




Malaria

Rapid Diagnostic Tests

An implementation guide

The essentials for RDT implementation

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The pdf of the Guide and the toolboxes can be found at http://www.finddiagnostics.org/programs/malaria-afs/malaria/improving_rdt_use/implementation.html

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Abbreviations

ACT	Artemisinin-based combination therapy
ACSM	Advocacy, communication and social mobilization (see also IEC/BCC)
AMREF	African Medical and Research Foundation
BF	Blood film
BMGF	Bill and Melinda Gates Foundation
BTD	Blood transfer devices
CBO	Community-based organization
CCM	Country coordinating mechanism
CDC	Centers for Disease Control and Prevention (USA)
CHW	Community health worker
CSO	Civil society organization
DFID	Department for International Development (UK)
DHS	Demographic health survey
FDA	Food and Drug Administration (USA)
FEFO	First to expire – first out
FIND	Foundation for Innovative New Diagnostics
GPP	Good procurement practices
HCW	Health care worker
HMIS	Health management information system
HQ	Headquarters
HRP2	Histidine-rich protein 2
HW	Health worker
iCCM	Integrated community case management
IEC/BCC	Information, education and communication / behaviour change communication
iMAD	Improving Malaria Diagnostics (USAID/PMI project)
IMAI	Integrated management of adolescent and adult illness
IMCI	Integrated management of childhood illnesses
ISO	International Organization for Standardization
KEMRI	Kenya Medical Research Institute
IVD	In-vitro diagnostic device
LLIN	Long-lasting, insecticide-treated bed net
M&E	Monitoring and evaluation
MIS	Malaria indicator survey
MDGs	Millennium Development Goals
MRDDs	Malaria rapid diagnostic devices
MoH	Ministry of health
MSH	Management Sciences for Health
NMCP	National malaria control programme
NMP	National malaria programme
NMFI	Non-malarial febrile illness
NGO	Non-governmental organization
PACE	Program for Accessible Health, Communication and Education
PCW	Positive control well
PDA	Personal digital assistant
PEP	Post-exposure prophylaxis
Pf	*Plasmodium falciparum*
PFP	Private for profit
PNFP	Private not for profit
pLDH	*Plasmodium* lactate dehydrogenase

POC	Point-of-care
PMI	President's Malaria Initiative (USA)
PNLP	Programme National de Lutte contre le Paludisme (NMP in Francophone countries)
PP	Procurement period
PSM	Procurement and supply chain management
QA	Quality assurance
QC	Quality control
RBM	Roll Back Malaria programme
RBM-MERG	RBM's Monitoring and Evaluation Reference Group
RDT	Rapid diagnostic test
SMS	Short messaging service (also known as text messaging or "texting")
SOP	Standard operating procedure
STI	Sexually transmitted infections
SWOT	Strengths, weaknesses, opportunities, threats
TDR	UNICEF-UNDP-World Bank/WHO Special Programme for Research and Training in Tropical Diseases
TOR	Terms of reference
TWG	Technical working group
URL	Uniform resource locator
USAID	United States Agency for International Development
WHO	World Health Organization
WHO/AFRO	WHO's Regional Office for Africa
WHO/GMP	WHO's Global Malaria Programme
WHO/WPRO	WHO Western Pacific Regional Office

Introductory note

This implementation guide is a step-by-step methodological approach to implementing the use of rapid diagnostic tests (RDTs) as a diagnostic tool in malaria control programmes.

It is important to state at the outset that the use of RDTs for malaria diagnosis is an opportunity to extend diagnostic services and strengthen general laboratory services. Similarly, the use of RDTs at community level should be part of efforts to strengthen health facility services at peripheral level and to create an effective referral network.

As national programmes undertake large-scale implementation of RDT-based diagnosis, the need for guidance and research to enable best practice implementation approaches has increased. While information is widely available on the need for parasite-based diagnosis through the use of malaria RDTs, there is limited guidance on how this should be achieved. This manual seeks to provide specific instructions on RDT implementation and incorporation into national malaria programmes.

This guide does not address basic research and policy formulation concerns or procurement practices. Details on the global policy for malaria treatment can be found in a World Health Organization (WHO) publication, *Guidelines for the treatment of malaria*.[1] The publication *Parasitological confirmation of malaria diagnosis*[2] clarifies requirements for malaria parasite-based diagnosis (RDTs and microscopy) for case management and surveillance. Good procurement practices and supply-chain management recommended by WHO are published in *Good practices for selecting and procuring rapid diagnostic tests for malaria*[3] and *Universal Access to Malaria Diagnostic Testing*[4] is an Interagency manual providing policy, strategy, technical and operational guidance on strengthening and establishing malaria diagnostic services.

Intended audience

This manual is intended for specific audiences, namely:

- national malaria programmes (national, provincial, regional and district malaria programme personnel and RDT end users) with an emphasis on sub-Saharan Africa
- donors considering the quality of funding requests and plans
- public and private sector organizations with an interest in implementing a malaria parasite-based diagnosis agenda.

What this guide aims to do for its users

- Provide guidance for well-planned and effective parasite-based diagnosis using quality assured RDTs.
- Ensure that cross-cutting aspects of other programmes are appropriately addressed in the planning and implementation of RDTs.
- Support the implementation of the WHO policy for the treatment of malaria based on parasitological diagnosis.

1 Guidelines for the treatment of malaria, 2nd ed. Geneva, World Health Organization, 2010.

2 *Parasitological confirmation of malaria diagnosis: Report of a WHO technical consultation Geneva, 6–8 October 2009.* Geneva, World Health Organization, 2010.

3 *Good practices for selecting and procuring rapid diagnostic tests for malaria.* Geneva, World Health Organization, 2011.

4 *Universal Access to Malaria Diagnostic Testing - An Operational Manual*, World Health Organization, 2011.

The structure of the guide

In order to address different target audiences, the guide is structured into four parts.

Part 1 provides background information on the role of malaria RDTs in NMPs and is important to all readers of this manual.

Part 2 targets the national planner who seeks to have a broad overview of what it takes to implement an RDT programme at national level, and senior NMP personnel charged with implementing national strategy.

Part 3 targets the implementer, whose role is to deploy the RDTs and establish systems for quality assurance and post-deployment monitoring and evaluation (M&E).

Part 4 briefly describes some of the new technologies now in development that will come into use within RDT programmes during the next few years. The structure of the guide is also set out in Figure 1.

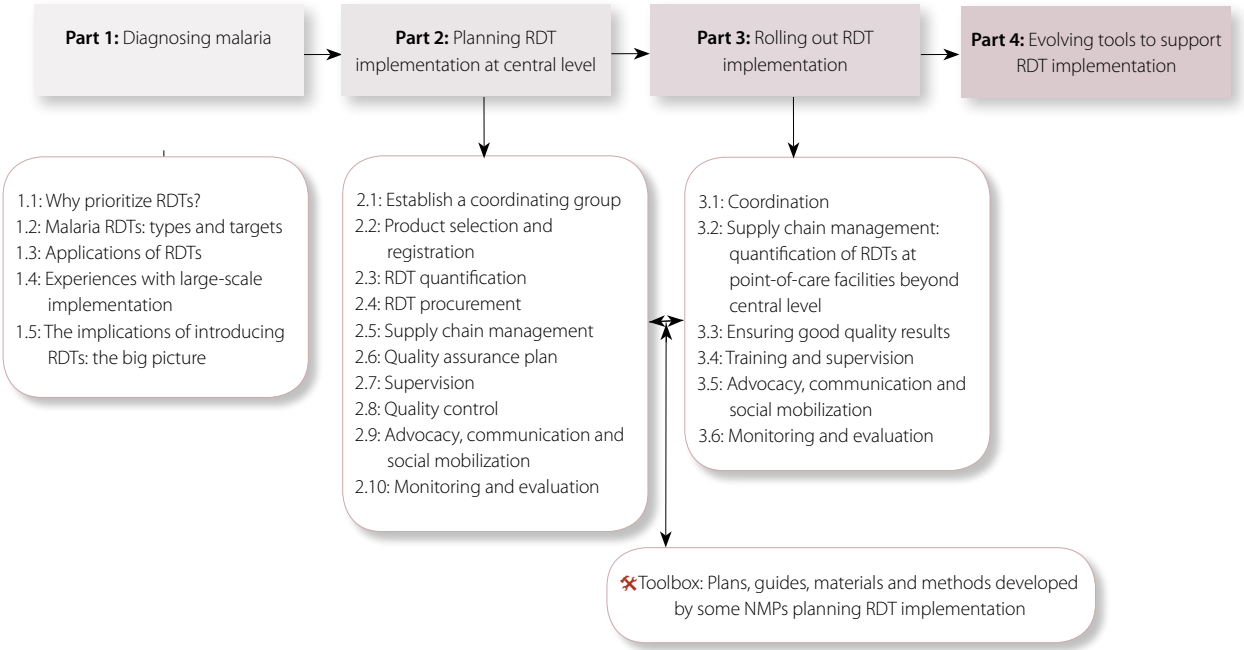
An RDT toolbox

An important feature of this guide is the Toolbox section. This includes examples of budgets, work plans, supervisory checklists and relevant forms that have been used for RDT implementation in NMPs in several countries. These tools may be adapted to suit the needs of RDT implementers in other countries.

The Toolbox is supplied both in text form and online in an electronic format. The tools provided here are generic examples, intended to be adapted to the needs of each national programme. As examples only, they complement versions already in use by various programmes and agencies.

The tools are numbered and are referred to with the following tool 🛠 symbol.

Figure 1: The structure of this implementation guide: essentials for RDT implementation



Part 1
Diagnosing malaria

The WHO guidelines for the treatment of malaria[5] recommend confirmation of the diagnosis of malaria in all suspected cases before administration of treatment. Confirmation requires the use of a test that demonstrates evidence of the malaria parasite in the blood of the patient (e.g. actual parasite or parasite protein), hence the term "parasite-based" or "parasitological" diagnosis. This new recommendation emphasizes the importance of high-quality microscopy or, where not feasible or available, quality-assured rapid diagnostic tests (RDTs). The recommendations in the WHO treatment guidelines are a response to several factors: the introduction of new, more costly antimalarial medicines, concerns regarding the rise of drug resistance, and the recognition that in most malaria-endemic areas (as a result of more effective antimalarial control measures), a minority of cases of febrile illness are actually due to malaria.

Effective control interventions and a strong demand from countries to strengthen both microscopy and malaria RDTs indicate the importance of scaling up parasite-based diagnosis, supported by guidance on best practice.

This manual is complementary to two further manuals, one of which deals with the procurement of RDTs[6] and the other with the overall management of microscopy and RDTs in NMPs.[7]

1.1 Why prioritize RDTs?

Malaria is clinically indistinguishable from many other diseases, several of them common, severe and potentially fatal, but treatable if appropriate management is given early enough. Even in areas with high malaria transmission, other treatable acute infections can cause significant morbidity and mortality. It is therefore important to distinguish malaria from non-malarial febrile illness early, to allow prompt and appropriate treatment of all causes of fever.

Distinguishing non-malarial fever from malaria will reduce wastage of antimalarial drugs, and potentially the selection pressure for the emergence of antimalarial drug resistance. Obtaining accurate figures on malaria incidence also enables tracking of disease trends, targeting of antimalarial resources to areas of greatest need, and more accurate evaluation of the impact of interventions.

The development of RDTs has been a major step forward in attempts to parasitologically diagnose malaria. These tests extend malaria diagnosis to populations with no access to good microscopy services. RDTs make this possible as a result of their:

- ease of use
- lower training requirements
- lack of requirements for electricity or expensive equipment.

5 *Guidelines for the treatment of malaria*, 2nd ed. Geneva, World Health Organization, 2010.

6 *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011.

7 *Universal access to malaria rapid diagnostic tests – An operational manual*. Geneva, World Health Organization, 2011.

As malaria transmission continues to decline across many malaria-endemic countries, due to the impact of interventions (e.g. use of long-lasting insecticide-treated nets, indoor residual spraying and artemisinin-based combination therapy, early treatment seeking behavior), the imperative to introduce parasite-based diagnosis and to distinguish malaria from other illnesses becomes more urgent.

1.2 Malaria RDTs: types and targets

Malaria RDTs, sometimes called "dipsticks" or malaria rapid diagnostic devices (MRDDs), detect parasite antigen in human blood and are now widely used in many countries.

Due to the variation in malaria parasite species and the target antigen, different RDTs may be appropriate for use in different epidemiological settings.

1.2.1 Currently available types of RDTs

Though the principle of the test is similar, there are variations among malaria RDT products. The most common RDTs used in the field consist of a nitrocellulose strip secured in a plastic '*cassette*'. Some formats consist of the '*strip*' without any casing, while some are secured to a cardboard plate ('*card*'). Cassettes and cards tend to be more expensive, but simpler to use. Other RDTs may be hybrids of these designs. The ease-of-use and appropriateness of these formats differ, and are discussed in more detail in the WHO procurement manual.[8]

It is important to note that, when well manufactured and in good condition, RDTs can achieve a level of sensitivity similar to that commonly achieved by expert-level field microscopy. They are therefore sufficient for case management of uncomplicated malaria in the field. The sensitivity of malaria RDTs is determined by the:

- concentration of parasite antigen present in peripheral blood
- total parasite load in the body
- species of parasite
- correctness of technique used to perform the test
- correctness of interpretation by the reader
- variation in antigen structure and expression (e.g. non-expression of HRP2 in certain parasite populations).

1.2.2 Target antigens of currently available RDTs

Some RDTs can detect only one species of malaria parasite (*Plasmodium falciparum*), usually by detecting either histidine-rich protein 2 (HRP2) or *plasmodium* lactate dehydrogenase (pLDH) as the target antigen. Some detect one or more of the other species of malaria parasite that infect humans, usually by detecting pLDH or aldolase antigen. These may be 'pan-specific' (detecting all species, i.e. *P. vivax*, *P. malariae*, *P. ovale* and *P. knowlesi*) or specific for particular parasite species (Table 1). The combination of antibodies targeting specific parasite antigens also differs, which determines the parasite species detected, and whether species can be distinguished from each other.

8 *Good practices for selecting and procuring rapid diagnostic tests for malaria.* Geneva, World Health Organization, 2011.

Table 1: Parasite species and target antigen of some commercially available RDTs

Species of parasites detected	HRP2	pLDH	Aldolase
P. falciparum specific	√	√	
P. vivax specific		√	
Pan-specific (all species)		√	√
Specific to some other species		√	

HRP2 – Histidine-rich protein 2; pLDH – *Plasmodium* lactate dehydrogenase

1.2.3 RDTs in different epidemiological settings

The choice of an RDT by the national programme or project is governed by numerous factors including the malaria parasite species to be detected, the likely users of the tests, the epidemiology of malaria in the area of intended use, and the anticipated conditions of transport and storage. The appropriateness of *P. falciparum*-specific, pan-specific and non-falciparum RDTs varies with the relative prevalence of the different human malaria species in the intended area of use. These areas are categorized by WHO as follows.

- Zone 1: *P. falciparum* only, or with non-falciparum species occurring almost always as co-infections with *P. falciparum* – most areas of sub-Saharan Africa and lowland Papua New Guinea.
- Zone 2: *P. falciparum* and non-falciparum infections occurring commonly as single-species infections – most endemic areas in Asia and the Americas, as well as isolated areas in Africa, particularly the Ethiopian highlands.
- Zone 3: areas with non-falciparum malaria only – mainly *P. vivax*-only areas of East Asia and Central Asia and some highland areas elsewhere.

These categories, as well the choice of an appropriate RDT and its subsequent procurement and delivery, are discussed in detail elsewhere.[9] This manual assumes that the national programme has selected the RDTs and arranged delivery. It focuses on the effective use of RDTs as they are distributed to the general health services.

1.3 Applications of RDTs

The specific performance requirements of a test will vary depending on its intended use or uses. While RDTs can be used in a number of settings, their greater potential for impact on public health is in case management at community or peripheral level, where good quality microscopy is difficult to maintain. Accurate malaria diagnosis is essential for several purposes:

- to confirm or rule out malaria infection in symptomatic patients
- to guide accurate prescription of treatment
- to monitor the incidence or prevalence of malaria, for targeting prevention activities and evaluating health programmes.

Malaria RDTs can be used to enable rapid care of patients presenting with fever, either by providing a definitive diagnosis of malaria (and enabling the timely administration of life saving antimalarial therapy) if the results are positive, or by supporting prompt assessment of alternative diagnosis and appropriate management of fever if the RDT results are negative. In delivering appropriate case management of fever, health workers should be aware that most non-malaria febrile illnesses can be managed effectively and appropriately by following national guidelines.

9 *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011.

1.4 Experiences with large-scale implementation

Malaria RDTs have been used successfully on a large scale in the public health sector in parts of South America, South Africa and South-East Asia. In these areas and some countries in sub-Saharan Africa, RDTs have been integrated into routine fever case management practice (e.g. Senegal, Zambia, Thailand, Cambodia and South Africa). In some countries (e.g. Guyana and Cambodia), the public health sector has cooperated with the private sector to promote the use of RDTs in private health care facilities, through large-scale social marketing. Success in these programmes will require careful policy formulation and planning that covers procurement, training of end users, community sensitization, and monitoring of diagnostic quality results.

However, many countries using RDTs on a large scale have only limited mechanisms in place to monitor RDT accuracy or determine problems causing loss of sensitivity. To this end, in 2002, WHO Western Pacific Regional Office (WPRO) and UNICEF-UNDP-World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) launched an evaluation programme to assess the comparative performance of commercially available malaria RDTs. Data from this programme are used to guide national procurement decisions and to identify necessary quality improvements to be made at manufacturing level. Since 2009, WHO, FIND and US Centers for Disease Control and Prevention (CDC) have published updated reports of comparative laboratory evaluations of RDTs for national programmes and research projects to utilize in selecting and procuring RDTs.[10] Up-to-date information for NMPs on malaria RDTs can be found on the WHO, TDR and FIND websites.[11]

1.5 The implications of introducing RDTs: the big picture

Diagnostic testing usually represents the starting point in a clinical intervention, and the use of diagnostic tests presumes that appropriate patient management based on testing will follow. NMPs should take into consideration that quantification of antimalarial drugs based on incidence of suspected malaria cases is not accurate. In many settings where RDTs have been introduced, the true rate of parasitaemia has been found to be considerably lower than expected. Therefore, to avoid wastage, quantification of antimalarials should be based on the expected proportion of laboratory-confirmed cases and expected compliance to negative test results. To avoid wastage of antimalarial drugs, it is important that ACT procurement and supply management be synchronized with the introduction of parasitological diagnosis. Within two years of RDT implementation, if an adequate HMIS system is in place, there should be more accurate data available through the national HMIS to drive evidence-based quantification of ACTs and RDTs.[12]

To have an impact on malaria diagnosis and treatment, RDTs must be seen – by both health workers and patients – to provide a reliable diagnosis. To achieve and maintain confidence in RDT-based parasite detection, a good quality control (QC) system must be in place (Figure 2) as part of a comprehensive quality assurance (QA) programme. Health workers will also need guidance on (as well as clinical diagnostic equipment) the investigation of patients for other causes of fever. Health workers must have access to and guidance on the use of appropriate alternative treatments to antimalarial medicines for managing fever cases that test negative with an RDT.

Funding from different development agencies and Ministry of Health (MoH) budgets is providing the resources to make accurate malaria diagnosis a reality. The key to success will be planning an effective, systematic, evidence-based implementation. Funding for the RDT implementation programme must, in addition to procurement costs, include significant components for: planning and coordination (including convening

10 *Malaria Rapid Diagnostic Test Performance: Results of WHO product testing of malaria RDTs: Round 3 (2011).* Geneva, World Health Organization, 2011.

11 http://www.wpro.who.int/sites/rdt; http://www.who.int/malaria/en/; http://apps.who.int/tdr/; http://www.finddiagnostics.org/index.jsp . Last accessed September 2011 (all sites).

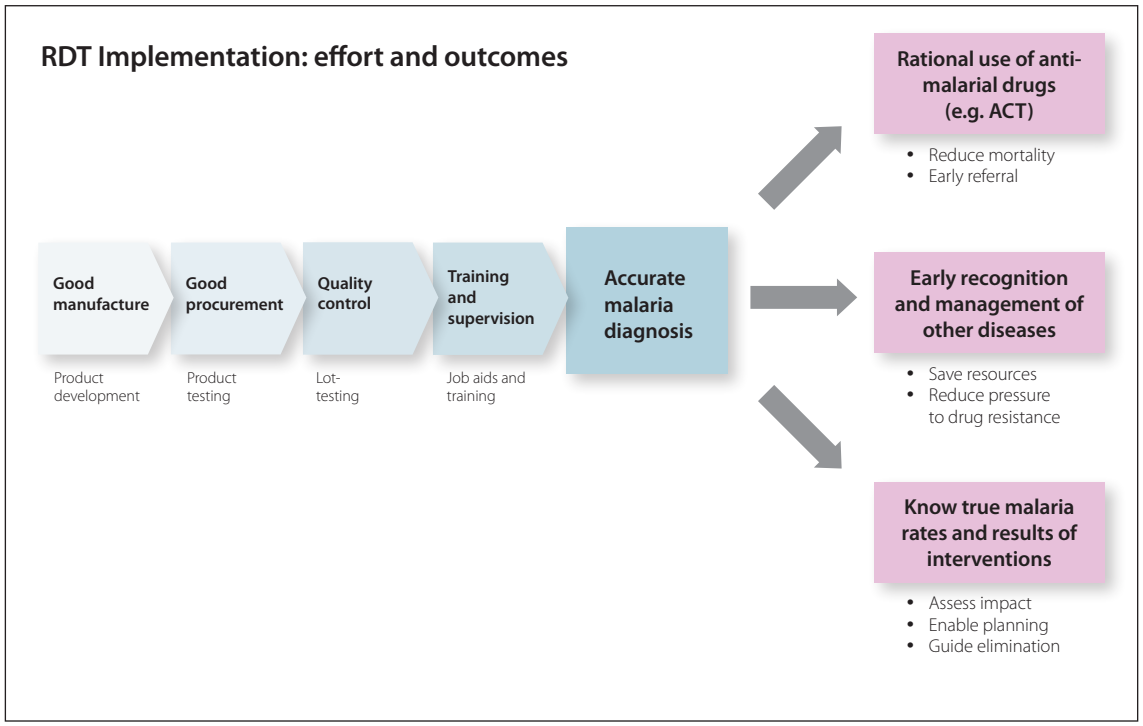
12 *Strengthening Pharmaceutical Systems. Manual for Quantification of Malaria Commodities: Rapid Diagnostic Tests and Artemisinin-Based Combination Therapy for First-Line Treatment of* Plasmodium Falciparum *Malaria.* Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health, 2011.

the national coordinating committee); advocacy, communication and social mobilization; training; quality control; supervision; logistics; monitoring and evaluation; and procurement of RDT-related supplies (i.e. gloves, timers, biohazard boxes). Without this, much of the funds expended on RDTs may be wasted, and a loss of confidence in RDT-based diagnosis may hinder the process of strengthening appropriate malaria case management.

