before treating patients. Treatment based on clinical assessment alone should be considered only when RDTs are not available.

Use of RDTs should be integrated into a clinical algorithm for the management of common causes of fever, such as integrated Community Case Management. In children, this should include at least acute respiratory infection and diarrhoea (see Figure 3).

The criteria used by community health workers to select patients for malaria testing should be based on those used by health facilities but adapted to the skills of the community health workers (see Figure 4).

Primary care level (with no inpatient facility)

At the first visit of patients presenting without danger signs, a qualitative malaria test result (positive or negative) is enough to decide on treatment. Either RDTs or microscopy can be used.

If the work load of the microscopists is too high and is likely to compromise the quality of the results, RDTs are preferable, as long as training, supervision, quality management and full support are ensured. If available, microscopy should be reserved for investigating treatment failures, to distinguish between treatment failure and another cause of febrile illness.

Secondary and tertiary care level (with inpatient facility)

At this level, microscopy is essential for the management of hospitalized patients with suspected severe malaria. For inpatients, microscopy is needed to confirm a diagnosis of malaria, for initial quantification of parasite density and for follow-up of parasite density until full parasite clearance. Microscopy is also needed for investigating treatment failure in outpatients, especially to assess patients referred from health-care facilities that do not have microscopy.

RDTs are an option for ensuring malaria testing in outpatient departments with a high malaria case load. Depending on the workflow and patient load, RDTs may be preferred to microscopy. In these settings, support staff might be trained to use RDTs, to avoid tying up busy health workers. RDTs are also needed for diagnostic testing for malaria when a laboratory is closed or microscopy is not available (after working hours).

Formal private sector

In countries in which a high percentage of patients are seen in private-sector facilities that lack good-quality diagnostic services, the widespread practice of treating malaria on the basis of clinical assessment alone jeopardizes the potential benefit of widescale parasitological diagnosis in the public sector. The same standards as those set for the public sector should apply to the formal private sector in clinics at primary, secondary and tertiary levels, with a proper quality management system. Therefore, malaria diagnosis with RDTs and microscopy should be promoted in the formal private sector, especially in the context of initiatives for improving access to antimalarial medicines.

Informal private sector

Several experiences of use of RDTs in the informal private sector have been conducted, for example in Brazil and Cambodia. Operational research is also ongoing in several African countries. The informal private sector should be targeted for the strengthening of malaria diagnostic testing in a phased approach, after widescale deployment in the public and formal private sectors.

2.4 Prepare an implementation plan

This section defines the components of an implementation plan for achieving universal access to diagnostic testing of malaria, after a national diagnostic committee has been established, gaps and challenges have been identified on the basis of a situation analysis and policy and technical guidelines have been formulated. The operational plan is derived from the plan of action prepared earlier, which served for budget approval. This plan gives additional, detailed operational information and further elaborates several of the components described in the plan of action.

2.4.1 Components of the implementation plan

The implementation plan should include at least the following steps, if not already in place (the below activities are described in the corresponding sections of the manual):

Deployment strategy and human resources

- identification of geographical areas and levels of care for phased implementation;
- criteria for setting priorities on use or strengthening of RDTs and microscopy;
- identification of staff in the national malaria control programme or national reference laboratory responsible for programme coordination;
- staffing of health facilities to perform RDTs and microscopy, in line with phased implementation;
- identification of human resources for training trainers and training of health workers;
- identification of human resources for supervising RDT users outside laboratories; and
- identification of human resources for supervising laboratories, including malaria microscopists and RDT performers.

Procurement of malaria tests and related equipment

- defininition of technical specifications for RDTs, microscopes and related equipment;
- selection of appropriate RDTs, microscopes, Giemsa stain and reagents;
- quantification and forecasting of RDT and microscopy needs;
- quantification and forecasting of commodities for diagnosis and treatment of non-malaria fevers;
- invitations to tender and review of tenders;
- pre-shipment lot-testing for RDTs; and
- transport, port clearance and receipt.

Distribution, storage and maintenance

- definition of national standards for storage of RDTs and maintenance of microscopes;
- definition of standards for storage requirements at central and subnational levels;
- plan for distribution of commodities requiring a cool chain (RDTs, tests and medicines for non-malaria fevers);
- plan for distribution of microscopes and related equipment;
- equipment installation and validation;
- guidance for stock management procedures; and
- maintenance of microscopes and related equipment.

Quality management system

- definition of national standards for performance at testing sites and competence of test performers;
- elaboration of standard operating procedures for:
  - — RDT and blood slide performance,
  - — RDT transport and storage,
  - — external quality assessment (slide proficiency testing),
  - — validation of routine blood slide results (cross-checking),

  - laboratory supervisory visits (including checklists) and
  - health facility supervisory visits (including checklists);
- strengthening reference laboratory services;
- training focal people for quality management at subnational levels;
- internal audits;
- supervisory visits to laboratories;
- feedback to laboratories and corrective actions; and
- quality monitoring.

Training

- defining competences and curricula for pre-service and in-service training of laboratory staff in microscopy and RDTs;
- defining criteria for training of other personnel in performing RDTs;
- preparing or updating training manuals for laboratory staff and clinicians (tutor and learner guides for microscopy and for RDT);
- updating training manuals for community health workers to include the use of malaria RDTs and the management of pneumonia and diarrhoea (integrated community case management);
- training of tutors (master trainers);
- training of laboratory staff for microscopy and RDTs;
- training of other staff in RDT use, e.g. clinicians, support staff;
- training of clinicians in integrated management of fevers, including use of RDTs in clinical management;
- training of community health workers in integrated management of fevers; and
- training of supervisors at all levels in quality management and supervisory techniques and requirements.

Supervision

- creating or updating checklists for supervising clinicians managing febrile patients on the basis of malaria diagnostic tests;
- creating checklists for laboratories performing RDTs or microscopy;
- creating a checklist for RDT performance for facilities with no laboratory;
- if possible, integration of the above checklists into general clinical and laboratory supervision of health facilities;
- conducting supervisory visits to health facilities; and
- providing feedback to health facilities and taking corrective actions.

Advocacy, communication and social mobilization

- designing a strategy for communications, behaviour change and social mobilization;
- preparing appropriate materials and messages;
- disseminating key messages to each targeted audience; and
- engagement of the private sector.

Monitoring and evaluation

- defining or updating core indicators for malaria diagnosis and the data necessary to calculate them;
- updating the health information management system and data reporting forms (or, if not possible immediately, setting up a temporary parallel system) to monitor RDT use;
- distributing reporting forms and training staff in their use;
- designing standardized templates and training appropriate personnel in data entry and analysis;
- analysing collected data to calculate indicators of malaria diagnosis; and
- providing feedback at subnational level and to health facilities and communities.

2.4.2 Defining timelines

Timelines should be defined for all new activities for strengthening both RDT and malaria microscopy (see Figure 6). Ideally, introduction of RDTs and strengthening of microscopy should be done in parallel, to take advantage of the synergies at each level. Malaria diagnostic tests are generally introduced in different geographical areas or extended to different levels of the health system in progressive phases. Successful national malaria control programmes that have rapidly scaled-up diagnostic testing over a short period (e.g. in Senegal) first used malaria diagnostic tests in the public sector only in selected priority districts, before extending their use to all malaria-endemic areas; subsequently, malaria diagnostic tests were extended to community level. In a few countries (e.g. Cambodia), this was then followed by deployment of malaria diagnostic tests in the informal private sector.

2.4.3 Budget components

At national level, a full budget should be prepared for all the activities in the implementation plan, including initial fixed costs (e.g. microscopes and other laboratory equipment), running costs (e.g. staff salaries and incentives) and commodity costs (e.g. RDTs, gloves, sharps boxes, slides and laboratory supplies). Costs should be determined for activities specifically related to the introduction of RDTs and for strengthening microscopy and also for activities common to both microscopy and RDTs, including management of non-malaria fevers.

The components and format of the budget depend on the requirements of the funding agency (e.g. government, international and bilateral agencies). Tools for costing in grant proposals to major funding agencies are being prepared and are not part of this manual. The distribution of costs into different budget components also depends on the requirements of the funding body. Generally, the components of the budget listed in Table 4 should be given in detail in the implementation plan.

Components specifically related to RDT implementation

The major component of the budget for RDT implementation is for procurement of the tests themselves. This cost is directly proportional to the quantification of RDT requirements over time.

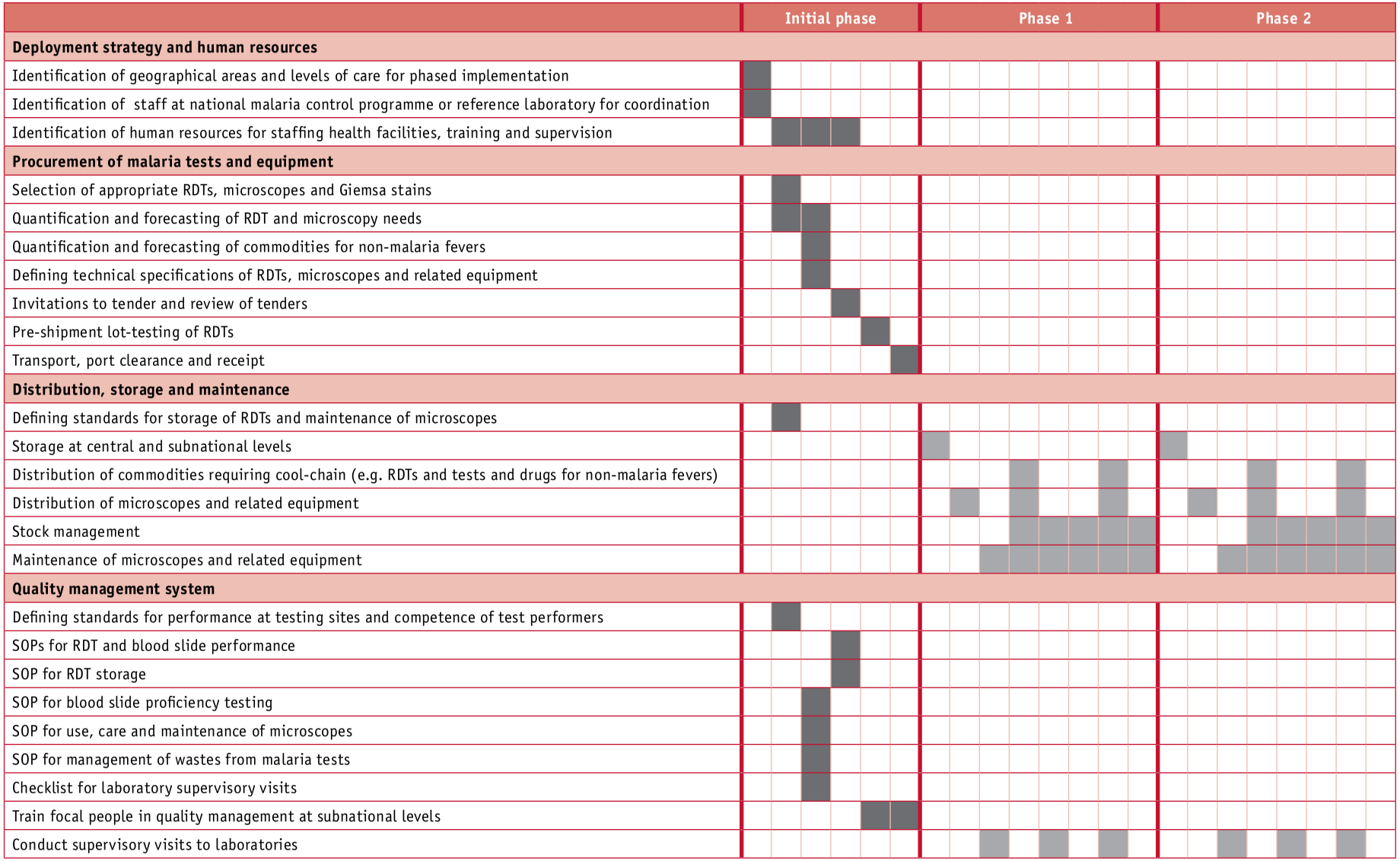
One component of the budget is assigned to formulating standard operating procedures and training materials and to storage and distribution of RDTs to health facilities. These costs vary considerably, and the agencies involved in supply management should be involved in estimating the costs for storage and distribution.

At present, quality management for RDTs is based mainly on lot-testing, which has a negligible cost (as testing is currently free in WHO reference laboratories), and direct observation of the

FIGURE 6.

Timelines in plans for introducing malaria diagnostic tests

Activities shown in dark grey are implemented once, at the beginning of the programme (initial phase), while activities shown in light grey are extended progressively during phased implementation of the programme.



Feed-back to laboratories and corrective actions																									
Monitoring quality management system																									
Training																									
Defining standards for pre-service and in-service training																									
Develop or update training manuals for laboratory staff and clinicians																									
Update training manual for community health workers																									
Pilot testing and modification of training manuals																									
Training of tutors																									
Training of laboratory staff for microscopy and RDT performance																									
Training of clinicians for RDT performance and clinical use of malaria tests																									
Training of clinicians for integrated management of fevers																									
Training of community health workers for integrated management of fevers																									
Advocacy, communication and social mobilization																									
Develop a strategy for behavioural change communication and education and communication																									
Prepare appropriate materials and messages																									
Disseminate key messages to each targeted audience																									
Engage the private sector																									
Supervision																									
Create or update checklist for supervision of clinicians managing febrile patients																									
Create checklists for supervision of malaria diagnostic testing in health facilities																									
Pilot test above checklists																									
Integrate above checklists into general supervision of health facilities																									
Conduct supervisory visits of health facilities																									
Feed-back to health facilities and corrective actions																									
Monitoring and evaluation																									
Define or update core indicators of malaria diagnosis and elements needed for calculation																									
Update health management information system at each level to integrate RDT use and missing elements																									
Train for and distribute reviewed reporting forms																									
Analyse collected data to calculate indicators for malaria diagnosis																									
Feed-back to subnational levels, health facilities and communities																									

Table 4. Components of the budget for a malaria diagnosis programme			
Component	**Activities specific to microscopy**	**Activities specific to RDTs**	**Activities for management of (malaria and non-malaria) fevers**
Preparation of technical guidelines, standard operating procedures and checklists			
Guidelines	Laboratory supervision[a]	RDT transport and storage	Fever management algorithm
Standard operating procedures for diagnostic testing	Microscopy performance	RDT performance	Other tests used at primary care level
Other standard operating procedures	Proficiency testing, validation of routine slide results	RDT storage	
Training material	Training manual for microscopy	Training manual for RDTs	Training manuals for integrated management of fevers
Checklists for supervision	Laboratory visits[a]	Health facility visits	
Procurement and supply of commodities			
Diagnostic tests	Microscopes and related supplies	RDT kits	Urine dipsticks, haemoglobin meter, hematocrit meter, glucometer
Medicines	ACTs		Antibiotics, zinc, inhaled salbutamol, rehydration salts
Other commodities	Gloves, lancets, alcohol, cotton wool, timers, sharps boxes		
Distribution of commodities to the field	All items listed above		
Quality management system			
Pre-shipment testing		Lot-testing	
Training of focal people	Quality management system focal people		
Monitoring the quality management system	Quality monitoring supervision visits and compilation of health information management data		
Training of health workers			
Training of tutors	Expert microscopists	Tutors for RDT performance outside laboratories and clinical management of fever cases	
Training of health workers	Microscopists	Health workers	Clinicians
Training of supervisors	Laboratory supervisors[a]	Clinical supervisors	
Supervision			
Supervisory visits	Laboratory visits[a]	Health facility visits	
Advocacy, communication and social mobilization			
Design of strategies and material	Communication on the need for malaria testing		Communication on other causes of fever
Dissemination of key messages	Through each delivery channel		
Monitoring and evaluation			
Updating the health information management system	Add row for RDTs in laboratory report and column for malaria test results in clinicians' book		Column for other test results in clinicians' book
Train health workers in the new health information management system	Training of person in charge or focal person for reporting on health information management in health facilities		

[a] To simplify, activities specific to laboratories have been mentioned under 'Microscopy', although both microscopy and RDT are generally performed in laboratories.

competence of health workers, community health workers and other staff in performing RDTs, which is included in the supervision of laboratories, health facilities and community health workers. Transport and per diem costs for the supervisors may be significant. Adequate supervision costs must be included in all budget plans submitted for approval.

Training of clinicians to perform RDTs should be part of training in patient management and ideally included in training on integrated management of fevers. Training of health workers and laboratory technicians in the correct use and interpretation of RDT is important for successful implementation of an RDT programme.

Components specifically related to strengthening microscopy

An important component of the budget for strengthening microscopy is that for quality management, in particular accreditation of microscopists, external quality assessment and supervision of laboratories. These costs are proportional to the number of laboratories and the number of microscopists in the programme rather than the number of tests performed. The most significant component of the budget for microscopy activities is recurrent costs for the salaries of laboratory technicians involved in malaria microscopy; however, most laboratory technicians do not conduct microscopy examinations only for malaria.

A small part of the budget must be assigned to formulation of standard operating procedures, supervisory checklists and effective training material. Such materials have already been developed for a number of countries, so that the only cost will be for adaptation of these materials to the specific country context. The costs of procurement of laboratory equipment, especially new microscopes, depends on the requirements for replacing old and obsolete microscopes, as identified in the situation analysis. As part of recurrent costs, the budget should also include funds for regular in-service training of microscopists and refresher training, on the basis of the results of microscopists' performance. Supervisory costs should be included in any detailed budget submitted for approval.

Activities common to both microscopy and RDTs

Financial resources should be available for training clinicians in the use of malaria tests for patient management, perhaps as part of broader training on the management of all fevers. Because of staff attrition and rotation, the budget should cover refresher training, especially in countries with phased implementation of malaria diagnostic tests.

The largest budget component will be however for setting up or expanding existing supervisory activities to include supervision of malaria diagnosis, in particular of clinicians managing febrile patients and of health workers performing RDTs.

Procurement of commodities for the diagnosis and treatment of both malaria and non-malaria fevers may represent a considerable part of the overall budget, depending on what is already available or planned in other programmes. These commodities (e.g. urine dipsticks, antibiotics, rehydration salts, zinc, inhaled salbutamol, …) are nevertheless essential to ensure adherence to malaria test results and to decrease the morbidity and mortality of febrile patients. Procurement of gloves and sharps boxes should be included as part of the commodity costs. A dedicated budget should be allocated for preparing technical guidelines and training materials, for upgrading the information system, for monitoring and evaluation and for communication activities. The budget should also include funds for conducting operational research as a basis for policies and practices.

KEY MESSAGES OF SECTION 2

- Clear criteria for a 'suspected malaria case' should be established to identify patients who should be tested for malaria, adapted to the national situation.
- Patients with a new non-severe episode of fever can be tested either with an RDT or by microscopy.
- Patients in whom antimalarial treatment failure is suspected should be tested by microscopy.
- Treatment of patients with severe febrile illness should be initiated immediately, even before diagnostic testing for malaria. Microscopy is the preferred diagnostic test for these patients.
- Clinicians should also be trained in the management of non-malaria febrile illness, and appropriate medicines and supplies should be provided, including antibiotics for pneumonia and oral rehydration salts and zinc for diarrohea.
- In health facilities with microscopy where the workload exceeds laboratory capacity, the use of RDTs for diagnosis of fever episodes may relieve the burden.

3. Procurement and logistics of malaria tests

3

3.1 Selection of products for malaria diagnosis

3.1.1 RDTs

According to the manual on *Good practices for selecting and procuring RDTs for malaria*, which has been published by WHO in 2011,[1] the criteria for selecting malaria RDTs include:

Target parasite species and antigens

The choice of RDT is based on the prevalence of malaria species in the country. Three geographical zones have been defined:

- Zone 1, in which *P. falciparum* is predominant and non-falciparum species cause mixed infection with *P. falciparum* (most areas of sub-Saharan Africa and lowland Papua New Guinea);
- Zone 2, where *P. falciparum* and non-falciparum infections occur commonly as single-species infections (most endemic areas of Asia and the Americas and isolated areas of Africa, particularly the Ethiopian highlands); and
- Zone 3, where only non-falciparum infections occur (mainly *P. vivax* in areas of East Asia, central Asia and South America and some highland areas elsewhere).

In Zone 1, RDTs that detect only *P. falciparum* are generally preferable. In Zone 2, combination RDTs that detect all species and distinguish *P. falciparum* from non-falciparum infections are indicated. In Zone 3, RDTs that detect non-falciparum species alone are appropriate (pan-specific or *P. vivax*-specific).

The type of antigen targeted depends on the species to be detected (see Table 5): for detection of *P. falciparum*, tests that detect HRP2 are generally preferred, as they are more sensitive than those that detect pLDH; for detection of non-falciparum species, tests targeting pLDH specific to non-falciparum species or common to all species, or aldolase, are recommended.

Table 5. Antigen targets of rapid diagnostic tests for malaria

Plasmodium species	HRP2	pLDH				Aldolase
		pLDH-Pf	pLDH-pan	pLDH-Pvom	pLDH-Pv	
P. falciparum	X	X	X			X
P. vivax			X	X	X	X
P. malariae			X	X		X
P. ovale			X	X		X

HRP2 – histidine-rich protein 2; pLDH – *Plasmodium* lactate dehydrogenase; Pf – *P. falciparum*
pan – all *Plasmodium* species; Pvom – *P. vivax*, *ovale* and *malariae*; Pv – *P. vivax*

[1] *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf

RDT performance requirements and WHO recommendations

Each national malaria control programme is responsible for selecting RDTs that perform well and reproducibly in the setting of intended use. Rather than the results of isolated studies of variable quality (see below) it is strongly recommended to use of the results of the WHO product testing programme for malaria RDTs,[1,2] including the most recent results of each product in order to prepare a short list of products eligible for procurement. In rounds 1 and 2 of the WHO RDT testing programme, a series of tests showed a good correlation among the performance parameters (mainly a high panel detection score, a low false-positive rate and a low invalid rate).The results of round 3 will be available in 2011.

An interactive guide, which allows users to identify RDTs by specific thresholds for various parameters of diagnostic performance, is available on the internet.[3] The user enters the desired parameters and the interactive guide identifies the RDTs coresponding to these criteria, on the basis of the results of the WHO RDT product testing programme.[1,2]

In addition, the WHO/GMP website lists RDT products assessed in the product testing programme, showing the performance of each in relation to the WHO recommended selection criteria.[4]

Country experience with RDTs

Field comparisons of different brands of RDTs are difficult and expensive to conduct; they are not recommended. Studies to assess the ease of use of different RDT kits can provide useful information for a country's selection of an RDT kit. Procurement should be guided by the needs of the national malaria control programme, taking into account previous experience of use and training requirements of health personnel, especially if a new type of RDT is to be procured. If more than one RDT is to be procured, selection of tests with a similar format, ancillary items and testing procedures is recommended to reduce training requirements and errors in performance.

The national health authorities should monitor what RDT products are available in their public and private sectors, as many substandard products are available on the market.

Additional considerations

Further criteria essential for selecting appropriate RDTs are: the supplier's production capacity and lead times, storage conditions, delivery schedules, shelf-life as well as registration and budget requirements.

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[1] *Malaria Rapid Diagnostic Test Performance: Results of WHO product testing of malaria RDTs: Round 1 (2008).* WHO Regional Office for the Western Pacific/FIND/CDC/TDR, 2009. Available at: **http://www.wpro.who.int/NR/rdonlyres/ED81BDE9-B812-4B80-8408-3A129A6365C4/0/OMSFINDRapportMalaria200900514v25.pdf**

[2] *Malaria Rapid Diagnostic Test Performance: Results of WHO product testing of malaria RDTs: Round 2 (2009).* WHO WPRO/GMP/FIND/CDC/TDR, 2010. Available at: **http://www.wpro.who.int/internet/files/rdt/RDTMalariaRd2_FINAL.pdf**

[3] Malaria RDT product testing: Interactive Guide. FIND. Available at: **http://www.finddiagnostics.org/programs/malaria/find_activities/product_testing/malaria-rdt-product-testing/index.jsp**

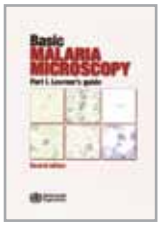
[4] Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests. Global Malaria Programme, WHO. Available at: **http://www.who.int/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf**

3.1.2 Microscopy

Microscopes

The national laboratory services, in collaboration with the national reference laboratory, should decide on the specifications of the microscope that is most appropriate at intermediate and central facilities on the basis of previous national experience and other types of evaluations.[1] Manufacturers of all laboratory equipment and supplies should meet national and internationally recognized general manufacturing quality standards (ISO 9000). Standard binocular microscopes should be used at all times, to simplify both maintenance and the acquisition and supply of spare parts (such as lamps, eyepieces and objective lenses). A binocular microscope with paired x10 eyepieces and x10, x40 and x100 objectives (the latter as 'oil immersion') and a built-in electrical light source is the 'gold standard'. Alternative power sources should be established where mains electricity is not available or is unreliable. The use of daylight as a light source is not recommended for malaria microscopy.

Giemsa stain and buffer solutions



The Romanowsky stains (staining nucleii red and cytoplasm blue), of which Giemsa is one, have proved to be the most reliable stains for routine malaria microscopy.[2] Field stain, which is still used in some programmes, is suboptimal and generally not recommended. Giemsa is the stain of choice also for peripheral laboratories. Giemsa stain powder should be bought from a reputable supplier, and, for preparation of Giemsa stock solutions, highly pure methanol (high quality, with < 1% water) and glycerol (high quality, with < 1% contaminants) must be used. Giemsa stain stock solutions should be prepared within the quality management programme in quality-controlled batches and distributed to the users. Alternatively, some chemical companies sell ready-made Giemsa stock solutions; these also require quality assessment at central level.

One of the critical variables in staining is the pH of both the staining solution and the water used for washing. Simple hand-held pH meters should be made available to all malaria diagnostic laboratories, as pH paper is not satisfactory. Buffer solution is made by combining di-sodium hydrogen phosphate and potassium di-hydrogen phosphate salts (both anhydrous) at specific concentrations. A precision balance is thus required to weight the salts. Alternatively, for small laboratories, buffer tablets to maintain solutions at the correct pH should be purchased.

Microscope slides

Only high-quality microscope slides, free of surface abrasions, should be used for malaria microscopy. Slides with one end frosted for labelling are preferable.

3.2 Quantification and forecasting of requirements for malaria testing

3.2.1 General considerations on the relative needs for microscopy and RDT supplies

As most patients will be tested with only one type of diagnostic test, the needs for microscopy and RDTs are interdependent in the precise deployment plan. Quantification of equipment and supplies for diagnostic testing of malaria should take into account:

[1] *Manual of basic techniques for a health laboratory, second edition*. Geneva, World Health Organization, 2003. Available at:
http://whqlibdoc.who.int/publications/2003/9241545305.pdf

[2] *Basic malaria microscopy, Part I. Learner's guide, second edition*. Geneva, World Health Organization, 2010; section 3.3.1. Available at:
http://whqlibdoc.who.int/publications/2010/9789241547826_eng.pdf

- diagnostic policy, including which test should be used in view of the malaria situation in different parts of the country (what and why); and
- the deployment plan, i.e. the locations where microscopy will be available and those in which only RDTs will be used, and the scale-up strategy (where and when).

The introduction of microscopy into a new facility requires the availability of laboratory services, with adequate staffing and infrastructure, including electricity and a water supply. When RDTs are introduced into health facilities in which microscopy already exists, account should be taken of how a decision is taken on which to use as the first-line test for patients who present with a new fever, and also the patient load when the laboratory is closed (when RDTs might be the only diagnostic test available).

In health facilities where outpatients are tested with RDTs, and microscopy is reserved for inpatients and suspected malaria treatment failure, the number of RDTs required is close to the total number of suspected malaria cases managed in health facilities (minus the number of suspected malaria treatment failures, which is generally low). When outpatients are tested with RDTs at certain health-care levels (for example health facilities in which microscopy is not available and health posts at the community level) and with microscopy at the other levels, the calculation of RDT requirements should be based on the number of suspected cases managed at the level at which RDTs will be used as only test.

For microscopy, the number of microscopes (and related equipment) required depends mainly on the number of laboratories in which microscopy will be or is already used and their capacity (i.e. trained laboratory technicians). The quantification of microscopes for malaria diagnosis and all essential supplies (slides, Giemsa etc) is thus generally not directly linked to the number of suspected malaria cases; however, in countries where microscopy is used widely, it is still necessary to estimate the numbers of patients tested by microscopy, so that this number can be subtracted from the total number of suspected malaria cases seen in the area in calculating the total RDT requirements. This also allows calculation of the number of slides or reagent required for microscopy.

3.2.2 Quantification of the number of suspected malaria cases

The estimation of requirements for RDTs and microscopy is a critical step in the procurement cycle. Depending on the availability and reliability of surveillance data, one of the following four different approaches should be used.[1] In any of the four scenarios, the addition of a safety stock needs to be considered.

a. *Area with no malaria surveillance data:* The estimate of requirements should be based on implementation capacity and programme aspects, i.e. the number of people performing the tests, the number of tests expected to be performed per day and the number of working days during which the test will be performed. To this estimate, a certain amount (e.g. 20%) should be added for safety stock.

b. *Areas with unreliable malaria surveillance data:* This situation is prevalent in many countries, due either to general underreporting or specific to certain health facilities, often in underserved geographical areas. In these countries, RDTs are generally introduced as a first-line diagnostic tool for outpatients, and microscopy is reserved for severe cases and investigation of suspected treatment failures. As the number of suspected severe malaria cases and suspected treatment failures is much smaller than the total number of suspected malaria cases, the quan-

[1] *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011; section 2.1.3. Available at: **http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf**

tities of RDTs required will be close to the total number of suspected malaria cases, and the requirements for malaria microscopy will be modest.

For these areas, quantification should be based on data from parts of the country with reliable surveillance data, similar malaria transmission and similar health-care systems, using the method (c) described below. When extrapolating from different areas, however, the following might influence the estimate and should be taken into account: differences in the number of health facilities and their level of functioning, which affect patient flow at different levels of the health-care system; expected variations in patient treatment-seeking behaviour after introduction of a new malaria treatment policy or differences in pricing of medicines and diagnostic testing; and a different scale of deployment of malaria diagnostic services to peripheral health-care facilities.

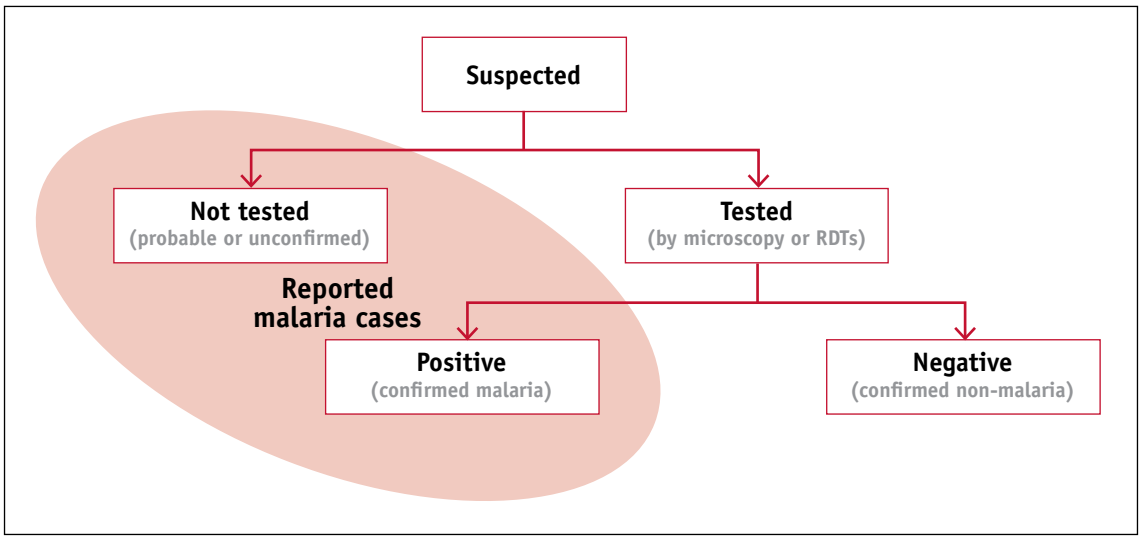
c. *Areas with reliable malaria surveillance but no reliable data on malaria test consumption:* The critical variable to be obtained from surveillance data is the number of suspected malaria cases, which is generally not reported as such. This information can, however, be derived from other data recorded in the health information system. The malaria reporting system in places where RDTs are already in use always contains the following data:

- the total number of reported malaria cases;
- the number of malaria cases confirmed by microscopy;
- the total number of slides examined for malaria by microscopy;
- the number of malaria cases confirmed by RDTs; and
- the total number of malaria RDTs performed.

In some countries, confirmed malaria cases are reported all together, without separating those diagnosed with RDTs or microscopy. Ideally, the positivity rates with microscopy and RDTs should be reported separately, with the number of slides examined and tests performed. It is possible to quantify RDT requirements from malaria surveillance data, on the condition that confirmed negative cases are not reported as malaria, as should be the case when the quality of routine microscopy or RDTs is high. In order to quantify requirements, it is necessary to do some calculations with this routinely recorded data; the relations among these parameters are illustrated in Figure 7.

FIGURE 7.

Relations between suspected cases tested (by microscopy and RDTs) and those not tested (probable or unconfirmed) for malaria



The number of suspected cases, which is the basis for calculating malaria test requirements, can be derived from the number of tested patients, the number of positive cases and the number of reported malaria cases (see section 8.1.1). For detailed information on the calculation, refer to the WHO manual *Good practices for selecting and procuring RDT for malaria*.[1]

d. *Areas with reliable malaria surveillance and reliable data on malaria test consumption:* The most reliable methods for estimating malaria test requirements are based on consumption data, which depend on a functioning logistics management information system. When using this quantification method, it is important to consider expected changes in the deployment strategy for malaria testing. If malaria tests are introduced in new areas or settings or if the type of test used for some groups of patients changes (for example RDTs instead of microscopy in uncomplicated cases), the data should be adjusted accordingly. The consumption data should also be adjusted by the number of days of stock-outs recorded on the stock record forms of the health facilities reporting consumption data. If consumption data are not available for all health facilities, it might be acceptable to estimate the requirements on the basis of a representative sample of health facilities with reliable consumption data.

Next steps

- Define the target coverage for quantification by geographical area and by level of the health system (e.g. health facility or community level).
- Consider whether current testing needs are likely to change over time, i.e. to increase or decrease, depending on many factors (e.g. the extent of testing by community health workers, health sector development plans or changes in the use of health services by the community).
- Consider how the estimates will be affected by the criteria for defining suspected malaria cases in the malaria treatment policy in relation to fever assessment (i.e. criteria for selection of patients for malaria testing, see section 2.3.4).
- Consider that, over time, large-scale deployment of RDTs will affect the consumption of ACTs; therefore the membership of the teams involved in quantifying RDTs and antimalarial medicines sould overlap significantly in competency and scope of work.
- Draw up a realistic plan for completing the quantification on the basis of whether it will be centralized (managed at central level) or decentralized (each facility compiling its own estimates, which are reviewed and consolidated at district and provincial level before submission to the procurement office).

3.2.3 Quantification of material needed for malaria testing

RDTs

One RDT kit (or box) generally contains all the material needed for performing 25–30 or more tests, including blood collecting devices and buffer solution. Generally, lancets and alcohol swabs are also provided, but this should be checked with the supplier. Other general supplies, such as gloves (if not already included by the manufacturer), timers and sharps boxes should be procured separately.

[1] *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011; section 2.1.3. Available at:
http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf

Microscopy

A list of recommended equipment and supplies for a peripheral health laboratory is given in the WHO *Manual of basic techniques for a health laboratory*.[1] A list of recommended equipment and supplies for a malaria microscopy laboratory in a small clinic is given in the WHO *Malaria microscopy quality assurance manual*.[2]

Replenishment of defective or obsolete equipment should also be considered in quantification of needs, taking into account national capacity for servicing and maintenance.

Material for both malaria microscopy and RDTs

A list of recommended equipment and supplies needed for both microscopy and RDTs is given in Table 6, with the corresponding specifications and quantities required. If the RDT kits already contain lancets or alcohol swabs, these items should be removed from the procurement list.

Table 6. List of material common to microscopy and RDTs, with specifications

Description	Specifications
General equipment	
Timers	From 1 min to 1 h, fitted with alarm sound
Consumables	
Absorbent cotton wool	White, non-sterile, in 500-g packages
Alcohol[a]	For skin disinfection
Gloves	Examination, latex, disposable, 50 pairs/box, sizes: large, medium and small
Lancets	Disposable, sterile, standard type, boxes of 200
Sharps container	For needles and syringes, cardboard for incineration size 15 l
Markers	Dye-, bleach- and water-resistant

[a] 'Spirits' generally contain a mixture of ethyl alcohol and methyl alcohol.

3.3 Procurement of supplies for malaria testing

All the steps in the procurement of RDTs are described in detail in the WHO manual *Good practices for the selection and procurement of malaria rapid diagnostic tests*.[3] (Many steps in the procurement of microscopes and related material are similar to those for RDTs.) The steps are:

- defining specifications for tenders on the basis of national requirements (see section 3.1.1);
- transforming quantification of needs (see section 3.2) into planned orders, considering the frequency of delivery to each supply point, safety stocks needed at each level of the supply chain, foreseen losses, available budget and lead times;

[1] *Manual of basic techniques for a health laboratory, second edition*. Geneva, World Health Organization, 2003; Table 2.2, page 36–39. Available at: http://whqlibdoc.who.int/publications/2003/9241545305.pdf

[2] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009; section 5 and annex 3. Available at: http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

[3] *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf

- procurement by restricted tender, in which only manufacturers with standards (in particular, ISO 13485:2003 certification) and the capacity to provide the quantities required within the desired timeframe are invited to apply. The tender specification should include RDT performance requirements based on WHO recommendation (see section 3.1.1); and
- procurement of other supplies needed for both microscopy and RDT (gloves, timers and sharps boxes), which should accompany the procurement of malaria tests.

Specific comments

RDTs: completeness, i.e. RDT kits that contain lancets, alcohol swabs and all other essential material should be one of the criteria for procurement.

Microscopy: Specifications for procuring microscopes and related equipment should be aligned against the standards recommended by the national health laboratory system, as microscopes are also used and procured for other public health programmes (such as tuberculosis).

3.4 Distribution, transport and storage

RDTs

The performance of RDTs is impaired when they are exposed to high temperatures or humidity. The sealed foil packaging protects them from moisture. They should be transported and stored under rigorous temperature control to ensure that they are always kept below the maximum temperature recommended by the manufacturer. When air-conditioning is not available, calibrated, validated thermometers (for daily recording of minimum–maximum) should be placed in various parts of the storeroom to monitor temperature. If the recorded maximum shows that the temperature repeatedly exceeds the limit recommended by the manufacturer, the storage conditions should be immediately improved. If there is a strong suspicion that RDTs have been exposed to high temperatures for several days, a sample should be sent for lot-testing.

Community health workers should avoid storing large quantities of RDTs; instead, they should obtain supplies more often and in smaller quantities to avoid damage to RDTs due to poor storage conditions. Further practical guidance on transporting, storing and handling of malaria RDTs is provided in two WHO/FIND manuals.[1,2]

Microscopy

Microscopes should always be stored in a dry environment, preferably in their storage boxes, to avoid dust and exposure to humidity, which promotes growth of fungus on lens surfaces. Dry conditions can be obtained by placing a lighted 25-watt bulb inside a small cupboard, in which the microscope is stored at night.

Stock staining solutions should be kept away from direct sunlight, in a cool place, in dark bottles with tightly fitting lids, as moisture can affect the quality of the stain. For this reason, it is suggested that the working solution be kept in a small volume in a different container from the main solution, and that only dry glassware be used for preparing staining solution daily.

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[1] *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests at Central and Peripheral Storage Facilities*, 2009. Available at: http://www.wpro.who.int/NR/rdonlyres/1BBCEFC2-46B3-40F5-9898-7455578145E8/0/MalariaRDT_CENTRAL_2009web.pdf.

[2] *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*, 2009. Available at: http://www.wpro.who.int/NR/rdonlyres/269BF1DC-BA7C-4422-A16E-F73016DA17B5/0/MalariaRDT_REMOTE_2009web.pdf

3.5 Stock management

An efficient transport and distribution system and a reliable logistics management information system are vital for coordinating a supply distribution network, whether for medicines, diagnostic devices such as RDTs or supplies for microscopy. Logistics management information system record forms are the core of the supply information system, as they contain information on supply needs, movement and associated financial transactions. The stock record form documents all transactions related to an item, with columns and rows for the source of each delivery, the quantities received and issued, lot numbers of items dispatched to health facilities, the balance available and the expiry date of each lot, if applicable (e.g. for RDTs). The stock record form may be different for small health facilities at peripheral levels and for central stores.[1] To facilitate stock inventory control of RDTs, the stock record form should state the smallest unit of dispatch, i.e. the number of boxes, rather than the number of individual tests (cassettes or cards).

The national policy should state what should be done with overstocks and commodities near their expiry date at each level. At point-of-care level, when the consumption is lower than expected (e.g. of ACT due to fewer malaria cases than expected), health facilities should be allowed to move excess stocks to other facilities that have higher consumption. The medical store unit must make regular, periodic counts of the actual stock on hand to ensure that the balance recorded in the stock record form is correct and that the minimal safety stocks are available.

A monthly report of stocks of all items should be produced to ensure that reordering is based on consumption, inventory levels, lead times and requirements for safety stocks. To calculate quantities for reordering at central level, in addition to the above, the estimates should also take into consideration the procurement period and the stocks on order but not yet received. For more information, refer to the *Malaria case management operations manual*.[2]

3.6 Maintenance of microscopes and other equipment

Maintenance of microscopes is often neglected; however, maintenance of microscopes and related equipment (pH meters, balance and water filter) should be part of general practice for the care and maintenance of laboratory equipment by the national laboratory services. Other relevant laboratory equipment (e.g. haemoglobin meter, centrifuge, glucometer) should also be included in the overall maintenance plan of equipment for all laboratory services.

If possible, a pool of technicians who have been trained in maintenance and know the preventive measures for maintaining microscopes should be set up at subnational level. Standard operating procedures for the use, care and maintenance of microscopes (see Annex 1) and for other relevant equipment, should be prepared.

Basic principles for microscope maintenance are:

- training of biomedical engineers by the manufacturer or agent on the specific maintenance requirements for the microscope model adopted by the country;
- existence of a maintenance workshop in the country, including a warehouse of spare parts;
- availability of complete technical information (service and user manuals) for use and maintenance of the microscope model used in the programme;

[1] *Malaria case management: Operations manual*. Geneva, World Health Organization, 2009; appendix 1. Available at: http://whqlibdoc.who.int/publications/2009/9789241598088_eng.pdf

[2] *Malaria case management: Operations manual*. Geneva, World Health Organization, 2009; section 5.2.3. Available at: http://whqlibdoc.who.int/publications/2009/9789241598088_eng.pdf

- training of all laboratory users in the basic care and maintenance of the microscope; and
- availability of spare microscope bulbs in every laboratory.

At laboratory level, a physical inventory of all equipment should be made, and each new item of equipment should be added to the list. A specification sheet should be prepared for each item of equipment (see example in Annex 2). When an item of equipment is maintained or repaired, a sheet recording what has been done should be filled in by the laboratory technician responsible for the equipment (see example in Annex 3). A register of all repairs should be maintained in the laboratory receiving the repaired equipment (see example in Annex 4).

KEY MESSAGES OF SECTION 3

- An RDT product with high diagnostic performance fulfilling the WHO recommended selection criteria for procurement should be chosen.
- Quantification of RDT and microscopy supplies and ACT is strongly interdependent and should not be done separately.
- RDTs should be stored in cool conditions; in hot climates, daily monitoring and recording of maximum temperature in storage places is important.
- To avoid stock-outs and wastage of tests, an efficient system of distribution and stock management should be put in place.
- Maintenance of microscopes and related equipment is often neglected, although it is a basic requirement for high-performance malaria microscopy.

4. Components of a quality management system

4.1 Overview of quality management activities at different levels

The quality management system for malaria diagnostic tests includes all the processes necessary to ensure that the diagnostic results from both microscopy and RDTs are as accurate as the test is designed to be, from the selection of the test to actual use of the results. Many activities that are essential to ensure the high quality of the final product (in this case, a correct malaria test result in the hands of the clinician) are described in the other sections of this manual (colour-empty boxes in Figure 8) and will not be discussed here. The activities that are specific to the quality management system (orange boxes in Figure 8) and that have not been discussed elsewhere are presented in this section.

4.2 Quality management activities at central level

4.2.1 Preparation of a plan for quality management

What to do

A quality management plan for malaria diagnostic tests should be prepared at central level and integrated with, or at least coordinated with, the quality management plans for other, related laboratory activities. The plan should describe all the activities discussed below, providing for various levels of responsibility (central, subnational and point-of-care) of the people in charge.

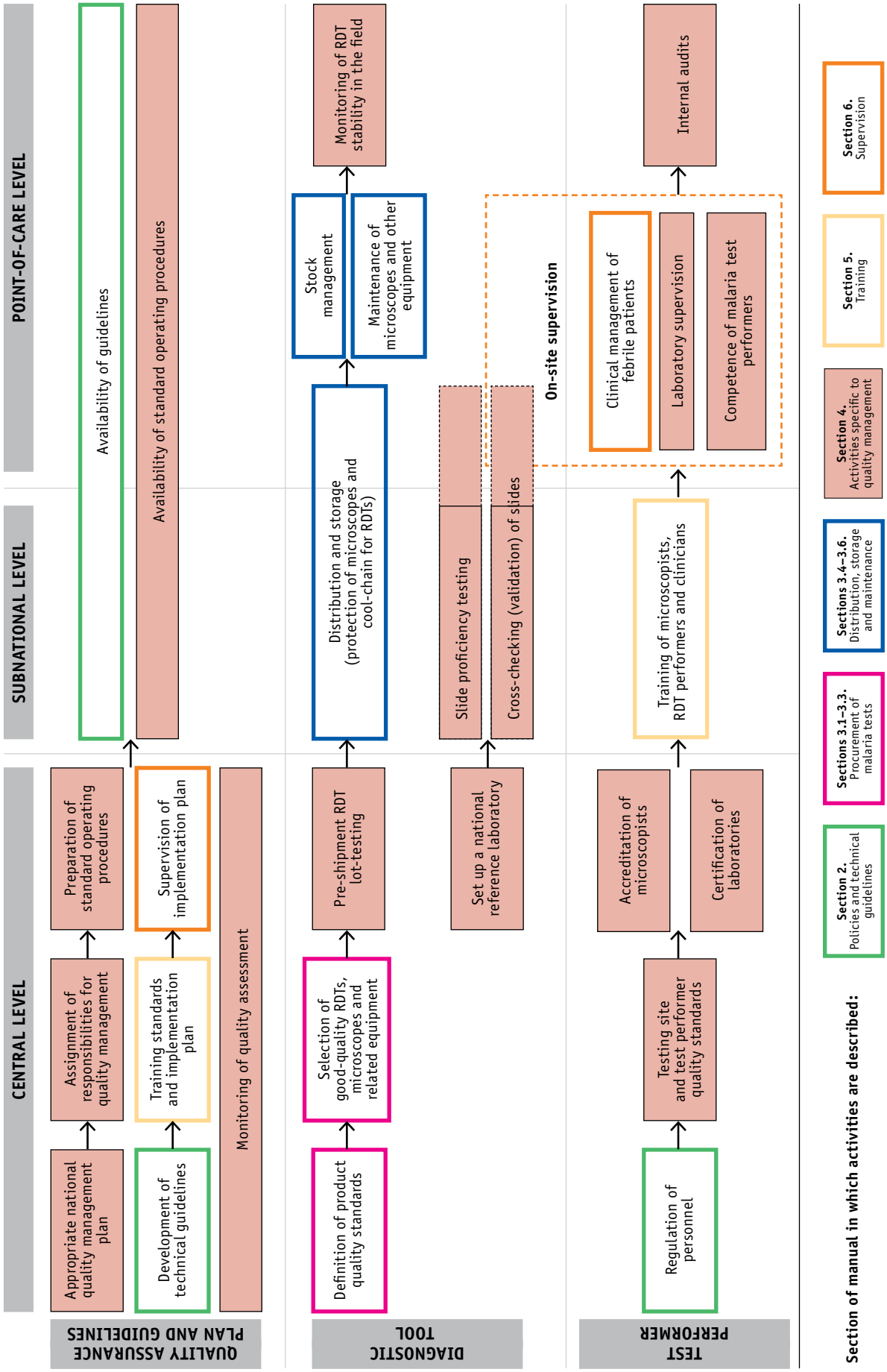
When possible, quality management activities should be integrated with other disease programmes and laboratory service activities. Quality management should be implemented for microscopy and RDTs at the same time to benefit from their mutual synergies and reinforcement.

How to do it

Identify key stakeholders, e.g. national malaria quality management system coordinator, person in charge of the quality management system at the national laboratory services, person in charge at the national malaria reference laboratory, malaria diagnostic coordinator in the national malaria control programme, as well as standardization, certification and accreditation bodies. Identify the focal person for quality management of malaria microscopy and RDTs. If quality management for RDT is handled by a different person than for quality management of microscopy, their activities should be carefully coordinated. The focal person is responsible for maintaining quality to agreed minimum standards.

A phased approach to quality management with a strong emphasis on monitoring will provide information on how to improve the system. Monitoring of the quality management system is therefore essential for 'learning by doing' and adapting the programme to changing needs (decreasing malaria endemicity, new diagnostic tools, increasing numbers of subnational reference laboratories). Feed-back is also an essential component for improvement over time.

FIGURE 8.
Activities required to ensure high-quality malaria testing, by level of health system



4.2.2 Quality standards for testing sites and test performance

The diagnostic performance of malaria microscopy depends strongly on the competence of the microscopist in preparing, staining, examining and interpreting malaria blood slides. For this reason, quality management systems in malaria microscopy have often focused on assessing and continuous improvement of the competence of individual microscopists rather than on certification of laboratories, which is the standard approach for other laboratory procedures. Both are however essential to ensure accuracy of the final test result. A functioning quality management system depends on acceptable performance standards, procedures and practices identified for organizations and individuals involved in the malaria diagnostic service at various levels of the health system. For this, a national standard-setting group should be formed that includes personnel from the national malaria control programme and public health laboratory service as well other relevant departments of health and educational institutions.

Standards must be defined in five main areas:

Competence of test performers

Peripheral level microscopy: a microscopist at the lowest level of the laboratory network should be able to detect the presence or absence of malaria parasites (in a slide set of 10 negative and 10 positive slides) with more than 90% accuracy A grading system for accreditation of microscopists that can be adapted for country settings as appropriate is available in WHO's *Malaria microscopy quality assurance manual*.[1]

RDTs: At present, there is no standardised way to measure the competency level of RDT performers. The key intervention for quality monitoring is regular supportive on-site supervision (see Annex 10).

Testing site performance (accuracy and timeliness of testing in routine practice)

The overall performance of a facility in microscopy can be determined by laboratory visits using quantitative checklist and by external quality assessment, with proficiency testing in a grading system similar to that used for assessment of individual competence. Low laboratory performance indicates that the competence of individual microscopists should be investigated.

Supervisor competence

Supervisors should undergo training and accreditation before undertaking supervision. They should be given a structured checklist to assess laboratory standards. They should provide on-site feedback of their findings, recommendations for improvements and on the spot trouble-shooting, when indicated.

Trainer competence

Trainers should have recognized competence in their areas of expertise and be accredited. They should be supported by a core group of experts and validators at central level, who have demonstrated measurable expertise.

Equipment and reagent standards

See section 3.1

[1] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009; section 6. Available at:
http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

4.2.3 Roles of the national malaria reference laboratory

The Ministry of Health should establish a national reference group of expert microscopists, generally based at the national reference laboratory,[1] set up a national blood slide bank and prepare reference slide sets for training,[2] reference purposes and external quality assessment of testing sites.

The national reference laboratory should participate in an international external quality assessment programme for reference laboratories. WHO has established a proficiency testing programme for several diseases, including malaria, for national reference laboratories.[3]

When organizing external quality assessment, priority should be given to important testing sites (such as district hospitals, laboratories participating in epidemic surveillance, laboratories working as references for other testing sites). Once a network of fully quality-assured subnational reference laboratories is in place, additional testing sites can be included.

At least three external quality assessment activities should be organized by the national reference laboratory, first applied to subnational reference laboratories adn then delegated to them to be applied to peripheral laboratories, if feasible

Supervision visits of laboratories

Laboratories at all levels should be monitored by on-site visits with a standard supervisory assessment tool (see Annex 8). During these visits, assessments should be made of microscopists' competence by direct observation during preparation and staining of blood slides (see Annex 9) and of the general quality of the blood slides at the testing site (see section 4.4.3). For more details on laboratory supervision, see section 4.4.1.

Slide proficiency testing (reference blood slide reading at the testing site)

This activity (also called 'panel testing') consists of distributing pre-prepared stained blood films in a blinded manner to laboratories performing malaria microscopy for examination. This allows monitoring of the competence of a microscopist or laboratory to detect, identify and quantify malaria parasites on a well-prepared, stained blood film. It is not a measure of the performance of malaria microscopy in routine practice. This activity might be focused in priority testing sites (e.g. subnational reference laboratories), as it requires a large number of standardized slide sets and is complex and time-consuming. On-site visits to these subnational reference laboratories are a good opportunity to distribute the reference blood slides and, on a subsequent visit, to collect the results of their reading. A standard form should be used to report reading accuracy to laboratories and take necessary remedial action in cases of suboptimal performance.

Validation of routine blood slide results (cross-checking)

The national reference laboratory can set-up a system to perform a second reading (cross-checking) of a sample of routine blood slides prepared at subnational reference laboratories (see section 4.4.3). Once the results of cross-checking show that the expected level of competence has been

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[1] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009; section 5 and annex 3. Available at: **http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf**

[2] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009; section 9 and annexes 8 to 10. Available at: **http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf**

[3] *Policy and procedures of the WHO/NICD Microbiology External Quality Assessment Programme in Africa Years 1 to 4, 2002–2006*. Geneva, WHO/CDS/EPR/LYO/2007.3. Available at: **http://whqlibdoc.who.int/hq/2007/WHO_CDS_EPR_LYO_2007.3_eng.pdf**

reached at subnational level, a similar system can be put in place between the subnational reference laboratories and peripheral laboratories.

Some countries have plans to modify this system to include a third reading of peripheral slides by expert microscopists at the national reference laboratory (either a random sample or slides with discrepant results after cross-checking), in addition to the second reading at subnational level. A third reading of the same slide complicates reliable calculation of the percentage of agreement (see section 4.4.3) and prolongs feedback to the peripheral laboratories. The competence of microscopists at subnational level can be evaluated by the national reference laboratory only on the basis of slides prepared at the subnational laboratory itself and not from their reading of blood slides prepared by others (peripheral laboratories).

For more discussion on different approaches for slide validation, see section 4.4.3.

4.2.4 Certification of reference laboratories

Certification is recognition of the performance of a laboratory. It is usually voluntary and complements mandatory licensing or registration. For example, ISO 15189:2007 accreditation has been established for laboratories that meet internationally recognized standards. Intercountry initiatives exist or are being set up in some regions. A training toolkit for learning how to implement a quality management system in a laboratory on the basis of internationally recognized standards is available on the WHO website.[1] Certification is, however, expensive to do and to maintain.

If full certification is not possible, national and subnational reference laboratories should try to achieve high standards by participating in a recognized quality management system, which is furthermore a prerequisite for accreditation.

4.2.5 Designing standard operating procedures and job aids

A series of standard operating procedures and job aids should be created (preferably at the national reference laboratory for both microscopy and RDT; sometimes at the national malaria control programme for RDTs). The following examples of standard operating procedures can be adapted to local contexts:

- RDT performance: job aids based on the WHO validated generic models of job aids and adapted to the type of RDT available in the country;[2]
- RDT storage at point-of-care: standard operating procedures (see Annex 4) and the pocket guide (see pages 5 to 11 of WHO/FIND *Transporting, Storing and Handling Malaria Rapid Diagnostic Tests in Health Clinics*);[3]
- use, care and maintenance of microscopes: standard operating procedures (see Annex 5) and bench aid (see Plate 5a of WHO *Bench aids for malaria microscopy*[4]);

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[1] *Laboratory Quality Management System Training toolkit*. Geneva, World Health Organization/Clinical and Laboratory Standards Institute/Centers for Disease Control and Prevention, 2009, Trainer's guide and handbook. Available at:
http://www.who.int/ihr/training/laboratory_quality/en/

[2] Malaria RDT Job-aids and Training Manuals. WHO/FIND. Available at:
http://www.wpro.who.int/sites/rdt/using_rdts/training

[3] *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*, 2009. Available at:
http://www.wpro.who.int/NR/rdonlyres/269BF1DC-BA7C-4422-A16E-F73016DA17B5/0/MalariaRDT_REMOTE_2009web.pdf

[4] *Bench Aids for Malaria Microscopy*. Geneva, World Health Organization, 2010. Available at:
http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codcch=3294

- preparation of Giemsa stain solution: bench aid (see Plate 7a of WHO *Bench aids for malaria microscopy*[1]); standard operating procedures (see annex 8 and sections 3.1.3–3.3.5 of the WHO *Malaria microscopy quality assurance manual*[2] and learning unit 5 of *Basic malaria microscopy, Part I*[3]);
- thick and thin blood film preparation for malaria: bench aid (see Plate 3a of WHO *Bench aids for malaria microscopy*)[1] and standard operating procedures (see learning unit 4 of *Basic malaria microscopy, Part I*[3]);
- blood film staining for malaria: bench aid (see Plate 7a of WHO *Bench aids for malaria microscopy*[1]) and standard operating procedures (see annex 8 and section 4.1.2 of the WHO *Malaria microscopy quality assurance manual*[2] and learning unit 5 of *Basic malaria microscopy, Part I*[3]);
- routine examination of blood films and parasite density calculation (see Plate 9a of WHO *Bench aids for malaria microscopy*[1] and learning unit 5 of *Basic malaria microscopy, Part I*[3]);
- waste management of malaria tests: standard operating procedures (see Annex 6) and, for RDT, pocket guide (see pages 20 to 29 of WHO/FIND *Transporting, storing and handling malaria RDT in health clinics*[4]); and
- proficiency testing (external quality assessment) for microscopy: standard operating procedures (see Annex 7).