The introduction of RDT-led, parasite-based diagnosis at smaller clinics and community level for fever case management is an opportunity to expand the use of confirmatory diagnosis of malaria. Deployment and scale-up must take into consideration the fact that communities and health workers have been taught that "fever equals malaria", sometimes "even when proven otherwise". To demonstrate that not all fever is caused by malaria parasites, it is important to ensure that diagnosis is accurate, to demonstrate to users and the community that RDTs produce reliable results, and that alternative diagnoses are considered and treatments for those conditions are available.

Prior to the introduction of RDTs to the field, the community should be fully sensitized to the reasons for parasite-based diagnosis, the expected RDT accuracy of RDTs, RDT interpretation, and the use of results. Similar education needs to be undertaken among health workers, laboratory staff and clinicians. Training to address diagnosis of other causes of fever, including the development of appropriate management algorithms for parasite-negative cases, is necessary during the deployment of malaria parasite-based diagnosis.

Figure 2: Quality control and quality of outcomes achieved through RDT-based diagnosis

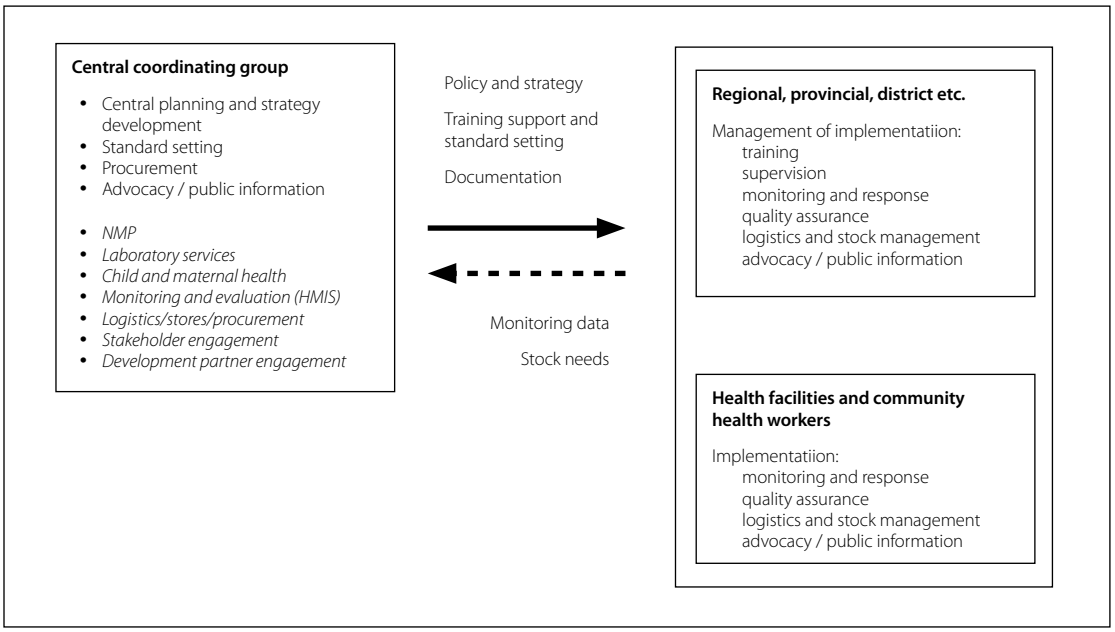


Part 2

Planning RDT implementation at central level

This chapter outlines the essential steps a national planner or decision maker should put in place for RDT introduction (Figure 3). Following the endorsement of a national (laboratory and/or malaria case management) policy, implementation requires careful, evidence-based planning. Overall planning at central level should be integrated with malaria microscopy, which is discussed in the WHO guide, *Universal access to malaria diagnostic testing: an operational manual*.[13] The exact structure of programmes will differ, depending on the structure of the national health services.

Figure 3: Core components of an RDT implementation programme and the interaction between them



HMIS Health Management Information System

The experience of countries that have successfully implemented large-scale RDT programmes has shown that the following minimum actions are needed.

1. Create strategies to build and maintain confidence in the RDT-based diagnosis policy, with a strong stakeholder and community engagement strategy, and a good RDT quality assurance plan.
2. Build capacity to manage other causes of fever in close collaboration with other health departments (e.g. maternal and child health).
3. Work with the national/central medical supplies stores to ensure effective distribution of RDTs.
4. Have a clear strategy on the respective roles of microscopy and RDTs at all levels of the health system.

13 *Universal access to malaria rapid diagnostic tests – An operational manual.* Geneva, World Health Organization, 2011.

Figure 4: A generic timeline which some experienced NMPs have used to guide their RDT implementation

RDT IMPLEMENTATION TIMELINE		Example of necessary steps for implementation of Rapid Test (RDT)-based diagnosis in a national malaria programme.
Coordinating group		
Appoint malaria diagnosis coordinator(s)		
Policy recommendations		*Written* — *MoH endoresment*
Program Planning		
Guidelines*		*Written* — *MoH endorsement*
Case management of fever of unknown origin		
Case management of malaria		
RDT (and microscopy) quality assurance		
RDT transport and storage		
Decide districts for initial / phased implementation		
Fever management algorithm		*Written* — *MoH endorsement*
Community sensitization		
General health care providers education		
Determine / designate transport and storage methods		
Regulatory Issues		
Define collaborative roles (NMP and Regulatory Body)		
Write/adopt regulatory guidleines		
Create RDT registry for reference		
Dsseminate regulatory criteria		
Product selection,supply chain management		
Select several products		
Samples for ease-of-use assessment		
Final decision on RDT		
Negotiate specifications with manufacturer		
Competitive bidding and Procurement		*Dependent on registration process*
Receive first batch (of staggered delivery)		
Distribution to field		
Procure gloves		
Procure sharps boxes		
Procure other associated materials		

Figure 4 *(continued)*

RDT IMPLEMENTATION TIMELINE		Example of necessary steps for implementation of Rapid Test (RDT)-based diagnosis in a national malaria programme.													
RDT Quality Control															
Write sentinel site SOP															
Set up/engage field based QC monitoring sites															
Decide on Lot-testing site						*Determne site*			*Commence*	*testing*					
Post-delivery surveillance**															
Training															
Conduct case management training for fever										May be conducted earlier, or already in place					
Develop training manual/job aids based on product instructions															
Field-test modfied training/instructions															
Training of trainers and supervisors															
Health Worker Training															
Advocacy, Communication, Social Mobilisation															
Engaging civil society organisations															
Community, including health worker, sensitisation															
Engaging opinion leaders															
General health care education															
Monitoring and Evaluation															
Develop/adopt appopriate record forms															
Define methods for capturing different indicators															
Integrate RDTs in the routine HMIS															
Plan for a post-introduction program review															
* May already be in place															
** Sentinel site mciroscopy, possibly positive control wells in future															

5. Develop a monitoring and evaluation plan to support phased RDT implementation and use. It should be noted that the deterioration of RDTs that sometimes occurs in the field is rare where good procurement practice and logistics management are in place.

A generic version of a preparatory timeline for an RDT programme is shown in Figure 4. Detailed examples from national programmes can be found in 🛠1 together with examples of this timeline and a similar monitoring tool currently being used.

Note that the pace and sequence of activities will vary for each NMP but the main components are as follows.

RDT programme coordinator: A national focal point should be appointed with a clear mandate to oversee the implementation of the RDT programme. The coordinator should be a senior health expert with good management experience who can lead a task force to work closely with the national laboratory services and stakeholders at the central level of the NMP. The coordinator is responsible for overseeing all aspects of implementation, and ensuring that the benchmarks and targets set during the planning and implementation phases are satisfied. This will permit coordination across the different technical areas (i.e. policy, training and QA) and logistical areas (i.e. supply chain and storage).

The coordinator will have to address the areas detailed below.

Programme planning and management: The NMP prioritize the formulation or review of the national malaria case management policy and guidelines, to enable RDT implementation with quality-assured RDTs. The programme planner should take into consideration the different options and associated consequences of a gradual or rapid scale-up of RDT deployment. The rate and mode of implementation may vary between programmes depending on experience and resources, but forward planning is vital to avoid situations where stock-outs, lack of training or other problems that interrupt progress and damage confidence in the programme. Integration with other relevant policies is also crucial to facilitate a QA programme integrated across disease platforms.

Product selection, regulation and registration: An appropriate product selection process, addressing the needs of the programme and meeting the requirements of donors, must be planned. Some countries have national regulatory guidelines for RDTs. In this case, the coordinator should make arrangements at the planning stage to obtain and utilize the national registry for medical diagnostics and devices or to consult with the national regulatory authority about the regulatory guidelines. It is important to understand at an early stage the roles played by the regulatory authority and the NMP. Regulatory guidelines should address matters related to RDT technical specifications for RDT manufacture, importation and use; for example, quality assurance at the time of procurement, transport and port clearance, supplier performance and product variation monitoring. These details are well elaborated in the WHO manual *Good practices for selecting and procuring rapid diagnostic tests for malaria*.[14]

Supply management: Good supply management is critical to the success of programmes, preventing stock-outs and preserving quality of RDTs through safe transport and storage. This must be centrally planned and integrated into supply management of the wider health system, allowing for whether there is a "push" or a "pull" system or a mixture of both. A push strategy is a scheduled, centrally-driven system that sends a set quantity of a product to each health facility, based on assumptions about projected quantities to be consumed. A pull system is health-facility driven; orders are placed based on actual RDT consumption. A healthy supply chain is almost always a combination of both push and pull.

Push systems will have the tendency to overstock or understock in some facilities. Careful attention should be given to consumption data, to allow a redistribution of stocks if required. If a pull system is used, an efficient

14 *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011.

method for restocking and good communications must be in place (consider electronic stock reporting) to ensure that re-provision occurs in time and adequate safety stocks are maintained. Detailed guidance specifically for RDT supply management (quantification and logistics) is provided in *Good practices for selecting and procuring rapid diagnostic tests for malaria*. The issue will also be dealt with in a forthcoming publication from MSH, provisionally entitled *Manual for quantification of malaria commodities: Artemisinin-based combination treatments and rapid diagnostic tests for diagnosis and first-line treatment of* Plasmodium falciparum.[15]

If RDTs are to be deployed at community level, relatively small quantities of RDT kit boxes may be distributed at any one time, to reduce exposure to poorly-controlled conditions. Facilities that are cut off for several months during this time will need buffer stocks in place, in order to avoid stock-outs. The following questions must be answered in order to help plan the most feasible method (and periodicity) of RDT distribution at this level.

- Will the RDTs be stored at the closest health facility or distributed directly from a more centralized hub?
- Does this health facility have adequate storage conditions and sufficient storage capacity to accommodate the RDTs intended for community health workers (CHWs)?
- Do they have stocks of RDT-related supplies such as gloves, timers, biohazard protective gear, etc.?
- Will the CHWs collect the RDT kits? How often and by which method will the kits be transported? What is access like during the rainy season?
- How frequently should resupply be undertaken?
- How will the waste management systems function? Is the waste going to be transported to the next level for disposal or destruction?
- Is the area reserved for disposal of infectious materials sufficient? If the waste is to be disposed of locally, have all the conditions been met?

Quality assurance plan: The combination of three activities – training, supervision and quality control – constitute critical components of quality assurance for RDTs at implementation level. For national programmes with established microscopy services, the RDT QA programme should be integrated with that of microscopy from the beginning, since the two methods complement each other. A well functioning microscopy QA programme is essential if microscopy is to be used in monitoring of RDT quality, as discussed in Section 3. Training and supervision should include all end users (e.g. clinicians, CHWs, laboratory personnel, and surveillance and logistics personnel) to foster an integrated approach to a sustainable QA programme. Many aspects of microscopy QC that are similar to those for RDT QA can be found elsewhere.[16]

Advocacy, communication and social mobilization: Sensitization of both clinicians and health workers and of the wider community is essential, including regular updating of decision makers on RDT implementation all require careful attention at the planning stage. The first step is to identify factors that might put the success of the RDT programme at risk. These include existing knowledge, attitudes, practices and beliefs about parasitological diagnosis of malaria by the target audiences, , including health workers, and simplistic perceptions of the importance and complexity of this intervention by decision makers and local funders. The primary and secondary target population groups for communication activities should then be defined. More specifically, secondary target groups are those which influence or deliver information to the primary group.

Specific questions to consider during the planning stage include:

- What behaviours and attitudes must be changed through communication activities? Examples include the prescribing of ACTs for patients who have tested negative, and the demand of communities that all cases of fever should be treated with antimalarials.

15 Geneva, World Health Organization, 2011.

16 *Malaria microscopy quality assurance manual*, Version 1. Manila, World Health Organization: Regional Office for the Western Pacific, 2009.

- What changes are needed to ensure:
  - personal commitment to make a change at national, district and community levels?
  - knowledge and skill acquisition to create a culture for seeking confirmatory services for malaria diagnoses?
  - supportive environments for health workers and the community?
- What design or adaptation of existing messages will appeal to the target groups? Secondary target groups should be involved in this step. The most effective communication channels and media should be chosen to reach the primary target audience.
- What must be in place to pre-test materials on the target group for comprehension, acceptance, attractiveness, and to strengthen the demand for parasitological confirmation of malaria?

Monitoring and evaluation: A review of the RDT implementation programme should take place as part of planning for scale-up, so that lessons learned in initial implementation can influence later stages of the RDT roll-out. Figure 4 illustrates the critical steps along the pathway to RDT implementation. Country programmes will be at different stages along these timelines. Different aspects of the implementation – including the communication strategy and barriers and facilitators of RDT utilization, as well as the quality of the implementation process – should be monitored continually by the national and peripheral coordinator(s) with reference to the implementation plan and timeline (🛠**1**). Some national malaria programmes have some of the stages already in place.

Documentation and records: Clear guidance must be developed on RDT-specific information to be recorded in patient registers (i.e. laboratory or clinic) and this must be communicated throughout the health network as part of routine monitoring and evaluation activities. Monitoring and evaluation units should be involved in final directives to ensure NMP indicators are adequately addressed and integrated within the routine HMIS system. Receiving accurate diagnostics information is essential for strategists and planners.

2.1 Establish a coordinating group

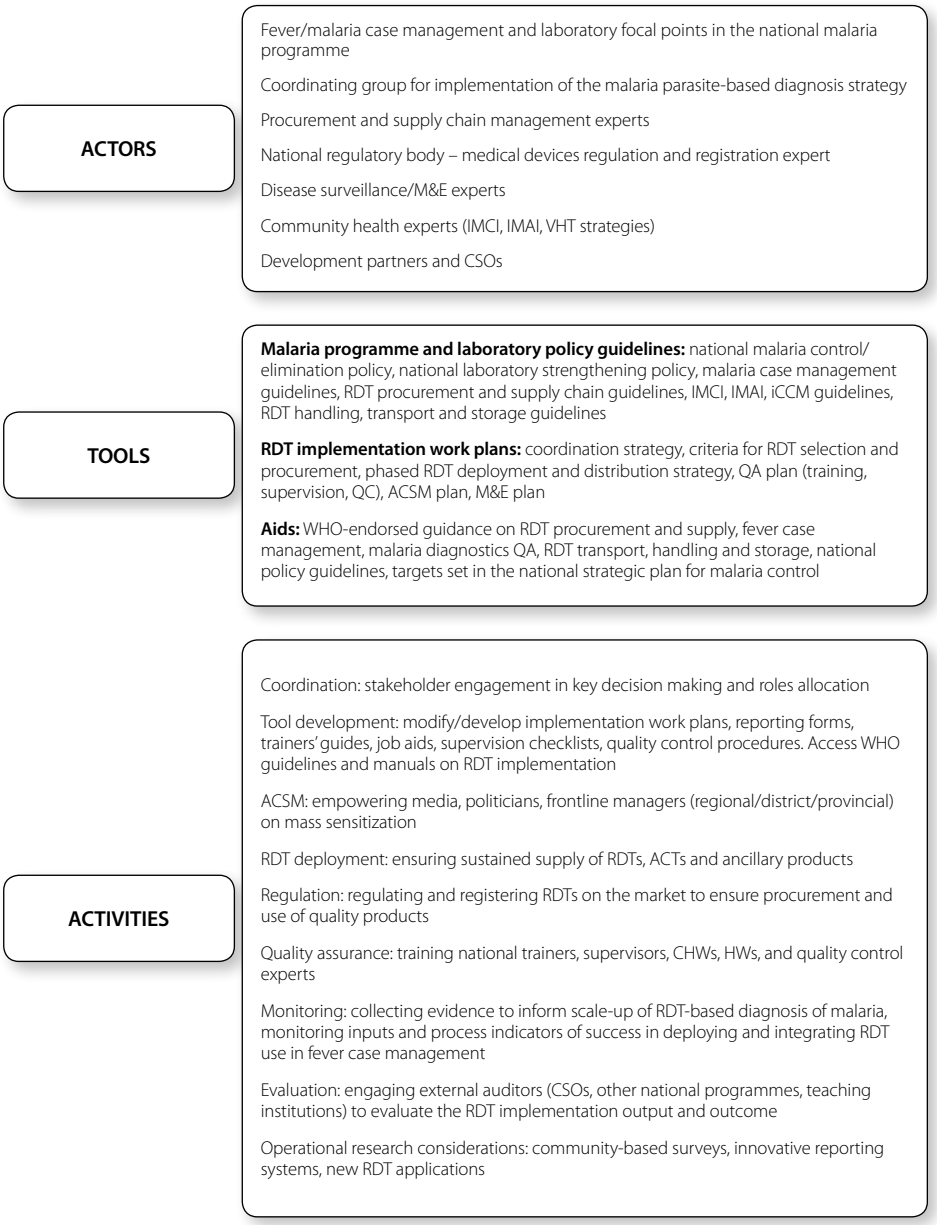
The NMP or implementing agency should designate a focal person(s), bring together the coordinating group, identify key stakeholders and secure their commitment for the introduction of RDTs. Stakeholders should include: ministry of health (MoH) and non-MoH partners with overlapping activities. The NMP should also:

1. Ensure representation of: clinical and public health laboratory services, QA department, regulatory and registration authority, central medical stores, medical training institutions, policy makers in maternal and child health, monitoring and evaluation unit, and HIV/reproductive health departments. It is useful to involve recognized partners with the potential to contribute financial resources.
2. Draw up the terms of reference for the coordinating group, including clear roles and responsibilities (see sample Terms of Reference in 🛠**2**).
3. Align the preparatory plans and decisions for RDT introduction with relevant national policies and guidelines. Guidance documents for review or consideration when planning to introduce RDTs include: case management of fever with unknown origin, integrated management of childhood illnesses (IMCI) and integrated management of adult illnesses (IMAI), RDT transport and storage guidelines, supervision plans, training, and quality control procedures including RDT performance evaluations.

Existing policies should be studied to identify gaps and areas where policies do not align, of which the relevant authorities should be informed.

An example of a more detailed list of potential stakeholders is shown in Figure 5, but each country's list must reflect its own situation. The work of the coordinating group will be to ensure the activities of implementing agencies are part of a comprehensive plan with practical action points.

Figure 5: A minimum package of actors, activities and tools to enable successful RDT implementation



ACSM - Advocacy, communication and social mobilization; ACTs - Artemisinin combination therapies; CHWs - Community health workers; CSO - Civil society organizations; HWs - Health workers; iCCM - Integrated community case management; IMCI - Integrated management of childhood illness; IMAI - Integrated management of adolescent and adult illness; M&E - Monitoring & evaluation; VHT - Village health team

2.2 Product selection and registration

The process of selecting RDTs should start early and take into consideration registration, procurement and import regulations. The process of selecting and procuring RDTs is discussed in the WHO recommendations manual.[17] The national medical devices registry, the WHO-FIND product testing reports and other performance data (e.g. at www.finddiagnostics.org or www.wpro.who.int/sites/rdt) are also important resources to consult.

As described in the manual for procurement and distribution of RDTs, the choice of the RDT should be based on (in order of their importance):

- appropriateness of the RDTs for the species and epidemiology of malaria in the country or region
- accuracy based on panel detection score assessed by the WHO product testing programme
- shelf-life and stability
- cost
- procurement lead-time and availability from the manufacturers
- quality (lot-testing results, required transport and storage conditions, good manufacturing practice)
- field experience with the product and ease-of-use.