4.2.6 Accreditation of microscopists

Accreditation of the competence of microscopists can significantly improve the accuracy of malaria diagnosis by microscopy and raise the confidence of the microscopist.[5] It is recommended that national programmes:

- establish a national malaria microscopy accreditation system;
- give formal recognition to the skills of individual microscopists;
- set up a training programme linked with the accreditation system to improve the competence of microscopists working at each level of the laboratory network;
- monitor and record their competence continuously; and
- provide a career path for certified microscopists.

It is recommended that accreditation be time-limited and, for the best-performing microscopists, should be valid for no more than 3 years. Earlier reassessment should be available for those who are not performing well.

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[1] *Bench Aids for Malaria Microscopy*. Geneva, World Health Organization, 2010. Available at: http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codcch=3294

[2] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009. Available at: http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

[3] *Basic malaria microscopy, Part I. Learner's guide, second edition*. Geneva, World Health Organization, 2010. Available at: http://whqlibdoc.who.int/publications/2010/9789241547826_eng.pdf

[4] *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*, 2009. Available at: http://www.wpro.who.int/NR/rdonlyres/269BF1DC-BA7C-4422-A16E-F73016DA17B5/0/MalariaRDT_REMOTE_2009web.pdf

[5] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009; sections 5 and 6. Available at: http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

4.2.7 RDT lot-testing

Because lot-to-lot variation in diagnostic performance is found for most malaria RDTs, it is good practice implemented by a number of funding and procurement agencies to test all lots (batches) of RDTs before deployment to the field.[1] Lot-testing can be done:

- before shipment, directly arranged with the manufacturer and a lot-testing centre;
- after shipment and delivery to the central warehouse and before distribution to the field; or
- after distribution to peripheral health facilities, to investigate reports from the field of unexpected test results.

Several funding agencies require pre-shipment lot testing and procure only production lots that meet the lot-testing requirement. Procurement agreements should include replacement of failed lots.

During lot-testing, RDTs are evaluated against a small panel of parasites at low densities and against negative samples. The RDTs are subsequently incubated at a temperature close to the manufacturer's specified storage temperature and retested at intervals until their expiry date. Initial results are available after 5 working days following receipt of the RDTs by the lot testing centres.[2]

4.2.8 Monitoring the quality management system

Performance indicators (see section 8.1) should be chosen on the basis of data collected by health facilities and reported through the national health information management system or, possibly, during on-site supervisory visits. In addition to routine data, problems reported from peripheral health facilities should prompt additional on-site quality monitoring. To monitor improvements over time, it is essential to collect performance indicator data regularly over a long period. The main problems identified during supervisory visits should also be reported at secondary or central levels.

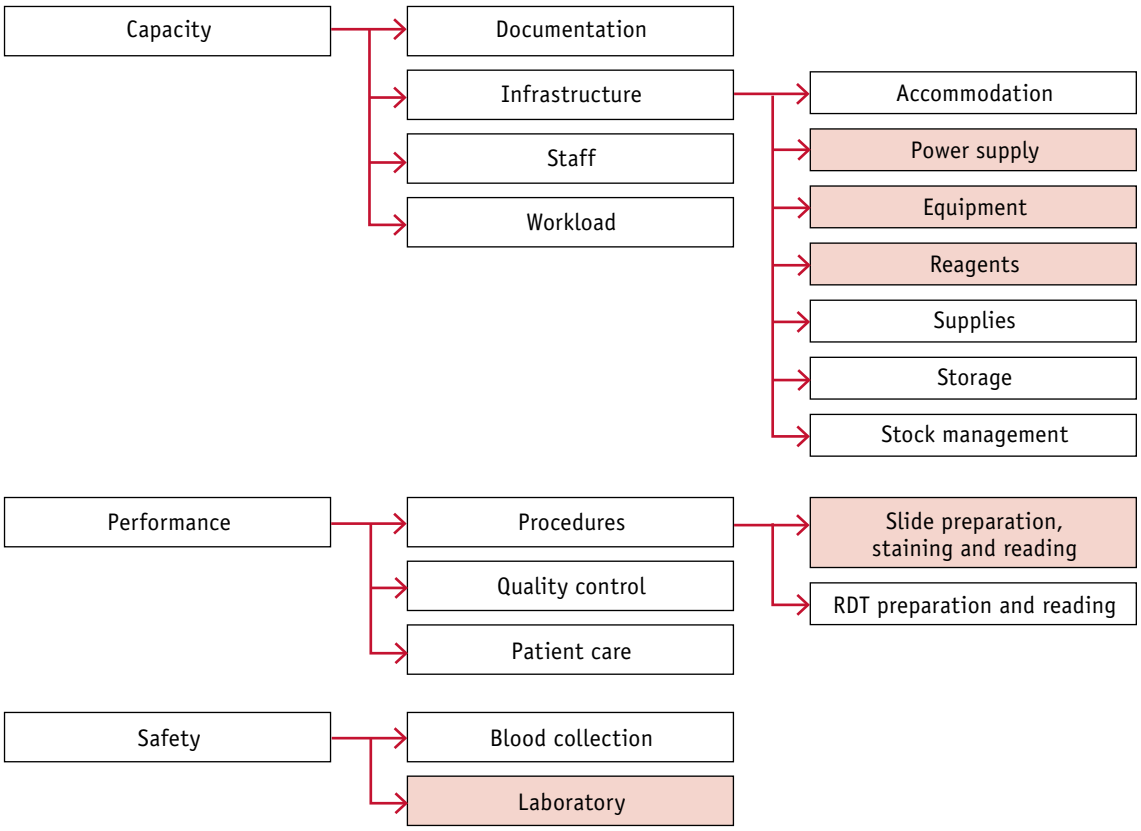
The main components of monitoring performance in malaria diagnosis are shown in Figure 9.

[1] *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf

[2] *Lot testing of Malaria Rapid Diagnostic Tests: Quality benefits all*. Geneva, World Health Organization/FIND, 2009. Available at: http://www.wpro.who.int/NR/rdonlyres/8DF454F7-1183-4930-8A39-80E225521AB9/0/Lot_testing_brochure.pdf

FIGURE 9.

Example of main components for monitoring performance in malaria diagnosis



Adapted from Walter Reed Army Institute of Research (2010). Malaria microscopy and rapid diagnostic testing quality management resource manual. Fort Detrick, Texas.

White boxes apply to all health facilities (with or without a laboratory); orange boxes apply only to health facilities with laboratory capacity.

4.3 Quality management activities at subnational level

The subnational (provincial or district) level should organize quality management activities coordinated by the national reference laboratory, such as a microscopy proficiency-testing scheme (reading sets of reference slides sent to peripheral laboratories) with slide sets prepared at national level. The following activities can also be conducted at points of care (see section 4.3):

Supervision visits of laboratories (see section 4.4.1): The laboratory focal person should supervise laboratories at peripheral level by on-site visits using a standard supervisory checklist (see Annex 8). This should identify problems in performance that may need correction.

Monitoring competence in malaria testing (see section 4.4.2): Direct observation of health workers performing RDTs should be integrated into the routine on-site supervision of health facilities (see Annex 10). Direct observation of microscopists preparing, staining and reading blood slides should be included in supervisory visits to laboratories (see Annex 9).

Validation of routine blood slide results (cross-checking) (see section 4.4.3): Assessment and cross-checking of routine blood slides at peripheral laboratories should be performed only by the subnational reference laboratory or, preferably, during on-site supervision visits. A third reading of a sample of slides or of discrepant slides by the national reference laboratory should be avoided.

Temperature monitoring of RDT storage in health facilities (see section 3.4): Recording temperature in storage places should include the daily maximum temperature, which is monitored by the supervisor as part of routine on-site supervision of health facilities.

To be effective, it is recommended that the number of supervisors in a province or district be based on: the number of people with the necessary skills to be supervisors, the workload of supervisors, the frequency of supervision required, ease of access to health facilities in terms of distance and available transport and financial resources for supervision. Reference laboratories at subnational level should be closely monitored by the national reference laboratory and participate in all quality management activities.

4.4 Quality assessment at points of care

For health facilities with a laboratory facility, the quality management activities for microscopy at points of care are generally better handled during on-site visits by laboratory supervisors. These visits will also allow evaluation of laboratory technicians' competence to perform microscopy and RDTs. Supervisory visits can be used to assess health workers' performance in handling patients with fever and to assess clinicians' use of laboratory test results.

For health facilities without a laboratory and for community health workers, all quality assessment activities for RDTs should be integrated into routine supervisory visits that include patient management. Therefore, clinical supervisors should be trained in all aspects of RDT performance and use.

The activities directly related to the quality management system that can be implemented at points of care, with their proposed frequency (to be adapted to the local requirements), are listed in Table 7.

4.4.1 Supervision visits of laboratories

A baseline assessment of laboratories' performance in the diagnosis of malaria (and if possible of non-malaria causes of fever) should have been performed during the initial gap analysis.[1] Supervisory visits to peripheral diagnostic facilities are important for monitoring performance and to take or facilitate the appropriate corrective actions and strengthen communication between the different levels of the quality management programme.

Supervisory visits should be made routinely, at a minimum of every 6 months or, if possible, quarterly. During establishment of the quality management system, more frequent visits may be necessary. Special visits may be necessary if problems are identified during external proficiency testing or cross-checking of blood slide results by reference laboratories. A follow-up supervisory visit shortly after a training session is also useful to correct any bad practices before they become fixed or to address any concerns of the health workers.[2] These visits should be integrated with supervision of the general health services and laboratory quality assessment of other laboratory procedures. Joint visits by clinicians and laboratory staff are recommended. Sufficient time must be allotted for the visit to include observation of all aspects of the work associated with

[1] *Malaria microscopy quality assurance manual, version 1.* World Health Organization, Regional Office for the Western Pacific, 2009; table 3. Available at: http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

[2] *Malaria microscopy quality assurance manual, version 1.* World Health Organization, Regional Office for the Western Pacific, 2009; section 7. Available at: http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

Table 7. Activities directly related to quality management at points of care					
Quality management activity	**Daily**	**Weekly**	**Monthly**	**Quarterly**	**Yearly**
In the laboratory					
Check for damage or malfunction of microscopes.	X				
Remove dust from microscopes with a clean cloth.	X				
Cover the microscope with a dust cover.	X				
Cover the lens ports.	X				
Check the expiry date on Giemsa stock solution.			X		
Check that sharps containers that are three quarters full are disposed of.	X				
Check that infectious waste (non-sharp) plastic bags that are three quarters full are disposed of.	X				
Prepare a report on blood slides prepared in the laboratory.			X		
Prepare a report on all RDTs performed in the health facility (both in the laboratory and in all other places used when the laboratory is closed).			X		
Archive blood slides for external slide validation.	X				
Read reference slides received for proficiency testing (if applicable).				X	
Directly observe laboratory technicians performing microscopy and RDTs.				X	
Check whether standard operating procedures should be updated (beside updates when a change occurs).					X
Perform internal audit of the laboratory in preparation for a supervisory visit from the district.					X
In the clinic					
Check that sharps containers that are three quarters full are disposed of.	X				
Check that infectious waste (non-sharp) plastic bags that are three quarters full are disposed of.	X				
Clinicians meet to discuss a few febrile cases they managed recently.		X			
Laboratory technicians, clinicians and nurses meet to solve practical problems of diagnosis of malaria and non-malaria fevers.			X		
Directly observe health workers performing RDTs.				X	
Directly observe clinicians managing febrile patients.				X	
Check whether guidelines should be updated (beside updates when a change occurs).					X
At storage places					
Check the expiry dates of RDTs and ACTs.			X		
Check the maximum temperature at the RDT storage place.	X				
Check stock inventories to calculate the number of RDTs and microscopy supplies that have been used.			X		
At management team level					
Check whether a monthly health information management report has been completed.[a]			X		
Compare the number of positive malaria tests, the number of malaria cases reported by clinicians, the number of ACT issued by the main store and the number of ACT dispensed to patients.			X		
Plan in-service training for clinicians and laboratory technicians.					X
Perform an internal audit of the health facility (or of parts of its activities) in preparation for a supervisory visit from the district.					X

[a] While monthly reporting is the minimum recommended frequency, some countries may report more frequently or even in real time through electronic or telephonic reporting systems.

malaria microscopy and RDT, the adequacy and safety of laboratories, the workload of laboratory staff and the adequacy of equipment and supplies. A checklist covering aspects of both microscopy and RDT assessment should be used (see Annex 8).

The staff of the facility to be evaluated should be informed in advance of a supervisory visit, although unannounced visits may be conducted, depending on the conventions in individual countries. The report of the supervisory visit should be sent promptly to the laboratory (i.e. within 14 days) through the usual channels.

4.4.2 Monitoring the competence of malaria test performers by direct observation

Microscopists

A supervisory visit for laboratory monitoring is an opportunity to observe microscopists directly while they are preparing, staining and reading routine blood slides (including cross-checking of 10 to 20 slides if time allows). Use of a checklist to be filled in for each observation separately (see Annex 9) is important in order to document each microscopist's performance, to give him or her feedback, to monitor improvement over time and to decide whether refresher training is necessary when the performance is below the national benchmark.

RDT performers

Direct observation of health workers' competence in performing an RDT (in or outside the laboratory) on a real patient requires human resources and time to visit each health facility regularly and observe each health worker at least once. This activity should be integrated into the overall health facility supervisory visit. Supervision of RDT preparation and interpretation with a standardized checklist is important. An example is given in Annex 10. When possible, corrective action should be taken during the visit, which might include retraining in blood collection and/or RDT preparation or interpretation of the result.

4.4.3 Quality of routine blood slides for malaria

Besides observing laboratory technicians while they are performing microscopy for malaria, it is often considered essential to assess the average quality of preparation and staining and, above all, the interpretation of blood slides at testing sites in a more systematic way. Many attempts at slide cross-checking have, however, failed, mainly because of lack of transport to bring the slides to the reference laboratory, the restricted number of qualified microscopists who can cross-check the result properly and the delay and even absence of feedback to the peripheral laboratory. It is clearly an activity that consumes time and human resources and is difficult to organize for every health facility performing microscopy. The priority should thus be the evaluation of subnational reference laboratories by the national reference laboratory.

For peripheral laboratories, it is often more sustainable to examine the quality of slides and to cross-check the results of routine slide examination on-site during a general supervisory visit rather than asking laboratories to send samples of slides to a reference laboratory for rechecking. The number of slides cross-checked during on-site supervisory visits is expected to be, however, limited due to time constraints. Therefore results from several supervisory will need to be aggregated to provide meaningful quantitative data.

Cross-checking of slides by any of the above methods should not replace internal audits in the laboratory (see section 4.4.5), which should remain the priority. If internal quality monitoring is well organized, external quality monitoring becomes easier and is needed less often.

Quality of routine preparation and staining of slides

Before a supervisory visit, the laboratory should be informed about the visit and asked to keep a predetermined number of blood slides (meeting specific criteria) that were routinely collected from patients seen at the facility up to that date. During the visit, a randomly selected sample of 10 to 20 slides should be evaluated on a standard form, including at least:

- correct size of films;
- correct volume of blood with correct opacity;
- uniformly spread;
- thick film not fixed with methanol;
- no parts of the film washed off;
- correct staining of thick film; and
- no stain precipitate.

As proposed above, these slides should be analysed on-site so that direct feedback can be given and corrective action taken immediately. The evaluation should be kept for monitoring improvement over time.

Validation of routine blood slide results (cross-checking)

Routine blood slide results are cross-checked in a blinded re-examination of a selected sample of slides by an expert microscopist from a reference laboratory, either on site during a supervisory visit or later at his or her own laboratory. The aim is to detect and quantify the number of false-positive and, especially, false-negative results given by the laboratory under evaluation.

The slides must be rechecked by an accredited malaria microscopist of proven competence, using a microscope of good quality and in good condition. A system should be in place to ensure blinded re-examination (for example, the results of the laboratory under examination in the right margin, folded and sealed with adhesive tape). A standard form to give feedback to laboratories should always be used. The validator must have a thorough understanding of the sources of errors and be trained in compiling a summary report with recommendations, which will eventually be returned to the laboratory under evaluation (and to the national malaria control programme).

All schemes for slide cross-checking require a minimum quality of slide preparation and staining. If the quality of slide preparation and staining is suboptimal, the interpretation of the slide result will not be reliable. In addition, all schemes for malaria slide cross-checking require that the microscopy reading of the reference laboratory has reached a high level of competence. If a system of cross-checking is already in place and the quality of reading at subnational laboratories is found to be insufficient, the latter might, for example, give feedback only on the quality of slide preparation and staining and not on the reading.

The level of investment required to maintain a cross-checking programme should be carefully evaluated. Some ways of cross-checking are more demanding than others in terms of human resources and logistics. Many countries have designed programmes that are unrealistic in relation to the capacity of their health system. For example, it might be decided that routine blood slides are read during supervisory visits, the advantage being immediate feedback on the result, on top of feedback on the quality of preparation and staining. Such a programme requires, however, a sufficient number of supervisors who have reached a high level of competence in malaria microscopy; it also has major limitations, because only a few slides can be cross-checked during a single supervisory visit. It might be rather decided that a certain proportion of routine slides are to be taken to the reference laboratory for rechecking, but the logistics of receiving slides from every participating laboratory every month and giving rapid feedback to each are often unfea-

sible. Indeed, experience has shown that this approach can overwhelm the reference laboratory and, as a result, feedback to the front-line technician is not given. Collecting slides on a quarterly rather than a monthly basis might be a viable alternative, as long as the reference laboratory does not receive all the slides to be rechecked at the same time.

The viability of all cross-checking programmes depends on their capacity to detect poor performance, identify where the problem lies, provide timely feedback and take the appropriate corrective action. The level of congruence that should be reached by all laboratories should be decided at national level; at least 90% congruence is expected for positivity detected by microscopy.

A new protocol for selecting a sample of routine slides to be cross-checked is proposed in the WHO.[1] This protocol is based on monthly assessment of five week positive (< 200 parasites/µl) and five negative randomly selected slides. The results are analysed monthly and quarterly as percentage agreement between field and expert microscopist, with an expected proportion of agreement > 90% for an acceptable level of competence. This method is considered more feasible than the standard cross-checking of all positive cases and 10% randomly selected negative slides, promoted in the past. The new WHO protocol for slide validation has not yet been widely implemented, and its capacity to detect false-negative results in low-transmission settings is not fully proven.

Even if a fixed number of positive and negative slides are rechecked, the capacity to detect false-negative results (lack of sensitivity) depends directly of the slide positivity rate. When this rate goes down, the chance of detecting false-negative slides becomes low. For example, the chance of detecting a lack of sensitivity (< 80%) when cross-checking five slides reported as negative is about one in four in a setting where the positivity rate is 20%. This chance goes down to one in eight when the positivity rate is 10%. In areas of low malaria prevalence, the sample of negative slides to be cross-checked should therefore be increased. When a small number of slides are tested, the percentage congruence will fluctuate widely from month to month by chance rather than because of real fluctuations of the laboratory's competence. Therefore, the absolute number of discrepant results (rather than percentage congruence) should be given as feedback. The results should always be analysed as trends over time.

4.4.4 Monitoring the stability of RDTs in the field

Evaluating the diagnostic performance of RDTs at a point of care by direct comparison with a reference test is more difficult than evaluating blood slides, because there is no standardized test with which to compare the end-point of RDTs (parasite antigen concentration). Even when expert microscopy is available, the results of an RDT and a blood slide performed on the same patient never correlate perfectly, as parasite antigen levels do not necessarily correlate with parasite density, and parasite antigen persists for some time after parasites have cleared from the blood. Some countries have chosen to overcome this problem by using, as a standardized comparison, a 'reference RDT', i.e an RDT of the same manufacturer, stored in controlled conditions at central level and performed on site by the supervisor on the same patients.

In view of these difficulties, it is generally better to focus on other parameters that are determinants of RDT diagnostic performance, i.e. ensuring that health workers are competent to prepare and read an RDT (see section 4.3.2) and that the storage conditions for RDTs are correct (in particular by temperature monitoring, see section 3.4). The maximum daily temperature of storage

[1] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009; section 8 and annexes 5 to 7. Available at: http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

rooms can be monitored with minimum–maximum thermometers, and these should be used to detect undue exposure to high temperatures, which can affect the performance of the test devices.

Positive control wells are being developed, which would allow testing of the quality of RDT devices with a lyophilized product containing a standardized amount of parasite antigens corresponding to a low parasite density. Once they are available, they will be a useful option for measuring the accuracy of RDTs in clinical use.

4.4.5 Internal audits for malaria testing

The functioning of the various activities that are required for malaria diagnostic testing should be reviewed periodically as part of a good quality management system. When the review is done by the staff of a health facility rather than external supervisors, this is called an internal audit.

Laboratory staff should conduct internal audits to check their own performance and to ensure the reproducibility and sensitivity of laboratory diagnoses. They should examine the elements of the quality management system in their laboratory in order to evaluate how well they comply with quality system requirements. Effective internal audits ensure a 'culture of quality' in peripheral laboratories, with the staff understanding the concepts and need for quality assessment. Organization of internal audits is the responsibility of the laboratory head, but all personnel must be involved and have responsibility for maintaining quality in their work area.

A technician working in isolation should also conduct internal audits, but the number of checks that can be done is more limited, and an independent check of his or her work by a second technician is more likely to show up errors than self-checking. Checks that are feasible, however, should be carried out routinely.[1]

A standardized form should be used to follow-up improvements over time, which may be similar to that used for supervising laboratories (see section 4.4.1 and Annex 8). Internal audits procedures should be checked regularly during visits by technical staff from supervisory laboratories. Trouble-shooting guides for equipment, reagents and methods are also useful, particularly for the most isolated laboratories, where immediate help is not available.

4.4.6 Quality of RDTs performed at community level

Generally, the RDTs used by community health workers are provided by a nearby health facility and have thus undergone quality assessment. To ensure the quality of RDTs, the competence of community health workers to perform an RDT and to interpret and correctly use the result is evaluated during supervisory visits, by direct observation with a standard check-list (see section 4.4.2)

The temperature at which RDTs are stored should also be monitored. Community health workers should be allocated limited numbers of RDTs, generally no more than they would use in 1–2 months. This limits damage of RDTs due to poor storage conditions. Cool boxes (not containing ice) or locally adapted cooling boxes should be used for storage of RDTs in the field by validated methods.

[1] *Malaria microscopy quality assurance manual, version 1.* World Health Organization, Regional Office for the Western Pacific, 2009; section 10 and annex 12. Available at: **http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf**

4.5 Action to be taken in cases of nonconformity with malaria testing

Reacting to nonconformity is a key component of a good quality management system, and all procedures should be documented. Health workers should be trained to be attentive to significant deviations from expected results in their facilities. If this occurs, the health worker should report the incident to their supervisors and request an unscheduled supervisory visit to assess all possible sources of the problem.

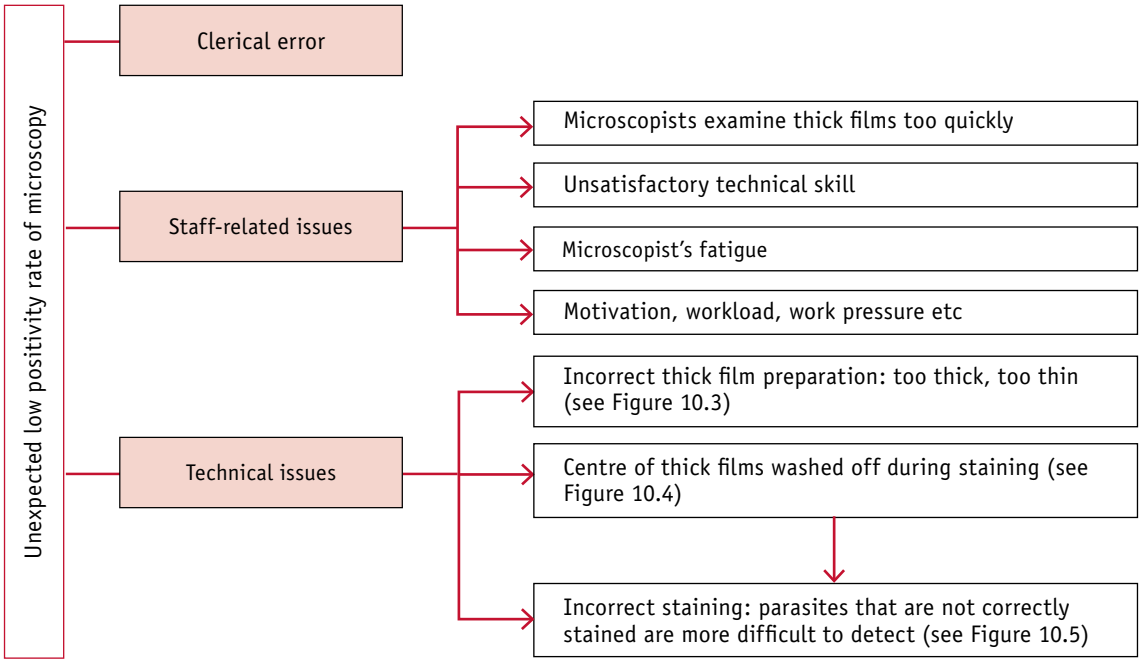
If the problem appears to be with the RDTs currently in use, the batch of suspected poorly performing RDTs should be replaced, if possible, by those from a different batch. If the problem appears to be associated with the quality of the RDT, a rapid initial comparison of the results with a "reference RDT" or with expert microscopy, if available, should be organized, keeping in mind the limitations described in section 4.4.4. In addition, a sample of the suspected batch can be sent to a reference laboratory for lot-testing (at the two WHO/FIND reference laboratories in Philippines and Cambodia, or when available a national reference laboratory for RDT lot-testing).

The aim of the algorithms in Figure 10 is to identify common problems in the field. Problems detected at programme level and the corresponding investigations and responses are described in section 8.2.

FIGURE 10.

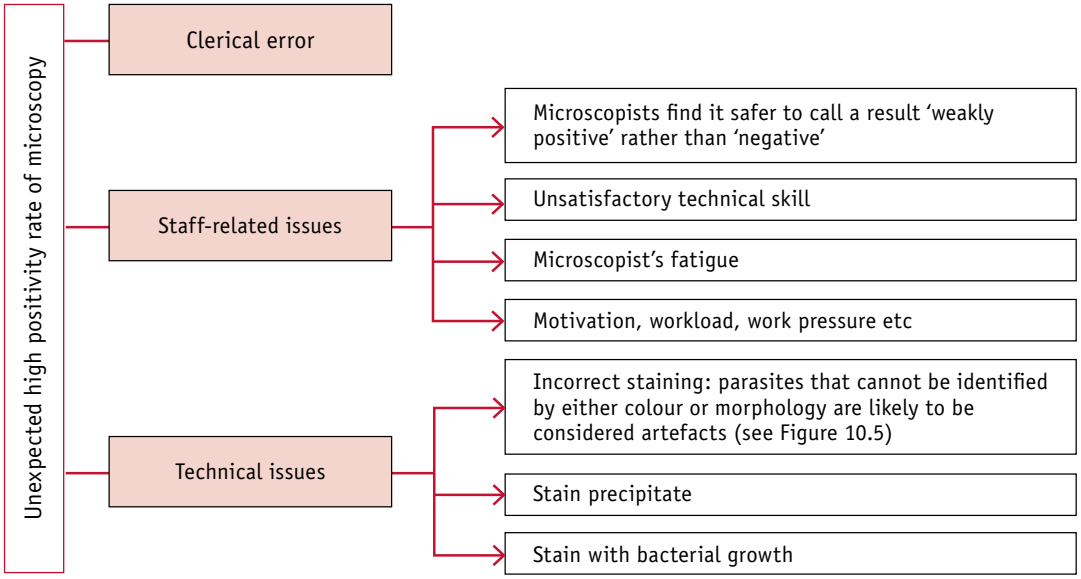
Actions to take on nonconformity in malaria testing

10.1 Unexpected low positivity rate of microscopy (not due to a decrease in malaria transmission)

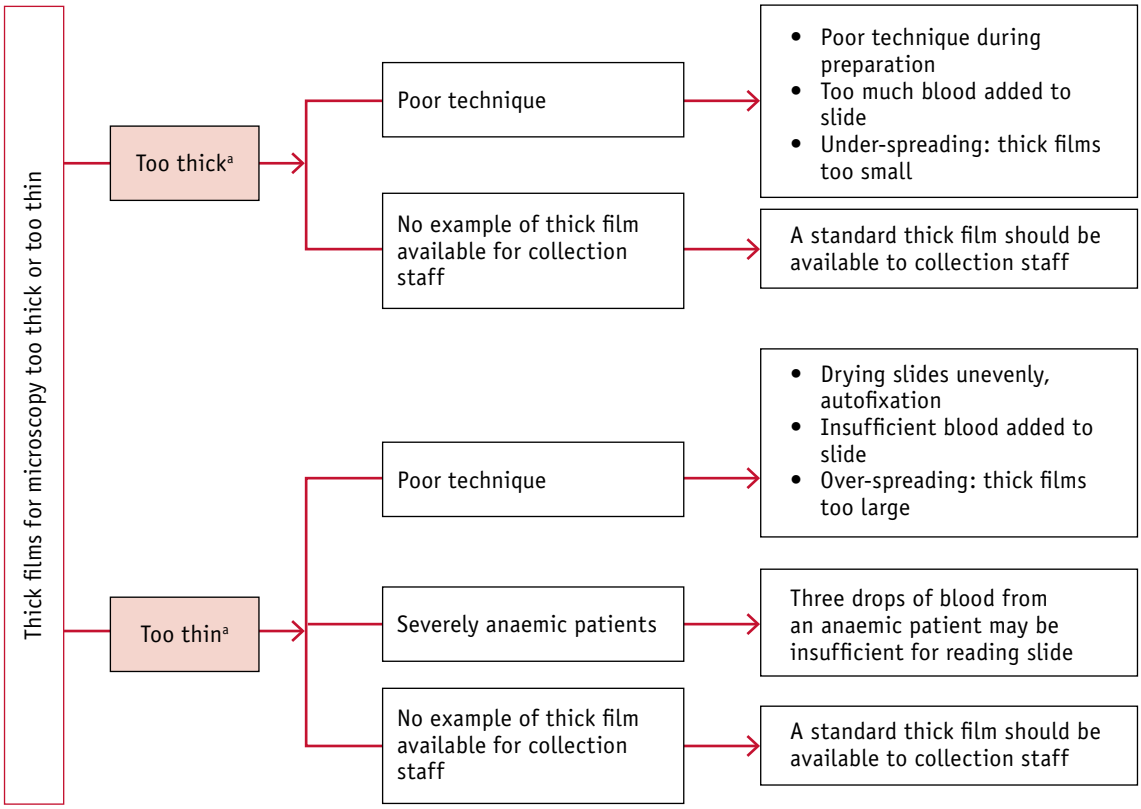


Adapted from MSF-OCA Malaria manual, version 1, 2008

10.2 Unexpected high positivity rate of microscopy (not due to an increase in malaria transmission)

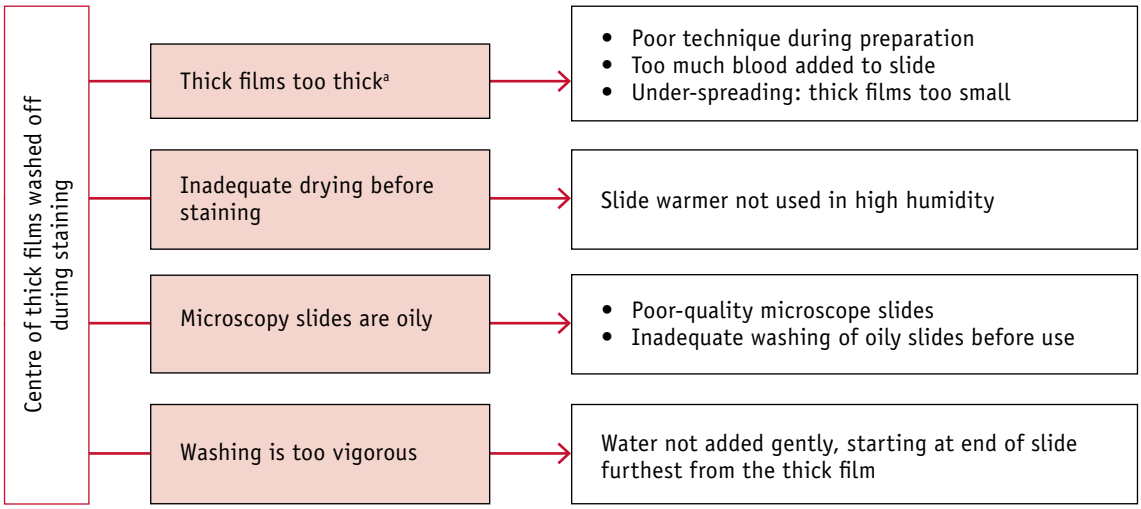


10.3 Thick films for microscopy too thick or too thin



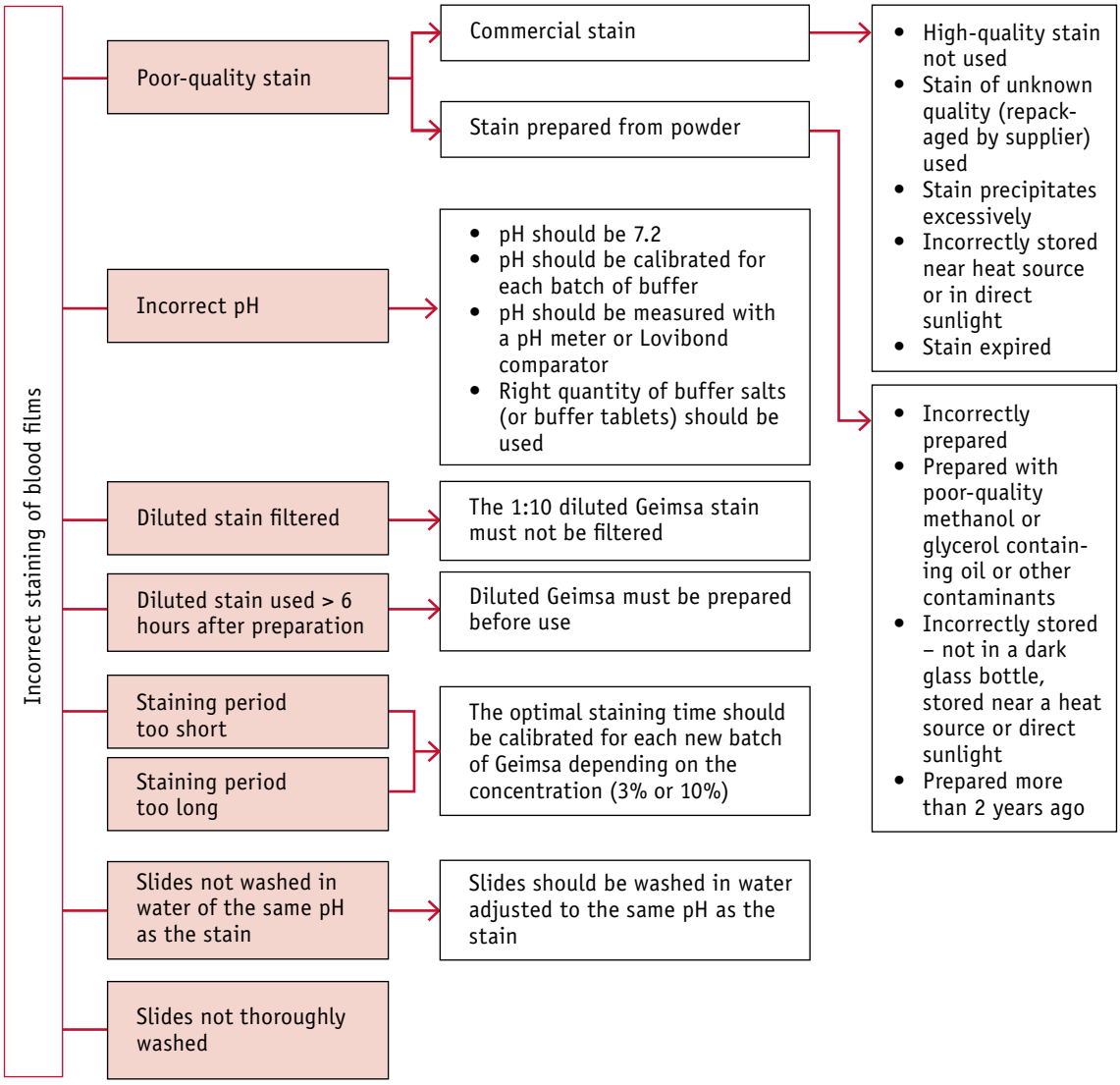
[a] Newsprint should be just readable through a wet thick film

10.4 Centre of thick films washed off during staining

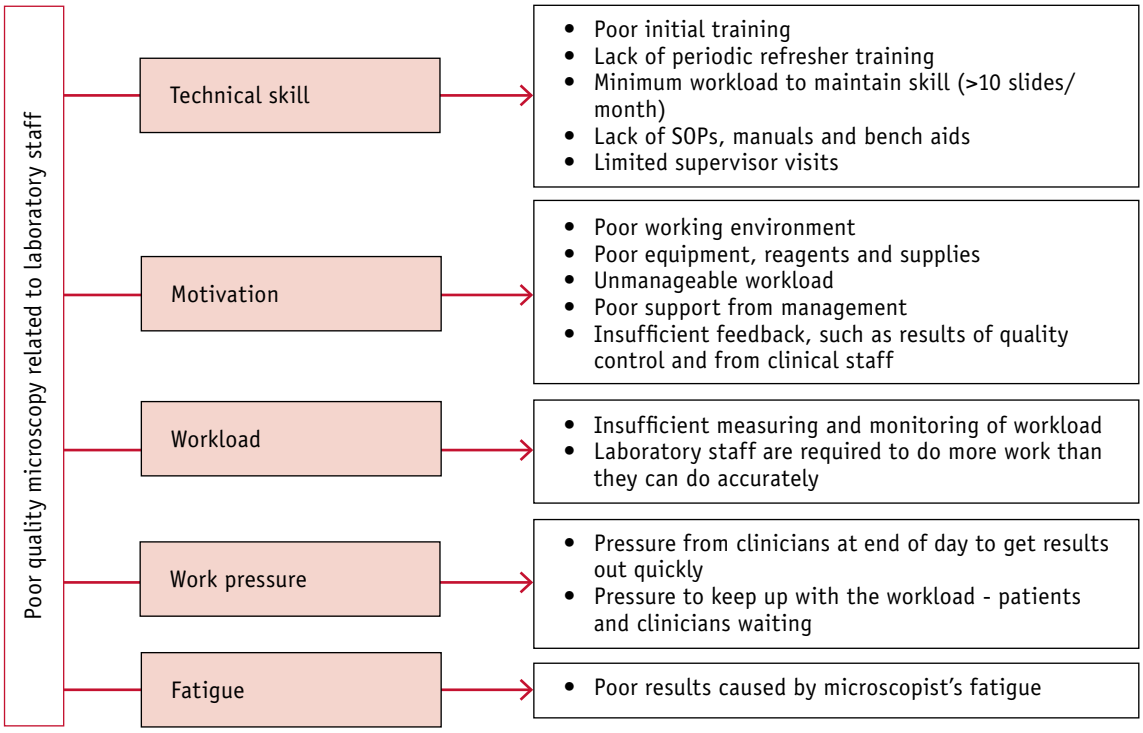


[a] Newsprint should be just readable through a wet thick film

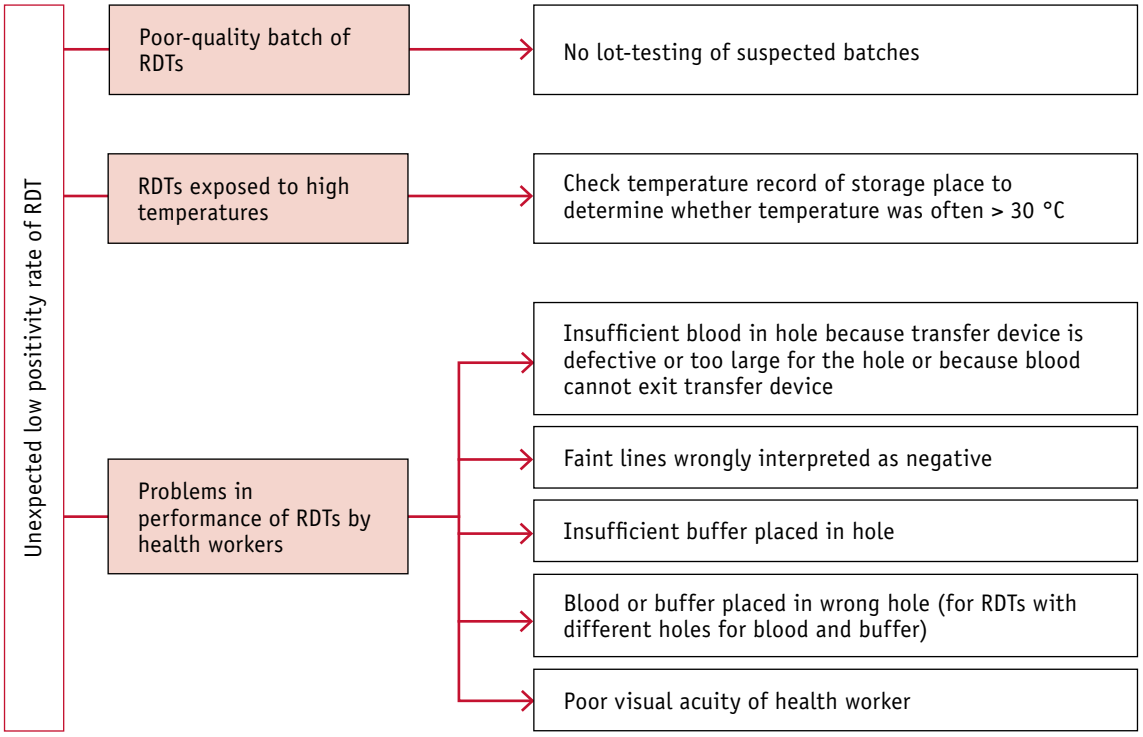
10.5 Incorrect staining of blood films



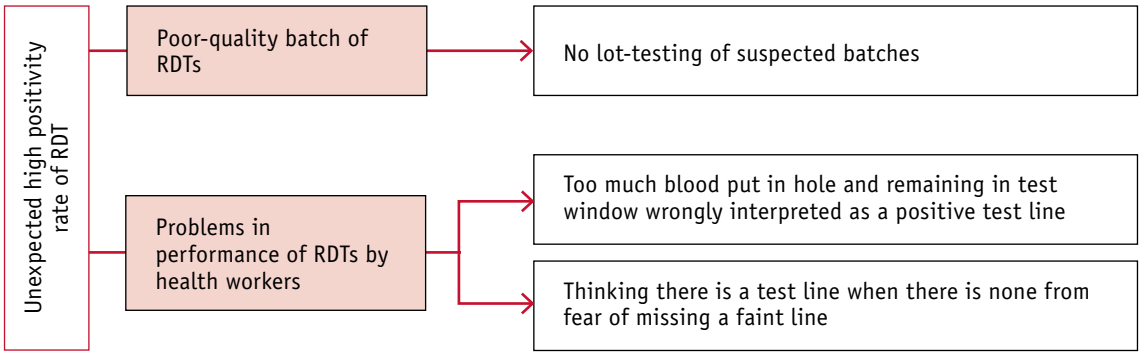
10.6 Poor quality microscopy related to laboratory staff



10.7 Unexpected low positivity rate of RDTs (not due to an decrease in malaria transmission)



10.8 Unexpected high positivity rate of RDTs (not due to an increase in malaria transmission)



4.6 Country scenarios

Three country scenarios reflecting frequently observed settings are represented below and describe priority actions that national malaria control programmes may consider to scale up access to malaria testing.

***Country scenario 1:* Country with predominantly areas of high risk for malaria (mainly *P. falciparum*; non-falciparum monoinfection is extremely rare) and limited areas of low risk; with poor microscopy, no quality management system, no use of RDTs and a high malaria burden based mainly on reported clinical cases**

Parasite-based malaria diagnosis is virtually absent in the country, wastage of antimalarial medicines is very high, and microscopy results, when available, are generally ignored by health providers in treatment decisions. In rural high-endemic settings where there are shortages of ACT, health providers still select patients for malaria treatment on the basis of the results of poor quality microscopy, and patients may not receive the appropriate non-malaria treatment they need.

The first step is to identify a coordinator for RDT use and malaria microscopy strengthening, who will plan and manage deployment of RDTs as soon as possible and establish, in collaboration with the national reference laboratory, a system for quality management of malaria microscopy. Then, phased deployment of RDTs at all levels of the health system, including hospitals, is planned. Priorities are set, e.g. starting with low-endemic regions where overdiagnosis is worst. After selecting a RDT that detects *P. falciparum* only and meeting WHO recommended selection criteria, procurement is started with planned delivery before the malaria transmission season. Pre-shipment lot-testing is completed before delivery to the central medical store. Transport to subnational warehouses (previously inspected to ensure that cool storage is possible) in the selected provinces is organized, in parallel with progressive training of laboratory technicians and clinicians in the performance and use of RDTs. RDTs are sent to health facilities immediately after the health workers return from training to their workplace. A first supervisory visit is organized in the week after use of RDTs has begun, to ensure that the storage conditions (including temperature) and health workers' competence to perform RDTs are in line with standard operating procedures and that clinicians are adhering to the results of the test and manage test-negative patients on the basis of integrated management of childhood, adolescent and adult illness. If possible, training of health workers and distribution of RDTs are planned to start during the malaria transmission season, when the proportion of positive cases is highest. Regular supervision, integrated into scheduled supervisory visits, is organized, with sensitization of the community about the necessity of testing for malaria before receiving antimalarial treatment.

In collaboration with the reference laboratory, a national core group of microscopists is trained and accredited in malaria microscopy. A reference slide bank is created, and the certified expert microscopists participate in training other microscopists and in setting up and supervising subnational reference laboratories in regional hospitals. A quality coordinator at the national reference laboratory starts to organize a quality management system for malaria microscopy, with slide cross-checking initially in subnational reference laboratories. In addition, quarterly laboratory supervisory visits will be started, with a checklist (and a score to follow up performance over time), and, if possible, external quality assessment with a proficiency-testing scheme.

The malaria surveillance programme is adapted to include a diagnostic component, and plans are made to report on RDT use in the next update of the health information management system.

***Country scenario 2:* Country with mainly low-risk areas, predominantly *P. falciparum* malaria, good-quality microscopy with a quality management system in place and no deployment of RDTs**

Parasite-based malaria diagnosis of good quality is available, but only in health facilities with a functioning laboratory. A national reference laboratory with accredited, experienced microscopists is in place. The main aim is to extend access to malaria diagnosis to health facilities without laboratory services by introducing RDTs, supported by a quality management system for both microscopy and RDTs, and to set up a system to monitor the outcomes of the diagnostic strengthening programme (including monitoring of the quality management system).

The priority for phased introduction of RDTs is health facilities without laboratory services. In addition, a review of the national standards for equipment, supplies and workload will be completed to identify gaps and needs. RDTs will be introduced to complement malaria microscopy in health facilities where laboratories have a heavy work load and for laboratory work 'after hours'.

After selection and procurement of an RDT product that fulfils the WHO recommendations, in particular with a high panel detection score (in WHO product testing), the national laboratory quality team is updated on the tools for strengthening quality management for microscopy and trained in the specificity of quality assessement of RDTs. Phased introduction of both RDTs and the quality management system is planned to cover the whole country progressively, maintaining good coordination of microscopy and RDT activities at each level.

In parallel, a strong sensitization programme on the equivalent performance of RDTs and microscopy for the management of malaria is planned for both health-care providers and the community.

***Country scenario 3:* Country with both *P. falciparum* and non-falciparum malaria, deployment of *P. falciparum*-detecting RDTs in the public sector only, heterogeneous quality of microscopy and no effective quality management system**

Parasite-based malaria diagnosis of good quality is available, including at community level, but only in the public sector. The quality management system is weak, and the malaria test used most often (RDT for *P. falciparum* only) does not detect *P. vivax* monoinfections. The policy is therefore that patients with an RDT-negative result should be treated for a possible *P. vivax* infection, obviating most of the potential saving of antimalarial medicines. A programme switch to a combination RDT is thus decided.

After selection of a few combination RDT products that fulfil the WHO selection criteria for procurement, the first step is to evaluate the ease of use of each product in order to understand the training requirements. Then, policies, guidelines and training materials can be updated for use of

the new RDT. The malaria treatment strategy should also be updated; for example, a *P. falciparum* line only (and control line) on the RDT indicates ACT; a pan-*Plasmodium* line only (and control line) indicates chloroquine (or ACT, if chloroquine-resistant *P. vivax* malaria is present); a *P. falciparum* and a pan-*Plasmodium* line (and control line) indicate ACT; a control line only indicates no antimalarial medicine; no control line indicates that the test is invalid.

In parallel, quality management of microscopy is reinforced with an implementation plan and timelines for proficiency testing, as well as cross-checking of blood slides in areas where the positivity rate is still > 20%. Private laboratories are involved, by decree, in this new quality assessment strategy. The formal private sector is involved in deployment of the new RDT, and a quality management system based on supervisory visits is organized to ensure adherence to the RDT result in the private sector.

KEY MESSAGES OF SECTION 4

- A well-performing diagnosis programme requires a well-designed, fully implemented quality management system.
- High quality standards in malaria diagnosis are needed to ensure that clinicians have faith in the results they receive. These take time, commitment and human and financial resources.
- The quality management system should be flexible and cover both malaria microscopy and RDTs.
- The quality management system should have measurable performance indicators for monitoring.

5. Training of health workers and supervisors

5.1 Sensitization

To ensure successful training, the following groups should be sensitized during meetings for this purpose:

- national and subnational (provincial and district levels) health managers from the ministry of health and the national malaria control programme;
- people in charge of laboratories and health facilities providing malaria diagnostic services;
- clinicians, laboratory staff and paramedics (nurses, pharmacists, community health workers and supervisors) involved in malaria diagnosis and treatment in the public sector;
- health workers in the private sector involved in malaria diagnosis and treatment; and
- representatives of the community.

The sensitization meetings should focus on the importance of parasitological confirmation of malaria diagnosis, the equivalence of microscopy and RDTs to detect malaria in symptomatic individuals and the safety of treating patients on the basis of the malaria test result. They should include a demonstration of the performance of a malaria RDT and group discussions on issues such as: the tasks and capacity of the focal person for malaria diagnosis at health facilities with no laboratory; where and by whom RDTs should be performed in health facilities; the role of clinical and laboratory supervisors in sites with laboratories; blood safety; waste management; beliefs and concerns of community members in relation to blood examination and finger-pricking; and patient fees and cost recovery.

5.2 Organization of in-service training at all levels

5.2.1 Reference laboratories for malaria microscopy

Groups of expert microscopists should be established at national and subnational (if any) reference laboratories. These microscopists should be selected on the basis of an objective evaluation made by the national accreditation system (see section 4.2.2). WHO recently introduced standard assessment courses designed for accreditation of malaria microscopists already in service (WHO malaria microscopy accreditation and certification training). These courses, based on practical tests, result in accreditation of microscopists according to their level of competence.[1]

Malaria microscopy refresher training courses should be provided for staff who do not reach the level of competence required for their service. The level of training and the length of the course

[1] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009; section 5 and annexes 2 and 3. Available at: http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

will depend on the level of expertise to be reached by the trainee. Training of expert microscopists should also include teaching of training and supervisory skills to give them competence in teaching malaria microscopy and in supportive supervision for their role as a national core team of malaria microscopists attached to the national programme or the national reference laboratory. To include all these aspects, training of previously qualified expert microscopists generally requires at least 4 weeks.

The national microscopy quality management programme should maintain a database of course participants and their accreditation levels. It is recommended that microscopists keep an individual training and competence logbook, in which relevant certificates and qualifications are recorded. This should be kept up to date by each microscopist.

An example of a 4 weeks training course on expert malaria microscopy and quality assurance is available on the WHO/EMRO website.[1] A section on teaching and assessing RDT performance (technical aspects of performing the test) may be added (see section 5.2.2) to the course to allow the laboratory supervisor to assess RDT use in health facilities with a laboratory.

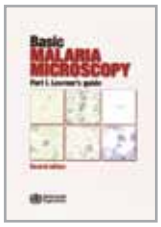
5.2.2 Tutors and supervisors

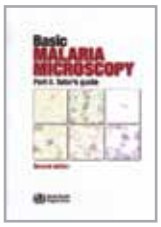
Supervisors and tutors should be identified at appropriate levels (i.e. provincial or district) and given training in both test performance and supervisory skills, including use of checklists.

Laboratory tutors and supervisors

Course tutors in microscopy and laboratory supervisors should be trained by accredited national trainers with extensive field experience. The training should include not only microscopy, but also comprehensive instruction on performance of RDTs, as a laboratory supervisor should be able to assess RDT use and interpretation in laboratories in which RDTs are being deployed.

The objective of laboratory training tutors and supervisors is to cover the areas listed in section 5.2.3, as well as organizing quality monitoring and assessment at points of care, supervision of RDT and microscopy performance and use, and monitoring of malaria diagnoses.





Learners' and tutors' guides for malaria microscopy are available.[2,3] These guides follow a timetable for a basic malaria microscopy training course of 5 weeks, which, for more qualified staff can be reduced to 2 weeks for use as refresher training.

RDTs tutors

A manual for tutors to train health workers in use of RDTs is being prepared. It should be used in countries, taking into account the epidemiology of malaria in different regions, the national algorithm for malaria diagnosis and treatment of febrile cases, the type of RDT that will be used, the organization of supervision and monitoring and the local perception of malaria diagnosis. An example of a timetable for a RDT tutors' training course of 3 days is given in Table 8. Topics 4 and 5 (how to perform a RDT; how to read and report RDT results) in this time-

[1] Fourth International course on advanced malaria microscopy and quality assurance. WHO/EMRO and Directorate of Malaria Eradication, Sultanate of Oman, 3 February–2 March 2011. Available at: http://www.emro.who.int/rbm/pdf/malaria_microscopy_course_%20oman_2011.pdf

[2] *Basic malaria microscopy, Part I. Learner's guide, second edition*. Geneva, World Health Organization, 2010. Available at: http://whqlibdoc.who.int/publications/2010/9789241547826_eng.pdf

[3] *Basic malaria microscopy, Part II. Tutor's guide, second edition*. Geneva, World Health Organization, 2010. Available at: http://whqlibdoc.who.int/publications/2010/9789241547918_eng.pdf

Table 8. Example of a timetable for a tutors' training course (days 1, 2 and 3) or a health workers' training course (days 1 and 2) for RDT

Day	Morning	Afternoon
1	Opening and administrative issues, pre-training knowledge assessment Topic 1: The situation of malaria in the country and province Topic 2: Importance of malaria diagnosis Topic 3: Algorithm for malaria diagnosis and treatment of febrile cases[a]	Topic 4: How to perform a malaria RDT (demonstration and return practical) Topic 5: How to read and report malaria RDT results
2	Topic 6: Safety, storage, stock and waste management Topic 7: Supervision and monitoring of malaria diagnosis Topic 8: RDT quality management system, problem-solving and trouble-shooting	Topic 9: Preparation of clinical case studies in small groups Topic 10: Presentation of group work on clinical case studies and discussion Topic 11: Community health education on adherence to malaria test result
3	Training in training of trainers: effective communication and presentation skills Key messages to be communicated and the training mode Practical exercise on how to train (as a tutor) health workers in use of RDTs, using the RDT field manual for health workers	Planning and running RDT training workshops, with a practical session in small groups Presentation of group work on plans for RDT training workshop and discussion Operational aspects of the RDT implementation programme, including monitoring and evaluation
	Post-training knowledge assessment, participants' evaluation and distribution of certificates	

[a] Including detecting danger signs and action to take, selecting patients for malaria testing, managing patients with a positive result, managing patients with a negative result.

table are covered by the WHO manual on training health workers in using RDTs.[1,2] No generic manual covering the other topics is presently available.

Based on practical experience, it appears that the tutors' competence should not be based on only a few days of training in a classroom; they should obtain practical field experience before being allowed to train others.

Clinical supervisors

In addition, clinical supervisors should be trained to supervise RDT performance and to oversee clinicians using diagnostic test results.

5.2.3 Health workers (laboratory technicians and clinicians)

Who should be trained?

The training should be planned to ensure that health workers actually performing malaria tests are enrolled. Clear criteria for selecting trainees should be established. Everyone who will perform malaria tests themselves and all clinicians who will use the results of the tests should be trained to ensure good test performance and compliance with test results. Subsequent training sessions targeting new staff should be organized at regular intervals. Training of health workers in the formal private system should be considered, ideally in parallel with training in the public system.

Performance of malaria tests: Laboratory technicians (including assistant laboratory technicians and health technologists) should be considered for microscopy training, but they should also be

[1] *How To Use a Rapid Diagnostic Test (Generic Pf only RDT)? A guide for training at a village and clinic level.* Available at: http://www.who.int/NR/rdonlyres/43909BF1-A955-4DA3-9470-0F05E0FBA267/0/Generic_pf_training_manual_web.pdf

[2] *How To Use a Rapid Diagnostic Test (Generic Pf-Pan RDT)? A guide for training at a village and clinic level.* Available at: http://www.who.int/NR/rdonlyres/23DD7DCB-48C4-4CFF-BD45-332F0BE3DCC7/0/generic_PfPan_training_manual_web.pdf

trained in performing RDTs. In order to make diagnostic testing available in places or at times of the day when laboratory technicians are not present, other health workers, such as clinicians, nurses and pharmacists, should be trained in RDT use. Community health workers should also be trained in RDT performance.

Use of malaria tests results in the context of clinical management of patients: All health workers giving care to patients with suspected malaria should be trained in using the results of RDTs and microscopy in the clinical management of patients. These will generally include physicians, clinical officers, nurses and community health workers.

Quality assessment of malaria tests: Health workers involved in quality management of malaria testing and also laboratory technicians and clinicians performing the tests should be trained in quality management.

What should be taught?

Some topics are common to both laboratory staff and clinicians, while others are more specific to groups of health workers. Laboratory staff should learn how to perform malaria tests (RDTs, blood slide preparation, examination and interpretation, recording results and internal audits) and also understand which test is most appropriate for which patients, as described in sections 2.3.3 and 2.3.4. The training should focus not only on techniques and skills but also the rationale for strengthening malaria laboratory diagnosis in general and in the local context.