Selection and procurement of RDTs is governed by the same laws and regulations that apply to other medical diagnostic devices in the country. Regulations may need to be developed or adapted to control the importation and use of malaria RDTs.

2.3 RDT quantification and budget considerations

For RDT quantification, it will be necessary to estimate RDT requirements for national or project needs, including supportive ancillary products (Table 2). Consider seasonal variation and time taken for roll-out of RDTs (phased or nationwide). Initial estimations should be made but should be refined as the programme evolves. Generally, RDT introduction requires an increase in procurement over normal clinic needs to fill the supply pipeline.

Major components of a malaria diagnostics programme budget should be considered when introducing RDTs into a national malaria programme (Figure 6). Without adequate provision for each of these components, it is likely that an RDT-based diagnostics programme will fail to achieve its goals.

Table 2: RDT quantification considerations

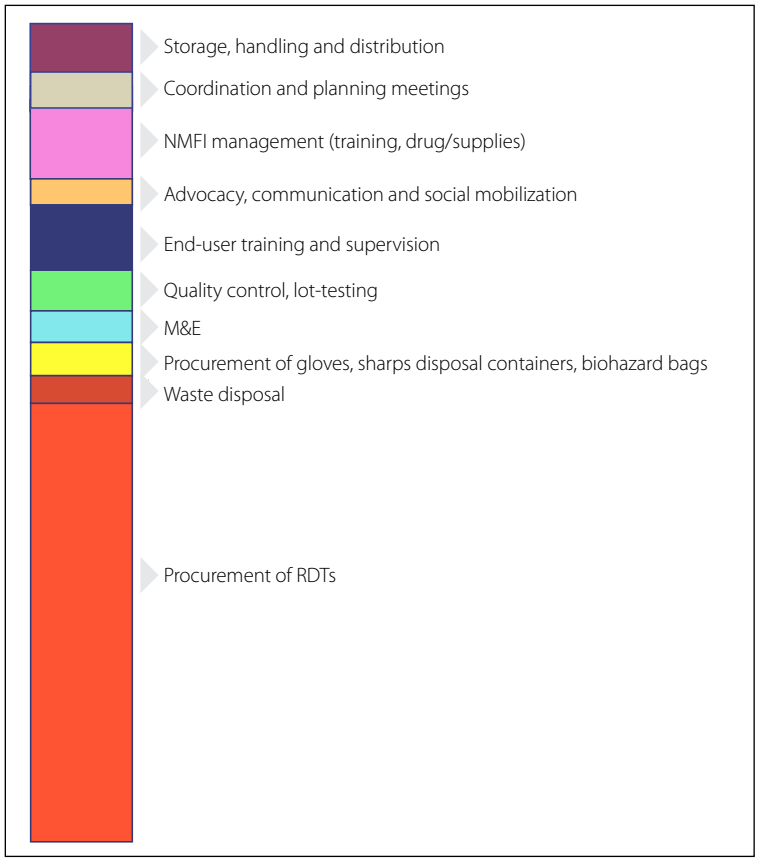
RDT quantification considerations	
Specific quantification dependent on needs for malaria diagnosis	**Quantification of other items required for use of RDTs**
RDT kits: • RDT • blood transfer device • running buffer	**Essential ancillary commodities:** • lancets • alcohol swabs • gloves • swabs • sharps disposal containers • biohazard bags • clocks for health facilities or timers for CHWs

RDT - Rapid diagnostic test; CHWs - Community health workers

Note: RDT kits may be ordered already packaged with some of the items in the right-hand column. Check with the manufacturer which ancillary products are included in each kit prior to purchase.

17 *Good practices for selecting and procuring rapid diagnostic tests for malaria.* Geneva, World Health Organization, 2011.

Figure 6: A schematic of budget components for RDT implementation



NMFI - Non malaria febrile illness

2.4 RDT procurement

Every country has its own procurement procedures used to control spending, ensure appropriate approvals are in place, and reduce the risk of overspending. RDT procurement costs encompass all spending activity, excluding the personnel payroll. It is vital for the national programme planner to understand the duration and implications of the whole procurement cycle on the implementation plan.

Guidance on procurement is well documented[18] and the basic steps involved are listed here below:

- Determine the specific RDT characteristics that your programme requires (including target species and antigen, stability and shelf-life, and ease-of-use characteristics). In addition, have specific RDTs been used previously in the country and, if so, do training materials already exist for them?
- Publicize tender bids based on these criteria, and select suppliers.
- Conduct contract negotiations.
- Place the order and make the payment.
- Expedite shipping, storage and distribution (by agent and/or central stores). The use of staggered deliveries (i.e. every four/six months rather than once a year) is recommended in order to prevent prolonged storage in-country and thus risking product expiry.

The cost of the whole procurement cycle, not just the unit cost of the RDT, should be taken into consideration when planning and budgeting. It is important to procure ancillary items (Table 2).

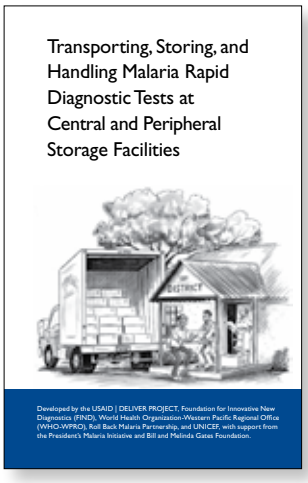
18 *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011.

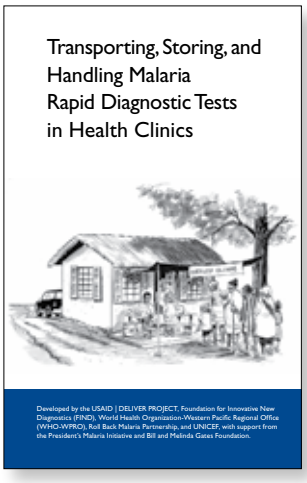
2.5 Supply chain management

The central coordinating committee should include logistics expertise and should liaise with the central medical stores and procurement unit to monitor the procurement process.

Two pocket-guides are available on the transport and storage of malaria rapid diagnostic tests. Designed for malaria programme managers, clinic workers, medical stores and transport personnel, the two guides concentrate respectively on both central and remote storage[19], and remote transport and storage[20] (🛠3). Many of the principles are applicable to other perishable medical supplies transported to, and used in, clinics in tropical and sub-tropical areas. The guides are available at the following websites:

- WHO-WPRO: http://www.wpro.who.int/sites/rdt/using_rdts/rdt_transport_storage.htm
- FIND: http://www.finddiagnostics.org/resource-centre/reports_brochures/rdt_transport_storage.html





Logistics operational procedures should cover RDT storage, stock management, customs and clearance issues. Align these with the existing commodity supply system, i.e. accounting for whether it is a "push" or "pull" system and distribution calendar, and draw up the procurement and supply chain management (PSM) plan.

Quantification

Determining the number of RDTs needed in a programme is alwayss a vital and difficult issue to resolve. This is dealt with in greater detail in section 3.2 Quantification and forecasting of requirements for malaria testing of the Universal Access to Malaria Diagnostic Testing manual . To provide the data essential to quantify needs, the following key questions must be addressed.

19 *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3; and Geneva: World Health Organization, 2009.

20 *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3; and Geneva: World Health Organization, 2009.

Key questions:

Detailed references to guide NMPs on quantification are provided in the good practices manual[21] and the RDT quantification manual[22] and should also be considered. A few key questions are listed below.

- Which type of health facilities, e.g. hospital, health centre, health post will implement RDTs, according to the national implementation plan?
- Do the targeted health facilities have sufficient data to guide quantification, e.g. the number of "suspected" malaria cases that have sought diagnosis and care across all the health facilities in the district – preferably two years of data? *Note that, for health facilities where parasite-based diagnosis has been used (microscopy and/or RDTs), the number of suspected malaria cases will also include those that have been tested, as well as those who have not been tested.*
- Alternatively, does the HMIS have data on the total number of febrile cases presumptively treated as malaria in the targeted health facilities or region/district? *Note that, for health facilities where no parasite-based diagnosis has been previously used (either microscopy or RDT), this figure may be the same as the number of "reported" malaria cases from previous years.*
- Has the MoH decided whether to deploy RDTs with microscopy in the same health facilities? If microscopy will continue to be used in these centres, then the number of suspected malaria cases that will be tested with RDTs needs to be adjusted to take into account the expected number of cases diagnosed by microscopy.
- If RDTs will be deployed in health facilities where there is no microscopy, what is the number of health facilities where microscopy will continue to be used and therefore RDTs will only be used on a proportion of the total number of patients?

If distribution of RDTs at district level is based on a pull system, then to quantify annual needs, the following questions should be taken into consideration.

- Will RDTs be deployed to the entire district at once, or only within a sub-district or part of a district?
- What are the required safety stock levels, taking into account ordering lead times, delivery schedule and the shelf life of RDTs (generally two years)? Ideally, delivery should take place at least twice a year, but more frequently where there is a danger of high storage temperatures at the peripheral facility. Peaks in consumption due to seasonal variation in incidence of fever should be taken into account when deciding how many RDTs need to be delivered. For instance, larger deliveries will probably be required shortly before seasons when fever is more common. Calculate this according to the estimated fever incidence in previous seasons.
- Has the RDT quantification been adjusted to cover expected damage, spoilage, and invalid tests (usually 10%)?
- Has the NMP or regulatory and registration focal point provided information on the RDT pack size, specifying clearly whether the number of packs or the number of individual tests is being ordered, as pack sizes can vary between manufacturers, e.g. 20 vs. 50 vs. 100 tests in a pack?

Limitations of the available data that may require adjustments include: changes in the number of health facilities using RDTs, attrition rate for community health workers using RDTs, and completeness of the data. Implementation of a good stock control system to monitor consumption is crucial, so that order accuracy can improve over time and in future years be based on actual demand rather than estimations. An essential component of RDT quantification is to collect accurate data on suspected cases from testing sites.

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21 *Good practices for selecting and procuring rapid diagnostic tests for malaria.* Geneva, World Health Organization, 2011.

22 *Strengthening Pharmaceutical Systems. Manual for Quantification of Malaria Commodities: Rapid Diagnostic Tests and Artemisinin-Based Combination Therapy for First-Line Treatment of* Plasmodium Falciparum *Malaria.* Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health, 2011.

Waste disposal has to be carefully planned, as there are a number of different types of waste which will be generated, such as sharps, gloves, boxes, cotton swabs, test cassettes, etc. Separate handling is necessary for sharps and for general contaminated waste, and national health services will have standard procedures for these already in place. A disposal plan should be considered for all commodities supplied by the programme, even if this simply consists of disposing general waste. Further details can be found in documents on transporting, storing and handling RDTs.[23,24]

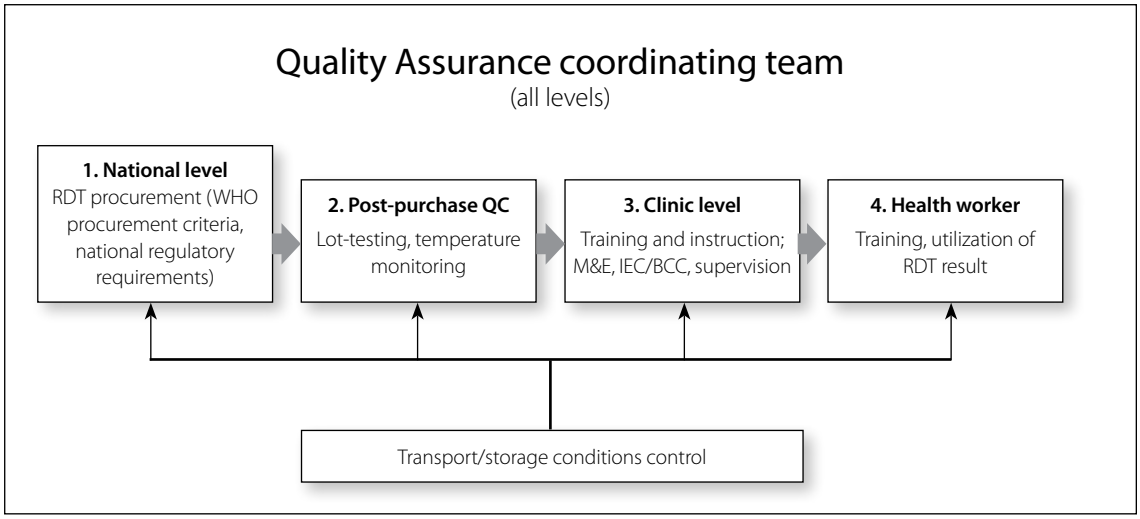
2.6 Quality assurance plan

This guide has structured QA into three main areas – training, supportive supervision and QC – all of which are dealt with in the following sections of this manual and are major areas of concern in ensuring in quality RDT implementation. The NMP must be closely involved at all levels of the malaria diagnostic QA programme. This needs to be centrally coordinated – see Figure 7. A good QA plan will ensure that clinical teams have confidence in the RDT and that the test results are of benefit to the patient and the community. Often forgotten are key issues that address QA in the private health sector and post-procurement quality monitoring.

It is important for planners to aim for a system or procedures for monitoring the quality of RDTs:

- during registration and/or procurement
- that are already in the public and private health sector

Figure 7: Central coordination is required to ensure that QA activities take place at all levels



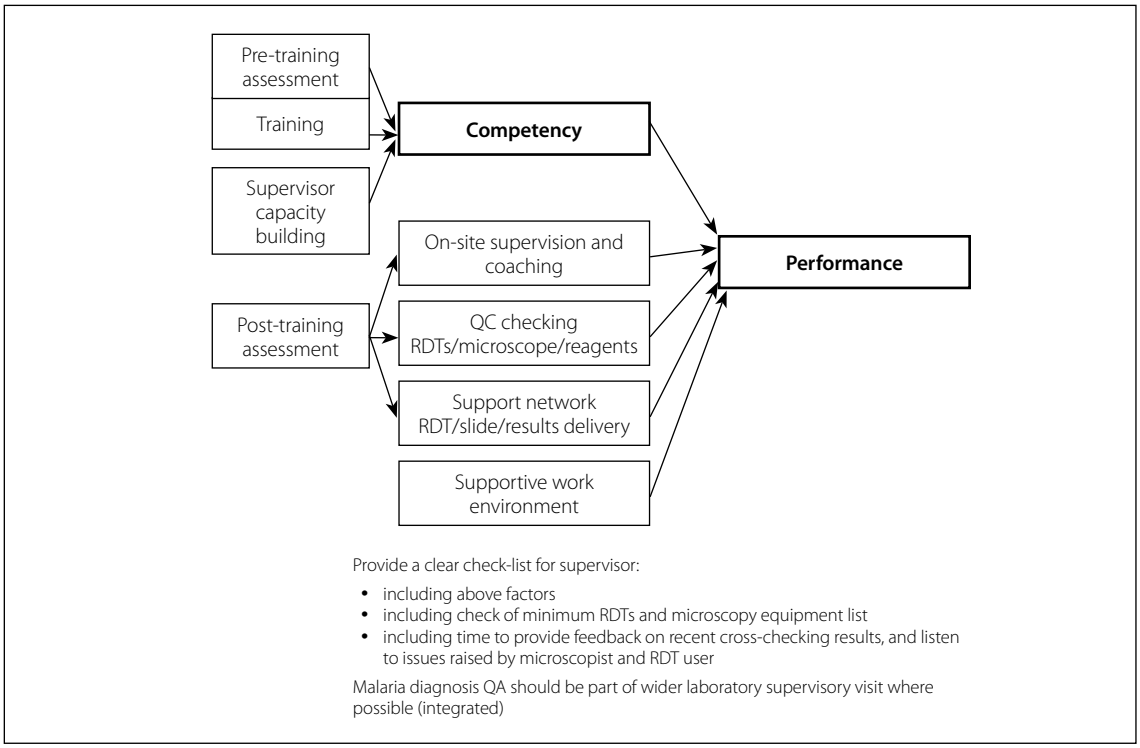
Where both microscopy and RDTs are used in a programme, as is the case in most malaria programmes, QA processes for both should be integrated as far as possible (see Figure 8). This is paramount where both are used in the same facilities. In drawing up plans for integration, the essential components of diagnostic performance that result in a good diagnostic outcome should be clear to all concerned and likewise the basis for the QA programme. Quality assurance for microscopy is dealt with extensively elsewhere[25] and requires a structured approach, more resource intensive than that for RDTs.

23 *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests at the Peripheral Storage Facilities*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3; and Geneva: World Health Organization, 2009.

24 *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3; and Geneva: World Health Organization, 2009.

25 *Universal access to malaria rapid diagnostic tests – An operational manual*. Geneva, World Health Organization, 2011.

Figure 8: Common elements impacting on performance of RDT and microscopy-based diagnosis (to be taken into consideration in developing supervisory plans)



Key questions to remember when implementing an RDT QA programme:

- Are manuals and operational plans for QA implementation in place?
- Are there opportunities for collaboration with locally-based partners to support the RDT QA–QC programme?
- Are performance monitoring processes in place for the RDT and the technicians/health workers who will use them?
- Is a supervisory plan in place to monitor the whole process and Inform the evaluation process?
- Is a training schedule in place?
- Are guidelines for RDT transportation/storage conditions available?
- Have RDT job aids, user guides, and manuals been prepared and supplied, along with RDTs? (This requires close collaboration with the other programs in non malarial febrile illness management and district/province MoH leaders.)
- Have the central medical stores prepared to supply ancilliary logistical needs alongside RDTs (e.g. gloves, sharps waste boxes, timers, microscopy reagents etc)
- Are there accredited districts trainers in clinical and management aspects with experience in delivering training on RDT use and case management of fevers?
- Are there procedures (or is a system in place) for obtaining feedback on any problems encountered with RDT use?

2.7 Training

While malaria RDTs are relatively simple, mistakes can easily be made that affect the accuracy of the result, and therefore the quality of management of the sick patient. Selection of suitable patients for testing with an RDT, and action on RDT results, is also a frequently difficult issue for a health worker, requiring wider training in fever case management. The use of RDTs in situations where supervision is often limited further increases the requirement for high-quality training and confirmation of health worker competency in RDT-based malaria case management, before health workers are supplied with RDTs. Training should therefore be part of wider case management and should be competency-based, ensuring that accurate and safe performance is demonstrated

by the trainee before training is completed. Evidence-based training materials are available, and discussed in this section and in Part 3 of this manual. Materials should be developed or adapted with the end users in mind, ensuring they are culturally and linguistically appropriate.

Key questions about training in the use of RDTs

- Is your training programme consistent with your national malaria case management policy?
- Does the national policy guideline clarify the training manuals and guides clarify the current malaria epidemiology in your country? This is important both in the choice of test (e.g. combination tests are not necessary where mono-infections with non-falciparum malaria are rare) and for RDT stock estimates, which vary in different malaria transmission intensity zones.
- Does the training manual reflect the definition of a malaria-like fever? RDT requirements vary depending on decisions to test fever cases or suspected malaria cases.
- Do your training plans specify the cadre of health workers who will roll out training at each subsequent level?
- Do the training manuals describe the QA programme for RDT implementation and trainees' participation in that programme, including what to do if a bad lot of tests is suspected?
- Do the training manuals describe how RDT results will be recorded in patient registers and what RDT-specific information should be collected in the register?

Based on these key questions, as a basic minimum, the following needs should be addressed.

- A work plan with defined objectives, plan for dissemination, curriculum development, participant profile, duration and teaching methodology – see example of an implementation plan adapted from the Uganda MoH 🛠**4**.
- A well reviewed checklist for all training requirements including training aids, a training implementation plan, RDT job aids, fever case management clinical algorithms, training manuals, IMCI and IMAI algorithms. This checklist should be prepared in collaboration with central child and maternal health units which should be represented on the coordinating committee.
- A well laid out approach to RDT dissemination, including: nationwide or cascaded RDT implementation by regions; health-facility or centrally-based training; and training of all health workers (or a representative number) in each facility.
- Plan for an evaluation of the training programme early on, and execute it immediately after training RDT end users. An example of such a plan is given in Table 3.
- Representation from the central medical stores, including personnel in logistics and storage (handling, transport and distribution of RDTs.
- A schedule for remedial training activities, in the event that new staff join health facilities or trained staff are transferred.
- A pre- and post-training assessment should be planned as part of the post RDT implementation evaluation program, such as the one described below.

The training "To do" list

- Identify partners with experience and expertise in training to support the national programme in coordinating the training of health workers.
- Develop a manual suitable for local users. See 🛠**5**, which shows the table of contents adapted from the 2nd Edition of a training manual produced by Uganda's MoH as an example.
- Update national treatment/fever case management training plans and operations manuals in line with the global malaria treatment policy guidelines. These programmes and manuals can also be adopted from other national programmes with documented success in RDT implementation.

Table 3: An example of a post RDT training evaluation form (prepared by PMI and NMP partners in Uganda)

District trained	Group that trained using NMP modules	Date of training (month/year)	Total HWs trained	Proportion of laboratory staff trained	Proportion of clinicians trained	Public HWs trained? Y/N (If Y, proportion)	Private HWs trained? Y/N (If Y, proportion)
District 1							
District 2							
District 3	SMP		48	24		Y	Y
District 4	SMP		17	14		Y	Y
District 5	SMP						
District 6	SMP		44	21		Y	Y
District 7							
District 8	UMSP	April, 2011					
District 9	MC	SMP	12/2009;1/2010; 2/2011	95	44		

NMP - National Malaria Programme; SMP - Stop Malaria Project, funded by the President's Malaria Initiative (PMI); UMSP - Uganda Malaria Surveillance Project; MC - Malaria

- Develop a generic user's guide for the trainees or adopt what other national programmes have used successfully. Suggested content for the guide:
  - how to select patients for testing with RDTs
  - performing and reading an RDT
  - management of a patient with fever and a positive RDT and a negative RDT result recognition, referral and treatment of patients with severe illness
  - patient education and community sensitization
  - reporting
  - biosafety, waste management and monitoring
  - quality control and supervision
  - RDT storage and stock management
  - RDT record keeping/documentation
- Develop an easy-to-follow algorithm to guide assessment, diagnosis and management of patients with fever at the point-of-care. This should be based on national policy for febrile disease management and should be consistent with the existing IMAI and IMCI guidelines 🛠6.
- Involve experienced health workers to help with planning, training, and ensure local experience and continuity in the training programme.
- Plan to equip the implementing level with skills to develop a schedule for rolling out the training package, with details of when and where training will take place and who will train. Trainer/trainee ratio aspects should be addressed to ensure quality delivery of the training package.
- Where possible, plan to begin the training in a few health facilities or districts, to gain skill and quality output before scaling up.

Figure 9: The minimum package of a supervisory plan in the RDT quality assurance programme

RDT/ microscopy/ both?	Has there been any follow up supervision? Y/N (if Y, frequency)	Any QC being done? Y/N (if Y, describe in Comments)	Comments
Both	Y; Apr, Sept, 2010	Y	External quality assurance (EQA) in 4 labs in the district
Both	Y; Sept, 2010	Y	Y
Both	Y; Sept, Nov, 2010	Y	External quality assurance in 4 labs in the district
			Planned
Y	Both	Y; Sept, Nov, 2010	

Consortium; HWs - Health workers; Y/N - Yes/No; RDT - Rapid diagnostic test; QC - Quality control

- Where possible, encourage the implementers to conduct the training in or near health facilities to permit on-the-job skill building.

2.8 Supervision

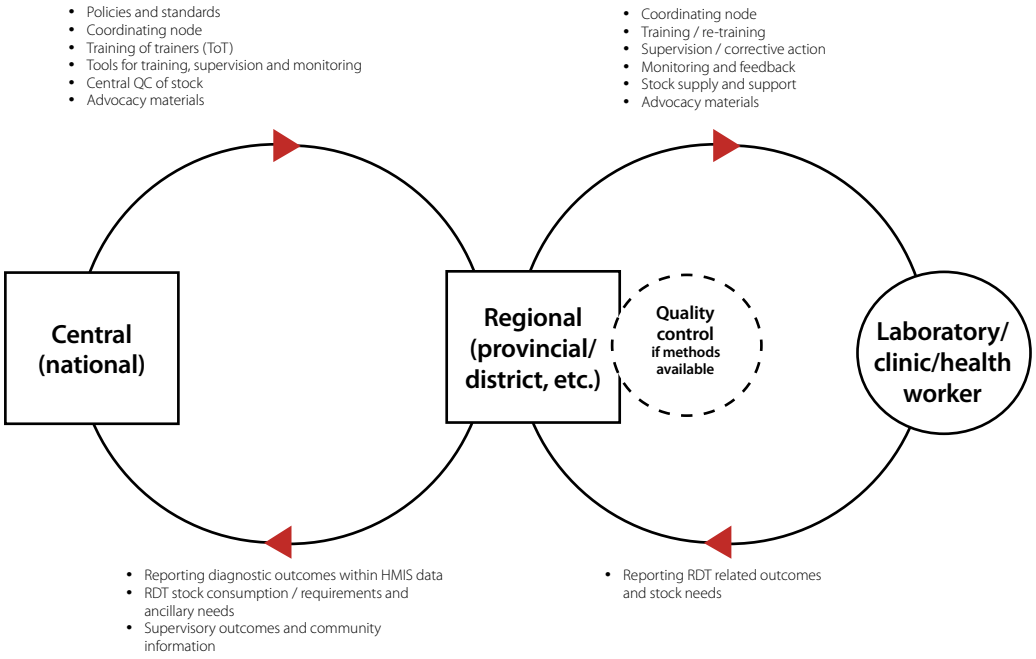
Supervision needs to be "supportive", meaning the supervisor plays a listening role to understand difficulties encountered by the supervisee. The supervisee needs to trust that such information will be acted upon, so structured debriefing of supervisors must occur after visits to ensure that findings are discussed at a more central level. Supervisors must also give feedback on issues raised during previous visits. This requires a structured supervisory checklist (🛠7). In-country partner groups with interest and expertise in surveillance and supervision may also take on this role.

Remember that it is important to integrate technical and managerial supervision (Figure 11 and 🛠7).

Supervisory plan:

- Prepare a supervisory checklist (🛠7).
- Provide guidance for the district level on the composition of the supervisory team and the different degrees of skills required.
- Develop a competency assessment system for supervisors to ensure they are technically proficient and able to communicate information accurately to health workers.
- Identify the need to train supervisors at district level on how to prepare and implement a supervision plan that is based on local circumstances and settings. Remember, there are many factors that influence supervision implementation including geographical terrain, nature of transport used, number of facilities implementing the intervention, number of supervisors available in a given district etc.
- Provide supervisors with standardized responses and procedures for dealing with issues of supply chain, storage and QA.
- Provide supervisors with a plan to ensure that output/reports from supervisory visits are communicated to the relevant district level persons and that debriefing at health facility occurs. Include district supervisory activities when formulating budgets for RDT implementation support.

Figure 10: The quality assurance loops: basic aspects for implementing malaria RDT quality assurance at different levels of the health system



2.9 Quality control

Quality control involves evaluation or monitoring of the performance characteristics of the diagnostic test, to ensure it is performing to the specifications required for accurate diagnosis. QC should be a routine part of the manufacturing process, and good procurement practice will ensure that RDTs are procured from manufacturers who follow international standards of good manufacturing practice. At the time of purchase, RDTs should be checked by lot-testing, i.e. evaluating the performance of production lots (batches) before they are deployed to the field. This helps ensure that the RDTs delivered to the field are of adequate quality. Lot-testing is usually carried out in a reference laboratory, following standardized procedures. This quality control process is vital to planning and implementation of a safe and effective RDT-based diagnostic programme, and is therefore an essential task for the coordinating group to plan and implement. Requirements are detailed in the WHO procurement manual[26] and procedures should be based on the practices outlined there.

In certain storage and field conditions, RDTs may be damaged by environmental conditions outside the specifications recommended by the manufacturer. Note that poorly manufactured tests may deteriorate under good storage conditions, emphasizing the importance of a good procurement practice and of monitoring RDT quality in the field. Monitoring the performance of a sample of the tests deployed to the field, after typical conditions of transport and storage, can provide information on the likely performance of the batch and therefore the accuracy of diagnosis that may be obtained. New methods to monitor accuracy in the field are under development – Part 4. While quality control at time of purchase is always strongly recommended, in some situations QC near point-of-care may need to be limited to close monitoring of results, such as a highly unexpected frequency of negative or positive results in a particular context or site, and investigation of unexpected variations or reported concerns of clinicians. Some of the necessary actions are illustrated in Figure 12. A detailed discussion of different QC methods is discussed in detail later in this manual (section 3.3).

26 *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011.

2.9.1 Monitoring quality in the field

The national coordinating team should plan for a comprehensive QA programme, with an embedded plan for monitoring RDT quality in the field, after deployment. A method of checking RDT results should be decided upon and then integrated into the health worker training and quality assurance schemes, to ensure that RDTs retain adequate performance to detect clinically-relevant malaria infections. This action plan will add a further margin of confidence to RDT deployment, and help to reassure users and clinicians that the test results are reliable. Current options to achieve this are limited. These methods confirm RDT capacity to detect parasite antigen – not the quality of use by field staff – and therefore do not replace the need for routine field supervision. Field monitoring methods need to be part of central level planning, so that adequate capacity to carry them out is put in place, and methods are standardized and adequately supported across a programme.

While none of the currently-available methods for field quality control are ideal, they can help detect unexpected major deterioration in RDT quality. They complement but do not replace central quality control, i.e. good manufacturing and lot-testing. In the future, the use of standardized wells containing recombinant antigens is likely to make field QC for malaria RDTs easier (Part 4). **If transport and storage of RDTs is carefully managed, quality control at the user level is of less importance.**

Below, various field QC monitoring methods (discussed in more detail in sections 3.3.1 and 3.3.2) can be considered if sufficient expertise is available. Choose a method that the programme has the capacity to implement.

a) **Cross-checking by microscopy at sentinel sites:** Monitoring of RDT results at sentinel sites, where patients are tested on both RDT and by microscopy, is one way to ensure that results are to a certain degree concordant between these diagnostic modalities. In many countries, sites have already been set up for in-vivo drug efficacy monitoring and it may be appropriate to use these same sites for RDT monitoring. Sentinel site monitoring is useful only if the RDTs have been transported and stored under typical field conditions.

RDT results by comparison with microscopy can be useful in providing on-going information on test performance as far as confirmatory diagnosis of malaria before treatment is concerned. It is essential to only choose sites with high-quality microscopy service for this comparison, limiting this to very few sites where microscopy quality can be assured. "Quality-assured microscopy" implies that there is a structured programme in place with monitoring of technician performance and retraining. Poor-quality microscopy should not be used for this, as it will reduce confidence in RDT performance, producing a large number of apparent false positive and false negative RDT results and give the impression that RDTs are not performing correctly. Periodic monitoring of RDTs should be cross-checked in a laboratory setting where malaria expert microscopy is available.

Periodic parallel testing using microscopy and RDTs has to be done on a sufficiently high number of malaria-positive patients to ensure accurate conclusions about RDT sensitivity and specificity. (Implementation issues at the clinic site are dealt with in more detail in section 3.3.2.) Guidelines for management of discrepant results must be written and disseminated as standard operating procedures (SOPs) to the sites monitoring RDT quality. These guidelines need to take into account the parasite density of the infections; RDTs may miss some infections below 100 parasites/µl and still be adequate for detecting clinically relevant malaria infections. Above 200 parasites/µl, false-negative RDT results are likely to have a significant impact on patient care.[27]

In the sentinel sites, the microscopy result should be cross-checked to ensure reliable detection of malaria parasites.

If RDTs are failing to detect a significant number of cases with parasite densities confirmed above 200 parasites/µl, e.g. over 10 out of 50, or several cases at parasite densities above 2000 parasites/µl, then the diagnostic coordinator should be informed and lot testing of RDTs at a centre with lot testing capabilities should be seriously considered.

In general, development of such RDT sentinel sites, if undertaken, should take the following into account.

- Rapid feedback of results is essential.

27 *Parasitological confirmation of malaria diagnosis: Report of a WHO technical consultation. Geneva, 6–8 October 2009.* Geneva, World Health Organization, 2010.

- There must be a plan and capacity to deal with poor performance:
  - site inspection and investigation
  - re-training if needed
- Microscopy must be of a very high standard.
- Transport and storage conditions to and at the testing site, including time of storage, should be typical for RDTs in field use.
- Sufficient parasite-positive (and parasite-negative) patients must be tested to provide a valid indication of performance (commonly 200-300 are required, more where positive rate is very low, below 10%).
- A process needs to be available to investigate a high proportion (e.g. >10% of 200 samples) of discordant results and determine the cause.

b) Comparison of stored microscopy slides and RDTs in some peripheral clinics: RDTs and slides can be made in parallel on a number of patients, and the slides read later by an expert microscopist. While possible in some settings, restrictions include the quality of stain and slide preparation at the site, and the additional logistical needs to keep microscopy supplies on site. It is important to remember that slides may also deteriorate before reading.

c) Comparison with PCR: Some national programmes and projects use PCR of dried blood spots for later comparison with RDT results. While simple to set up at the peripheral clinic, this is restricted by the availability and cost of PCR. The results also need careful analysis and interpretation, as PCR will be expected to detect sub-clinical parasitaemia not detected by RDTs, and not causing acute illness, giving a false impression that the RDTs may have insufficient sensitivity for case management.

d) Use of dried parasitized blood in tubes: Some national programmes and projects use wells prepared at a central reference laboratory containing dried parasitized blood of known parasite density, taken to the field by supervisors to test RDTs stored in clinics. While this method will detect very poorly-performing RDTs, the expected variability of antigen expressed by parasites requires careful standardization of the sample on the RDT to be quality controlled.

e) Withdrawal from the field for laboratory testing: A few programmes withdraw RDTs from the field, e.g. on supervisory visits, and transport them under a controlled environment to prevent further deterioration during transport (a cool box) for laboratory analysis. Field withdrawal of RDTs has the advantage of testing the RDTs against a standard designed to distinguish adequate from inadequate test performance. However, this is logistically difficult for many programmes, and requires ready access to a laboratory with appropriate standards for testing.

While direct monitoring of RDT quality in some field locations is desirable, it should not be considered an essential prerequisite for RDT use if good procurement criteria and quality control at time of purchase are in place and if proper transport and storage recommendations have been followed.[28] Where a method is implemented, it can add confidence to users of RDTs and flag early deterioration in performance. In all cases, cross-checking of results in a lot-testing laboratory is important, after transport under controlled conditions. A standard operating procedure (SOP) must be in place to guide action on poor results. Evidence of poor RDT performance should be rapidly addressed with lot testing, with close monitoring of field diagnostic results, and with withdrawal or replacement of a lot, if inadequate performance is confirmed.

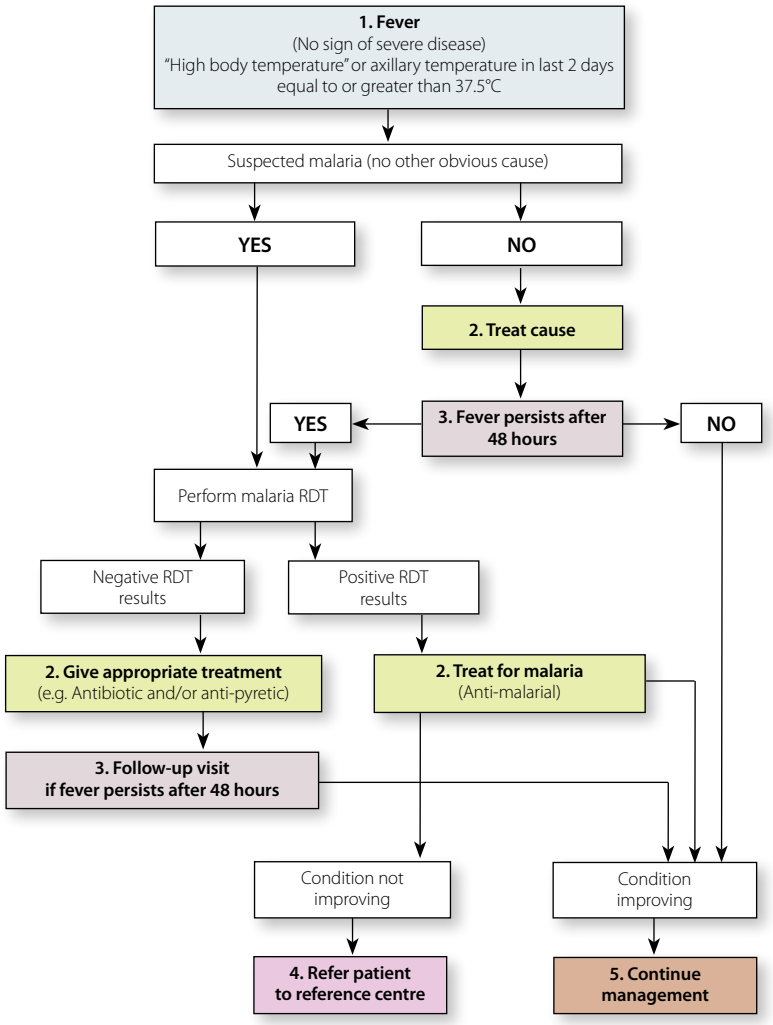
2.10 Advocacy, communication and social mobilization (ACSM)

Ensuring efficient RDT delivery under controlled transport and storage conditions, and accuracy in performance, result reading and interpretation are essential. However, it is not all that needs to be done. Assuring that drug prescription is based on the results – and that the patient accepts and follows the prescribed treatment – is equally important. The national planner needs to invest in behaviour change (Figure 11). The level of confidence of the patients and clinicians in the test results provided may be a significant facilitator or barrier to the parasite-based diagnosis policy and therefore drug management. To have an impact, RDTs must be shown to provide

28 *Good practices for selecting and procuring rapid diagnostic tests for malaria.* Geneva, World Health Organization, 2011.

accurate diagnosis and this can be achieved through satisfactory health worker education and widespread community sensitization on the cycle of health care for a patient presenting with malaria-like fever.

Figure 11: A typical non-severe fever case management algorithm



Adapted from the algorithm of the Senegal NMP. Also, see *Universal Access to Malaria Diagnostic Testing: An Operational Manual,* WHO, Geneva 2011, pp 27-28

Major points for communicating to the community about diagnostics for fever case management are shown in Figure 11. An ACSM plan should address the community's or patients' experience in line with a treatment algorithm that

- encourages consultation (including diagnostic testing, if necessary) with the health worker / clinic if fever is present
- advises on the importance of returning to the health worker / clinic for review if fever is not resolved, or if new symptoms develop
- reminds you that if you are referred for further investigation and management, you should attend to this immediately as advised by the health worker / clinic
- advises you to follow the full management course recommended by the health worker /clinician

At each step, it is important to explain the reasons for the importance of the action. These explanations should be factual, and appropriate for the educational and cultural background of the target audience.

Key actions for advocacy, communication and social mobilization

It is vital to plan for all of the following:

- A strategy for ACSM addressing clinicians and health workers, and also local communities and key opinion leaders, including messaging strategy and materials, in order to enhance confidence in the RDTs.
- Develop community messages to encourage the preferential use of private providers who diagnose before treating, ensuring that diagnosis therefore benefits both the patient and the provider.
- Developing, producing and disseminating key messages.
- M&E: Inclusion of process, outcome and output indicators to measure ACSM in line with national M&E planning, the RDT policy and guidelines available to pre-service training institutions, e.g. medical schools, nursing schools, laboratory training schools. This will ensure tutors and students are aware and informed of these new technological developments, their applications and behavioural change strategies.

In order to prepare for the key ACSM actions listed above, the following must be planned and undertaken:

- Preparing communication and/or media materials.
- Identifying reviewers to revise communication materials and media possibilities.
- Pre-testing final draft communication materials and media ideas. This can be done alongside RDT deployment.

2.11 Monitoring and evaluation plan (M&E)

RDT programme monitoring should be viewed as an integral part of the national fever case management programme – as a tool for both learning and accountability. Programmes should therefore set parameters for trends requiring further investigation, based on current and historical local data. Opinions of various programme stakeholders need to be incorporated in this process through a national self-assessment workshop or electronic based questionnaire that aims at answering questions such as those in Table 4.

Table 4: M&E stakeholder discussion points on malaria case management

Sample programmatic questions	M&E indicators
What is needed to give the desired outcome? • Who will be involved? • What skill set is required? • What tools and resources are required?	**Input indicators**
What route/procedure will be undertaken to achieve the outcome? • Is the national malaria treatment policy and guideline updated? • Is there a qualified team to coordinate implementation of RDTs with quality assurance? • Is training scheduled and are the trainers equipped? • Is the RDT procurement, storage, and distribution well coordinated?	**Process indicators:** direct measures of quality of care
How many guides/items/procedures will be produced? • How many workshops/meetings will be held, where? • How many RDTs and associated products will be procured and supplied? • How many districts will be trained for RDT deployment, and when?	**Output indicators**
What is the extent to which the interventions will be implemented? • What is the expected achievement? • What geographical area will be covered? • What is the expected level of utilization and access of the intervention? • How many fever cases have been confirmed to be malaria with the intervention?	**Outcome indicators:** evidence collected to measure progress

M&E - Monitoring and evaluation

Monitoring: WHO is currently revising the indicators for malaria case management evaluation, of which some directly addressed monitoring of a programme for parasitological confirmation of malaria diagnosis[29] (🛠**8**). The RDT implementation coordinators should utilize guidance provided to plan for immediate follow-up after RDT deployment. Seasonal variation is common in malaria-endemic settings, and may affect both the rate of patients tested for malaria, and the test-positive (confirmed) malaria rate. Interventions such as bednet distribution may also have an effect on true malaria incidence. Such variations need to be taken into account (triangulating data) when assessing the significance of changes in malaria RDT results. Programmes should therefore use current and historical local data to set parameters for trends requiring further investigation. Detailed guidance is provided annually by WHO on collecting and applying various indicators in malaria programming.[30]

Electronic reporting: The introduction of electronic reporting is worth considering, because it enables near real-time monitoring of essential stocks and data on certain notifiable or outbreak diseases, e.g. dengue shock syndrome at national level (see Part 4 of this manual). Report forms may require modification to facilitate prioritization of data that are useful to obtain on a regular basis, and which may assist with a timely response to point-of-care needs, e.g. weekly HMIS data reported by internet or mobile phone 🛠**9**.

Evaluation: This is important for sustained follow-up and review of past activities. Internal and external evaluations should be planned for, after a given period of time following RDT deployment. In collaboration with stakeholders, the national programme should develop evaluation indicators that describe the expected changes in behaviour and practice after a given period of RDT use.

It is important to review the rationale for the RDT programme periodically to ensure that it remains relevant. Based on practical experience, the programme should look at whether new partners with expertise in and resources for M&E have come on board; whether others have been dropped; and whether the vision, mission, outcome challenges, progress markers and monitoring system are still appropriate and relevant.