Clinicians and community health workers should be trained in performing RDTs but also to include the context of malaria diagnosis (level of malaria transmission in the country and in their area, policy for malaria diagnosis and treatment), criteria for selection of patients for malaria testing (see section 2.3.3), action to take on a test result, especially when negative, and integrating malaria testing into the overall management of patients with fever.

If possible, clinical and laboratory staff should be trained together (in the shared part of the RDT training curriculum) to exchange experiences and increase mutual trust. A successful experience with such an approach was reported in Uganda.[1]

Training objectives

For RDTs, the following learning objectives should be covered:

- Explain the importance of malaria diagnosis in the context of malaria control and elimination, the local epidemiological context and the local situation of malaria diagnosis.
- Recognize the basic differences and similarities between RDTs and microscopy.
- Discuss the algorithm for malaria diagnosis and treatment in febrile cases (selection of patients for malaria testing, action to take on malaria test result, search for non-malaria causes of fever, criteria for referral, advice to the patient on when to return).
- Describe and demonstrate the precautions required when handling blood.
- Demonstrate performance of a malaria RDT (demonstration and practice).
- Know how to read, record and report RDT results, in line with the revised health information management system that includes RDT results.
- Explain the importance of safety, storage, stock and waste management.
- Understand the RDT quality management system.
- Discuss patient counselling on adherence to malaria test results.

[1] JUMP Integrated Management of Malaria Training. Uganda Malaria Surveillance project and Infectious Diseases Institute. Available at: http://www.muucsf.org/umsp/jump.html

- Solve clinical case studies.

For *microscopy*, the training objectives are:[1]

- Know the basic differences and similarities between RDTs and microscopy.
- Know the clinical criteria for selecting patients for malaria testing and the action to take on the test result on the basis of the official algorithm.
- Describe and demonstrate the precautions required when handling blood.
- Prepare acceptable, good-quality thick and thin blood films on the same slide.
- Correctly stain blood films for microscopic examination.
- Accurately record patient details and results in the laboratory register.
- Ensure that clinicians receive the result in a timely manner.
- Understand the correct set up, care and maintenance of a microscope.
- Understand the correct procedures for examining thick and thin blood films.
- Reach the level of competence required for the level targeted by the trainee.
- Understand the quality management system for malaria microscopy.

Teaching methods

The aim of training is to increase general levels of knowledge and understanding about malaria diagnosis and treatment in the management of fever (Why?), not only to improve the trainee's skills in performing a malaria test (How?). If the trainees do not understand the rationale behind what they are supposed to do, they will not do it. They must therefore be given the evidence on which the guidelines are based and be convinced that they are being taught the best clinical or laboratory practices. For clinicians, this training should be integrated (whenever possible) with training on management of febrile patients, including non-malaria causes of fever, such as acute respiratory infections and diarrhoea.

An interactive approach with both theoretical and practical sessions should be considered, including provision of clinical algorithms for malaria diagnosis (see section 2.3.4), case studies, role-play and frequently asked questions. Trainees should understand the rationale for use of quality-assured microscopy and RDTs, especially as experience in many settings is based on presumptive treatment or poor-quality microscopy-based diagnosis. Time should be spent on the rationale for not giving an antimalarial medicine to patients with a negative malaria test result. The teaching should stress the evidence for the safety of this strategy, as it is critical for clinicians to change their behaviour (Table 9). The reasons for taking safety precautions when drawing blood should be reinforced.

Clear messages should be given at the end of the training sessions, such as:

- Do not ask for a malaria test in the absence of a history of fever or elevated temperature.
- Do not give antimalarial medicines when the result of the malaria test (reliable RDT or reliable microscopy) is negative.
- Look for other causes of fever whenever the malaria test result is negative or positive.
- Do not give antibiotics without a clear indication (in children, follow Integrated Management of Childhood Illness (IMCI)).

[1] *Malaria microscopy quality assurance manual, version 1*. World Health Organization, Regional Office for the Western Pacific, 2009; section 6. Available at:
http://www.who.int/malaria/publications/malaria_microscopy_QA_manual.pdf

Table 9. Published clinical studies supporting the safety of withholding antimalarial treatment for patients with a negative malaria test result

Reference	Country	Population studied	Setting of study
Njama-Meya et al. (2007). *Malaria Journal*, 6:7.	Uganda	Children under 5 years	Hospital with expert microscopy, area highly endemic for *P. falciparum*
Ngasala et al. (2008). *Malaria Journal*, 7:199.	United Republic of Tanzania (main land)	Children under 5 years	Dispensaries with routine microscopy, area highly endemic for *P. falciparum*
Msellem et al. (2009). *PLoS Medicine*, 6:e1000070.	United Republic of Tanzania (Zanzibar)	Children and adults	Dispensaries with routine RDTs, area of low endemicity for *P. falciparum*
D'Acremont et al. (2010). *Clinical Infectious Diseases*, 51:506–511.	United Republic of Tanzania	Children under 5 years	Dispensaries with routine RDTs, areas of moderate and high endemicity for *P. falciparum*

5

- Tell the patient to return for worsening symptoms or persisting fever.

Training material

Inter-country exchanges and sharing of experiences can be helpful in preparing training material.

RDTs: Generic material is available,[1] which should be adapted to the RDT products chosen by the country and translated into local languages. For certain commercially available tests, the Foundation for Innovative New Diagnostics have issued versions that are ready to use.[2]

The generic documents depend of the type of RDT that will be used: type 1: *P. falciparum*-only tests; type 2: combination Pf-pan tests in which the *P. falciparum* band is next to the control band; type 3: combination pan tests in which the pan-*Plasmodium* band is next to the control band.

Job aids for performing a malaria RDT (Types 1–3): *How to do the rapid test for malaria*[3,4,5]

Training manuals on use of RDTs (Types 1–3): *How to use a rapid diagnostic test (RDT)*[6,7]

[1] Malaria RDT Job aids and Training Manuals. WHO/FIND. Available at: http://www.wpro.who.int/sites/rdt/using_rdts/training

[2] Training material for malaria RDTs. FIND. Available at: http://www.finddiagnostics.org/programs/malaria/find_activities/rdt-job-aids

[3] *Job Aid – How To Do the Rapid Test for Malaria (Generic Pf only RDT)?* Modified for training in the use of the Generic Pan-Pf Test for falciparum and non-falciparum malaria. Available at: http://www.wpro.who.int/NR/rdonlyres/F8C3BCCE-780B-4182-8166-546005012C83/0/GenericPfJobAid_lowres.pdf

[4] *Job Aid – How To Do the Rapid Test for Malaria (Generic Pan Pf RDT)?* Modified for training in the use of the Generic Pan-Pf Test for falciparum and non-falciparum malaria. Available at: http://www.wpro.who.int/NR/rdonlyres/4EB21BD1-70B4-40FE-8BC5-614B3ED6EBF6/0/GenericPanPf-JobAid_lowres.pdf

[5] *Job Aid – How To Do the Rapid Test for Malaria (Generic Pf-Pan RDT)?* Modified for training in the use of the Generic Pan-Pf Test for falciparum and non-falciparum malaria. Available at: http://www.wpro.who.int/NR/rdonlyres/74C2B789-6B94-4D70-AD70-A6CFA89AFD49/0/GenericPfPan-jobaid_lowres.pdf

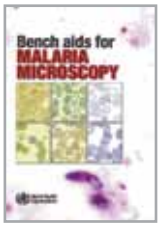
[6] *How To Use a Rapid Diagnostic Test (Generic Pf only RDT)? A guide for training at a village and clinic level.* Available at: http://www.wpro.who.int/NR/rdonlyres/43909BF1-A955-4DA3-9470-0F05E0FBA267/0/Generic_pf_training_manual_web.pdf

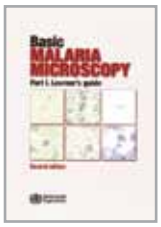
[7] *How To Use a Rapid Diagnostic Test (Generic Pf-Pan RDT)? A guide for training at a village and clinic level.* Available at: http://www.wpro.who.int/NR/rdonlyres/23DD7DCB-48C4-4CFF-BD45-332F0BE3DCC7/0/generic_PfPan_training_manual_web.pdf

Guidance on the interpretation of RDT results using pictures (types 1–3): *Malaria generic RDT results guide*[1]

Exercises (questions and answers) for interpretation of RDT results based on pictures (types 1–3): *Generic quiz examples (quiz 1, quiz 2, quiz 3)*[1] and *Generic answer sheets for quizzes*[1]

The aim of this material is to teach the performance and use of an RDT. It does not include information on how to use the test in the clinical management of febrile patients nor on when to use an RDT rather than microscopy. To teach these aspects, case studies can be prepared and adapted to the national guidelines on the management of malaria and non-malaria fevers. Five clinical case scenarios used to teach clinicians or to measure their competence at integrating malaria testing into the management of fever cases are given in Annex 11 (questions and answers).





Microscopy: The following material is available:

Bench aids for preparing, staining and interpreting malaria blood slides: *Bench aids for malaria microscopy*[2]

Training manuals for performing malaria microscopy: *Basic malaria microscopy, Part I, Learner's guide*[3] (This manual comes with a CD-ROM on malaria microscopy that can be used in the training sessions and for self-teaching)

How should the training be organized?

A schedule should be drawn up for administering the training packages (for RDTs and microscopy), with details of who, when, where (national, provincial, district or community levels) and what will be taught. The relevant authorities should be involved in planning and conducting the training (e.g. ministry of health, provincial managers, nongovermental organizations).

Training should be conducted in anticipation of the malaria transmission season, to avoid suddenly confronting health workers with the low positivity rate of the dry season, which they may not believe. In addition, training should be timed to coincide with distribution of the necessary equipment and supplies, including gloves and sharps boxes. These should arrive immediately after the training has been completed, so that the health workers can apply what they have learnt.

The length of the training sessions for microscopy depends on the target audience: for novice microscopists, WHO recommends 4–5 weeks; for already trained laboratory technicians requiring refresher training, WHO recommends 2 weeks with the training materials listed above. For RDTs, the training course with the presently available manual[1] can be completed in one half day (3.5 h). Based on practical experience, in places where changing treatment practices on the basis of test results is the main focus, a 2-day training workshop is required, of which half a day is generally dedicated to performance of the test itself and the rest on the other topics described under 'What should be taught' (see Table 8).

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[1] Malaria RDT Job aids and Training Manuals. WHO/FIND. Available at: http://www.wpro.who.int/sites/rdt/using_rdts/training/

[2] *Bench Aids for Malaria Microscopy*. Geneva, World Health Organization, 2010. Available at http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codcch=3294

[3] *Basic malaria microscopy, Part I. Learner's guide, second edition*. Geneva, World Health Organization, 2010. Available at: http://whqlibdoc.who.int/publications/2010/9789241547826_eng.pdf

The maximum number of participants at a training session should also be defined: for RDTs, a training session usually involves 20–30 participants supervised by two main tutors who have full theoretical knowledge and field experience, and one or two assistants mainly with field experience. For microscopy, the number of participants depends on the number of microscopes available, but one experienced tutor assisted by one or two microscopists can generally train 20 participants.

The training material should be based on the training objectives and might be adapted from the generic material proposed above. The modules for laboratories, health facilities and the community should be evaluated to ensure their effectiveness for training (learning skills). For RDT training, sensitization of health managers and training sessions for national trainers, tutors and supervisors should be planned. If feasible, plan for delayed rather than immediate training of RDT performers, to leave time for tutors to gain experience in using RDTs in the field.

Organize accreditation of microscopists and training of RDT performers. Whether refresher training is necessary to maintain competence in RDT use is controversial. For RDTs, experience in the United Republic of Tanzania and Zambia showed that performance was maintained without formal retraining for 18 and 12 months, respectively. Maintenance of skills requires however effective routine supervision and a working quality management system. If refresher training is planned, the learning objectives should be clarified, and they should be different (focused on trouble-shooting) from that of the initial training.

Plan for earlier supervision if performance is considered to be poor on the basis of the results of quality monitoring and supervisory visits. Additional supervisory visits should be arranged, and, if the problem persists, the health workers might benefit from corrective training. If, after supportive supervision and corrective training, malaria test performers fail to improve, they should not be permitted to perform RDT or microscopy and report on a malaria test result.

5.2.4 Community health workers

Community health workers should be trained in the performance of RDTs and to interpret and use the result. The topics to be covered in the training sessions are the same as for facility-based clinicians (see section 5.2.3). Integrated community case management for both malaria and non-malaria diseases is now recommended instead of home-based management of malaria, which addressed only malaria and not the frequent diseases that can be safely managed by community health workers. Therefore, training in malaria diagnosis should be integrated into broader training on the management of the main causes of illnesses (for children aged less than 5 years, to include malaria, acute respiratory infections and diarrhoea, see Figure 3), depending on national policy. This integrated approach will also reduce the temptation of community health workers to treat RDT-negative patients with an antimalarial medicine, as they will be able to identify and treat other common diseases.

Community health workers tend to adhere to malaria test results better than formal clinicians. They nevertheless need to be taught how to educate the community on the utility of malaria testing before treatment rather than requesting treatment on the basis of a clinical diagnosis alone. Training should include how to identify the danger signs that require immediate referral and administration of pre-referral treatment (for example, rectal artesunate and antibiotics for children).

5.3 Integration into pre-service training

Paradigms in medicine, particularly on how to manage patients, are changing rapidly with the accumulation of new scientific knowledge. These changes must be integrated as quickly as possible at points of care and also at pre-service levels. For example, the new policy on diagnostic

testing for malaria before treatment should be included immediately in pre-service training curricula.

To ensure proper use of malaria tests (and of diagnostics in general), students should learn to recognize the patient's probability of having a certain disease, the useful clinical predictors for those diseases, and which laboratory test(s) should be performed to support the diagnosis, or, if no laboratory test is available, whether presumptive treatment should be given. Evidence-based practice guidelines are constructed from this approach and should be the core of in-service training on the management of malaria and non-malaria fevers, rather than the classical description of all possible symptoms, signs, tests or treatments for each disease. This will prepare health workers, once in service, to quickly understand why a recommendation or policy has been changed.

5.4 Training in integrated management of fever

To improve clinicians' adherence to malaria test results when deciding whether to prescribe an antimalarial treatment, they must be trained not only on malaria diagnosis but also on the management of fevers in general. Clinicians should be trained on the epidemiology of non-malaria causes of fever, the clinical predictors of these alternative diagnoses (e.g. 'cough and fast breathing' for pneumonia in children under 5 years of age), the laboratory tests for confirming these diagnoses, when available (e.g. urine dipstick or microscopy for suspected urinary tract infection) and how to treat these conditions (e.g. no antibiotic for upper respiratory tract infections or other viral causes of fever).

In the same way that reliable laboratory tests are essential for the rational use of medicines, reliable clinical assessments of patients are essential for the rational use of laboratory tests. Because malaria tests have high diagnostic performance (in comparison with diagnostic tests for most other infectious diseases), the decision to treat malaria is based on the test result only and not on the symptoms or signs presented by the patient. For this reason, clinicians often consider that precise history-taking and physical examination are no longer necessary if a reliable test for malaria is available. During training, it is therefore essential to correct this misconception by explaining the poor specificity of multiple signs and symptoms in the diagnosis of malaria (see section 5.3). Clinical elements are, however, essential for deciding whether to test the patient (e.g. fever or palmar pallor: test for malaria; fever in child aged < 2 years or urinary complaints: test with urine dipstick) and whether to give treatment on the basis only of clinical manifestations (e.g. cough and fast breathing: give antibiotics). Clinicians should spend the necessary time to assess the patient clinically in order to avoid missing non-malaria causes of fever and indiscriminately using a broad range of laboratory tests.

Evidence-based decision charts should be given to clinicians and community health workers to improve the management of patients and the rational use of antimalarial and antibiotic treatments. This will help to protect both categories of medicines against rapid development of resistance. The Integrated Management of Childhood Illness (IMCI) algorithm has been now updated to include a diagnostic test for malaria in the 'fever box' (see Figure 2). The appropriate decision charts (for example, Integrated Management of Childhood Illness (IMCI) for primary care, blue pocket book for district hospital) should be included in the training of all type of clinicians, including senior clinical officers and physicians, adapting the way of explaining the scientific evidence to their level of knowledge.

KEY MESSAGES OF SECTION 5

- If possible, clinicians and laboratory technicians should be trained together in RDT performance and use, to allow exchanges and reinforcement of mutual trust.
- Clinicians should be trained not only on how to perform an RDT but also on who should be tested and how to use the test result for the clinical management of patients.
- Clinicians should be reassured about the safety of withholding antimalarial treatment from patients with a negative malaria test result.
- Clinicians should be trained on how to advice patients on when to return to the health facility
- To increase adherence to malaria test results, clinicians should be given decision charts and appropriate tools for managing both malaria and non-malaria febrile illness.

6. Supervision at points of care (health facilities and the community)

Supervision is conducted to assess the quality and performance of diagnostic testing on site by qualitative surveys at all levels of service delivery. Supervision involves:

- observation of procedures;
- verification of recorded and collected data;
- identification of constraints and causes of deficiencies;
- identification of corrective measures;
- provision of on-site reorientation, training and mentoring; and
- formulation of recommendations for improvement.

When possible, supervision of malaria diagnosis should be integrated with that of the clinical management of malaria and of febrile patients in general. Some countries have begun to integrate supervisory programmes for malaria into those for HIV, tuberculosis and other vertical programmes.

All health facilities and communities in which malaria diagnostic services are provided should undergo regular supervision. The recommended frequency is at least once every 6 months, but this can be adapted to country specific needs. Integration of supervisory activities for efficient use of resources must be encouraged, but not at the cost of incomplete supervision.

Supervision includes direct observation of clinicians during patient assessment and care,[1] (see Annex 13) assessment of laboratory services (see section 4.4) and, if possible, interviews with patients.

To avoid duplicating visits, health facilities supervision should also include components of quality management for malaria diagnostics, such as:

- the availability and regular use of standard operating procedures and bench aids;
- competence in performing RDTs, by direct observation of health workers performing an RDT and interpreting the result (see Annex 10);
- quality of microscopy for malaria (and if possible for non-malaria testing), including:
  - — monitoring microscopists' competence by direct observation of preparing and staining blood slides (see Annex 9); and
  - — validation of routine slide results (cross-checking), by re-reading a selection of slides to review and giving feedback on blood film preparation and staining, accuracy of diagnosis and reporting (if reading of the same slide by an expert microscopist is possible on site), (see section 4.4.3);

[1] *Malaria case management: Operations manual*. Geneva, World Health Organization, 2009; annex 8. Available at: http://whqlibdoc.who.int/publications/2009/9789241598088_eng.pdf

- RDT storage (general conditions and temperature) (see section 3.4);
- stock management (see section 3.5);
- waste management (see section 4.2.5);
- internal audits (see section 4.4.5); and
- equipment (including calibration) and its maintenance (see section 3.6).

Standardized supervisory checklists should be drawn up for each country, all of which should include:

Laboratory (see section 4.4.1 and Annex 8):

- prior training of staff;
- availability of reference documentation and training tools;
- water and power supply;
- working environment (bench space, lighting, ventilation) and furniture;
- laboratory equipment and supply (system, functionality, maintenance);
- slide preparation and labelling (see Annex 9);
- slide staining (see Annex 9);
- slide reading and storage (see Annex 9);
- performance of non-malaria tests (e.g, urine dipstick, microscopy of urine or stools, haemoglobinometer, glucometer);
- blood safety and waste management;
- compliance with all standard operating procedures, including slide validation, if operational; and
- recording and reporting results.

RDTs (see Annex 12):

- prior training of staff;
- availability of reference documentation and training tools;
- stock management (including expiry date);
- storage conditions;
- RDT preparation and reading (see Annex 10);
- safety and waste management (see Annex 6);
- compliance with all standard operating procedures; and
- recording and reporting results.

Clinicians and health facility staff in general (see Annex 12):

- existence of a quality management system;
- prior training of staff;
- observation of fever diagnostic procedures (see Annex 13);
- availability of reference documentation and training tools;
- specimen collection;

- safety and waste management (see Annex 6);
- compliance with test results;
- recording, reporting and transmitting results to the appropriate health authorities;
- compliance with all standard operating procedures; and
- appropriate timing of consultations (not too short, reasonable waiting time, covering the expected time slot).

The level of adherence of health workers to the criteria for patient selection for malaria testing and prescription of antimalarial medicine on the basis of the test result should be a central part of clinical supervision. In addition to direct observation of clinicians (whose behaviour might be different from usual, knowing that they are observed), such information can be obtained by comparing, for a defined period (e.g. the past 3 months), the following data from the available registries:

- number of patient attendances;
- number of malaria tests performed (RDTs and blood slides);
- number of positive malaria tests (microscopy and RDTs);
- number of malaria cases reported; and
- number of courses of antimalarial medicines issued by the main store or dispensed to patients.

The number of malaria tests performed should be lower than the number of attendances, the ratio depending on the criteria for suspecting malaria and on the type of patient (mostly acutely ill, or also with chronic or special medical conditions) attending the health facility. The number of confirmed positive malaria cases (by microscopy and RDTs) should be close to the number of antimalarial courses issued by the main store. Moreover, the number of positive malaria cases (confirmed by microscopy and RDTs) should be close to the number of malaria cases reported, if all suspected malaria cases are tested, as per the recommendations.

Obtaining these data during supervision allows immediate corrective action if the numbers do not tally. For example, if the monthly number of antimalarial courses recorded in the prescription book is much higher than the number of positive malaria tests recorded in the laboratory, clinicians should be asked why they do not adhere to the test results.

The outcomes of supervision can be compared over time for each health facility. They should not be aggregated, because outcomes are specific to each health facility and indicate further specific, focused technical support.

KEY MESSAGES OF SECTION 6

- Regular supervision is the mainstay of a successful malaria diagnostics programme.
- During supervision, health workers must be observed directly while performing an RDT or microscopy to ensure strict adherence to standard operating procedures.
- Supervision should also include observation of clinicians attending patients to ensure their adherence to malaria test results, their ability to manage malaria-negative patients and their ability to advise patients on when to return.
- The observations and corrective actions taken during supervisory visits should be documented on checklists, to give prompt feedback and to monitor changes over time.

7. Information, education and communication

7.1 Preparing a communication plan

Universal access to malaria diagnostic testing requires a major shift, from presumptive treatment of febrile episodes to treatment based on test results. This change in behaviour requires a change in health workers' and patients' attitudes and habits with regard to fever. This should be the focus of an information, education and communication campaign.

Communication for behavioural change is a specialized intervention, which requires the involvement of technical groups from the ministry of health and specialized international and national nongovermental organizations or agencies. All the stakeholders – policy-makers, government, multilateral and bilateral agencies, medical and pharmacy societies and associations, nongovermental organizations, community-based organizations, hospital organizations and community and private sector representatives – should be brought together to determine what changes in behaviour should be achieved with the communication activities. The main outcomes should be:

- rational use of medicines by patients: active demand for proper diagnoses; no demand for antimalarial medicines when a malaria test is negative or for antibiotics in the case of upper respiratory tract infections; and no demand for injections for uncomplicated illnesses; and
- correct diagnostic and medicine-dispensing practices by health-care providers: confirmation of a malaria diagnosis by microscopy or RDT, reliability of test results, compliance with positive and negative test results, and prescription of antibiotics when, and only when, indicated.

The behavioural objectives and results should be specific, measurable, achievable, relevant and time-bound (Table 10).

Once the behavioural outcomes have been defined, the roles and responsibilities and the timeframe for communication activities of different partners should be stated. Then, determine how the communication plans will be funded, implemented, coordinated, monitored, documented and reported. Once the target audience has been chosen (e.g. population at-risk or by age, gender or geographical area), the messages to be communicated should be designed, with the communication delivery channels (Table 11).

Monitor the communication plan and strategy in the field and evaluate and revise the plan accordingly.

7.2 Roles and responsibilities

A sustainable change can be brought about in a population only if people at all levels actively promote malaria diagnostics and rational use of medicines:

- *Central level:* Prepare and finance a plan for advocacy, communication and social mobilization.
- *Intermediate level:* Diffuse the messages as widely as possible.
- *Peripheral level and community:* Adopt the messages and transmit them through the agreed delivery channels, e.g. during routine interactions with patients and community members, particularly those with influence, such as teachers and village leaders.

Table 10. Example of behaviour objectives of a communication strategy for malaria diagnostics: Priority problem: adherence to test results (health professionals and the general public)	
Communication challenge or behaviour problem	Clients and health professionals disregard laboratory results, especially a negative RDT result, and treat for malaria anyway. They believe that the symptoms indicate malaria and do not believe the test result.
Target audience	Primary: patients, service providers Secondary: community leaders, community owned resource persons
Communication objective	Increase the percentage of clients and health professionals who act in accordance with laboratory test results for malaria.
Main messages	1. Malaria laboratory tests are accurate and should be believed. 2. Disregarding laboratory results delays proper treatment and results in more harm than good. 3. Laboratory testing techniques and equipment have been improved.
Message delivery channels	Television and radio spots, print media, health facilities
Key promises	Treating malaria on the basis of laboratory results will lead to rational use of antimalarial medicines. Following the results of laboratory tests will reduce exposure to multiple treatments and adverse drug reactions.
Desired actions and responses	Patients and health workers follow the guidelines for treating or not treating on the basis of the result of the laboratory test.

Source: Communication strategy for malaria control interventions, United Republic of Tanzania 2008–2013.

Table 11. Type of communication for urban and rural target audiences

Target audience	Urban	Rural
Men	Radio, television, places of worship, announcements, newspapers	Places of worship, radio, community health workers, announcements
Women	Health clinics, television, radio, antenatal clinics, community health workers, newspapers, places of worship, announcements	Community health workers, antenatal clinic, husbands, places of worship, announcements
Young people	Schools, university, television, radio, newspapers, places of worship, announcements	Schools, radio, places of worship
Returnees	Radio, television, places of worship, announcements, newspapers	Places of worship, radio, community health workers
Nomads	Radio, vaccination programmes	Radio, vaccination programmes

The above communications channels are given as example only, and appropriate communication channels for each of the target audiences should be identified and will vary in countries for different population groups.

Adapted from *Communication for behaviour impact strategic plan for Afghanistan, 2008–12*.

KEY MESSAGES OF SECTION 7

- The main focus of a communication plan is to shift behaviour from presumptive treatment to treatment based on test result.
- Messages specific to the type of diagnostic test intended for use should be pre-tested in the field.
- Communication and education activities should be synchronized with training and distribution of the diagnostic test.

8. Monitoring and evaluating the programme

8.1 Establishing indicators and monitoring

8.1.1 General indicators

The framework for measuring the performance of a malaria control programme includes information about the programme, such as inputs, activities and outputs (for example, number of RDTs delivered in one year), and information from populations and health facilities, such as outputs and outcomes.[1] This section on monitoring and evaluation covers the output and income measures, while section 9 covers the impact on malaria surveillance.

Monitoring is based on assessments of monthly data collected through the routine health information management system. A small set of key indicators can be analysed continuously at different levels of the health system. Monitoring and evaluation of malaria diagnostic testing are important, as parasitological confirmation of malaria diagnoses is essential for a robust surveillance system, which in turn is used for planning and decision-making. As treatment and diagnostic testing are interdependent, monitoring and evaluation should always include at least these two components as a continuous activity. Monitoring and evaluation of treatment and diagnostic testing should also, if possible, be integrated with that of other diseases that cause fever, such as pneumonia. A good monitoring and evaluation system should include:

- a defined list of indicators for tracking implementation of malaria diagnostic testing;
- reliable methods of data collection, analysis and use; and
- a system for providing regular feedback to testing centres.

All indicators should be integrated into the health information management system. If the system cannot be updated immediately, a temporary, parallel system for retrieving this information should be put in place.

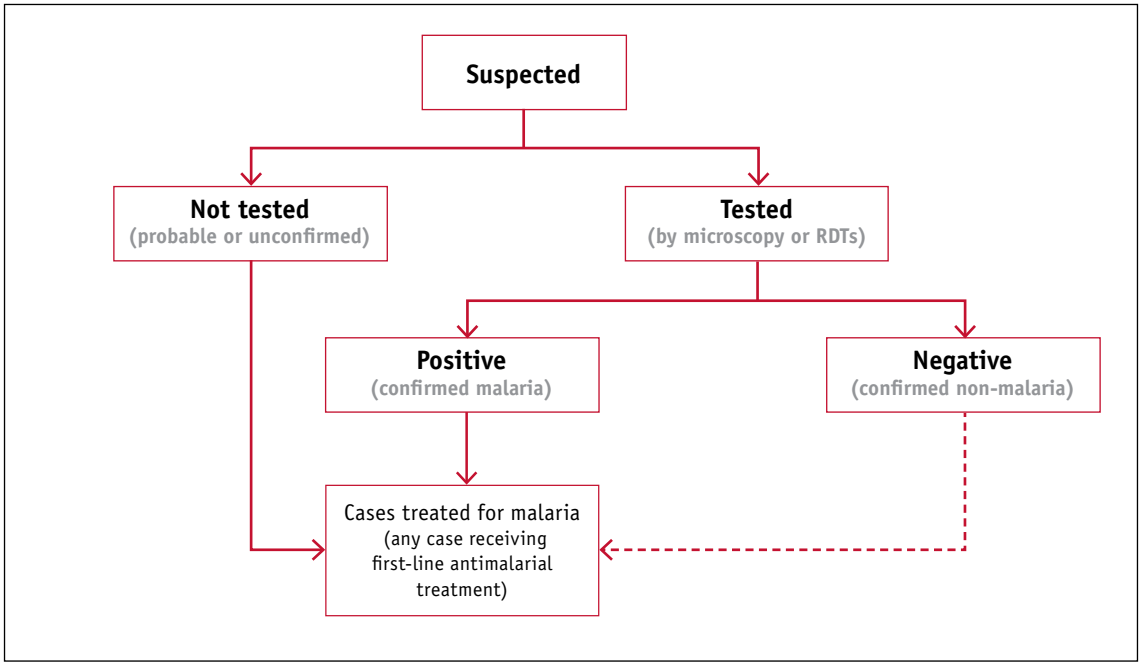
A clear clinical definition should be established for a 'suspected malaria case', to guide a decision to perform a malaria diagnostic test. Each country should prepare clinical criteria for a suspected malaria case on the basis of the probability that the fever is due to malaria. The same definition should be used in areas with similar epidemiological patterns of malaria, taking into account population movement, and included in the algorithm for diagnosis and treatment used by clinicians (see section 2.3.4).