Practical sources of monitoring information, include, but are not limited to the following:

- Routine data sourcing: HMIS summary reporting forms with fields for collecting parasitological confirmation of malaria diagnosis data:
  - updated or available stock cards and health facility record forms, with a field for RDT-related data recording
  - updated or available data record forms for malaria cases tested and treated at community level
  - checklists for malaria case management supervision reflecting RDT specific issues for investigating the quality of parasitological confirmation of malaria diagnosis at the facility.
- Special surveys: generic guidance on how to interview patients or care givers on the quality of case management at the health facility, including parasitological confirmation of malaria diagnosis, through disease surveillance systems, demographic health surveys, health facility reports and community surveys.

From experience, the minimum periodicity of data collection in special surveys is:

- continuous – disease surveillance system and routine HMIS
- five years – demographic health surveys
- two to three years – health facility survey
- two to three years – community survey
- two to three years - Malaria Indicator Surveys

29 *Malaria case management: operations manual.* Geneva, World Health Organization, 2009

30 *World Malaria Report 2011*; p 10. Geneva, World Health Organization, 2011.

Part 3

RDT implementation at district and community level

Part 3 of this manual outlines the practical steps of RDT implementation below central level. It is designed to provide specific guidance and basic minimum standards for assuring quality implementation of malaria RDTs. While planning for overall implementation of the national case management strategy is determined at central level (addressed in Part 2) with major input from the implementing managers, health service personnel beyond central level are charged with the task of providing information for the development, as well as translation, of these plans and processes into the activities impacting patient care. This part of the guide, therefore, provides the relevant information and tools required for practical implementation of RDTs. Good coordination at this level will ensure a well-managed implementation process and avoid inconsistent and erratic coverage that will reduce the effectiveness of case management and damage the credibility of the programme.

Moving from symptom- to parasite-based diagnosis involves a major and difficult shift in thinking for health service personnel and the community. Success will depend very much on consistent delivery of programme inputs and effective implementation, the messages that are passed down, and the engagement that health personnel has in the plan and in its monitoring and outcomes.

Once the national malaria programme has formulated, endorsed and disseminated the policy guidelines for including RDT-based parasitological confirmation of malaria diagnosis, these must be translated into practical implementation tools and activities at the various levels of the health system – from laboratory and clinic all the way to the village health worker. While the plan must be adapted to suit conditions and needs at each level and in each geographical area, a high degree of uniformity is also important to ensure standards are maintained and outcomes can be monitored. The outline provided here, and the example of implementation timelines and plans in 🛠**1, 4** are intended to assist personnel tasked with translating the national plan into action in each area of RDT implementation. The guidance in this section is dependent on a solid national plan being in place, as outlined in Part 2.

3.1 Coordination

Once plans to deploy malaria RDTs in specified regions have been approved by the national authorities (in a centralized health system), the authorities at provincial and district levels will need to adapt the central deployment plans to take into account district-specific issues; for example, frequency of supervisory visits, restocking during different seasons, and local variations in rates of consumption. It is important to identify or appoint a laboratory focal person at sub-national level – depending on the existing health system structure – to coordinate local implementation. A group of supporting partners with relevant expertise will be needed. If RDTs are to be deployed at community level, for example, a district-based representative with experience in implementing community based health initiatives should be included. Clear lines of communication with the national coordinating structure must be in place.

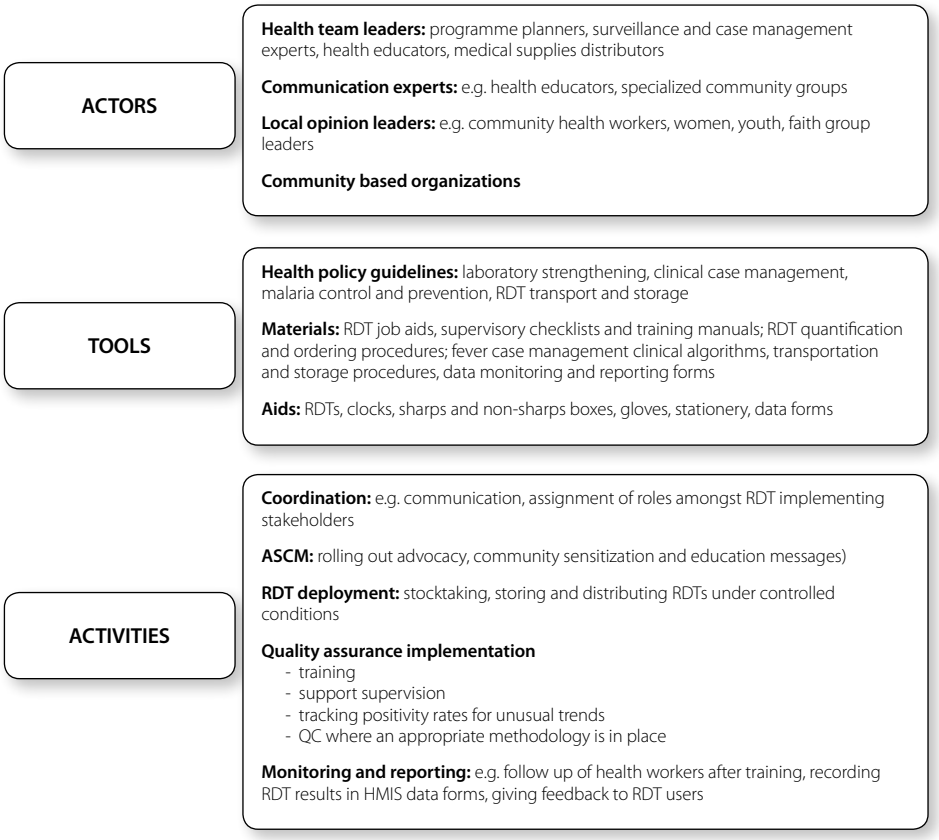
3.1.1 The role of a coordinator

The coordinator described above will be expected to supervise and support implementation of a wide range of activities and to do so according to specific policies and performance standards set out at national level. Coordination will involve:

- keeping a relevant mix of stakeholders all committed to collaborative efforts towards implementing RDTs
- disseminating RDT implementation plans, outlining the method of deployment, expected output and outcomes of deployment
- assigning responsibilities and identifying deliverables: where, how, when, who is involved
- implementing the community sensitization plan through channels that reach out to political and opinion leaders, schools, and the community at large.

The minimum required actors, actions and tools involved (Figure 12) require coordinated efforts to translate them into point-of-care health benefits.

Figure 12: Getting to the point of use: converting central strategy to action at point-of-care



ACSM - Advocacy, communication and social mobilization; HMIS - Health management information system; RDT - Rapid diagnostic test

3.2 Supply chain management: quantification of RDTs at point-of-care facilities

In a centralized supply system, the annual needs for RDTs will have been estimated at national level, taking into consideration factors such as: the planned geographical coverage of RDT implementation; the level of care and types of health care facilities where RDTs will be deployed (i.e. hospitals, health centres, dispensaries, health posts and community-based providers); the national diagnostic algorithm for managing suspected malaria cases; and the continued use of microscopy services for malaria diagnosis. Guidance for RDT quantification and logistics is described in detail in the manual for malaria RDT selection and procurement[31] and in the operational manual on access to malaria diagnostic testing.[32]

At point-of-care level, it is important to be aware both of the national implementation plan and of the responsibilities of those working at district and community levels for determining annual needs for RDTs and ordering RDTs at that level. This level supports the national quantification exercise and the distribution process in both a centralized and decentralized supply system, through gathering basic data as summarized in Table 5. This exercise is outlined in Section 2 and is detailed in the Quantification manual.

Table 5: Minimum quantification needs required from the level of RDT use to inform stock supply process

Quantification issues beyond the central level	
Specific quantification dependent on needs for malaria diagnosis	
• Number of health facilities targeted for RDTs and/or microscopy • Proportion or number of community health workers to perform RDTs and stock required. • Proportion of health facilities with functional microscopy • Number of blood films examined for malaria • Estimated number of suspected malaria cases in targeted health facilities (at least 2 years of data) • Required safety stock levels and ordering lead time	
Specific items to consider during quantification for RDT implementation	
Current RDT kits • RDT • blood transfer device • buffer	*Essential ancillary commodities* • lancets • alcohol swabs • gloves • swabs • sharps disposal containers • multi-task timers for all health workers

Note:
- RDT kits may include some items in column on the right or may require separate procurement.
- RDT introduction may require increase in procurement over basic clinic needs in some settings.

It is essential that health workers using malaria RDTs should understand that the logistics unit at national level relies on the availability of accurate information from where RDTs are actually used. It is therefore important that health facilities in which RDTs are deployed keep accurate and complete data to inform the quantification process in a timely manner, to ensure re-stocking, and to provide information needed for planning the overall malaria budget in future years. Paper-based information systems are frequently inadequate to achieve reliable data transfer. Systems based on electronic messaging (e.g. SMS-based messaging) should be considered. If paper-based systems have to be used, immediate/timely transfer of data into electronic databases is critical for accuracy and prompt reporting.

31 *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva, World Health Organization, 2011.

32 *Universal access to malaria diagnostic testing - An operational manual*. Geneva, World Health Organization, 2011.

3.3 Quality assurance: ensuring accurate and safe results

Ensuring good quality results from malaria RDTs depends on more than maintaining a high degree of precision and accuracy in the analytical performance of the test. Quality cannot be achieved by purely administrative and regulatory means; it requires commitment from all concerned.

Quality assurance is defined as a total process, both inside and outside the laboratory/testing unit, including human and test performance standards, good laboratory practice, and the management skills to achieve and maintain a quality service. The purpose of QA is to ensure that test results are reliable, relevant and timely. QA requires a system that encompasses organization, management, processing and reporting of RDT and microscopy results in an integrated manner (see Figure 7 and 10).

3.3.1 Quality control in the field

Quality control describes the monitoring of performance of a test, to ensure that it performs correctly and results are accurate and precise. RDTs will have gone through rigorous QC at time of purchase or after shipping (i.e. lot testing) to ensure the RDTs delivered to the implementer have adequate performance, and that the RDTs chosen are stable enough for the anticipated storage conditions. The implementation team at the peripheral level should ensure ambient conditions for RDT storage, with guidance from the district level. The method of any further checking of RDT quality will be decided at a national level, but implemented locally. Monitoring the effectiveness of RDTs at peripheral level, where they are used, should be integrated as far as possible into existing health worker training and QA schemes.

Quality control of malaria RDTs in the field aims to ensure that RDTs have retained adequate performance to detect clinically-relevant malaria infections. This adds a further margin of confidence to RDT deployment, and helps to reassure users and clinicians that the results are reliable. These methods confirm RDT capacity to detect parasite antigen – not the quality of use in general by field staff – and therefore do not replace the need for routine field supervision. New methods and tools for QC are expected to become available in the future (Part 4).

In addition to reporting on the quality of diagnostic test performance, reporting should include observations of the ancillary products deployed with RDTs including dry alcohol swabs, discoloured desiccant in humid conditions, broken or misshaped blood transfer devices (BTDs), discoloured or dry buffer bottles, and status of other commodities provided with the RDTs.

3.3.2 Monitoring of results of RDT procedure

All RDT results should be reported in the HMIS, or temporarily in a parallel malaria surveillance system (e.g. NMP-specific database) until the HMIS can include them. It is essential that these statistics are accessible to district planning teams to support monitoring of trends for planning processes. At a central level, these data should form the basis for performance indicators to monitor programme effectiveness. Where large changes in the reported rate of positive and negative results (confirmed malaria) occur, and these are not readily explained by seasonality or the impact of changes in interventions, they should be specifically investigated and reported to the NMP through the supervisors (regional or district), coordinators or reference laboratory. This may include, for example, changes in positivity rates of tested patients that are not consistent with seasonal variation, differ widely from preceding years, or differ markedly from surrounding facilities. This investigation should include:

- evaluation of health worker performance in RDT preparation, and confirmation that manufacturers' instructions were followed
- assessment of storage and transport conditions
- withdrawal of RDTs for lot-testing.

Monitoring of RDT results should also include a record of:

- invalid rates: no control line, RDT repeated

- spoilt tests: damaged packages, etc.
- other major abnormalities such as very poor blood clearance, lack of blood flow within the RDT, abnormalities in BTD, etc.

Data from the monitoring should be noted in record books and stored at the clinic, so that they can be presented and discussed during supervisory visits. A clear reporting channel should be available to the health worker to report increased levels of invalid tests, damaged packaging, or any unexpected results or concern over tests not functioning correctly. This is part of training.

Where periodic sentinel site monitoring is in place (this may be routine at a site, or intermittent when a supervisor with proven competency in malaria microscopy is present), clear guidelines must be developed centrally to address discrepancies (e.g. a patient who is RDT-negative but has a positive test result with microscopy) and indicate the action that should be taken in response. These guidelines should be closely followed, with rapid communication of results and follow up to ensure that feedback and guidance from supervisory levels is received. Guidelines for management of discrepant results need to take into account the parasite density of the infections (RDTs may miss some infections below 100 parasites/µl and still be adequate for most general field use. Above 200 parasites/µl, false negative results are likely to have a significant impact on patient care.[33] Other issues that require consideration are "human error", safety and disposal of contaminated waste.

3.3.3 Human error in QA

While malaria RDTs are easy to perform and can produce very high quality results when used appropriately, mistakes are still relatively common. However, this can be addressed by good, standardized training and supervision. Training should be practical, and users must demonstrate proficiency before being allowed to use RDTs for case management. Experience suggests that this training aspect of RDT QA is often ignored. National malaria programmes should consider this to be a critical component of RDT rollout. Training and supervision are covered in detail in section 3.4. From previous experience with RDTs used in routine conditions at health facilities, several common problems have been identified.

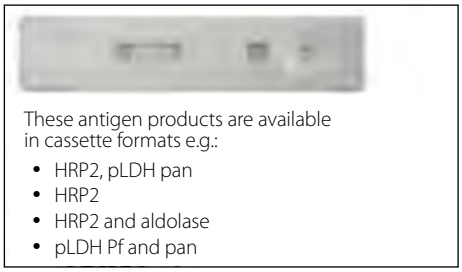
1. Inaccurate blood volume collected and/or applied to the test, often due to difficulties in using the BTD or failure to use the device.
2. Wrong buffer used or wrong volume applied. Only the buffer supplied with the RDT lot should be used for that particular lot; buffer is not interchangeable between products or between production lots of a product. Using the wrong buffer could produce false positive or false negative results. Check product information guide to check the number of drops that need to be dispensed.
3. Blood and buffer placed in wrong wells. Placing the blood and buffer in the wrong wells will produce only negative or invalid results, because only the buffer moves towards the test and control lines.
4. Failure to wait the specified time before reading negative results. Weak test lines may appear late in the reading period, when the blood staining has cleared. However, RDTs should not be read after the maximum specified reading time.
5. Inadequate light for reading test results. In order to read RDT results and not to miss faint positives, RDTs must be read in bright light. During daylight hours an open window may provide sufficient light, but at night a bright flashlight/torch is necessary; penlights and kerosene lamps are usually not sufficient.
6. Failure to interpret faint lines as positive (any line in the test line area should be considered evidence of malaria infection).

RDTs vary in design, in buffer and blood volume required, and in reading time. Clear job aids in a locally-appropriate language should be produced. Manufacturer's instructions and aids should never be ignored. It is essential to ensure that NMP RDT job aids are consistent with the RDT manufacturer's instructions. It is

33 *Parasitological confirmation of malaria diagnosis: Report of a WHO technical consultation Geneva, 6–8 October 2009.* Geneva, World Health Organization, 2010.

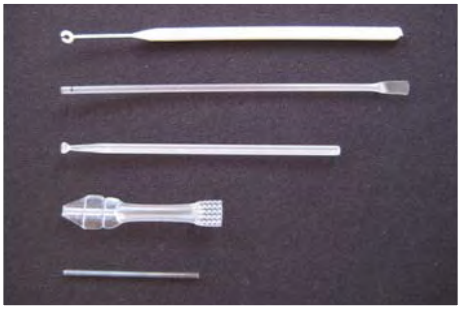
important to have job aids and actual examples or pictures of the different types of RDTs and BTDs that may be encountered in the country (Figure 13).

Figure 13: RDT blood transfer devices, RDT types and job aids that are worth mentioning or displaying during health worker training sessions

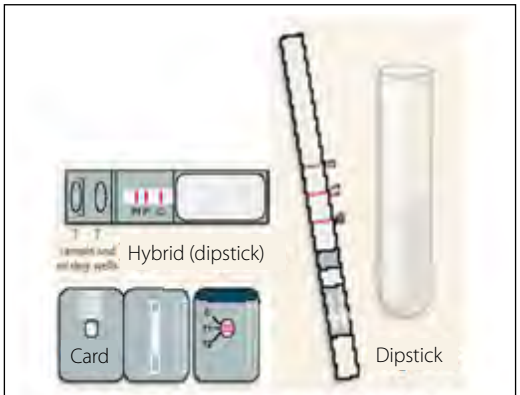


These antigen products are available in cassette formats e.g.:

- HRP2, pLDH pan
- HRP2
- HRP2 and aldolase
- pLDH Pf and pan



Range of malaria RDT products



These antigen products are available in dipstick and card formats:

- HRP2, pLDH-pan, pLDH-Pv, pLDH-Pf, pLDH VOM
- aldolase

3.3.4 Safety and contaminated waste handling

RDT use raises issues of blood safety and waste disposal that may have not been encountered before on a routine basis by village health workers or at small clinics. This must be a major part of training in RDT use, and practices must comply with national guidelines on management of laboratory waste. International guidance is available to shape this area of training and support supervision (Figure 8).[34] There are a number of different types of waste which will be generated by the RDT programme (such as gloves, sharps, boxes, cotton wool, etc.) that need to be addressed during training and support supervision. Further details can be found in documents on transporting, storing and handling RDTs in health facilities.

Key blood safety principles:

- consider every blood sample as potentially infectious
- you should ALWAYS wear gloves when handling blood
- NEVER reuse lancets
- do not leave lancets in places accessed by children
- once used, be sure to place them in contaminated waste materials box

These instructions are especially relevant for lower level HWs who are now being asked to do these tests rather than just examine patients. .

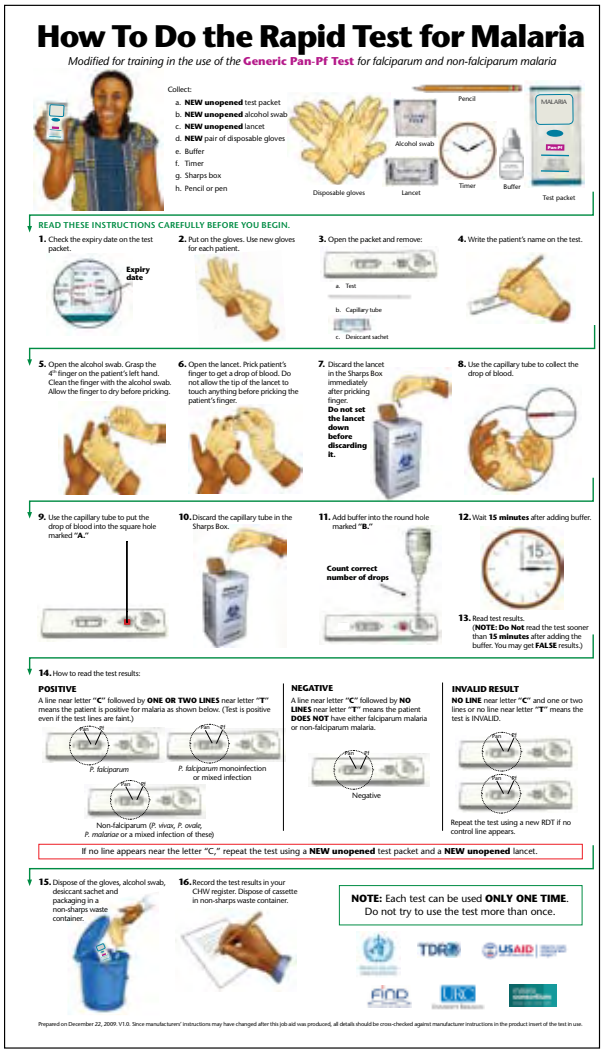
Key safe disposal principles:

- ensure that sharps containers are available and that they are within reach, so that the lancet or needle may be disposed of immediately after the patient is tested

34 *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests at the Peripheral Storage Facilities*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3; and Geneva, World Health Organization, 2009.

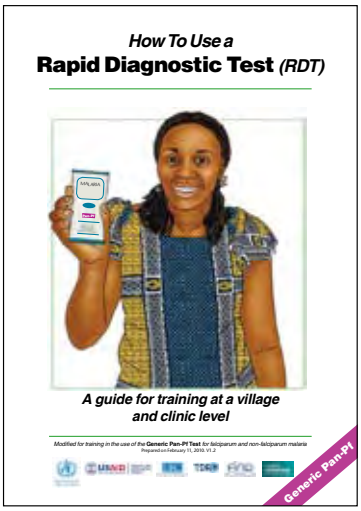
- place RDTs, gloves, blood transfer devices and other potentially contaminated material in bags specifically for this purpose, separated from non-contaminated waste
- keep sharps boxes and contaminated waste bags in a safe place, away from children and the public
- have an acceptable practice in place for permanent disposal of sharps and contaminated waste, on site or through safe return to a higher level.

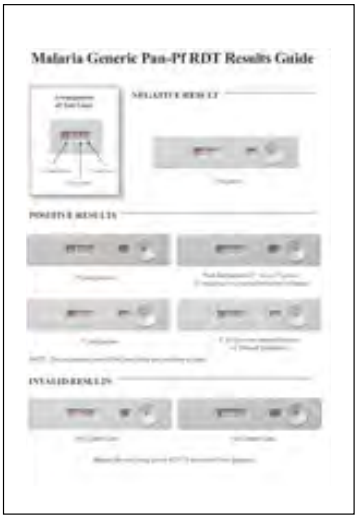
Job aids and training materials:



Generic Pan-Pf job aid, available for RDTs using:

- capillary tube
- loop
- using pipette





Top: Generic Pan-Pf training manual: A guide for training at a village and clinic level

Malaria generic Pan-Pf training RDT results guide

Training materials and job aids - instructions and high quality training for community health workers on RDT use - have been developed to improve the accuracy of RDTs, as well as user safety. They are part of the training requirements for use of RDTs at community and small clinic level. These materials can be adapted to local contexts.