Health facility registers should be standardized to include at least the age, malaria (and other) test results, final diagnosis(es) (uncomplicated or severe) and treatment prescribed to each patient. Cases should be classified as 'suspected', 'tested', 'confirmed' (test positive) and 'treated', as shown in Figure 11. If possible, cases should be stratified by age (children under 5 years, children over 5 years and adults).

[1] *Malaria programme reviews: a manual for reviewing the performance of malaria control and elimination programmes, trial edition, March 2010*. Geneva, World Health Organization, 2010; Table 2. Available at: http://www.who.int/malaria/publications/atoz/whomprmalariaprogramperformancemanual.pdf

FIGURE 11.

Relations among classifications of malaria cases



If the data element 'number of suspected malaria cases' cannot be obtained from the registry, it can be deduced from the number of reported cases as follows (see Figure 11):

Suspected malaria cases = **tested cases** + not tested cases

Not tested cases = **treated cases** – **positive cases**

If the number of patients receiving first-line antimalarial treatment is not available, it can be replaced by the total number of malaria cases reported, because clinicians tend to report patients whom they have treated for malaria as malaria cases. The assumption behind this formula is that malaria-negative patients are not treated with antimalarial medicines (i.e the dotted line in Figure 11 does not exist). The number of suspected malaria cases obtained will correspond to all patients considered by clinicians as possibly having malaria but not necessarily to the number of patients who meet the national definition of a suspected case.

This information will form the basis for calculating the core data elements (Table 12), from which the indicators for monitoring malaria diagnoses can be calculated (Table 13). The indicators can be calculated at various levels (health facility, district, subnational or national).

The main outcome of a programme for strengthening diagnostic services is the 'percentage of suspected malaria cases tested for malaria'. Universal access to malaria diagnostics is reached when this indicator is close to 100%. If it is < 100%, there is under-testing of patients, and more effort should be made to achieve universal access; if it is > 100%, there is over-testing of patients and thus wastage of malaria tests. The latter can be calculated only if the number of suspected malaria cases is based on data available in the registry rather than deduced from the other data as shown above.

The second main indicator is the 'percentage of confirmed positive malaria cases receiving first-line antimalarial treatment (ACT)'. This indicator reflects effective malaria case management. It should also be close to 100% in order to promote a decrease in morbidity and mortality due to malaria.

Table 12. Core data elements for calculating indicators for malaria diagnosis and treatment	
Data element	Comments
Number of suspected malaria cases[a]	Fulfilling the national definition
Number of patients tested by RDT[b]	
Number of patients positive by RDT[b]	For countries with a significant prevalence of different species of *Plasmodium*, this number should be stratified by species.
Number of patients tested by microscopy	
Number of patients positive by microscopy	For countries with a significant prevalence of different species of *Plasmodium*, this number should be stratified by species.
Number of patients tested for malaria	Equal to the number of patients tested by RDT and/or microscopy Patients tested by both RDT and microscopy should be counted once.
Number of people tested by RDT[b] and/or microscopy per year[c]	Everyone, whether symptomatic or not, thus including both patients and the healthy community
Number of confirmed malaria cases	Equal to the number of patients positive by RDT and/or microscopy For countries with a significant prevalence of different species of *Plasmodium*, this number should be stratified by species.
Total number of patients receiving first-line antimalarial treatment (ACT)[b]	
Number of confirmed malaria cases receiving first-line antimalarial treatment (ACT)[b]	This requires that the diagnosis and treatment of a given patient are not recorded separately.
Stock-out[d] of RDTs this month	On the form for a health facility or community, the response would be Yes/No. On the summary form for the district, the number of health facilities or communities reporting no stock-out would be recorded.
Stock-out[d] of key microscopy consumables this month	
Stock-out[d] of first-line antimalarial drugs (ACT) this month	
Number of health workers trained to perform RDTs for malaria per health facility	For community programmes, per village
Number of technicians accredited for malaria microscopy per targeted laboratory	

[a] If the number of suspected cases is not directly available, it should be calculated from the number of tested cases plus the number of treated cases minus the number of positive cases, provided that negative cases are not treated.
[b] When RDTs are performed and ACT provided at community level, the data should be added to those given by health facilities.
[c] This element is often used in low-endemic countries, where a significant part of individuals are tested through active case detection, in addition to the core element 'Number of patients tested for malaria'.
[d] Generally defined as 7 days or more (not necessarily consecutive) of stock-out. This may depend on the strength of the supply system.

The third main indicator for rational use of antimalarial medicines (at least of first-line treatment) is the 'percentage of first-line antimalarial treatment (ACT) used for confirmed malaria cases'. It should be close to 100%. When this is the case, there is no wastage of ACTs to treat unconfirmed or even negative malaria cases.

The positivity rate of RDTs or malaria blood films (slide positivity rate) is an important indicator in malaria surveillance; however, it may also indicate a local problem in the accuracy of RDTs or microscopy if a sudden, unexpected change (not explained by the seasonality of malaria transmission or by an epidemic) is noted in a certain geographical area (see Figures 10.1, 10.2, 10.7 and 10.8).

Indicators based on data provided by sources other than the health information management system can also be used, such as the quantities of RDTs and ACTs ordered by health facilities or

Table 13. Indicators for monitoring malaria diagnosis and treatment

Indicator	Numerator, denominator
Percentage of suspected malaria cases tested by RDT	*Numerator:* Number of patients tested by RDT × 100
	Denominator: Number of suspected malaria cases
Percentage of suspected malaria cases tested by microscopy	*Numerator:* Number of patients tested by microscopy × 100
	Denominator: Number of suspected malaria cases
Percentage of suspected malaria cases tested for malaria	*Numerator:* Number of patients tested by RDT and/or microscopy × 100
	Denominator: Number of suspected malaria cases
Annual blood examination rate (number per 1000 people)[a]	*Numerator:* Number of people tested by RDT and/or microscopy per year x 1000
	Denominator: Population living in areas at risk for malaria
Percentage of confirmed malaria cases receiving first-line antimalarial treatment (ACT)	*Numerator:* Number of confirmed malaria cases receiving first-line antimalarial treatment (ACT) x 100
	Denominator: Number of confirmed malaria cases
Percentage of first-line antimalarial treatments (ACT) used for confirmed malaria cases	*Numerator:* Total number of patients receiving first-line antimalarial treatment (ACT) x 100
	Denominator: Total number of confirmed malaria cases receiving first-line antimalarial treatment (ACT)
Percentage of health facilities reporting no stock-out[b] of RDTs per month	*Numerator:* Number of health facilities reporting no stock-out of RDTs this month × 100
	Denominator: Number of reporting health facilities receiving RDTs
Percentage of health facilities reporting no stock-out[b] of key microscopy consumables	*Numerator:* Number of health facilities reporting no stock-out of key microscopy consumables × 100
	Denominator: Number of reporting health facilities
Percentage of health facilities reporting no stock-out[b] of first-line antimalarial drugs (ACT)	*Numerator:* Number of health facilities reporting no stock-out of first-line antimalarial drugs (ACT) × 100
	Denominator: Number of reporting health facilities
Percentage of health facilities with at least one health worker trained in performing RDT for malaria	*Numerator:* Number of health facilities with at least one health worker trained in performing RDT for malaria × 100
	Denominator: Number of reporting health facilities
Percentage of targeted laboratories with at least one accredited malaria microscopist	*Numerator:* Number of targeted laboratories with at least one accredited malaria microscopist × 100
	Denominator: Number of targeted laboratories

[a] This indicator is often used in low-endemic countries, where a significant part of individuals are tested through active case detection.
[b] Generally defined as 7 days or more (not necessarily consecutive) of stock-out. This may depend on the strength of the supply system.

issued by central medical stores at national and subnational levels. All efforts should be made to link these data to those of the health information management system in order to measure the real impact of the malaria diagnosis strengthening programme.

8.1.2 Monitoring testing capacity over time

In order to understand rapidly why one or more indicators of the malaria diagnosis programme show poor results, a system is needed to monitor testing capacity. This generally corresponds to the indicators used to monitor the quality management system described in section 4.2.8, which show the evolution over time of the quality of malaria testing in laboratories and health facilities. For laboratories, this system should be integrated into global monitoring of all laboratory procedures and not organized for malaria testing only. To avoid duplication of visits and efforts, these indicators should be based on data collected on checklists during supervision (see Annex 8 for laboratories and Annex 12 for health facilities).

8.2 Trouble-shooting, investigation and response

The indicators listed in Table 13 can reveal a variety of problems in malaria diagnosis and treatment at different levels. Each indicator should have a specific threshold for corrective action. Usually, an investigation at the health facility by an on-site visit will show the reasons why the indicators did not reach the target. After discussion with supervisors at district level, it might be necessary to extend the investigation and discuss any action needed with the community. An adequate response should be given and understood by everyone involved. Risk prevention strategies should be also put in place (see Table 14).

8

KEY MESSAGES OF SECTION 8

- Feasible, reliable indicators should be chosen to monitor a malaria diagnostic testing programme.
- The data necessary for calculating the indicators should be in the health information management system.
- The main outcome indicator of a programme for strengthening malaria diagnostic services is the 'percentage of suspected malaria cases tested for malaria'.
- A strategy for investigating and responding to problems identified in the monitoring programme should be prepared in advance.

Table 14. Identification of problems, investigation and response in malaria diagnosis (with a focus on the public sector)

No.	Problem	Indicators	Indicators thresholds[a]	Mechanisms of investigation	Actions to take
1	Limited use of malaria diagnostics by health workers	Percentage of suspected malaria cases tested for malaria Numbers of RDTs issued by central store or ordered by health facilities	< 90% < 70% of foreseen quantities	Analysis of health facility on-site supervision checklists and discussion with supervisors to detect: • Too few RDT performers for work load • Frequent stock-outs of RDTs • Few clinicians trained in malaria diagnosis (RDT use) • Few clinicians trained in management of fevers	Train more RDT performers Refer to problem 8 Train and supervise clinicians for malaria diagnosis and management of fevers in general
2	Over-testing of patients for malaria	Percentage of suspected malaria cases tested for malaria	> 100%	Analysis of health facility by on-site supervision, checklists and discussion with supervisors to detect: • Too few clinicians trained in malaria diagnosis (RDT use) • Pressure from patients to be tested (for example, adults coming for a general check-up)	Train clinicians in patient selection for malaria testing Advocacy, communication and social mobilization, in particular for selection of patients for malaria testing
3	Sudden increase in malaria test positivity rate	Positivity rate of RDTs and/or microscopy	Increase of > 50% over expected (baseline)	Look for anomalies in reporting RDT and microscopy results (confusion or no difference made) *If anomalies are present:* • Look for prolonged stock-outs of RDTs leading to an increase in use of microscopy of poor specificity *If reporting of results is accurate:* • Look for use of RDTs by untrained staff (problems in reading RDT results) • Look for poor-quality RDT batches • Analyse possible changes in malaria transmission (e.g. population movement)	Train and supervise health workers on reporting laboratory results Refer to problem 8 On-site training in reading RDT results Lot-testing of suspected batches If due to an increase in malaria prevalence, investigation of malaria epidemic and response
4	Sudden decrease in malaria test positivity rate	Positivity rate of RDTs and/or microscopy	Decrease of > 50% under expected (baseline)	Look for anomalies in reporting RDT and microscopy results (confusion or no difference made) *If anomalies are present:* • Look for sudden uptake of RDTs, replacing microscopy of poor specificity *If reporting of results is accurate:* • Look for use of RDTs by untrained staff (problems in reading RDT results) • Look for poor-quality RDT batches • Analyse temperature monitoring of RDT storage to detect deterioration of RDTs due to prolonged exposure to high temperature	Train and supervise health workers on documentation of laboratory results and use of health information management system On-site training in reading RDT results Lot-testing of suspected batches Train health workers in storage conditions, and improve storage places (e.g. add fans)

Table 14. *Continued*

No.	Problem	Indicators	Indicators thresholds[a]	Mechanisms of investigation	Actions to take
5	Decreased use of ACT	Percentage of confirmed positive malaria cases receiving first-line antimalarial treatment (ACT)	< 90%	• Look for frequent stock-outs of ACT • Look for a high proportion of febrile cases treated for malaria[b] on the basis of clinical diagnosis alone • Look for misperceptions about ACT efficacy or safety in the community	Refer to problem 8 Train and supervise clinicians in malaria diagnosis and management of fevers in general Advocacy, communication and social mobilization on malaria diagnosis and treatment; consider implementing a programme of integrated community case management
6	Use of ACT for unconfirmed and negative cases	Percentage of first-line antimalarial treatment (ACT) used for confirmed malaria cases	> 120%	Analysis of health facility by on-site supervision, checklists and discussion with supervisors to determine whether this is due to: • a large number of patients treated for malaria on the basis of clinical diagnosis alone and/or • a large number of patients tested negative but still treated for malaria *If the latter, look for:* • Few clinicians trained in malaria diagnosis (RDT use) • Few clinicians trained in management of fevers • Lack of sensitization of consumers to malaria testing, in particular RDTs • Conflicting national guidelines or ambiguous messages to health workers during training	Refer to problem 1 Train and supervise clinicians for malaria diagnosis and management of fevers in general Organize sensitization meetings Update guidelines Update training material
7	No reduction in amount of ACT issued by central store or ordered by health facilities	Amount of ACT issued by central store or ordered by health facilities	No change in ACT consumption in relation to situation before malaria diagnostic strengthening	Exclude a simultaneous increase in non-use of first-line antimalarials after a positive test, which reflects a decrease in the number of confirmed malaria cases. If this is not the problem, differentiate between: • Transfer of ACT to the private sector • Poor uptake of malaria diagnostics by health workers • Prolonged stock-outs of RDTs • Loss of confidence in malaria test results	Subsidize RDTs and ACT for the private sector Refer to problem 1 Refer to problem 8 Refer to problem 6

Table 14. *Continued*

No.	Problem	Indicators	Indicators thresholds[a]	Mechanisms of investigation	Actions to take
8	Stock-outs of RDT	Percentage of health facilities reporting no stock-out of RDTs	> 90%	*Look for:* • Not enough RDTs available in the country (wrong quantification) • Poor stock management at central or subnational stores • Poor stock management at health facilities • Poor selection of patients by health workers (over-testing) • Leakage of RDTs to the private sector	Look for additional resources to buy more RDTs Train staff, reorganize and monitor medical stores Train and supervise health workers on stock management Refer to problem 2 Interventions to improve access to RDTs (and ACT) in the private sector
9	Overstocks of RDTs	Number of RDTs issued by central store or ordered by health facilities	> 20% higher than reported cases tested with RDTs	*Look for:* • Poor stock management at central or subnational stores • Poor uptake of malaria diagnostics by health workers • Leakage of RDTs to the private sector • Underreporting of malaria cases by surveillance system	Train staff, reorganize and monitor medical stores Refer to problem 1 Interventions to improve access to RDTs (and ACT) in the private sector Correct data underreporting
10	Too few health workers trained in performing RDTs for malaria	Percentage of health facilities with at least one health worker trained in performing RDTs for malaria	< 90%	*Look for:* • Not enough training sessions • Not enough tutors • Incorrect target group • Inadequate resources for training • Attrition of health workers (to the private sector)	Organize new training sessions Train more tutors Supervise choice of staff selected for training Increase the number of health workers in the public sector
11	Too few laboratory technicians trained in malaria microscopy	Percentage of targeted laboratories with at least one accredited malaria microscopist	< 90%	*Look for:* • High turnover of laboratory technicians • Too few expert microscopists who can act as tutors • Inadequate resources for training • Attrition of laboratory staff (to the private sector)	Organize new accreditation courses Train more expert microscopists Increase the number of laboratory technicians in the public sector
12	Stock-outs of microscopy consumables	Percentage of health facilities without stock-outs of key microscopy consumables	< 90%	*Look for:* • Not enough supplies available in the country (wrong quantification) • Poor stock management at central or subnational stores • Poor stock management at health facilities • Poor selection of patients by health workers (over-testing)	Review data and calculations used for quantification Train staff, reorganize and monitor medical stores Train and supervise health workers on stock management Refer to problem 2

Table 14. *Continued*

No.	Problem	Indicators	Indicators thresholds[a]	Mechanisms of investigation	Actions to take
13	Too few accredited malaria microscopists	Percentage of laboratories with at least one certified accredited malaria microscopist	< 90%	*Look for:* • Not enough training sessions • Not enough tutors • Inadequate resources for training • Attrition of laboratory technicians (to the private sector)	Organize new training sessions Train more tutors Increase the number of laboratory technicians in the public sector

[a] The thresholds for the indicators are only indicative and should be chosen by each country on the basis of their malaria strategic plan and national targets.
[b] Patients treated for malaria on the basis of a clinical diagnosis alone often do not have malaria and will thus not be cured by ACT. Health workers and patients then lose their trust in the efficacy of ACT.

9. Expected impact on malaria surveillance

Accurate measurement of the burden of malaria has direct implications for the selection and planning of interventions at national or international level. Reliable data on the incidence of malaria also influence the requirements for ACT, RDTs and microscopy supplies, which in turn can minimize the risks of stock-outs or over-stocks of these life-saving commodities; therefore, reliable figures are needed at all levels. With the decreasing transmission of malaria in Africa and elsewhere, the geographical heterogeneity of malaria distribution is increasing.

In countries with poor malaria diagnostic services, an increase in RDT testing could greatly improve the reliability of surveillance data. If malaria test results are properly recorded in health facilities and properly transmitted to the central level, the number of malaria cases can be determined precisely and trends followed over time.

With progressive deployment of high-quality malaria diagnostics, the picture of reported malaria incidence will change drastically. For instance, in places where overdiagnosis of malaria was the rule, an apparent decrease in malaria transmission (besides the real decrease due to malaria control) is simply due to the introduction of accurate malaria diagnostic testing. In these circumstances, trends in the numbers of cases of anaemia and blood transfusions in children under 5 years could be used to monitor impact, as these figures are unlikely to be affected by malaria testing. As soon as a large percentage of outpatient suspected cases (> 80%) are tested, indicators of the success of malaria control at national scale[1] can be calculated precisely from surveillance data, as long as data are accurately reported (Table 15).

[1] *Guidelines for malaria disease surveillance and core indicators for control and elimination, draft version*. Geneva, World Health Organization, 2011.

Table 15. National indicators used in malaria surveillance

Indicator	Numerator, denominator	Interpretation
Confirmed malaria cases[a]	Number of cases positive for malaria (by RDT and/or microscopy) reported by health facilities	Can be presented as cases per week, month or year In countries in the malaria elimination phase and in some low-transmission countries in the control phase, any person, whether symptomatic or not, with a positive result (microscopy or RDT) would be considered to be a confirmed case of malaria.
Confirmed malaria incidence rate[a] (number per 1000 people)	*Numerator:* Number of malaria-positive cases reported by health facilities per year x 1000 *Denominator for rate:* Population living in areas at risk for malaria	Should be stratified by age (< 5, all ages) Incidence rate of < 1 confirmed case per 1000 people per year indicates readiness for elimination phase
Percentage of suspected malaria cases tested for malaria	*Numerator:* Number of suspected malaria cases tested (by RDT and/or microscopy) × 100 *Denominator:* Total number of suspected malaria cases reported by health facilities	A suspected case fulfils the national definition.
Annual malaria parasite incidence rate (number per 1000 people)	*Numerator:* Number of people positive by RDT and/or microscopy per year x 1000 *Denominator for rate:* Population living in areas at risk for malaria	This indicator is used mainly in low-incidence countries and if the annual blood examination rate is > 10%
Inpatient confirmed malaria cases[a]	Number of hospitalized malaria-positive cases (by RDT and/or microscopy) reported by health facilities	Can be presented as cases per week, month or year
Inpatient confirmed malaria incidence rate[a] (number per 1000 people)	*Numerator:* Number of hospitalized malaria-positive cases reported by health facilities per year x 1000 *Denominator for rate:* Population living in areas at risk for malaria	Should be stratified by age (< 5, all ages)
Confirmed malaria deaths	Number of malaria-positive (by microscopy and RDT) deaths reported by health facilities	
Confirmed malaria mortality rate (number per 1000 people)	*Numerator:* Number of malaria-positive deaths reported by health facilities per year x 1000 *Denominator for rate:* Population living in areas at risk for malaria	
Malaria RDT positivity rate[a]	*Numerator:* Number of malaria-positive cases by RDT × 100 *Denominator:* Total number of suspected malaria cases tested with an RDT	Annual rates should be used, not only the rate during the peak season
Malaria slide positivity rate[a]	*Numerator:* Number of malaria-positive cases by microscopy × 100 *Denominator:* Total number of suspected malaria cases examined by microscopy	Test or slide positivity rate < 5% throughout the year indicates readiness for pre-elimination phase
Malaria test positivity rate[a]	*Numerator:* Number of malaria-positive cases by RDT and/or microscopy × 100 *Denominator:* Total number of suspected malaria cases examined by RDT and/or microscopy	
Malaria parasite prevalence rate[a]	*Numerator:* Number of people tested positive by RDT and/or microscopy *Denominator for rate:* Number of people tested by RDT and/or microscopy	People are tested during a community survey (healthy population).
Percentage of confirmed malaria cases treated with ACT	*Numerator:* Number of confirmed malaria cases treated with ACT × 100 *Denominator:* Total number of confirmed malaria cases reported by health facilities	If the information system does not collect the number of patients treated, the number of ACTs received or dispensed can be used as a surrogate numerator.

[a] For countries with significant prevalence of different species of Plasmodium, this number should be stratified by species.

10. Diagnostic strategies in particular settings

10.1 Advanced malaria control and pre-elimination

Programmes that have achieved an advanced stage of malaria control and are progressing towards pre-elimination should maximize efforts to ensure universal access to malaria diagnostic testing. Further, the distribution of malaria transmission is often highly heterogeneous within a country, so that a good malaria surveillance system is necessary to guide subnational malaria control strategies.

When malaria incidence falls, the great majority of febrile illnesses are not due to malaria, and treatment of each fever episode with antimalarial medicines is not only ineffective but is harmful in most cases, because the correct treatment for the cause of the fever is not given. In these conditions, diagnostic capability for other causes of the presenting illness is needed, in addition to malaria. When the outpatient malaria positivity rate in health facilities is below a certain threshold (e.g. 1%), malaria testing should be restricted to those patients with a high probability of having malaria (see section 2.3.4). This restriction should be extended to all levels of the health system, including communities using simple criteria (for example, 'fever and no pneumonia and no diarrhoea'). In such settings, the strategy of active case detection is used to find and treat all positive febrile cases among people living in the area in which an index case (detected at the health facility) lives. This strategy is easier to implement if there are community health workers who are fully integrated into the health system. It requires the use of sensitive diagnostic tools (RDTs with a high panel detection score or quality assured expert microscopy). RDTs have the advantage of permitting immediate treatment on site.

In focused screening and treatment (screening all people living in a defined geographical area) or mass screening and treatment (screening of an entire community in a broad geographical area), the people to be detected, and treated if positive, are asymptomatic and generally have a low malaria parasite density. The sensitivity of the malaria tests presently available are insufficient, and alternative assays of high sensitivity are needed that are reasonably specific and minimally invasive. High-throughput PCR is a promising tool, which is being evaluated for this use. Mass screening and treatment strategies are currently being evaluated for use in certain malaria containment projects. Strategies similar to focused screening and treatment, based on active case detection with microscopy or RDTs, were used in Taiwan (China) and Venezuela in the 1950s and in China, India, Oman and the Philippines in the 1990s and possibly contributed to reducing malaria transmission.

When malaria transmission falls, it is important to map individual malaria cases to the household level in order to determine the effectiveness of various control policies. New reporting systems (for example mobile phones and global positioning systems) are being developed to record the results of accurate malaria testing in health facilities and even villages. Strategies based on surveys in which serology for malaria is coupled with geospatial analyses are also being evaluated.

10.2 Areas in which malaria has been eliminated

Once malaria has been eliminated in an area, considerable resources are required to sustain surveillance in order to detect possible reintroduction as early as possible and to maintain the

capacity for rapid investigation and containment of reintroduced cases if they are found. The requirements for surveillance and screening in areas in which malaria has been eliminated but which are still vulnerable to malaria transmission are similar to those of programmes in countries in the elimination phase.

The diagnostic strategy might involve screening migrant populations, investigating large populations around detected cases and devising criteria for screening suspected patients, such as recent travellers to malaria-endemic areas. RDTs with high panel detection scores must be readily available in places where technicians are not skilled in malaria microscopy. As expert microscopy might still be required for confirmatory diagnosis and specific surveys, centres of excellence for microcopy must be maintained, even in this situation.

When malaria is rare and no longer perceived by local health services and the community to be a significant public health concern, ways must be found to maintain high-quality malaria diagnosis in order to continue screening for suspected malaria cases and to target malaria diagnostic testing to cases that are likely to be malaria.

10.3 Non-endemic areas

In non-endemic areas, highly sensitive malaria diagnostic testing (RDTs with a high panel detection score and expert malaria microscopy) is needed to investigate non-immune febrile patients (who can develop fever even before patent parasitaemia) who travelled to an endemic area within the past 3 months. In non-endemic areas, there are generally too few patients to be tested to justify malaria diagnostic services at all levels of the health system. They should, however, be available at least at secondary care level, and a system should be in place to refer suspected malaria cases (or their blood sample) rapidly to these centres with malaria diagnostic capacity. In these centres, the test positivity rate tends to increase because of restricted criteria for malaria testing to travellers from endemic areas. In this situation, microscopists generally see enough positive slides to maintain their skills.

10.4 Epidemic-prone zones

In epidemic-prone zones, good quality malaria diagnosis must be available, not only for case management but also for surveillance, i.e. investigation of an unexpected increase in cases of fever. During outbreak investigations and field surveys, RDTs have the advantage of allowing both detection and immediate treatment of malaria-positive cases. When the positivity rate is very low, it becomes difficult to maintain the interest and skills of microscopists and their capacity to implement an effective quality management system based on slide cross-checking (because of problems of sensitivity).

10.5 Complex emergencies

In emergencies and complex situations, there are several logistic and practical advantages to using RDTs rather than microscopy: rapid deployment in the field, less training needed than for microscopy, no need for an electricity supply, immediate availability of results for treatment of positive cases in the field, and potential for testing more cases.[1]

[1] *Malaria control in complex emergencies: an inter-agency field handbook*. Geneva, World Health Organization, 2005. Available at:
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Resource documents

National guidelines for malaria diagnosis from sub-Saharan countries

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2. Guidelines on the implementation of rapid diagnostic tests including quality assurance and control in Rwanda. National Malaria Control Programme, Ministry of Health, Rwanda 2009
3. Directives nationales pour le traitement du paludisme. Programme national de lutte contre le paludisme, Ministère de la Santé, République du Sénégal 2006
4. Swaziland National Malaria Diagnosis and Treatment Guidelines. National Malaria Control Programme, Ministry of Health, Kingdom of Swaziland, 2009
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WHO technical documents, manuals & training materials

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Annexes

ANNEX 1

Standard operating procedures for the use, care and maintenance of microscopes

Adapted from Walter Reed Army Institute of Research Malaria (2010). *Microscopy and rapid diagnostic testing quality management resource manual*, Fort Detrick, Texas.

Standard operating procedure No. XXX: Use, care and maintenance of microscopes

Last update on: ..... , by .....

Purpose: to provide the protocol for the use, care and maintenance of microscopes

Application: sites where malaria microscopy is performed

Principle: The accuracy of malaria microscopy depends on the correct functioning and use of the microscope. Microscopes should be set up for optimal performance, protected from damage, used ergonomically, regularly maintained and, if required, repaired by qualified personnel.

Maximum depth of field can be achieved only if the microscope light source has sufficient luminosity to allow the iris diaphragm to be closed optimally without loss of brightness. It is generally not possible to achieve maximum depth of field when using a mirror as a light source, and an artificial light source from a substage lamp with a substage condenser is required.

Precautions and safety:

Electrical connections to the microscope and the internal circuitry can be potentially hazardous.

The power source and connections to the microscope should be secure and not expose staff to a risk for electrocution.

The microscope and electrical connections should not be exposed to water.

Repairs to a microscope, other than the replacement of bulbs and fuses, should be performed by qualified service engineers or technicians.

Care should be taken to prevent damage to the eyes by exposure to the high light-intensity halogen lamp.

The microscope should not be cleaned with xylene, as it damages the microscope.

The microscope should be used ergonomically to prevent back and neck strain.

Reagents, chemicals and materials:

Commercial microscope cleaning solution

Dust cover

Lens-cleaning tissue

Soft cloth

Equipment and instruments:

Microscope and electrical connections

Procedures

Transporting and moving the microscope:

Transport microscopes in the original container with the internal packing materials to prevent the microscope from moving within the container.

If the original packaging is not available, use a specifically designed microscope transport box supplied by the manufacturer or a fabricated container containing foam or similar packing materials to prevent the microscope from moving within the container during transport.

During transport, protect the microscope from excessive movement or vibration: pack the microscope so that it does not move around in the transport vehicle and cannot fall from the top of other items being transported; protect the microscope from exposure to water (such as rain, flooding, falling into water), excessive heat, direct sunlight and rodents.

Carry a microscope with two hands, supporting the base and the arm.

Placement:

Place the microscope on a firm bench, free from vibration. Because of the high magnification, very small movements of the bench will cause large movements in the image being viewed by the microscopist.

Place the microscope in a position where there is space for the microscopist to place his or her legs fully under the bench.

Do not place the microscope in front of a brightly lit window. Place the microscope in front of a wall or a darkened window.

Microscope set-up:

Follow the manufacturer's directions for optimal set-up of the optical system and general use.

Adjust the iris aperture to the setting recommended by the manufacturer to achieve maximum depth of field.

If the manufacturer provides an iris diaphragm setting on the condenser, set this to the x100 objective lens setting.

Use the following method if the eyepiece of the microscope can be removed: fully raise the condenser; set the lamp to 'low'; select the x40 objective; close the iris diaphragm; remove one eyepiece; look down the tube, then adjust the condenser until the edge of the diaphragm is in sharp focus without showing an outer fringe ring in green or in red; open the iris diaphragm until the objective lens completely fills with light; the shape of the light is usually octagonal; when the points of the octagon touch the outside of the objective lens, open the iris diaphragm until the light appears circular; replace the eyepiece.

Prevent damage to the x40 objective:

Immediately remove any immersion oil that accidentally comes into contact with the x40 objective. Because the x40 lens is located next to the x100 lens and because it is also a long lens, it is easy for it to come into contact with immersion oil accidentally. The x40 objective is not sealed against oil penetration, and any immersion oil left in contact with the x40 objective will penetrate the lens and be deposited on the inside of the lower lens. This can be repaired only by the manufacturer by dismantling the objective lens.

Lower the stage before removing a slide.

Daily maintenance:

Inspect the microscope for damage or malfunction.

Record any damage or malfunction in the register for 'Maintenance of laboratory equipment'.

Use a clean cloth to remove dust from the surfaces of the microscope.

Clean the parts of the microscope with a clean cloth and commercial microscope cleaning solution. Ensure that immersion oil residues are removed. Do not clean any part of the microscope with xylene.

Clean the objective lens with a lens cleaning tissue only. Never clean lenses with alcohol, ordinary tissues, cleaning paper, toilet paper, cotton wool or hand towels, as they scratch the lens surface.

Cover the microscope with a dust cover.

Do not leave lens ports uncovered; use the port cover or sealing tape.

Repairs:

Site staff can replace a broken bulb or replace a blown fuse (with caution). Other repairs must be performed by a qualified service engineer or technician.

Do not exchange lenses and ports with those of other microscopes.

Routine servicing, such as realignment of the optics, replacement of lens and maintenance and lubrication of the stage, should be performed by a qualified service technician.

Bulb replacement:

Strictly follow the manufacturer's instructions.

Fuse replacement:

Extreme caution should be exercised in attempting to replace a blown fuse. Fuses are fitted by the manufacturer to protect the microscope from electrical damage, and if there is an electrical fault the replacement fuse could be destroyed. This could expose the site staff to danger of electrocution.

Fuses should be replaced only if there is reasonable evidence that the fuse was damaged by a power surge that is not likely to recur.

Strictly follow the manufacturer's instructions. Disconnect the microscope fully from the power source. Do not perform the repair alone.

After replacing the fuse, ensure that the microscope 'on/off' switch is off. Connect the microscope to the power supply and switch the power supply on. Switch on the microscope, wearing heavy rubber gloves to provide as much insulation protection as possible.

If the replacement fuse fails again, do not attempt to replace the fuse a second time. Decommission the microscope, and have it repaired by a qualified service technician.

After all repairs, whether successful or not, complete the register for 'Maintenance of laboratory equipment'.

Quality assessment procedures

The set-up and maintenance of the microscope(s) should be inspected during routine supervisory visits. The register for 'Maintenance of laboratory equipment' should also be inspected.

Causes of error

Unskilled repairs attempted on malfunctioning microscopes

Removing eyepieces unless they are designed to slide in and out of the tube

Removing eyepieces from sealed microscopes, which exposes the internal optics to dust and fungi

ANNEX 2.

Specification sheet for laboratory equipment

Adapted from *Mantenimiento preventivo y correctivo de equipos de laboratorio*. Instituto Nacional de Salud, Ministerio de Salud, Peru 2005.

Name of health facility:		Technical sheet number:	
Laboratory/area:		Date:	
DESCRIPTION			
1.	Name of equipment		
2.	Brand: Model:	3.	Serial number:
4.	Location:		
5.	Warranty period:	6.	End of warranty (date):
7.	Date of receipt in central warehouse:	8.	Date of receipt at the laboratory:
9.	Person responsible for installation:	10.	Date of installation:
		11.	Date put into service:
ACQUISITION			
12.	Financing or donation source:	13.	Approval number:
14.	Purchase order number:	15.	Cost:
16.	Condition in which the device was received: New ☐ Used ☐ Rehabilitated ☐		
17.	Name of manufacturer:	18.	Phone: Fax:
19.	Address of manufacturer:	20.	E-mail:
21.	Name of distributor in the country:	22.	Phone: Fax:
23.	Address of distributor:	24.	E-mail:
TECHNICAL INFORMATION			
25.	Operational manual: Yes ☐ No ☐	26.	Warranty certificate: Yes ☐ No ☐
27.	Installation manual: Yes ☐ No ☐	28.	Production certificate: Yes ☐ No ☐
29.	Service manual: Yes ☐ No ☐	30.	Other certificate (describe):
31.	Manual of accessories: Yes ☐ No ☐		
32.	Other manual (indicate which):		
TECHNICAL SPECIFICATIONS			
33.	General: Mechanical ☐ Electrical ☐ Electronic Automatic ☐ Semi-automatic ☐		
34.	Power supply: 110-120 V / 50-60 Hz ☐ 210-240 V / 50-60 Hz ☐		
35.	Display: Analogue ☐ Digital ☐	36.	Capacity:
37.	Specifications (describe):		
38.	Accessories:		
Person responsible for the equipment:		Person in charge of the laboratory:	
Signature:		Signature:	
Date:		Date:	

ANNEX 3.

Maintenance service report for laboratory equipment

Adapted from *Mantenimiento preventivo y correctivo de equipos de laboratorio*. Instituto Nacional de Salud, Ministerio de Salud, Peru 2005

Name of health facility:		Report number:	
Laboratory/area:		Date:	
DESCRIPTION OF THE EQUIPMENT			
1.	Name of equipment:		
2.	Brand: Model:	3.	Serial number:
4.	Location:		
PERSON RESPONSIBLE FOR MAINTENANCE			
5.	Name:	6.	Position or area of activity:
7.	Name of institution/company:	8.	Phone: Fax:
9.	Address of manufacturer:	10.	E-mail:
DATES OF MAINTENANCE SERVICE			
11.	Period 1: from to	12.	Period 2: from to
MAINTENANCE SERVICE CARRIED OUT			
13.	Description:		
14.	Findings and actions taken:		
15.	Types of equipment used for maintenance:		
WARRANTY PERIOD OF THE MAINTENANCE SERVICE (IF APPLICABLE)			
16.	The warranty for the maintenance service for the above-mentioned equipment is valid from ..... until		
COMPLIANCE WITH THE REQUIREMENTS OF THE MAINTENANCE SERVICE			
17.	We declare that the equipment described above has been tested for a period of ..... days, during which it has not shown any failure in functioning. We therefore confirm compliance of the maintenance service with service order number ..... , by the technician cited above.		
Person responsible for the equipment:		Person in charge of the laboratory or maintenance coordinator:	
Signature:		Signature:	
Date:		Date:	

ANNEX 4.

Register for maintenance of laboratory equipment

ANNEX 4

Adapted from *Mantenimiento preventivo y correctivo de equipos de laboratorio*. Instituto Nacional de Salud, Ministerio de Salud, Peru 2005.

A list of all existing laboratory equipment and a schedule for maintenance (and calibration when appropriate) should be attached to this register.

Name of health facility:					Page number:	
Report number	Date of maintenance	Name of equipment	Findings of maintenance	Maintenance technician or company	Signature	Next maintenance (month/year)

ANNEX 5.

Standard operating procedures for storage of rapid diagnostic tests at points of care

Adapted from Walter Reed Army Institute of Research Malaria (2010). *Microscopy and rapid diagnostic testing quality management resource manual*, Fort Detrick, Texas and from WHO/FIND *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*, 2009.

Standard operating procedure No. XXX: RDT storage at points of care

Last update on: ..... , by .....

Purpose: To provide guidelines for storage of malaria rapid diagnostic tests

Application: Sites performing malaria diagnostic testing (not supply warehouses before distribution to sites)

Principle: Malaria RDTs must be stored correctly within the temperature range stipulated by the manufacturer.

Equipment and instruments: Maximum–minimum thermometer

Procedures:

Storage conditions:

- Store malaria RDTs in cartons rather than as individual items. This helps to insulate the supplies and provides protection against moisture damage.
- Do not expose malaria RDTs to direct sunlight.
- Do not store malaria RDTs in a freezer.
- Limit access to the storage area as much as possible: constantly opening the door of a cooled or semi-cooled storage room allows access of hot air from the outside.
- RDTs should be kept cool. Ideally, in hot or humid places, malaria RDTs are stored in an air-conditioned room.
- If air-conditioning is not available, to prevent from exposure to high temperatures, store malaria RDTs by one or more of the following methods:
  - Storage room selected and adapted to achieve as cool an ambient temperature as possible
  - Located in coolest part of the building (eastern side of the building or part of the building shaded by a tree)
  - Protected from direct sunlight
  - Awnings fitted over windows, if possible
  - Windows shaded with blinds or curtains or covered with solid material (e.g. cardboard)
  - Room with as high a ceiling as possible

— Prevent high ceiling temperatures: rooms with thatched roofs are significantly cooler than those with metal roofs; insulate the inside of the roof if possible; provide air vents in the ceiling to allow hot air to escape; a roof ventilation turbine is an inexpensive, efficient cooling mechanism; install a ceiling fan or standing fan if possible; create as much natural ventilation as possible, but avoid allowing hot breezes into the room; ensure that rain cannot penetrate the air vents.

- Store supplies at least 30 cm away from the walls of the room and at least 1 m from the ceiling to avoid exposure to heat radiated from the walls and ceiling.
- Store supplies as close to the floor as possible (but at least 10 cm above the floor), as this is the coolest part of the room.

Temperature monitoring:

- Store supplies according to the manufacturer's specifications: check the specified temperature range for each new lot of malaria RDTs (temperature specifications may change).
- Storage temperature must be monitored with a maximum–minimum thermometer. The thermometer should be attached to an internal dividing wall at the same height as the highest stored carton. Temperature must be monitored and recorded daily, except on weekends if nobody is on site. The minimum and maximum daily temperature readings must be recorded. Reset the thermometer after each reading.
- Reduce the storage time if it is not feasible to store the malaria RDTs continuously within the temperature range specified by the manufacturer. Inform the focal person on malaria diagnostics at a higher level if the correct storage conditions cannot be achieved for a maximum storage period for the conditions of the site.

Moisture control:

- Supplies can be damaged rapidly by moisture, particularly malaria RDTs removed from their primary packaging.
- Ensure that the storage area is dry: there are no leaks in the roof; the floor is sealed; the area is not vulnerable to flooding by groundwater.
- Store the supplies on pallets or by other means so that they are stored at least 10 cm above the floor to avoid any moisture being absorbed from the floor.
- Do not store supplies in an area where there is fungal growth on the walls or floor.

Rodent control:

- Protect the supplies from rats and mice.

Causes of error:

- Using a defective thermometer
- Inaccurate use of the maximum–minimum thermometer; not resetting the thermometer after recording results
- Inaccurate reading of the thermometer

ANNEX 6.

Standard operating procedures for management of wastes from malaria diagnostic tests

Adapted from Walter Reed Army Institute of Research Malaria (2010). *Microscopy and rapid diagnostic testing quality management resource manual*, Fort Detrick, Texas and from WHO/FIND *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*, 2009.

Standard operating procedure No. XXX: Waste management of malaria tests

Last update on: ..... , by .....

Purpose: To provide guidelines for waste management at sites performing malaria diagnostic testing. This standard operating procedure provides general recommendations for handling infectious waste. National guidelines and policies, if available, supersede this standard operating procedure.

Application: Sites performing malaria diagnostic testing

Principle:

Waste materials resulting from malaria diagnostic testing can be infectious or environmentally damaging. Sites should have organized waste management systems to protect the staff, other people and the environment. It is efficient and cost-effective to manage different types of waste products separately. This standard operating procedure is intended to supplement existing waste management programmes by categorizing malaria diagnostic testing waste as sharps, infectious and non-infectious.

Precautions and safety:

Blood samples and blood-contaminated materials are potentially infectious. Follow the safety precautions prescribed in the national biohazard protocol for avoiding blood safety risks.

Specimen and sample requirements:

Waste materials produced during malaria diagnostic testing

Reagents, chemicals and materials:

- Sharps boxes
- Sharps pit
- Waste bins
- Wastebin liners
- Disposable gloves
- Penetration-resistant gloves

Procedures:

Types of waste materials:

- Waste is categorized as sharps; infectious, non-sharps; and non-infectious, non-sharps
- The different types of waste are handled differently. Sites should use a colour-coding system, if possible, to identify waste receptacles, in order to minimize the chances of the waste being accidentally placed in the wrong container: e.g. sharps, red; infectious non-sharps, yellow; non-infectious non-sharps, green

Waste management during testing:

Sharps

- Correctly designed commercial sharps boxes should be used whenever possible.
- Sharps should be placed in puncture-resistant plastic.
- Cardboard containers fitted with covers could be used as sharps containers if commercial sharps boxes are not available.
- The use of glass jars for sharps should be avoided because accidental breakage of a glass container containing sharps presents a significant danger to staff.
- When the sharps container is three quarters full, dispose of the entire container into a correctly designed sharps pit or incinerate the entire container. Do not overfill sharps containers or attempt to force sharps through a blocked entry hole.
- Do not reuse sharps containers. Attempting to empty and clean a sharps box is extremely hazardous.
- Do not place sharps or sharps containers in the general waste.
- Refer to national guidelines for the proper use and construction of a sharps pit.

Infectious non-sharps waste

- Infectious non-sharps waste should be placed in a strong, leak-resistant plastic bag placed in a metal or plastic bin with a secure lid.
- The wastebin should be clearly labelled 'hazardous materials' or similar.
- Store the wastebin in a safe place, where it is protected from accidentally being knocked over and is out of reach of children and stray animals.
- When the plastic bag is three quarters full, seal the bag by tying the open end into a knot and remove the bag from the wastebin.
- Dispose of the bag either by placing it in a burial pit or by incineration.
- Wearing gloves, disinfect the wastebin with household bleach before putting in a new plastic bag.
- Refer to national guidelines for appropriate waste disposal methods.

Non-Infectious non-sharps waste

- Non-infectious non-sharps waste can be managed according to the usual practice at the site.

Storage of sharps and infectious non-sharps waste before final disposal:

- Do not mix sharps, infectious non-sharps and non-infectious non-sharps waste.
- Clearly mark the storage area for sharps and infectious non-sharps waste with a warning sign, such as 'Caution: infectious and sharps waste. Unauthorized persons keep out'.
- Do not store sharps and infectious non-sharps waste in patients' rooms or in public areas.

Disposal of sharps and infectious non-sharps waste:

Sites should comply with national guidelines.

Disposal of sharps

- Avoid incineration of sharps whenever possible. Metals (lancets) and glass cannot be burnt and should be discarded after incineration. Sharps should not be placed in the infectious non-sharps waste disposal system. Cardboard sharps boxes produce a considerable amount of harmful smoke. Plastic sharps containers produce toxic smoke.
- If burning is unavoidable: burn only in areas separated from public spaces, as burning produces harmful smoke and airborne particles; bury the residual ashes and unburnt glass and metals in an isolated location well covered with soil.
- People disposing of sharps into a sharps pit or by incineration should wear heavy-duty penetration-resistant gloves (such as leather gloves). Disposable gloves do not provide sufficient protection. Disposable gloves may be worn underneath penetration-resistant gloves.
- A simple, safe method is to use a large solid plastic or metal drum (or barrel, such as a 44-gallon drum) in a secure location and drop the full sharps containers through a hole in the top. When the barrel is three quarters full, fill with concrete and dispose of in a deep burial pit.
- Alternatively, dig a deep hole in the ground and line the floor and sides with clay, bricks or cement, or use a hole constructed with large cement pipes. Make sure that the pit has a concrete cover with a narrow cylinder, so that sharps containers can be dropped into the pit. When the pit is full, fill it with concrete and seal it. Keep the pit fenced off or secured.

Disposal of infectious non-sharps

- People working with infectious waste should wear gloves, including cleaning, maintenance and ground staff.
- Infectious non-sharps waste can be buried in a pit 2–5 m deep, with the bottom at least 1.5 m above the water table.
- Do not locate the pit near water supplies such as water courses or wells. The pit should be lined with low-permeability material, such as clay. The pit should be protected from rain with an appropriate cover (e.g., tarpaulin or a constructed roof) and protected from flooding with groundwater (e.g. construct a trench or a ridge around the perimeter to divert groundwater).
- Add a layer of soil or sawdust after each layer of waste.
- Clearly mark the storage area for infectious non-sharps waste with a warning sign such as 'Caution: infectious waste. Unauthorized persons keep out'.
- Avoid burning waste if possible, as waste may contain a considerable amount of plastic that will pollute the environment. If burning is unavoidable, burn in areas separated from public spaces, as burning produces harmful smoke and airborne particles; bury the residual ashes and unburnt glass and metals in an isolated well covered with soil.

Causes of error:

Insufficient care and diligence in safely disposing of waste materials

ANNEX 7.

Testing for proficiency in reading blood slides against reference slides

Adapted from Walter Reed Army Institute of Research Malaria (2010). *Microscopy and rapid diagnostic testing quality management resource manual*, Fort Detrick, Texas.

Standard operating procedure No. XXX: Slide proficiency testing

Last update on: ..... , by .....

Purpose: External quality assessment of malaria microscopy by reading reference blood slides at testing sites

Principle:

- Thick and thin blood films are prepared and stained by the national reference laboratory and sent to field laboratories performing malaria microscopy for examination in a blinded manner. The results are analysed centrally and used as an indicator of performance.
- This type of external quality assessment is a measure of competence to examine well-prepared and stained blood films. The reference blood films are used internally by laboratories to monitor the competence of individual microscopists. At programme level, external quality assessment addresses the overall competence of a laboratory, as the blood films may have been examined by more than one microscopist.
- External quality assessment monitors partially the accuracy of routine blood film examination, as this depends on many factors in addition to reading skill, such as blood film preparation, staining and workload.

Specimen and sample requirements: Five external quality assessment blood films prepared and distributed quarterly to all participating laboratories.

Procedures:

National reference laboratory

- A set of five[1] external quality assessment blood films should be prepared and distributed quarterly[1] in secure slide boxes to each laboratory.
- Prepare a sufficient number of blood films so that each laboratory receives the same set. They should be prepared by the standard operating procedures for preparation of thick and thin blood films and stained by the standard operating procedures for Giemsa staining. They should be protected with coverslips. They can be prepared in advance and stored in slide storage boxes, protected from heat and humidity.
- Specific reporting instructions should be prepared for each set of external quality assessment blood films, including reporting the blood films as positive or negative for malaria parasites; reporting the presence of *P. falciparum*; reporting the presence of a mixed infection; reporting the presence of schizonts or gametocytes.[2]

[1] Other programmes are sending 10 slides per survey three times a year, to reduce logistic constrains.
[2] Other programmes are also evaluating the parasite count for *P. falciparum* positive slides.

- The participating laboratories should retain the external quality assessment blood films as part of a laboratory slide bank for teaching and self-instruction.
- The external quality assessment set should consist of negative blood films, weakly positive blood films (80–200 parasites/µl) and moderately-to-strongly positive (> 500 parasites/µl) blood film illustrating a diagnostic feature (e.g. schizonts, mixed infection).
- The composition of the positive blood films should vary each month. The type of slides selected should take into account the target national competency levels of microscopists.
- The external quality assessment results reported by the laboratories should be analysed against the reporting instructions issued with each set of blood films. A report should be prepared and distributed to the laboratories within 6 weeks of the distribution of blood films. The results should be checked for cheating by laboratories that shared results before reporting (for example, two or more laboratories reporting similar errors).

Participating laboratories

- The laboratory supervisor should ensure that each malaria microscopist in the laboratory has the opportunity to examine the external quality assessment blood films at least once a year.
- The laboratory supervisor should send the completed report form to the national reference laboratory within 1 week of receipt of the external quality assessment blood films. This time does not include the transport or postage time for sending the results.
- On receipt of the report from the national reference laboratory, if there are discrepancies between the overall laboratory and the national reference laboratory results, the blood film(s) should be re-examined as a training exercise; if one or more microscopists reported incorrect findings, the laboratory supervisor should take appropriate corrective action.

Quality assessment procedures:

Before distribution to the participating laboratories, 5% of the external quality assessment blood films should be examined for staining quality. Blood film sets with unsatisfactory staining quality (as defined in standard operating procedures for Giemsa staining) should be rejected.

Before distribution to the participating laboratories, five blood films from each external quality assessment set should be examined in a blinded manner by at least three expert microscopists to confirm the correct result for the blood film.

Reporting of results: The results should be reported to the participating laboratories within 6 weeks of distributing the blood films.

Causes of error:

- Poor preparation and staining of the external quality assessment blood films
- Incorrect reading of the external quality assessment blood films by the national reference laboratory
- Participating laboratories sharing findings before reporting results
- Participating laboratories examining external quality assessment blood films under unsatisfactory microscopes

Limitations and procedure notes:

This type of external quality assessment by panel testing monitors partially the routine accuracy of malaria microscopy, which also depends on the quality of blood film preparation and staining and on the workload. It can be complemented or combined by other types of quality management activities such as crosschecking (validation) of blood slides.

ANNEX 8.

Checklist for supervision of laboratories performing malaria testing

Adapted from WHO (2009). *Malaria microscopy quality assurance manual*; Walter Reed Army Institute of Research Malaria (2010). *Microscopy and rapid diagnostic testing quality management resource manual,* Fort Detrick, Texas; and *Consultation on technical and operational recommendations for clinical laboratory testing harmonization and standardization,* Maputo, Mozambique 2008.

All laboratories should add the checklist for direct observation of laboratory technicians performing malaria microscopy (Annex 9) and the checklist for direct observation of health workers performing RDTs for malaria (Annex 10) to this checklist.

The score for each item should be chosen on the basis of the relative importance that the programme gives to it.

I. General Information

Name of laboratory/Facility: Date of visit (mm/dd/yyyy)

Type of facility: ☐ Rural ☐ Clinic ☐ District hospital ☐ Provincial Hospital ☐ Private Hospital ☐ Other

Address of the laboratory:

Municipality: Province:

Telephone/Fax

E-mail:

Name of head of laboratory:

Name of facility head/director:

Names of laboratory technicians trained for malaria microscopy and RDT

1. .....

   Date of last training ....–....–.... No. of months in the laboratory .....
   dd mm yyyy

2. .....

   Date of last training ....–....–.... No. of months in the laboratory .....
   dd mm yyyy

3. .....

   Date of last training ....–....–.... No. of months in the laboratory .....
   dd mm yyyy

4. .....

   Date of last training ....–....–.... No. of months in the laboratory .....
   dd mm yyyy

5. .....

   Date of last training ....–....–.... No. of months in the laboratory .....
   dd mm yyyy

Routine working hours of the laboratory	Monday–Friday	.....
	Saturday	.....
	Sunday	.....

Is malaria RDT testing available out of the working hours of the laboratory ☐ Yes ☐ No

II. Procedures

			Score if good	Laboratory score
A. Archiving of slides				
Number of slides read in the previous month		.....		
Slide positivity rate in the previous month		..... %		
B. Review of quality of slide preparation (randomly selected)				
	NUMBER	PERCENTAGE[1]		
Total number of slides reviewed	.....	—		
Number of slides fully and clearly labelled	.....	.....%		
Number of slides without surface abrasions	.....	.....%		
Number of slides without a blue background coloration	.....	.....%		
Number of slides without fungal contamination	.....	.....%		
Number of slides where Giemsa stain was used	.....	.....%		
Number of slides with a correct size of films	.....	.....%		
Number of slides with correct blood volume and opacity	.....	.....%		
Number of thick films that are uniformly spread	.....	.....%		
Number of thick films not fixed with methanol	.....	.....%		
Number of slides without washed off parts	.....	.....%		
Number of slides with pink to light purple background coloration[2]	.....	.....%		
Number of slides without stain precipitate[2]	.....	.....%		
Number of slides without bacterial contamination[2]	.....	.....%		
C. Direct observation of malaria microscopy performance (use checklist for the direct observation of laboratory technicians, Annex 9)				
	NUMBER OF STEPS PERFORMED CORRECTLY			
Name of technician	...../24	*Correct each technician for the steps performed wrongly and watch him/her again while performing a new test*		
Name of technician	...../24			
Name of technician	...../24			
Name of technician	...../24			

[1] Number of slides fulfilling the criteria times 100, divided by the total number of slides reviewed. The target is 100%.
[2] This can only be assessed microscopically.

ANNEX 8

			Score if good	Laboratory score
D. Blood slide validation (cross-checking of routine slides)				
Total number of slides cross-checked by validator	.....			
of which	.....	are weak positive,[1]		
and of which	.....	are negative.[1]		
Number of false positive slides	.....			
Number of false negative slides	.....			
Percentage of agreement[2]	.....%			
E. Direct observation of RDT performance (use checklist for the direct observation of health workers, Annex 10)				
	NUMBER OF STEPS PERFORMED CORRECTLY			
Name of technician	...../14	*Correct each technician for the steps performed wrongly and watch him/her again while performing a new test*		
Name of technician	...../14			
Name of technician	...../14			
Name of technician	...../14			
F. Direct observation of urine dipstick performance (use specific checklist)				
	NUMBER OF STEPS PERFORMED CORRECTLY			
Name of health worker	...../xx	*Correct each technician for the steps performed wrongly and watch him/her again while performing a new test*		
Name of health worker	...../xx			
Name of health worker	...../xx			
Name of health worker	...../xx			
G. Direct observation of acid-fast bacillus performance (use specific checklist)				
	NUMBER OF STEPS PERFORMED CORRECTLY			
Name of technician	...../xx	*Correct each technician for the steps performed wrongly and watch him/her again while performing a new test*		
Name of technician	...../xx			
Name of technician	...../xx			
Name of technician	...../xx			
H. Direct observation of other (non-malaria) RDT performance (use specific checklist)				
	NUMBER OF STEPS PERFORMED CORRECTLY			
Name of technician	...../xx	*Correct each technician for the steps performed wrongly and watch him/her again while performing a new test*		
Name of technician	...../xx			
Name of technician	...../xx			
Name of technician	...../xx			

[1] Based on the reading of the assessed laboratory.

[2] (Number of real positive slides + Number of real negative slides) / total number of slides cross-checked.

	Score if good	Laboratory score

III. Laboratory set-up

	GOOD	POOR	REMARKS		
Bench space					
Sink/washing area/staining area					
Access to clean water supply					
Natural lighting					
Power source					
Ventilation					
Storage space for supplies and materials					
Waste management system					
Post exposure prophylaxis in case of injury available within 24H					

IV. RDT kits (malaria, HIV, syphilis and pregnancy) and urine dipsticks kept in the laboratory

Specify which RDT has been inspected:

1. .....

2. .....

3. .....

4. .....

	YES	NO	REMARKS		
RDT kits are protected from direct sunlight					
RDT kits are protected from humidity, rain or water					
RDT kits are not expired					

V. Microscopes

	YES	NO	REMARKS		
The microscope(s) is binocular					
The microscope lamp(s) has sufficient power to provide good illumination when the condenser aperture is set at the correct setting for the x100 objective					
Blood films can be brought into sharp focus at x100 oil immersion magnification					
The stage movement mechanism is precise and stable					
The microscope(s) is regularly serviced					
The microscope(s) is protected with a cover when not in use					
Xylene is never used to clean the nicroscope(s), objectives or eye pieces					
Spare bulbs are stored in the laboratory					

				Score if good	Laboratory score

VI. Microscope slides

	YES	NO	REMARKS		
Microscope slides are of good quality and are thoroughly cleaned before use					
Microscope slides do not have scratches or surface aberrations					
Microscope slides do not give a blue background colour after staining					
Microscope slides do not have fungal contamination					
Microscope slides that have been damaged by fungus are discarded and not used again					
In settingss with high humidity, microscope slides are protected against fungal contamination					

VII. Stain solutions

	YES	NO	REMARKS		
Stock staining solutions are stored in the dark and far from a heat source					
Commercial stain solutions are within the manufacturer's expiry date					
Commercial stain solutions do not contain excessive stain precipitate					
The cap of the reagent bottle is always tightly sealed except when stain is being removed for use					
Stain is always removed from the reagent bottle using a clean pipette or something similar					
Water is never added to the stock stain solution					
Unused stain is never returned to the stock bottle					

VIII. Other laboratory tests available at peripheral level laboratories

	YES	NO	REMARKS		
Glucometer properly stored					
Haemoglobinometer properly stored					
...					