In addition, RDT users should be fully trained in the national post-exposure prophylaxis (PEP) for HIV protocols and have access to the necessary drugs and supplies.

3.4 Quality assurance: training and supervision

Training and supervision are essential parts of QA. The apparent simplicity of the RDT must not lead to shortcuts in a training programme that could result in serious defects in quality. RDTs are easy to perform but it is also very easy to make errors while using them.

3.4.1 Training

Trainers of health workers at point-of-care should be carefully selected based on their knowledge, field experience and good interpersonal skills. Training activities beyond the central level should include messages that not only promote accuracy in performing and reading the RDT, but should also promote mutual respect and confidence amongst end users. While training curricula, guides and materials are typically developed at national level, they will be largely implemented at district level. The content should therefore be field tested at local or community level and feedback then sent to national level, to improve the training materials in the light of experience **5-8, 10**.

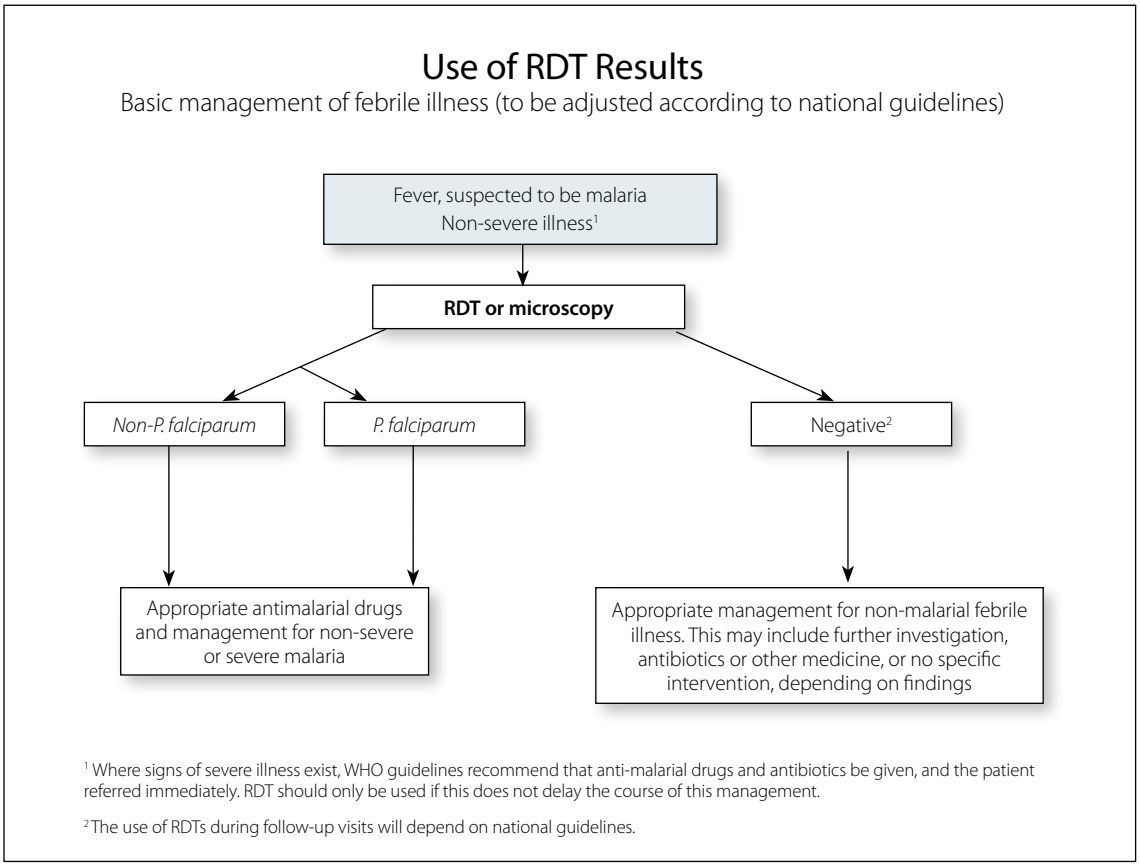
Training should be competency-based, deriving its schedule from a training plan. An assessment during training should take place to ensure that all trainees are observed to successfully prepare an RDT, and correctly interpret a panel of RDTs (or photos of results) including all the results that may be encountered using that product. When training health workers and volunteers at community level, the following points are important.

- Make sure that all materials are easy to use or read and are available in sufficient quantities. They should be specific for the product in use and in an appropriate language. Provide trainees with a solid rationale for the importance of parasitological diagnosis, especially the use of RDTs, as their previous experience may be symptom-based. Also address the consequences of common errors in performing RDTs.
- Limit the size of training groups (ideally not more than about 15 people per trainer) and have sufficient additional trainers or assistants to enable small group or individual training on blood sampling and safety, with additional facilitators for practical sessions (e.g. three or four trainees per facilitator).
- Ensure that guidance on waste management/disposal is suited to the particular circumstances.
- Reinforce the reasons for taking universal precautions for drawing and handling blood.
- Certify that participants are well-versed in the other aspects of case management and diagnostics management, including:
  - the different QA/QC methods that will be employed at various levels of the health network;
  - reporting, especially in cases where laboratory registers do not currently have a space allocated for RDT results;
  - communications with the community/patients on the need to diagnose before treatment.
- Practical session on test result scenarios (positive, negative, inconclusive and why)
- Arrange for on-the-job training to take place during the first supervisory visits, to equip staff who may not have had the opportunity to attend the training session.

Practical sessions should be held during training or during a supervisory visit at a health facility, to clarify difficulties encountered in fever case management and patient communication. Different scenarios should be arranged through role play, interactive discussions, and case studies, to better understand how to use RDTs and utilize test results (Figure 14). A guide for training and several training tools in the use of RDTs at community and clinic level[35] has been published by WHO and partners on which specific national training materials can be based **12**.

35 *How to use a rapid diagnostic test (RDT): A guide for training at a village and clinic level. 2008.* The USAID Health Care Improvement (HCI) Project and the World Health Organization (WHO), Bethesda, MD, and Geneva.

Figure 14: Generic guidance on the use of RDT results in fever case management



3.4.2 Supervision

The national programme will have prepared and disseminated standard supervisory checklists and guidelines to enable RDT supervision and quality assurance **7, 8, 11**. This section of the guide is intended to provide practical advice on how to conduct a malaria diagnostics QA visit and how to solve commonly encountered problems in the field. However, it is important to maintain regular contact with colleagues at the national public health laboratory so they may help solve additional problems encountered in the field. These problems and responses can inform future plans for RDT scale-up.

Following RDT training and deployment, immediate and sustained follow-up is important, to facilitate and support health workers to integrate RDTs into routine case management and record keeping. Support from surveillance sentinel sites and other partners who are specialized in M&E are instrumental in ensuring that the right tools and schedules are set for regular supportive supervision and overall post-implementation programme review. All aspects of RDT implementation should be reviewed in the training curriculum, including QA/QC, training and communication, the RDT supply chain, and the national coordinating mechanism that oversees the programme. In decentralized health systems, malaria control is conducted by regional or district health authorities. Field visits allow the authorities to observe how malaria control activities are being delivered and to mentor the implementers.

Supervision plan

- Determine the objective of the supervision and balance it with the required human and logistic resources: e.g. malaria or case management-specific supervision may require a different set of resources from integrated health systems supervision.
- It is cost-effective to schedule the RDT-specific supervision visits to other health services-related supervisory visits, or community outreach programmes. If this procedure is used, combine the RDT supervision schedule with that of another related supervisory programme.
- Checklists should be well adapted to improve cost effectiveness. Align supervisory plans with other clinical and laboratory supervision checklists, and QA schemes. A national supervisory checklist will help ensure that all supplies and requirements for a successful supervisory visit are available.
- Equip frontline health facility managers with supervisory skills specific to performing RDTs and conducting quality control procedures.
- Plan for feedback on the spot, to ensure corrective action is taken on pertinent implementation issues that may call for improvement at the point of RDT use.
- Plan to utilize the skill set of different expertise among implementing partners to address specific speciality needs, e.g. stock control, storage conditions and temperature control, health data management and feedback, RDT performance, clinical case management, and community sensitization.
- Ensure that the checklists address all areas of infection prevention and control, RDT and gloves stock availability, waste disposal facilities and water supply.
- Evaluation:
  - supervisors must have an opportunity to discuss their experiences with other supervisors and at central level, in order to make systematic improvements to the programme
  - supervisors should frequently participate in provincial or district health meetings to present findings, and as a means to troubleshoot issues with the local health community.

The supervisor's terms of reference: Among the skill sets necessary for supervision, competent supervisors should help RDT users to initiate corrective measures, improve efficiency by increasing their knowledge and perfecting their skills, and maintain motivation despite existing challenges. Many factors have to be considered in choosing an appropriate person to take on this role.

In addition, supervisors are responsible for the well-being and safety of their team, overseeing the completion of the workload and the maintenance of data quality. Since it is often difficult to sustain adequate levels of supervision in malaria programmes due to travel and staff shortages, it is important that supervision of RDT use include other aspects of malaria case management. For example, malaria health workers often handle related matters such as vaccinations, maternal and infant health, IMAI and IMCI, and other febrile illnesses, which are not due to malaria.

3.4.3 Developing a supervision plan

The recommended approach to supervision of health workers engaged in RDT-based diagnosis is described below. Matching checklists are provided in 🛠**7**. RDT-specific supervisory plans should be added to the existing supervisory plans for other aspects of malaria case management and the health workers' role. The structure of visits will also vary depending on whether the visit is to a clinic or to a single health worker. It is important that supervisory visits occur at the actual workplace wherever possible, rather than at a central point which health workers must attend in order that issues such as waste disposal, safe work environment and storage of commodities and records can be assessed.

Supervisors should record results of visits in a standard manner, including use of checklists with recommendations documented where appropriate. These should be accessible to future supervisors before further visits, but otherwise considered confidential and not available to colleagues of the supervised staff. A process should be put in place at the management, e.g. district level to ensure this.

The tasks that should be Included in a supervisory visit can be divided into the following five areas:

Task one: Personnel and management issues

It is important that health workers are free to raise any issues connected with their work, and that they are updated on personnel and policy issues concerning the health service; if they hear from their managers directly rather than second-hand, they will feel they are valued and morale will be supported.

However, supervisors should also have a checklist of points to discuss with the health worker, including the following:

- Recent or future retraining and updates
- Planned health service policy or strategy changes
- Clinic/workplace operations:
  - concerns over outcomes and disease prevalence
  - workload
  - community relations
    - issues concerning clinic-community relationships that affect the workplace
    - sensitization of the community to parasite-based diagnosis and case management needs
  - patient response to management
  - storage and handling of RDTs and other commodities documentation and reporting issues
  - receipt of feedback on results sent

Task two: Workplace assessment

The expectations for the workplace will vary widely, depending on whether the supervised staff are working in an established laboratory, or in a clinic or village setting. However, certain fundamental standards, discussed below, should be in place in all settings where patient samples are collected and tested. Most countries have established laboratory standards and manuals to guide the implementation of these; these documents should form the basis of the workplace assessment **7**, Task 2.

At a minimum, the workplace assessment should include confirmation of the following:

- Adequate working space and availability of necessary utilities:
  - clean water supply
  - washing and toilet facilities
  - lighting
  - bench space
  - patient waiting space and adequate privacy where required
- Cleanliness

- Adequate disposal facilities:
  - secure, safe sharps storage and disposal
  - secure safe contaminated waste storage and disposal
  - adequate general waste storage and disposal[36]
- Adequate secure storage:
  - for RDTs, drugs and other commodities
  - for documents, manuals, and records
  - for community education materials
- Clear visibility of RDT job aids and results guides to health workers and patients

Task three: RDT preparation

It is essential to observe preparation of malaria RDTs during a supervisory visit. The visit should take place during a time when patients attend the clinic. If observation cannot be done with a real patient, the procedure should be observed on a volunteer. In case there are no patients, or in the case of stock-outs, supervisors should hand-carry a few RDTs so that observations can still take place. It is important to observe the whole process, including finger-pricking, to ensure that blood safety practices are being followed. The supervisor should observe and not intervene, unless practices are considered to be of direct danger to the patient or health worker. A standard checklist (🛠**7**, Task 3) should be used. Feedback should then be given to the health worker when the patient is not present. It may be necessary to observe additional tests if major deficiencies are identified.

Task four: RDT interpretation

Checking RDT interpretation can be accomplished with a pre-prepared set of used RDTs, or with photographic quizzes with clear interpretive guides 🛠**12**. Health workers should be tested on each visit. They should be shown and asked to interpret examples of the following:

- Strong positive results
- Weak positive results, often missed by health workers; if missed, then the health worker should be advised to have his/her vision checked
- Negative results
- Invalid results; RDTs can be prepared to show such results by opening a used RDT cassette, turning the test strip around (so that the control line is now where the test line was) and adding buffer only to the well, if actual invalid tests are unavailable

36 *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests at the Peripheral Storage Facilities*. Arlington, VA: USAID | DELIVER PROJECT, Task Order 3; and Geneva, World Health Organization, 2009.

Task five: Documentation and reporting

A formal review should be conducted of the documentation in the clinic, including the following:

- Laboratory registers – ensure that this new data is being recorded correctly
- HMIS data including patient attendance, results, and management
- Management of commodities:
  - stock received
  - consumption
  - stock-take records
  - requests for stock
  - where appropriate, temperature and other storage monitoring
- Records of quality control and internal and external quality assurance activities.

Examples of data from the monitoring of RDT results should be stored in the clinic and in record books, so that they can be presented and discussed during supervisory visits 🛠**11**.

3.5 Advocacy, communication and social mobilization (ACSM)

In order to encourage the target population to adopt appropriate behaviour towards the national policy of parasite-based confirmation of malaria diagnosis, it is important to include a communication plan in the RDT implementation strategy (see Figure 15). Implementation of RDTs offers a good opportunity for supervisors and community educators to equip the target population with information on parasite-based diagnosis, so that they are more likely to request a test when seeking care for malaria-like infections. The plan should reinforce improved access, affordability, consistent supply/availability of RDTs, and trust in policy decisions as well as interventions. For the following reasons the strategy should involve the community, village leaders, village health volunteers, private health care providers, youth and women's groups, as well as community-based organizations.

- Although services for malaria prevention and treatment may be available, many communities are unaware of the need for diagnostic services to identify the true cause of fevers.
- In the process of trying out RDTs, communities may gain better understanding and experience, which could nurture acceptance and the adoption of parasite-based diagnosis of malaria.
- A well-planned ACSM strategy will improve the level of knowledge about when and where to access health services, when to use a diagnostic test and what management should be undertaken based on those results.
- It will emphasize the importance of good quality RDTs in the private health sector, and demand for parasite-based diagnosis, within 24 hours of onset of fever.
- Above all it should emphasize adherence to a full course of ACTs following parasitological confirmation of malaria.

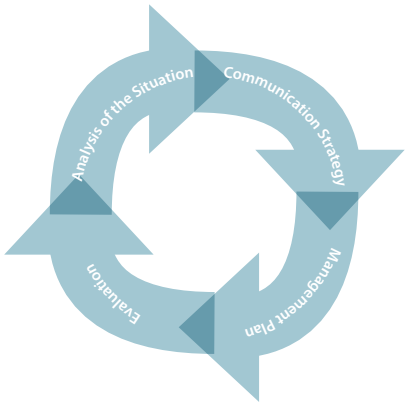
Key actions

- Secure community sensitization materials from the national level.
- Plan to integrate parasitological confirmation of malaria diagnosis communication training into health education programme implementation, to minimize costs and allow expansion of the pool of trainers. It is essential to build up a level of awareness, so that parasite-based diagnosis becomes accepted as standard.
- Discuss operational aspects of RDT implementation with people who can influence a community, such as teachers and religious leaders.
- Plan meetings and discussions with these people and community leaders (political, cultural, religious, partner organizations).
- Agree on the best methods for disseminating information to the community about malaria RDTs and their potential benefits, and other malaria control and prevention interventions.
- Schedule media-based announcements and/or public meetings with community members.

Key questions to confirm that planning has been adequate:

- Have you prepared culturally appropriate communication materials, based on feedback from formative research?
- Do you have a dissemination plan in place to support the ACSM strategy, including production of promotional and communication materials and distribution of materials to health centres, pharmacies, non-government and community-based organizations?
- Does the plan include a strategy for implementation of community-based activities, e.g. theatre group dramas, presentations with chances to win promotional items?

Figure 15: Sample communication strategy outline



I. Analysis of the situation
- *A. Purpose (Health situation that the program is trying to improve)*
- *B. Key health issue (Behaviour or change that needs to occur to improve the health situation)*
- *C. Context (Strengths, Weaknesses, Opportunities and Threats [SWOT] that affect the health situation)*
- *D. Gaps in information available to the program planners and to the audience that limit the program's ability to develop sound strategy. These gaps will be addressed through research in preparation for executing the strategy*
- *E. Formative research (New information that will address the gaps identified above)*

II. Communication strategy
- *A. Audiences (Primary, secondary and/or community leadership audiences)*
- *B. Objectives*
- *C. Positioning and long-term Identity*
- *D. Strategic approach*
- *E. Key message points*
- *F. Channels and tools*

III. Management considerations
- *A. Partner roles and responsibilities*
- *B. Timeline for strategy implementation*
- *C. Budget*
- *D. Monitoring plan*

IV. Evaluation - Tracking progress and evaluating impact

Adapted from PACE (formerly PSI), Uganda
PACE - Programme for Accessible health, Communication and Education; PSI - Population Services International

3.5.1 Use of RDT results and community education

No single communication intervention can ever be 100% effective in achieving the desired outcomes. The key to a successful campaign is to develop an integrated approach (Table 6) equipped with user-friendly tools that are appropriate for the community and cultural context. At village level, baseline assessments of knowledge, attitudes and behavioural change drivers should be undertaken to inform decisions on the best package of approaches for ACSM. Activities should be carried out in collaboration with the local community health workers to emphasize their role in disease detection and management.

Take steps to ensure that the local community is aware of the prevalence and impact of malaria. This could include the use of HMIS data to empower community members to seek medical advice and quality care at formal health facilities in the private and public sectors. A typical community action plan would include the following approaches:

1. Administrative mobilization and public advocacy: Meet and discuss with senior community members and leaders to ensure that the programme is on the public administrative and programme management agenda.

2. Community and face-to-face communication: Target face-to-face communication at community level, particularly in schools and homes, by teams assisting health workers.

3. Point of access posters and other print material: Use such materials to clearly indicate the aims and actions of the diagnostic programme, and where the programme can be accessed for the public and, if possible, the private sector.

4. Mass advertising: Promote the RDT programme through the use of advertising media/community radios.

3.5.2 Addressing non-malarial febrile illness (NMFI)

One of the recognized risk factors for successful malaria RDT implementation is poor planning for comprehensive fever case management, and community sensitization about non-malarial fevers demonstrated through negative RDT results. If RDTs are to be an effective tool in malaria programmes, the importance of addressing case management of parasite-negative febrile illness cannot be overemphasized.

National programmes with experience in community-based RDT programmes suggest the following:

- Make available QC results of RDT performance to demonstrate their accuracy when used correctly.
- Work closely with IMCI strategists, making use of their experience in improving the skills of health workers and in developing appropriate community health-seeking behaviour.
- Obtain access to resources to train and equip health workers and community-based volunteers to manage common NMFIs, particularly bacterial diseases such as pneumonia , and ensure adequate drug supplies.
- Prepare and disseminate NMFI case management algorithms alongside the RDT training package.
- Incorporate NMFI-specific observation skills in the supervision plan.
- Inform other CBOs delivering child survival interventions of the role of RDTs in ruling out malaria and the need for proper management of NMFIs.

Algorithms for NMFIs will be developed centrally and integrated with guidelines for IMCI (🛠**6**) and other common illnesses, but implementation will be important to enable these algorithms to take effect in the context of local referral capacity and training. Community understanding that fever has multiple causes – and

Table 6: Example of different types of channels, tools and target groups to aim at in the implementation of an ACSM strategy (adapted from PACE [PSI] Uganda)

Administrative advocacy	*Establish and maintain strong links with the following:* ❑ local government representative ❑ print production houses ❑ NGOs ❑ cultural leaders ❑ religious institutions ❑ gender and youth groups *Establish and maintain strong links with the following:* ❑ local government representative ❑ print production houses ❑ NGOs ❑ cultural leaders ❑ religious institutions ❑ gender and youth groups
Interpersonal communication channels	❑ one-to-one ❑ beauty salons ❑ hotels and restaurants ❑ youth and women's clubs ❑ village health workers ❑ community recreation groups
Community mobilization strategies	❑ school talk shows ❑ sports days ❑ religious congregations ❑ antenatal care days ❑ traditional festive days ❑ community film shows
Point of service ACSM	❑ illustrational posters ❑ inspirational posters ❑ 'available here' signposts
Advertisement	❑ showcasing success stories ❑ radio, television ❑ theme songs ❑ feature articles ❑ press releases ❑ bulk SMS messaging ❑ local 'goodwill ambassadors'

that malaria RDTs are for both rapid detection of malaria and to preclude malaria when other causes of febrile disease are involved – is essential. Algorithms for malaria case management and common non-malarial febrile illnesses are available from WHO and elsewhere.[37,38]

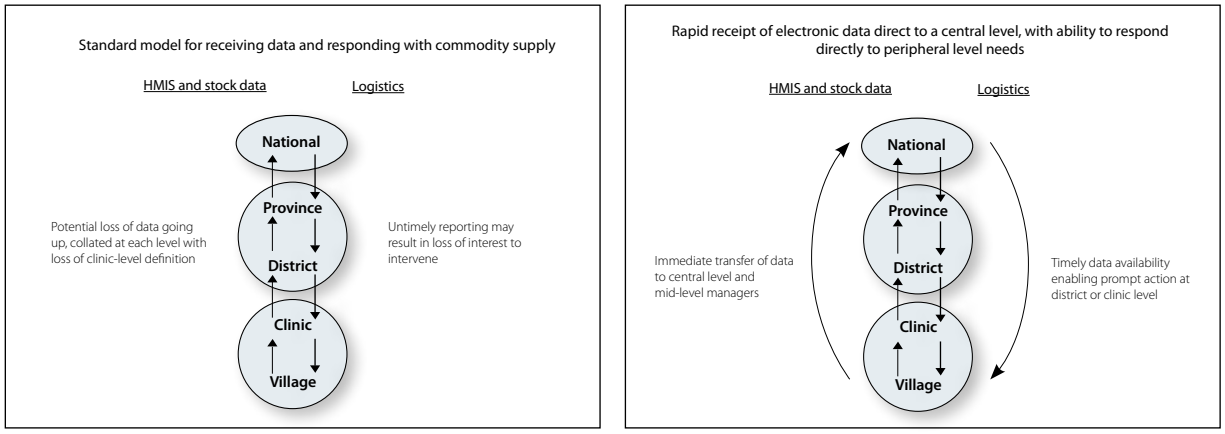
3.6 Monitoring and evaluation (M&E)

It is becoming increasingly important for countries to be able to report accurate, timely and comparable data to national authorities and donors, in order to sustain and expand health programmes and, most importantly,

37 *Universal access to malaria rapid diagnostic tests – An operational manual.* Geneva, World Health Organization, 2011.

38 *Integrated Management of Adolescent and Adult Illness (IMAI): Guidelines for first level facility health workers at health centre and district outpatient clinic*. Geneva, World Health Organization, 2009

Figure 16: Standard versus electronic methods of information transmission



to utilize this information at district level and locally to strengthen evolving programmes. Monitoring and evaluation can assist the manager of lower level health facilities, for example, in planning RDT and ACT stock requirements and outbreak detection in line with national indicators for achieving a 'malaria-free' programme. Electronic reporting is one way of overcoming some of the problems that arise in M&E (Figure 16).

Key questions for M&E

- Are there tools for collecting and recording health data to ensure completeness of data on fever case management, e.g. tally sheets, standardized forms and registers?
- Are roles and responsibilities defined at district and national level so that there is an effective response to M&E results, e.g. low stock levels and changes in disease prevalence?

District surveillance/M&E teams should be involved in the planning of RDT roll-out to ensure these measures are in place.

Knowledge of the true malaria burden is vital to good programme management. Without parasite confirmation, reported malaria cases do not present the true incidence of malaria. Therefore, confirmed cases reported to the national health information systems represent incidence. As parasite-based confirmation of malaria diagnosis becomes more widely used, the reported incidence of malaria more closely reflects true incidence. True incidence of malaria directly or indirectly impacts other elements of the NMP, including the quantity of other interventions required.

The following are examples of data elements (numerators and denominators) required to calculate core and supplemental indicators,[39] which national programmes have used to prepare an M&E plan for rolling out.

- The number of microscopy slides or RDTs performed as a proportion of the total outpatient/inpatient workload.
- Positive malaria test results, +/- parasite species.
- Proportion of suspected malaria cases (in the private or public health sector) diagnosed with RDT/ microscopy.
- Percentage of health facilities reporting no stock out of antimalarial medicines and diagnostics:
  - numerator: number of health facilities, in areas of risk for malaria, reporting no stock out of RDTs for more than one week in a month
  - denominator: total number of health facilities reporting, supervised or surveyed in the same area at risk for malaria x 100.

39 *World Malaria Report 2010*. Geneva, World Health Organization, 2010.

- Percentage/proportion of malaria cases that are laboratory confirmed.
- Percentage of health facilities with malaria diagnostic tools.

The following is a sample health facility report form featuring some of these indicators.

Table 7: Data collection form with elements reported at health facility and sub-national levels, including RDTs

Example of health facility reporting form
(includes core data elements needed to produce indicators and core analyses)

Health facility
District
Month
Year
Date reported to district

Classification	Outpatient numbers <5 years	Outpatient numbers 5+ years
Suspected or clinica malaria cases		
Suspected cases tested for malaria		
Confirmed cases		
Total all-cause cases		

Classification	Inpatient numbers <5 years	Inpatient numbers 5+ years
Malaria cases		
Malaria deaths		
All-cause cases		
All-cause deaths		

Logistic information
Stock-outs this month

Type of item	Yes / No
ACT	
RDT	
LLIN	

IPT in pregnant women	Number
Second dose	
First ANC visit	

Information on ANC, LLIN	Number
Patients treated with ACT	
LLIN given to ANC clients	
Total LLIN distributed	

Example of summary reporting form for district level
(includes core data elements needed to produce indicators and core analyses)

District
Province
Month
Year
No. HF expected to report: _____ No. HF reported: _____ No. HF timely: _____
Date form sent to next level

Classification	Outpatient numbers <5 years	Outpatient numbers 5+ years
Suspected or clinica malaria cases		
Suspected cases tested for malaria		
Malaria cases confirmed		
Total all-cause cases		

Classification	Inpatient numbers <5 years	Inpatient numbers 5+ years
Malaria cases		
Malaria deaths		
All-cause cases		
All-cause deaths		

Logistic information
Stock-outs this month

Type of item	Number of health facilities reporting stock-outs*
ACT**	
RDT	
LLIN	

* Stock-outs of any duration during month
** Stock-outs of any ACT PrePak

IPT in pregnant women	Number
Second dose	
First ANC visit	

Information on ANC, LLIN	Number
Patients treated with ACT	
LLIN given to ANC clients	
Total LLIN distributed	

Additional data elements to consider:

Data from community workers	Number
Workers expected to report	
Workers reporting this month	
Suspected malaria cases seen	
Suspected cases tested for malaria	
Malaria cases confirmed	
Cases referred	
Workers with stock-outs of ACT	
Workers with stock-outs of RDT	

Stock-outs of ACT	"Yes/No" or "Number of health facilities*"
PrePak 1	
PrePak 2	
PrePak 3	
PrePak 4	

*Use "Yes/No" if using health facilityreporting form; use "Number of health facilities" if using district reporting form

Part 4

Tools under development to support RDT implementation

New tools for diagnosing malaria, and for monitoring the quality of current diagnostics including RDTs, are likely to be introduced into malaria programmes over the next several years. These may improve the sensitivity of diagnosis and in particular allow detection of low-grade infections that cause no symptoms and are difficult to detect by current field methods. Improvements in the diagnosis of other causes of fever, and in the transmission of results, will present new opportunities and challenges to health systems, requiring changes in QA and support, and management of greater volumes of data.

4.1 Positive control wells (PCWs) and lot-testing panels for QC testing

A number of programmes currently use positive control wells developed from freeze-dried parasitized blood or similar preparation. It is likely that wells containing freeze-dried parasite antigen, i.e. pLDH, HRP2, and reconstituted with water will be available within the next few years to test RDTs at village level, ensuring that they are still effective after storage and delivery. In addition, a panel of wells is also under development for standardized lot-testing at national level, facilitating national regulatory testing and pre- or post-purchase lot-testing.

Wells can contain varying concentrations of single target antigen, as shown in the figure below.

Figure 17: Positive control wells for point-of-care RDT QC

Technology for the future: positive control wells (PCWs)
- under development by FIND, WHO and partners
- (Mark 1) labratory trials from March 2011
  - one well: HRP2, Pv-pLDH, aldolase: one well: Pf-pLDH equivalent to 200 (400) para/µl

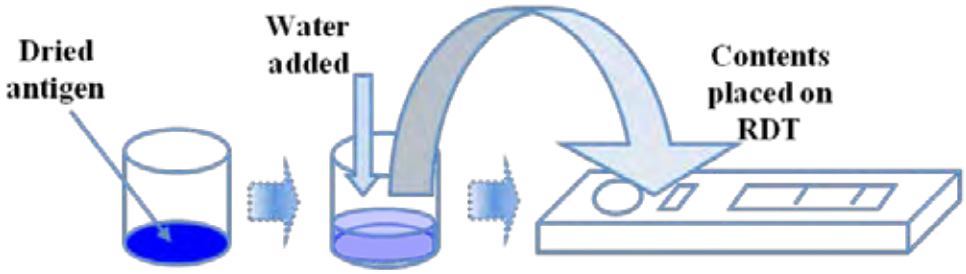
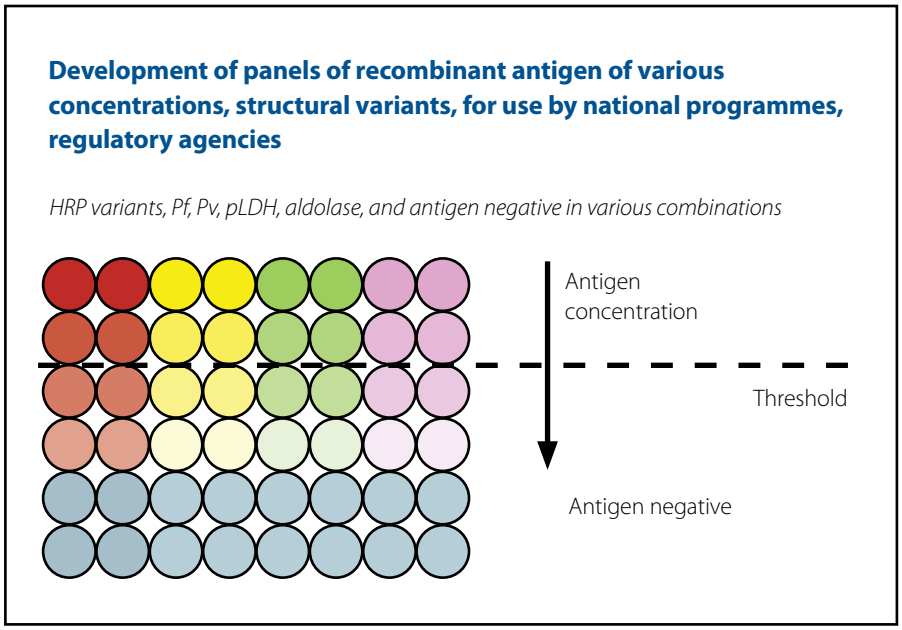


Figure 18: Example of possible format for recombinant antigen-based panel for lot-testing



4.2 Mobile phone and other electronic reporting methods

The use of microscopy or RDTs to confirm malaria diagnosis prior to treatment adds great value to data collection and management from community level. The potential of approaches based on mobile (cell) phones and mobile devices to address the gaps in field data collection and reporting is now widely recognized, and a number of so-called mHealth initiatives have been piloted in low-income settings. One approach, tested in several settings, uses reporting systems based on SMS (short message service, or mobile phone text messaging). It does not require the installation or maintenance of any software application on the cell phone itself and therefore can be used on even the most basic of cell phones by users in remote areas – Figure 19.

Access to more sophisticated health care technologies is likely to improve, but the effectiveness of these new tools will be dependent on adequate human resources and logistics being in place. When such tools become available it will be necessary – as with RDT introduction – to determine how effectively they perform in the field and how their impact can be maximized.

1 Implementation Plans

Generic RDT implementation timeline

Adapted from WHO, FIND and Uganda NMCP

RDT IMPLEMENTATION TIMELINE	Example of necessary steps for implementation of Rapid Test (RDT)-based diagnosis in a national malaria programme.
Coordinating group	
Appoint malaria diagnosis coordinator(s)	
Policy recommendations	*Written* — *MoH endoresment*
Program Planning	
Guidelines*	*Written* — *MoH endorsement*
Case management of fever of unknown origin	
Case management of malaria	
RDT (and microscopy) quality assurance	
RDT transport and storage	
Decide districts for initial / phased implementation	
Fever management algorithm	*Written* — *MoH endorsement*
Community sensitization	
General health care providers education	
Determine / designate transport and storage methods	
Regulatory Issues	
Define collaborative roles (NMP and Regulatory Body)	
Write/adopt regulatory guidleines	
Create RDT registry for reference	
Dsseminate regulatory criteria	
Product selection,supply chain management	
Select several products	
Samples for ease-of-use assessment	
Final decision on RDT	
Negotiate specifications with manufacturer	
Competitive bidding and Procurement	*Dependent on registration process*
Receive first batch (of staggered delivery)	
Distribution to field	
Procure gloves	
Procure sharps boxes	
Procure other associated materials	

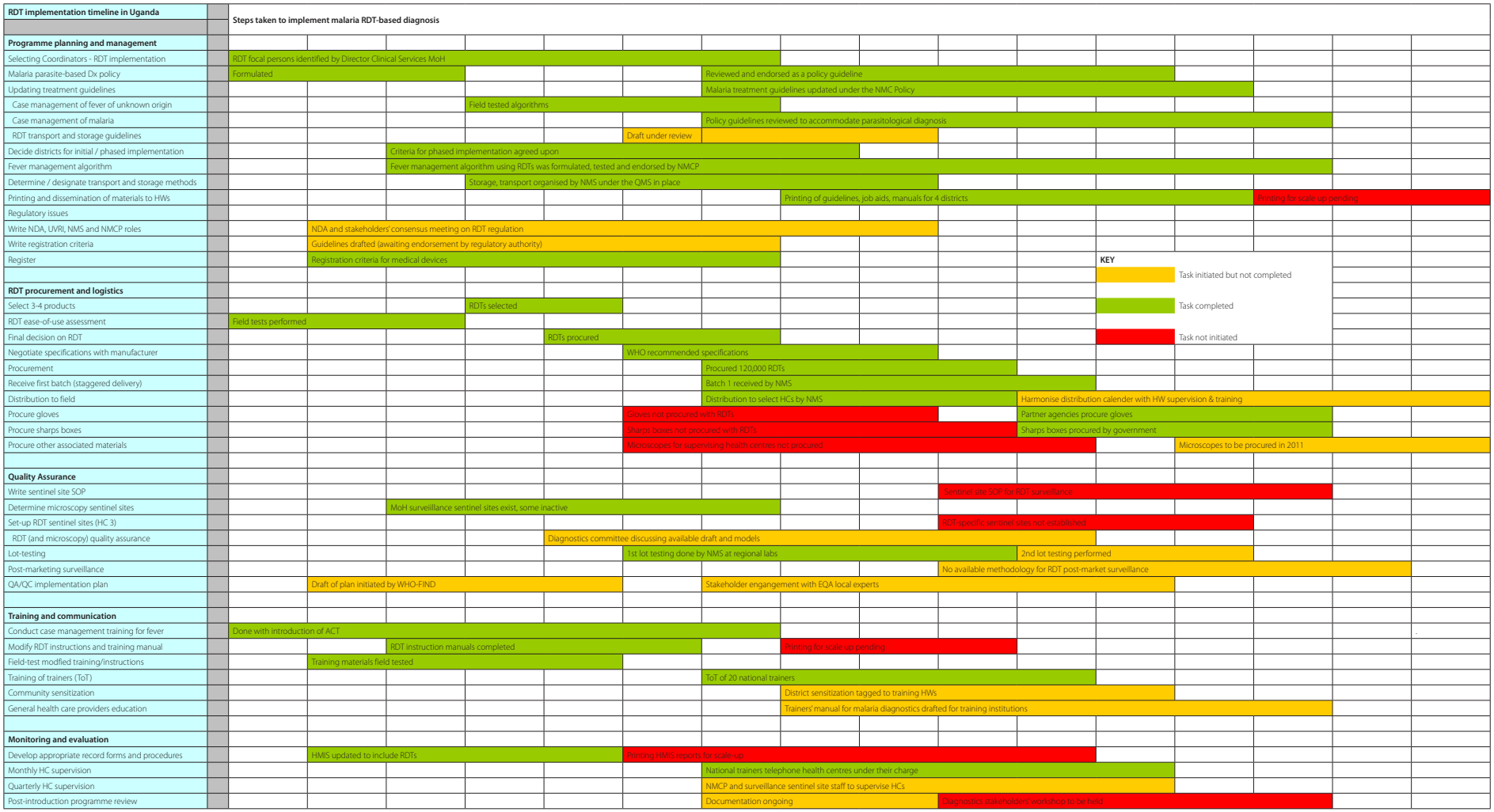
(Continued on next page)

Generic RDT implementation timeline *(continued)*

Adapted from WHO, FIND and Uganda NMCP

RDT IMPLEMENTATION TIMELINE	Example of necessary steps for implementation of Rapid Test (RDT)-based diagnosis in a national malaria programme.
RDT Quality Control	
Write sentinel site SOP	
Set up/engage field based QC monitoring sites	
Decide on Lot-testing site	*Determne site* / *Commence testing*
Post-marketing surveillance**	
Training	
Conduct case management training for fever	May be conducted earlier, or already in place
Modify RDT instructions and training manual	
Field-test modfied training/instructions	
Training of trainers and supervisors	
Health Worker Training	
Advocacy, Communication, Social Mobilisation	
Engaging civil society organisations	
Community sensitisation	
Engaging opinion leaders	
General health care education	
Monitoring and Evaluation	
Develop/adopt appopriate record forms	
Define methods for capturing different indicators	
Intergrate RDTs in the routine HMIS	
Plan for a post-introduction program review	
* May already be in place	
** Sentinel site mciroscopy, possibly positive control wells in future	

Example of RDT implementation timeline in use by a programme. This tool guides the monitoring of the central coordinating group.
Adapted from Uganda NMCP



Example of a planning table in another format, to fit national programme planning requirements.
Adapted from Nigeria NMCP[a]

Draft Gantt chart for RDT implementation in malaria-endemic country																		
						Year	Year 1											
						Quarters	Q1			Q2			Q3			Q4		
SN	**Activities**	**Flag (Red/ Green/Yellow)**	**Status**	**Responsible focal point**	**Stakeholders involved**	**Output**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**
1. Operational Research (OR)																		
1.1	Identification and prioritization of research question for operational research		Yet to be done	Yet to be selected	Case Management Sub-committee/ Working Group/Task Force	Priority list of OR questions												
1.2	Development of research protocols		Yet to be done		NMCP, research institutes	Concept notes & protocols developed												
1.3	Identification of resources for research		Yet to be done		NMCP, research institutes	Resources mobilized and OR commissioned												
1.4	Selection of cohort of pilot facilities and collection of baseline information		Initial selection carried out by NC of some Health Facilities (HFs) to respond to imminent stock of RDTs	Branch head case mgt	Research team, NMCP	List of selected service point involved in studies												
1.5	Limited deployment of RDTs within OR framework		Plan on ground by NMCP and research partners to deploy limited quantities of RDTs to selected HFs	NMCP, research partners, PSM partners	NMCP and research partners	RDTs deployed to selected Service delivery mechanisms												
1.6	Formative research on needs and behaviors with providers		Yet to be done	ACSM (or IEC/BCC) focal point	Partners involved in ACSM (or IEC/BCC)	OR question defined , protocol developed , study contracted out , report of OR findings												
1.7	Formative research/ review of docs on needs/ behaviors of beneficiaries		Some studies on going	ACSM (or IEC/BCC) focal point	Partners involved in ACSM (or IEC/BCC)	OR question defined , protocol developed , study contracted out , report of OR findings												

a. See electronic toolbox for full version.