				Score if good	Laboratory score

IX. General laboratory supplies

	YES	NO	REMARKS		
Alcohol and cotton (or similar) for cleaning skin prior to blood collection					
Lancets					
Methanol					
Buffer salts or buffer tablets					
pH meter that reads to two decimal places					
pH calibration solutions					
Staining jar					
Staining rack					
Drying rack					
Graduated cylinders of the correct size					
Wash bottles					
Timers – sufficient number for staining and for each microscopist					
Immersion oil					
Tally counters – sufficient number for the number of staff					
Lens paper					
Slide boxes for storage					
For laboratories that prepare stain from powder – sufficient glycerol, methanol, powder, beakers, measuring cylinders, filter paper, funnels, stirring rods, scales, spatulas and storage bottles					

X. Documentation

	YES	NO	REMARKS		
Logbook or record book located in the laboratory					
Logbook or record book for all RDT performed out of laboratory working hours available					
Blood slides and malaria RDT information recorded separately					
Patient's name and details recorded in an organized and legible manner					
Date malaria test was performed recorded					
Species identification performed					
Parasite counting performed (if yes, specify method used under remarks column)					

	YES	NO	REMARKS	Score if good	Laboratory score
Forms					
Pathology request forms used					
Result/report forms completed correctly					
Referral forms used					
Analysis					
Monthly analysis prepared including: *Malaria:* Number of slides examined, the number of RDT performed, positivity rates for each type of test and, for slides, percentage of species identified (as appropriate) and quantification					
Other tests: Number of tests performed, positivity rate for each test					
Maintenance of laboratory equipment					
Register for maintenance of laboratory equipment is up-to-date					
Specification sheet available for every laboratory equipment					
All maintenance service reports available					
Availability of up-to-date standard operation procedures and/or bench aids					
Malaria RDT performance					
Use, care and maintenance of microscopes					
Preparation of stock Giemsa					
Thick and thin film preparation					
Blood staining for malaria					
Waste management of malaria tests					
Urine dipstick performance					
Measurement of glycaemia					
Measurement of haemoglobin and haematocrit					
HIV RDT performance					
Syphilis RDT performance					
Pregnancy test performance					
Internal audit of laboratory					

ANNEX 9.

Checklist for direct observation of laboratory technicians performing malaria microscopy

Adapted from *Improving Malaria Diagnostics (IMaD). Improving malaria diagnostics outreach: training and support supervision manual*, Ghana 2010.

Name of health facility:	Position of health worker performing test: .....
Name of observer:	Number of days during which health worker performed microscopy in the past month: ...../...../.....
Date of observation:	

No.	Steps observed	Yes	No	Comment
PREPARATION OF STAIN				
1.	Giemsa stain stock solution labelled with time and date			
2.	Giemsa stain stock solution kept well-stoppered			
3.	Giemsa stock diluted to 10% (or 3%)			
4.	pH of buffer used for dilution is 7.2.			
5.	Diluted Giemsa discarded after a maximum of 6 h			
SLIDE STAINING				
6.	Slides are clean and not scratched.			
7.	Only thin films are fixed with methanol (2–3 s) or ethanol (20 min) and dried before staining.			
8.	Slide stained for 8–10 min (if 10% dilution) or 45–60 min (if 3% dilution)			
9.	Slide rinsed with clean water			
10.	Slide drained and dried on rack			
11.	No heating used to dry films			
SLIDE EXAMINATION				
12.	Immersion oil placed on slide			
13.	Stage of microscope racked down before placing slide			
14.	Focus with x40 objective before focus with x100 oil immersion objective			
15.	≥ 100 fields examined before declaring slide negative			
SLIDE READING				
16.	Negative result differentiated from positive result			
17.	Species identified			
18.	Parasite density quantified by counting ≥ 200 white blood cells			
19.	If parasite density is high, thin film used for counting			

No.	Steps observed	Yes	No	Comment
RESULT REPORTING				
20.	Result reported as negative or positive for parasites			
21.	Species of parasite reported			
22.	Parasite density reported as number of parasites per 200 white blood cells or converted to number of parasites per microlitre			
23.	Date and time of result recorded			
24.	Result properly delivered back to clinician or patient and recorded in the laboratory register			
SLIDE CLEANING AND SLIDE AND MICROSCOPE STORAGE				
25.	Slides placed on tissue to remove oil			
26.	Slides for quality management system stored according to protocol			
27.	Microscope cleaned appropriately (manufacturer's instructions)			
28.	Microscope stored properly to avoid fungus and covered to avoid dust			

ANNEX 10.

Checklist for direct observation of health workers performing Rapid Diagnostic Tests (RDT) for malaria

Adapted from 'Improving Malaria Diagnosis in health facilities' (IMALDIA) project. Dar es Salaam City Medical Office of Health, United Republic of Tanzania, and the Swiss Tropical and Public Health Institute, Basel, Switzerland 2006–2008.

Name of health facility:	Position of health worker performing test: .....
Name of observer:	Number of days during which health worker performed RDTs in the past month: ...../...../.....
Date of observation:	

No.	Steps observed	Yes	No	Comment
1.	Procedure explained to the patient or caregiver			
2.	Expiry date checked			
3.	Device labelled with patient's name			
4.	Gloves worn			
5.	Finger disinfected and allowed to dry before pricking			
6.	New sterile lancet used for each patient and disposed of immediately in appropriate sharps container			
7.	Right amount of blood collected with the blood transfer device			
8.	All collected blood deposited in right well			
9.	Correct number of buffer drops deposited in right well			
10.	Proper timing observed before reading test result			
11.	Proper interpretation of test result			
12.	Used test, capillary tube and alcohol swab disposed of in appropriate container			
13.	Result recorded accurately in the register			
14.	Result recorded accurately on the patient's card			

ANNEX 11.

Case scenarios for training in use of Rapid Diagnostic Tests (RDT) in clinical management

Adapted from 'Improving Malaria Diagnosis in health facilities' (IMALDIA) project. Dar es Salaam City Medical Office of Health, United Republic of Tanzania, and the Swiss Tropical and Public Health Institute, Basel, Switzerland 2006–2008.

Questions

Case study 1:

A child aged 3 years is brought in for fever over the past 24 h. The father reports no cough or diarrhoea.

Physical examination shows a temperature of 38.6 °C but no other major sign.

RDT is negative.

(1) What is your diagnosis?

(2) What advice do you give to the father, and what treatment do you prescribe?

Case study 2:

An infant aged 11 months is brought to a dispensary for fever over the past 48 h. The mother reports difficulty in breastfeeding since the previous day and one episode of convulsion.

Physical examination shows a temperature of 38.6 °C and slight drowsiness but no other major sign.

Explain the actions you would take, one by one.

Case study 3:

A boy aged 4 years is brought to a health centre by his brother because he has been 'hot' for 3 days and has been coughing since the previous day. There are no other major signs.

On examination, the boy is found to have a temperature of 38.3 °C and a respiratory rate of 45/min. Chest auscultation gives normal results.

(1) What is your diagnosis?

(2) Which test(s) do you ask for?

(3) For each possible test result, which treatment(s) would you give?

Case study 4:

A girl aged 12 years is brought to a dispensary for fever and headache since the previous week. She reports having had malaria (documented by a malaria test) 1 week previously and taking an artemisinin-based antimalarial medicine. The fever abated within 1 day but recurred after 3 days.

(1) What do you ask her?

(2) What do you do (a) if microscopy is available and (b) if microscopy is not available at all?

Case study 5:

A boy aged 10 years presents at a dispensary with joint pain and cough for the past week. He has no fever and no other symptoms. His temperature is 37.3 °C, and a physical examination shows normal findings.

What do you do?

Answers

Case study 1: non-specific fever (without danger signs)

1) Diagnosis: non-specific fever or non-malaria fever or flu-like syndrome
2) Reassure the father that his child does not have malaria. Tell him to bring the child again if the fever persists or if a new problem appears. Treat the child with an antipyretic only.

Take home message: RDT is negative → no malaria → no antimalarial treatment

Case study 2: severe febrile illness at dispensary level

— Difficulty to suck, convulsion, drowsiness = Danger signs

— Do not lose time by asking for malaria tests; they will be done at the hospital.

— Immediately prescribe an antimalarial and an antibiotic treatment (and antipyretic)

— Refer the infant urgently to hospital

Take home message: Danger signs antimalarial + antibiotic + immediate referral

Case study 3: pneumonia with or without malaria

In the presence of cough, measure the respiratory rate:

If it is ≥ 50/min for infants aged 2–12 months or if it is ≥ 40/min for children aged 12 months–5 years, there is fast breathing, which is a sign of pneumonia.

1) Diagnoses: Pneumonia (because of fast breathing) with or without malaria
2) Tests: RDT
3) Result: if RDT is positive, give an antimalarial and an antibiotic
   if RDT is negative, give an antibiotic only

Take home message: Fast breathing → pneumonia (whatever the result of RDT) → antibiotic

No fast breathing → no pneumonia → no antibiotic

Case study 4: persisting fever after antimalarial treatment

1) Ask the patient if she took full ACT treatment (all tablets without vomiting thereafter) or only partial treatment
2) If she took full treatment:
   a) *If microscopy is available:* ask for a blood slide AND look for other causes of fever
      If the blood slide result is positive, give second-line antimalarial treatment
      If the blood slide result is negative, do *not* give antimalarial treatment at all

b) *If microscopy is NOT available:* perform RDT AND look for other causes of fever

If the RDT result is positive, give second-line antimalarial treatment (even if the patient might be already cured)[1]

If the RDT result is negative, do *not* give antimalarial treatment at all

If she took only partial treatment:

Give (or complete) *first-line* antimalarial treatment, look for other causes of fever and advice her to come back if fever persists (malaria tests are not needed at this stage)

Take home message: Persisting fever after antimalarial → ask if patient took full treatment:

If yes → ask for microscopy (if available)

If no → give (or complete) the first-line antimalarial treatment

In any case → look for other causes of fever

Case study 5: cough and joint pain without fever

In absence of fever, the child does *not* suffer from a malaria episode. He probably has an upper respiratory tract infection.

To exclude pneumonia, measure the respiratory rate and give an antibiotic *only if* fast breathing is present.

Reassure the caretaker that the child has no serious illness and give an analgesic.

Take home message: No history of fever and no elevated temperature

→ do not ask for any malaria test

→ do not give antimalarial treatment

Conclusion: avoid mis-management of patients with no danger signs:

— Do not ask for a malaria test if there is no history of fever and no elevated temperature.

— Do not give antimalarials when the malaria test (RDT or reliable microscopy) is negative.

— Do not forget to look for other causes of fever, whatever the result of the malaria test.

— Do not give antibiotics without a clear indication: follow the recommendations of Integrated Management of Childhood Illness (IMCI).

[1] In this situation, the RDT result might be positive either because of the presence of parasites due to treatment failure (the patient is not cured), or because of persisting antigens despite clearance of parasites (the patient is cured). In the absence of microscopy, it is impossible to distinguish between these 2 situations and second-line antimalarial treatment should be given.

ANNEX 12

Checklist for supervision of malaria diagnostic testing in health facilities

Adapted from WHO (2009). *Malaria microscopy quality assurance manual*; Walter Reed Army Institute of Research Malaria (2010). *Microscopy and rapid diagnostic testing quality management resource manual*, Fort Detrick, Texas; WHO (2009). *Malaria case management operations manual*; and 'Improving Malaria Diagnosis in health facilities' (IMALDIA) project. Dar es Salaam City Medical Office of Health, United Republic of Tanzania, and the Swiss Tropical and Public Health Institute, Basel, Switzerland 2006–2008.

All health facilities should add the checklist for supervision of clinical management of febrile children at health facility level (Annex 13) and the checklist for direct observation of health workers performing RDTs for malaria (Annex 10) to this checklist.

Health facilities with a laboratory should add the checklist for supervision of laboratories performing malaria testing (Annex 8) and the checklist for direct observation of laboratory technicians performing malaria microscopy (Annex 9) to this checklist.

I. General Information

Name of laboratory/Facility: Date of visit (mm/dd/yyyy)

Type of facility: ☐ Rural ☐ Clinic ☐ District hospital ☐ Provincial Hospital ☐ Private Hospital ☐ Other

Address of the laboratory:

Municipality: Province:

Telephone/Fax

E-mail:

Name of person in charge of the health facility:

Name of focal person for all rapid diagnostic tests:

Name of health workers performing RDT for malaria or for other diseases (e.g. HIV)

1. .....
   Formal training received ☐ Yes ☐ No No. of months in health facility ☐☐
2. .....
   Formal training received ☐ Yes ☐ No No. of months in health facility ☐☐
3. .....
   Formal training received ☐ Yes ☐ No No. of months in health facility ☐☐
4. .....
   Formal training received ☐ Yes ☐ No No. of months in health facility ☐☐
5. .....
   Formal training received ☐ Yes ☐ No No. of months in health facility ☐☐

Is RDT testing available at any time during the working hours of the health facility ☐ Yes ☐ No

Post exposure prophylaxis for HIV available within 24 hours in case of injury ☐ Yes ☐ No

Assess conditions	Solve identified problems	Score if good	Health facility score

II. Space and equipment

1. Examination area? ☐ Yes ☐ No	• Reorganize space and help health workers set up examination area • Identify minimal requirements for furniture that could be moved to the examination area • Report needs to district level (scale, timing device, thermometers, guidelines, charts, patient record cards) If other solution, please describe:		
2. Lighting of examination area? ☐ Yes ☐ No			
3. Space to see patient? ☐ Yes ☐ No			
4. Chair and table for health worker? ☐ Yes ☐ No			
5. Functioning weighing scale? ☐ Yes ☐ No			
6. Thermometer? ☐ Yes ☐ No			
7. Watch or other timing device? ☐ Yes ☐ No			
8. Patient record cards? ☐ Yes ☐ No			
9. Malaria patient register? ☐ Yes ☐ No			
10. Supplies for assessing patient? ☐ Yes ☐ No			

III. Organization of case management tasks

1. Register patients, manages triage/ patient flow? ☐ Yes ☐ No	Solve problems that interfere with case management of fever, e.g.: • Help trained worker to train other staff • Organize patient flow • Identify ways to make case management more efficient, less time-consuming Help trained/untrained staff to determine how to ensure case management tasks can be carried out.	
2. Weigh patient? ☐ Yes ☐ No		
3. Take body temperature? ☐ Yes ☐ No		
4. Enough time spent to assess patient? ☐ Yes ☐ No		
5. Are rapid tests performed? ☐ Yes ☐ No		
6. Are drugs dispensed? ☐ Yes ☐ No		
7. Instructions on how medication should be given? ☐ Yes ☐ No		
8. Give first dose of drug? ☐ Yes ☐ No		
9. Complete patient records? ☐ Yes ☐ No		

Tasks not routinely carried out well by trained workers:
- *Find out why tasks are not carried out well*
- *Determine whether the task is carried out by other staff*
- *Determine whether the way in which the task is carried out by other staff interferes with work of trained heath worker*

IV. Clinic and referral services

1. Clinic opens during all scheduled hours? ☐ Yes ☐ No	Reconfirm scheduled clinic hours for services offered Discuss difficulties encountered in providing essential services every day and identify possible solutions Review what to do when referral is not possible Report unsolved problems to district level	
2. Reasonable waiting time for patients? ☐ Yes ☐ No		
3. Is patient load balanced by staff distribution during clinic hours? ☐ Yes ☐ No		
4. Pharmacy services available during open hours? ☐ Yes ☐ No		
5. Diagnostic services available? ☐ Yes ☐ No		
6. Preventive and control services provided? ☐ Yes ☐ No		
7. Immunization services available every day? ☐ Yes ☐ No		
8. Referral care possible within reasonable time? ☐ Yes ☐ No		

Assess conditions		Solve identified problems	Score if good	Health facility score
V. Malaria RDT performance				
(*Use checklist for the direct observation of RDT performers, Annex 10*) Name of health worker ..... Name of health worker ..... Name of health worker	Number of steps performed correctly ..... /14 ..... /14 ..... /14	Correct the steps performed wrongly by each health worker and watch him or her performing a new RDT on a real patient.		
VI. Performance of other rapid tests				
Urine dipstick (*use the corresponding checklist*) Name of health worker ..... Name of health worker ..... Name of health worker	Number of steps performed correctly ..... /XX ..... /XX ..... /XX	Correct the steps performed wrongly by each health worker and watch him or her performing a new test on a real patient.		
HIV RDT (*use the corresponding checklist*) Name of health worker ..... Name of health worker ..... Name of health worker	Number of steps performed correctly ..... /XX ..... /XX ..... /XX	Correct the steps performed wrongly by each health worker and watch him or her performing a new test on a real patient.		
VII. Availability of drugs and other supplies in stock on day of visit				
1. First-line antimalarial drug	☐ Yes ☐ No	Identify appropriate solution, e.g.: • Review and give practice in using drug stock card or book • Review rational use of drugs with persons responsible for prescribing • Identify ways to combine use of transport Report stock shortages to district level.		
2. Second-line antimalarial drug	☐ Yes ☐ No			
3. First-line antibiotic for pneumonia	☐ Yes ☐ No			
4. First-line antibiotic for dysentery	☐ Yes ☐ No			
5. First-line antibiotic for skin infections	☐ Yes ☐ No			
6. Inhaled salbutamol	☐ Yes ☐ No			
7. Zinc	☐ Yes ☐ No			
8. Oral rehydration salts	☐ Yes ☐ No			
9. Iron	☐ Yes ☐ No			
10. Vitamin A	☐ Yes ☐ No			
11. Mebendazole	☐ Yes ☐ No			
12. Tetracycline eye ointment	☐ Yes ☐ No			
13. Spacer for inhaled salbutamol	☐ Yes ☐ No			
14. Malaria RDTs	☐ Yes ☐ No			
15. Urine dipsticks	☐ Yes ☐ No			
16. Glucometer	☐ Yes ☐ No			
17. Haemoglobin or haematocrit meter	☐ Yes ☐ No			
18. HIV RDTs	☐ Yes ☐ No			

Assess conditions		Solve identified problems	Score if good	Health facility score
19. Syphilis RDTs	☐ Yes ☐ No			
20. Pregnancy RDTs	☐ Yes ☐ No			
21. First-line parenteral antibiotics for severe illness	☐ Yes ☐ No			
22. Quinine injection	☐ Yes ☐ No			
23. Sterile syringes	☐ Yes ☐ No			
24. Sterile needles	☐ Yes ☐ No			
25. Butterfly needles and cannulae	☐ Yes ☐ No			
26. Antipyretics	☐ Yes ☐ No			
27. Cotton swabs	☐ Yes ☐ No			
28. Skin disinfectant	☐ Yes ☐ No			
29. Intravenous administration sets	☐ Yes ☐ No			
30. Nasogastric tubes	☐ Yes ☐ No			
31. Dextrose 5%, 10% and 50%	☐ Yes ☐ No			
32. Normal saline	☐ Yes ☐ No			
33. Intravenous and rectal diazepam	☐ Yes ☐ No			
Determine problem in availability of drugs and other supplies, e.g.: • *needs not adequately assessed* • *inadequate records and ordering* • *drugs not used rationally* • *not enough drugs available in central store* • *high seasonal demand* • *no transport*				

VIII. Storage and stock management

1 Organization of stocks according to expiry date?	☐ Yes ☐ No	Ensure expired medicines and RDTs are discarded.		
2. Medicines and tests stock control in place?	☐ Yes ☐ No	Report need for medicine and tests stock control to district level.		
3. Medicines or RDTs expired?	☐ Yes ☐ No			
4. Medicines, tests and supplies stored securely?	☐ Yes ☐ No			
5. Medicines and tests protected from direct sunlight?	☐ Yes ☐ No			
6. Medicines and tests protected from humidity, rain or water?	☐ Yes ☐ No			
7. Daily monitoring of temperature in place?	☐ Yes ☐ No			
Compare storage conditions with corresponding standard operating procedure and correct discordances. *Compare stock management with corresponding standard operating procedure and correct discordances.* *Which items have expired and how much?*				

Assess conditions	Solve identified problems	Score if good	Health facility score
IX. Quality of records			
1. Are individual patient records or registers maintained? ☐ Yes ☐ No	Teach health workers how to fill in registers. Propose ordering or creating missing registers. In health facilities with laboratory: ensure records of all RDTs performed outside the laboratory are merged with records of RDTs performed in the laboratory.		
2. If yes, assess whether most include:			
— RDT (for malaria, HIV) or urine dipstick or other laboratory test result ☐ Yes ☐ No			
— final diagnosis(ses) ☐ Yes ☐ No			
— treatment prescribed ☐ Yes ☐ No			
— treatment given ☐ Yes ☐ No			
— follow-up, indicating date ☐ Yes ☐ No			
3. Logbook or record book for all RDTs, with date, name and test result ☐ Yes ☐ No			
X. Monthly analysis			
1. Correct number of attendances ☐ Yes ☐ No	Teach health workers how to count and report each indicator correctly. **Selection of patients for RDT testing:** Compare monthly number of attendances with monthly number of RDTs performed during the past 3 months. **Accuracy of malaria diagnosis:** Compare monthly number of RDT-positive results with monthly number of malaria cases during the past 3 months. **Appropriateness of malaria treatment:** Compare monthly number of first-line antimalarials prescribed and the monthly number of malaria cases during the past 3 months.		
2. Correct number of malaria tests performed ☐ Yes ☐ No			
3. Correct malaria test positivity rate ☐ Yes ☐ No			
4. Correct number of malaria cases ☐ Yes ☐ No			
5. Correct number of first-line anti-malarials prescribed ☐ Yes ☐ No			
6. Correct total number of patients receiving first-line antimalarial treatment (ACT) ☐ Yes ☐ No			
7. Correct number of confirmed malaria cases receiving first-line antimalarial treatment (ACT) ☐ Yes ☐ No			
XI. Availability of standard operating procedures and/or bench aids (latest versions)			
1. Integrated Management of Childhood Illness (IMCI) ☐ Yes ☐ No	Provide latest versions of missing standard operating procedures and/or bench aids.		
2. Treatment guidelines ☐ Yes ☐ No			
3. Malaria RDT performance ☐ Yes ☐ No			
4. Urine dipstick performance ☐ Yes ☐ No			
5. Performance of other rapid tests (e.g. HIV) ☐ Yes ☐ No			
6. Storage of medicines and tests ☐ Yes ☐ No			
7. Stock management of medicines, tests and supplies ☐ Yes ☐ No			

ANNEX 13.

Checklist for supervision of clinical management of febrile children at health facility level

Adapted from WHO (2009). *Malaria case management operations manual* and WHO (2003). *Health facility survey, tool to evaluate the quality of care delivered to sick children attending outpatient health facilities.*

A similar checklist for febrile children can be developed, taking into account that the differential diagnosis is much wider in adults than in children.

Name of health facility:	Position of health worker attending patient: .....
Name of observer:	
Date of observation:	Number of days during which health worker attended patients in the past month: ...../...../.....

No	Steps observed	Yes	No	Comment
HISTORY-TAKING				
1.	Does the health worker ask about the age of the child?			
2.	Does the health worker ask if the child is able to drink or breastfeed?			
3.	Does the health worker ask if the child vomits everything?			
4.	Does the health worker ask if the child has convulsions?			
If not spontaneously mentioned by the caregiver:				
5.	Does the health worker ask about fever?			
6.	In case of fever, does the health worker ask for how long?			
7.	Does the health worker ask about cough or difficult breathing?			
8.	Does the health worker ask about diarrhoea?			
9.	Does the health worker ask about ear problems?			
10.	Does the health worker ask about possible other problems?			
11.	Does the health worker ask if the child or the mother has had an HIV test?			
12.	Does the health worker check the child's vaccination card?			
PHYSICAL EXAMINATION				
13.	If the child is not visibly awake, does the health worker try to wake him or her up?			
14.	Does the health worker (or other staff) check the child's temperature?			
15.	Does the health worker (or other staff) weigh and record the weight of the child?			
16.	Does the health worker check the child's weight against a growth chart?			

No	Steps observed	Yes	No	Comment
17.	Does the health worker look for severe wasting or oedema of both feet?			
18.	Does the health worker look for palmar pallor?			
19.	In case of cough or difficult breathing, does the health worker measure the respiratory rate?			
20.	Does the health worker look for dehydration?			
CLASSIFICATION				
21.	In case of danger signs, does the health worker refer or admit the child?			
22.	In case of fever, does the health worker ask for a malaria test?			
23.	Does the health worker appropriately classify the illness?			
TREATMENT				
24.	In case of danger signs or severe malnutrition, does the health worker give treatment to prevent low blood sugar?			
25.	In case of convulsions, does the health worker immediately give diazepam?			
26.	In case of wheezing, does the health worker immediately give inhaled salbutamol using a spacer and prescribe salbutamol for home use?			
27.	In case of severe dehydration, does the health worker immediately give intravenous fluids or oral rehydration salts?			
28.	In case of referral, does the health worker give an antimalarial medicine and an antibiotic as pre-referral treatment?			
29.	Does the health worker prescribe an antimalarial medicine if, and only if, the malaria test is positive?			
30.	Does the health worker prescribe an antibiotic if, and only if, the clinical classification is pneumonia, dysentery, mastoiditis or significant skin infection?[a]			
31.	In case of diarrhoea, does the health worker prescribe zinc?			
32.	In case of dehydration, does the health worker prescribe oral rehydration salts?			
COMMUNICATION AND ADVICE				
33.	Does the health worker tell the caregiver what is wrong with the child?			
34.	Does the health worker give the caregiver advice on how the child should take the prescribed medicines?			
35.	Does the health worker check whether the caregiver has correctly understood the prescription?			
36.	Does the health worker give the caregiver advice on when the child should return?			
37.	Does the health worker give the caregiver advice on HIV testing?			
38.	Does the health worker ask the caregiver if he or she has any questions?			

[a] If a urine dipstick is performed and is positive for leukocytes or nitrites, an antibiotic should be given to treat urinary tract infection.

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Universal Access to Malaria Diagnostic Testing
An Operational Manual

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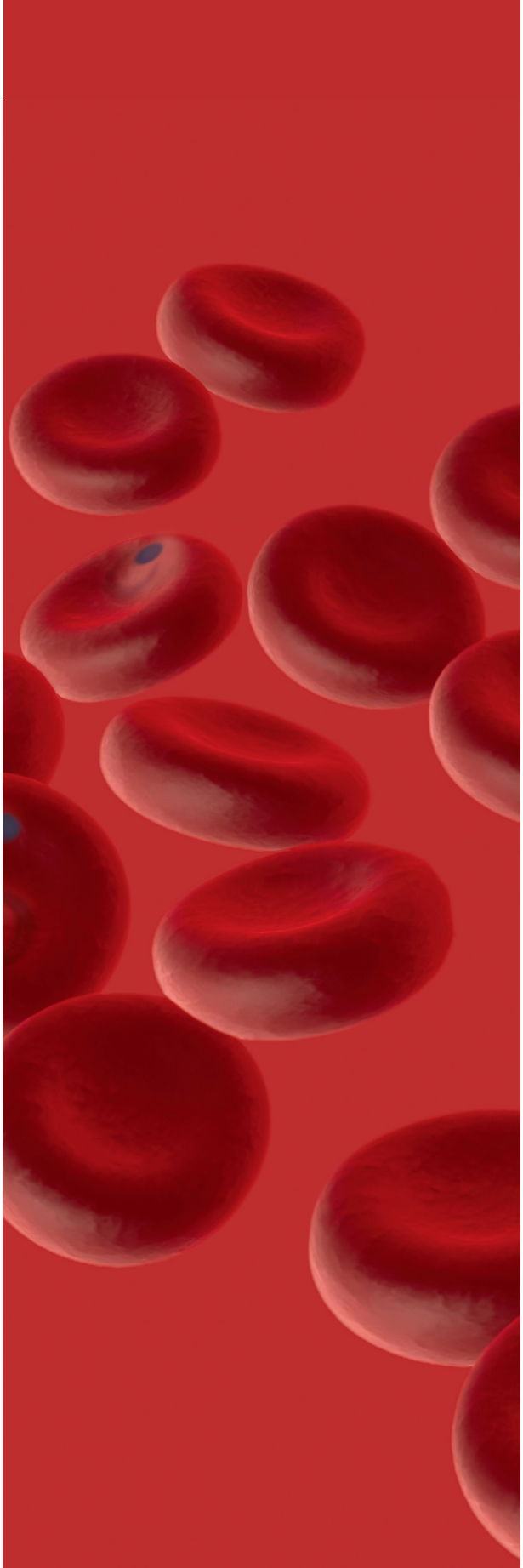
Switzerland

http://www.who.int/malaria/en/



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