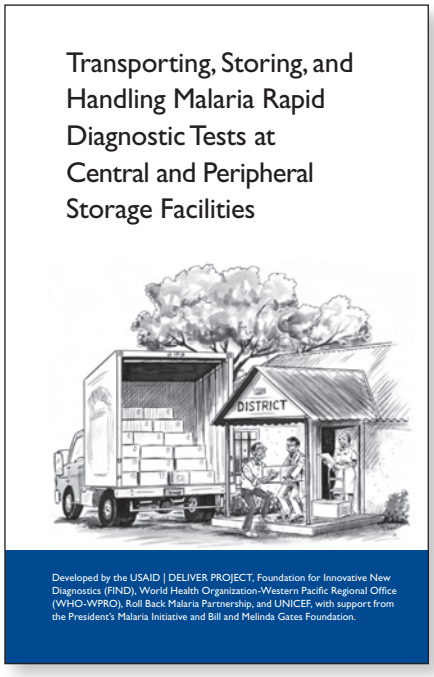
2 Sample Terms of Reference

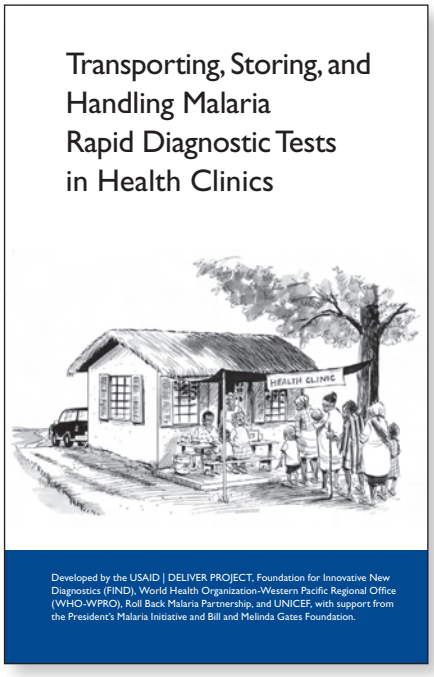
Sample Terms of Reference (TOR) for the National Malaria Diagnostics *Coordinator/Coordinating Group*

OFFICE	MALARIA DIAGNOSTICS IMPLEMENTATION COORDINATOR(S)
REPORTING TO	NATIONAL MALARIA PROGRAM
PRIMARY ROLE	To coordinate the implementation of the parasite based diagnosis of malaria strategy with quality assurance in fever case management
EXPERIENCE, SKILLS AND KNOWLEDGE	**Pool of expertise required** NMP, CSOs, child and maternal health specialists, clinical laboratory representatives, national reference laboratory representatives, researchers, national regulatory authority representatives, regional and district representatives, public policy and programmers, private health sector representatives, Monitoring and evaluation, training and tools development specialists. **Generic competencies** • Malaria control policy and programming competencies • Commitment to the vision of the NMP and Case management work stream in terms of quality assured implementation of the parasite based diagnosis strategy • Effective time management • Integrity and leadership • Self-motivation, zeal and willingness **Salient Capabilities** • Strategic thinking abilities • Embrace and promote change • Motivating and inspiring others • Promoting and fostering teamwork and relationships • Skilled in fostering communication and team work • Good conflict management skills
DUTIES AND RESPONSIBILITIES	**COORDINATION AND PARTNERSHIPS** • Create an inventory of all the malaria case management intervention implementers and other partners working in the sector • Update and maintain the inventory, and report data from it to the NMP and other partners in the sector • Build and maintain internal and external partnerships **PLANNING** • Assist NMP in planning, implementation and conducting program appraisals • Support organizations in the sector to use malaria confirmatory diagnosis data when planning malaria services • Ensure that the NMP and partners use the latest WHO recommendations, planning tools and templates for malaria case management with confirmatory diagnosis. • Prepare budgeted plans for the coordinating meetings and M&E activities **KNOWLEDGE SHARING AND CAPACITY BUILDING** • Facilitate the scale up of the malaria RDT programs of the malaria case management system in the public and private sector, basing on the global and national RDT implementation guidance **QUALITY ASSURANCE** • Support the NMP to establish and perform end user training, diagnostics quality control, supervision and overall quality assurance of relevant variables in malaria case management • Support the NMP to gain access to malaria RDT related information from WHO, donor agencies and other organizations **M & E** • Advocate for a timely and complete data reporting system in the HMIS system • Advocate for a review of the elements of data for malaria case management in the NMP data base, which yield indicators recommended by the WHO • Participate in the development of an electronic repository of malaria data • Support the process for reviewing or formulating the M&E plan of the NMP in relation to malaria diagnostics

3 Guidance on Transport and Storage

Transporting, storing, and handling malaria rapid diagnostic tests at central and peripheral storage facilities and in health clinics





2009

Pocket-guides designed for malaria programme managers, medical stores and transport personnel, and clinic workers on transport and storage of malaria rapid diagnostic tests. The separate guides concentrate on central transport and stage, and remote transport and storage, respectively. Many of the principles are applicable to other perishable medical supplies transported to, and used in, clinics in tropical and sub-tropical areas. The guides are developed jointly by FIND, WHO/WPRO, USAID/Deliver, the RBM Partnership and UNICEF.

Available at the following URLs:
http://www.wpro.who.int/sites/rdt/using_rdts/rdt_transport_storage.htm
http://www.finddiagnostics.org/resource-centre/reports_brochures/rdt_transport_storage.html

or from:

FIND
Avenue de Budé 16
1202 Geneva
Switzerland
Tel: + 41 (22) 710 05 90
Fax: + 41 (22) 710 05 99
info@finddiagnostics.org

4 RDT Deployment Plan (weekly schedule)

Malaria RDT implementation plan at central level

Example of large-scale RDT deployment plan (adapted from Uganda MoH)

Schedule	Activities	Responsible group	Outputs	Expected outcome
Week 1	Dissemination of a funded plan to national task force for RDT implementation	NMCP, Coordinator RDT implementation	Ongoing stakeholders engagement	Targeted number of stakeholders buying-in, with demonstrated willingness to participate
	Defining composition of training team	RDT task force	Accountant (MoH), trainers (NGO & Research/University)	National training teams with administrative and finance management skills as well as clinical and laboratory expertise
	Procuring extra RDT ancillary supplies and training materials not included with RDTs	Development partner	Stationery, RDTs, RDT ancillary for interim use before scheduled central medical store supply	Targeted districts receiving starter kits for RDT implementation immediately after training
	Communicating to District officers and scheduling district training implementation dates and trainee invitations	NMCP	Radio announcements, SMS messaging	Proportion of targeted health workers receiving an invitation for training in time
Week 2	Debriefing and equipping national team of trainers with training plans, accountability plans, vehicles, logistic supplies	Diagnostics implementation task force	Training groups get well equipped with administrative, financial and technical information	Targeted number of stakeholders buy-in, with knowledge of entire spectrum of the training plan
	Central teams meet with district officers to plan district roll-out	District health officer	Decentralizing the RDT program, financial, administrative and technical information to target districts	Targeted district stakeholders buying-in with willingness to supervise, monitor and report on RDT program implementation
Week 3	Sensitization of district and political leaders (1/2 day)	District health team and opinion leaders	Decentralizing the RDT program, financial, administrative and technical information to target districts	Targeted district stakeholders buying-in with willingness to supervise, monitor and report on RDT program implementation
	District ToT selection and subsequent training (3 days)	National trainers and district health officer	Training in parasitological confirmation of malaria, transferring administrative and technical information to target districts	Targeted number of district personnel trained, equipped with skills to plan training, handle and disburse finances for health worker training budgets
Week 4	Training health workers (3 days)	All health workers in target clinics	Skill build in parasitological confirmation of malaria, transport fare refund, duty allowance payment	Targeted number of health workers trained
Week 5	Immediate follow up of trainees (1 day/clinic)	National and district trainers, M&E focal	On the job support to integrate RDTs in routine work, fever case management and HMIS records	Targeted clinics begin RDT use with quality assurance measures
	Report writing and financial accountability by trainers to the MoH	National trainers	Accountability and quality assurance report	Number of reports completed and submitted by the national trainers
	Dissemination of training report to central level RDT task force	RDT task force	Field based experience sharing, report dissemination and endorsement, reports archiving	Number of reports conforming to agreed format and content

5 Trainer's Manual/Guide

Basic components of a trainers' manual/guide for implementing malaria RDTs in fever case management at health facility level
Adapted from Uganda NMCP

1. Recognition and Referral of Patients with Severe Illness
1.1 Symptoms and Signs of Severe Illness
1.2 Appropriate Referral of Patients with Severe Illness
1.3 Pre-Referral Treatments for Patients with Severe Illness

2. How to Evaluate Patients with Fever and Select Patients for RDT Testing
2.1 The Importance of Fever in Selecting a Patient for Diagnostic Testing
2.2 Assessing a Patient with Fever
2.3 Physical Examination of a Patient with Fever

3. Performing and Reading a Malaria RDT
3.1 Description of RDTs – How Do They Work?
3.2 Performing an RDT
3.3 Reading an RDT

4. Safe Handling of Blood and Sharps, Disposal and Waste Management
4.1 Universal Precautions for Safe Handling of Blood
4.2 Disposing of Used RDTs and Other Waste Materials

5. Management of Fever with a Positive RDT
5.1 Meaning of a Positive RDT in a Patient with Fever
5.2 How to Treat a Patient with Fever and a Positive RDT
5.3 Supportive Treatment

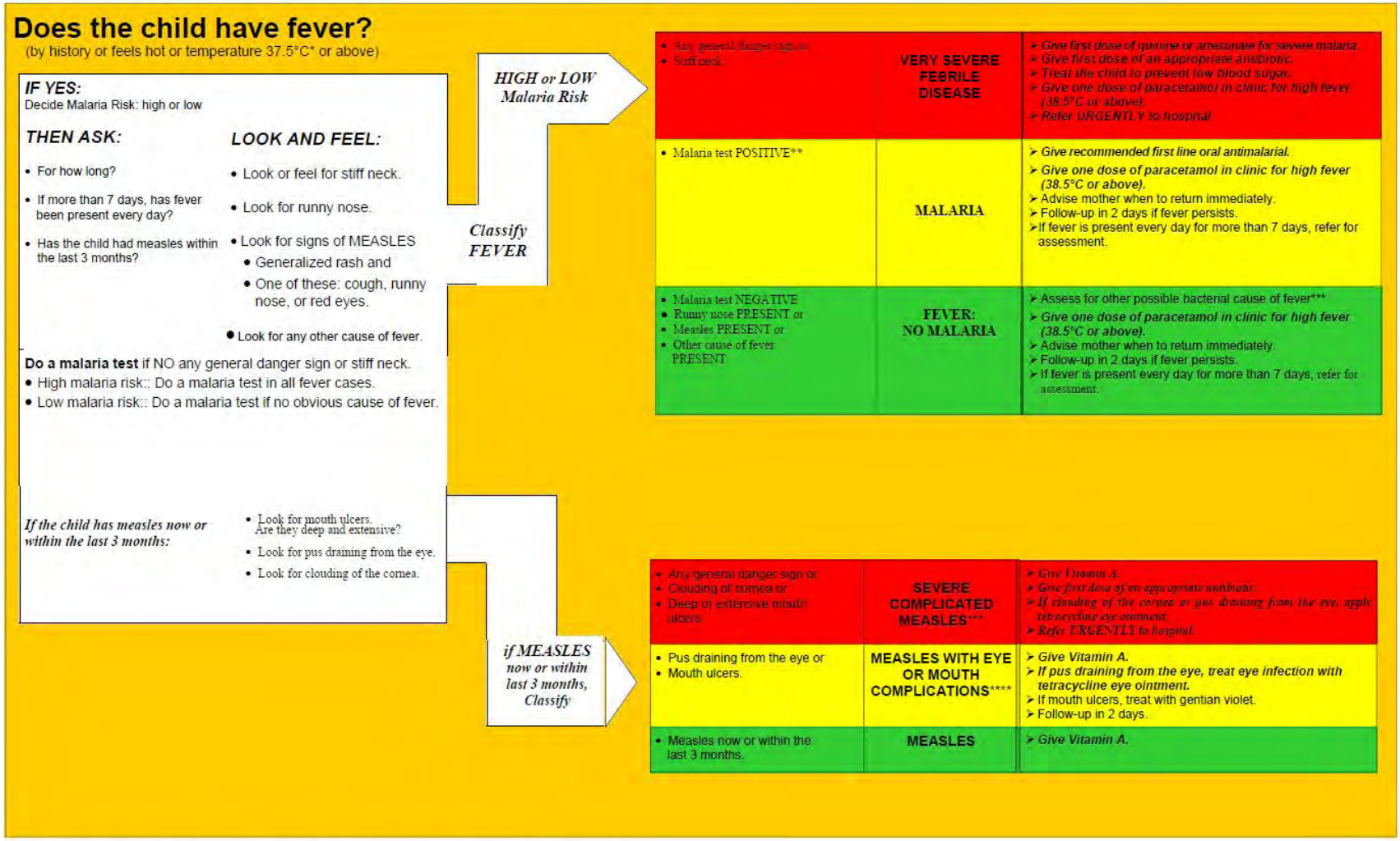
6. Management of a Patient with Fever but a Negative RDT
6.1 Benefits of Correctly Managing Patients with Negative RDT Results
6.2 Management of a Patient with Fever but a Negative RDT
6.3 Management of Common Non-Malarial Febrile Illnesses

7. Patient Education/Counseling
7.1 Good Communication Skills
7.2 Important Messages to Give a Patient or Caregiver on Adherence to Treatment
7.3 Important Messages to Give a Patient or Caregiver on when to Return for Further Care
7.4 Messages to Give to a Patient or Caregiver on Prevention of Malaria

RDT Transport and Storage

6 Fever Management Algorithm

Source: IMCI - Integrated Management of Childhood Illness, WHO Department of Child and Adolescent Health, 2010



* These temperatures are based on axillary temperature. Rectal temperature readings are approximately 0.5°C higher.
** Other ** If no malaria test available classify as malaria
*** Other possible causes of bacterial infection may include urinary tract infection, typhoid, cellulitis and osteomyelitis..
**** Other important complications of measles - pneumonia, stridor, diarrhoea, ear infection, and malnutrition - are classified in other tables.

7 Supervisory Checklist for Clinics Performing Malaria RDTs

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

SUPERVISORY CHECKLISTS

These example checklists include essential areas of malaria RDT use at a small clinic level. They should normally be incorporated into more comprehensive checklists that include evaluation of procedures and conditions related to other laboratory and clinic activities, depending upon the clinic level and function. Individual items and nomenclature should be carefully reviewed and modified to correspond with local usage. All results should be discussed with clinic staff before visit ends.

TASK 1: PERSONNEL AND MANAGEMENT ISSUES

Form 1: Personnel, workplace

1. Health facility / Laboratory			
Region / Province			
District		Name head of laboratory	
Level of health facility*		Contact (telephone/e-mail)	
Name health facility		Hrs of operation HF: weekdays	
Address (P.O. Box)		Hrs of operation lab: weekdays	
Telephone/fax/e-mail		Hrs of operation: **	
Name head of health facility			
Contact (telephone/e-mail)		Date of visit	

Date of visit	
Date of previous visit	
Visit Round number	

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

RDT training of health staff

	Number	Name(s) of course(s) attended, certificate	Who provided the training?	Date, duration in days	Comments
Number of **laboratory** staff / community health workers who attended a formal training (including refresher training) for RDTs in fever case management during the previous 2 calendar years					
Number of **clinical** staff who attended a formal training (including refresher training) for RDTs during the previous 2 calendar years					

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

Quality Assurance in situations where RDTs are cross-checked against microscopy

(Only for laboratories where cross-checking of RDTs against microscopy is routinely undertaken)

				1=yes 0=no	Information recorded 1=yes 0=no	Date of last check / update	Comments
QC of RDTs	RDT results checked against stained slides						
Storing of slides	RDT results checked against stained slides						
	QA assurance book available and up to date						
	Slide storage boxes available						
Microscopy QA	Supervisor should follow national supervisory checklist for malaria microscopy in clinics where microscopy is used						
Cross-checking RDTs against microscopy	**1=yes 0=no**	**RDT brand**	**Procedure**	**Date of last validation**	**Who validates?**	**Feedback?**	**Comments**
Participation of microscopy technicians in EQA schemes?	**1=yes 0=no**	**Name/affiliation of monitors**		**Date of last validation**	**Feedback? 1=yes 0=no**	**When?**	**Comments**

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

TASK 2: WORKPLACE ASSESSMENT

Water and Power Supply

	Item	1=yes 0=no	Comments / problems	Recommended actions?
Water supply	Running tap water			
	Running tap water: Give source of water in comments section (e.g. municipal/city supply, borehole, etc.)			
	Rain water			
	Well			
	Creek / stream / river			
	Other: specify:			
	Which of the water sources is reliable?			
	Which of these sources is not reliable?			
	Other problems with water supply?			
	Item	yes / no	Comments	Recommended actions?
Power supply	Mains			
	Generator			
	Solar			
	Other: specify			
	Functional back-up generator?			
			Comments / problems	Recommended actions?
	Do power cuts interfere with the ability to perform laboratory malaria diagnosis?			
	Number of hours of electricity per day			
	Number of power cuts occurring per day			
	Specify how long they last (duration)			
	Which of the power sources is reliable?			
	Which of the power sources is not reliable?			
	Is there any other problem with power supply?			

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

Laboratory Guides and Standard Operating Procedures

Add/delete according to relevant essential materials provided by health service

Type reference material	Topic	1=available 0=not available	Location	Comments
Standard operating procedures (SOPs)	Use of Rapid Diagnostic Tests (RDTs)			
	External quality assurance for microscopy			
	Biosafety			
Job aids and photographic guides 7 12	Malaria RDTs			
Reference books	Please list the title(s):			
		1=yes 0=no	**Comments**	
Have the reference materials been updated within the last 12 months?				

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

Laboratory equipment, supplies and consumables

Check the ledger book for stockouts of essential supplies lasting ≥ 7 days in a row during the last 3 months and fill in the table below.

Item	Stockout lasting ≥ 7 days in a row? 1=yes 0=No	Comments	Item		Stockout lasting ≥ 7 days in a row? 1=yes 0=No	Comments
Alcohol			RDT Type:			
Lancets			RDT Type:			
Timers			Cotton wool			
Lead/grease pencils, marker pens			Disinfectants			
Gloves			Soap			
Biohazard waste bags			Sharps container			

Was there any stockout ≥ 7 days in a row of any pack size of **ACTs** during the last 3 months? (1=yes 0=no)	
Was there any stockout ≥ 7 days in a row of **RDTs** during the last 3 months (1= yes 0 = no)	
Was there any stockout ≥ 7 days in a row of **ancillary items** during the last 3 months (1= yes 0 = no)	
Was there any stockout ≥ 7 days in a row of **other antimalarials** during the last 3 months? (1=yes 0=no)	
If yes, please indicate which items were missing	

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

General observations

C1a. Did HW use the job aid while preparing the test?	☐	a. Yes	☐	b. No	☐	c. Cannot determine (explain)	
C1b. Is the poster prominently displayed?	☐	a. Yes	☐	b. No			
C1c. Did HW use photographic guide when reading results?	☐	a. Yes	☐	b. No	☐	c. Used to explain result to patient	
C2. How many RDTs has HW performed since he/she had the last supervisory visit?	☐						
C3. What is your source of information for question C2?	☐	a. HW register	☐	b. Used RDTs	☐	c. HW verbal report	☐ d. other (explain)
How many were positive?			How many were under 5 years?				

D1. Mark any critical steps HW failed to perform. Tick as many boxes as apply. (NOTE: the 4 steps below are *critical* because you must stop the HW from continuing if you observe one of them and inform the study coordinator and/or DHMT immediately)

☐ a. Used lancet or pipette on more than one patient ☐ b. Did not treat positive result ☐ c. Unsafe sharps disposal ☐ d. Cannot read RDT results correctly

D2. Describe any feedback or additional training given to HW:
D3. Additional observations and record here if a critical event occurred that required stopping the HW:

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

TASK 3: SUPERVISION CHECKLIST

Observation of RDT preparation and use

Clinic / Site: | **Staff ID:**

Observer (Supervisor)	**Date observed** (Day / Month / Year)	General notes

Was this test done on a real patient? *Circle the correct answer: 1=Yes 2=No*	1 Y	2 N			**Comments**
Was patient febrile? *Circle the correct answer: 1=Yes 2=No 3=Not applicable (if not a real patient)*	1 Y	2 N	3 N/A		
For each step below, circle 1 if the CHW performed the step correctly, circle 2 if the HW performed the step incorrectly, circle 3 if the HW skipped the step, circle 4 if observer missed the step					
1. Assemble new test packet, swab, buffer, pipette, lancet & gloves.	1	2	3	4	
2. Put on new pair of gloves.	1	2	3	4	
3. Check expiry date on package	1	2	3	4	If not clear, ask questions 20 and 21 at end of procedure
4. Check desiccant sachet is still dry (do not include answer in total score)	1	2	3	4	
5. Write patient's name or ID on cassette.	1	2	3	4	
6. Place cassette on a level surface.	1	2	3	4	
7. Clean finger with antiseptic / alcohol.	1	2	3	4	
8. Allow finger to dry before pricking it.	1	2	3	4	
9. **Use a sterile lancet for finger prick**	1	2	3	4	
10. Puncture the side of the ball of the finger	1	2	3	4	
11. Dispose of lancet in sharps bin immediately after pricking finger.	1	2	3	4	
12. Collect blood with the enclosed *pipette* making sure to fill close to the first cross line.	1	2	3	4	
13. Using the *pipette*, blot blood onto the pad in the correct well.	1	2	3	4	
14. Dispose of pipette in sharps container immediately	1	2	3	4	
15. Dispense correct number of drops of clearing buffer into the correct well.	1	2	3	4	
16. Wait correct time before reading *negative* results[a]	1	2	3	4	
17. Read test results correctly.	1	2	3	4	
18. Record results in HW register.	1	2	3	4	
19. Dispose of gloves, wrappers, alcohol swab and desiccant safely (Describe)	1	2	3	4	
Row Total:					

a. Positive results may be read before the specified reading time if control line has also appeared. Results should not be read after the maximum specified time minutes. *(Modify highlighted steps to match the RDT device in use)*

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

Observation of RDT preparation and use *(continued)*

After the procedure is completed, ask the HW the following questions:					
20.	Was the RDT expired?	Y	N	Don't Know	
21.	How do you know? _____ a. Looked at the expiry date on the packet _____ b. Knows the expiry date from the box _____ c. Gives the exact date _____ d. Other (Explain)				

Sample supervision checklist

Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

TASK 4: INTERPRETATION OF AN RDT PANEL

Second part of table to be completed by the health worker according to a panel/photographic plate of RDTs with various results.
Results then to be corrected by supervisor according to a results template, and any incorrect results reviewed immediately with the health worker.

DRAFT **Clinic / Site:** **Staff ID:**

Table 4: Interpretation of an RDT panel

Observer (Supervisor)	**Date observed**			General notes
	Day	Month	Year	

Battery #	**B1**	**B2**	**B3**	**B4**	**B5**	**B6**	**B7**	**B8**	**B9**	**B10**
Test result	*(Write an **"X"** in the appropriate box below each test number to indicate if the HW interprets the test result as "Positive" "Negative" or "Ambiguous")*									
Positive										
Negative										
Unsure										

Health worker to complete with cross in correct box

Correct results: /10

For examples of RDT panels, refer to quizzes in 7 12 and also to the materials found on the WHO/WPRO and FIND websites:
WHO/WPRO: http://www.wpro.who.int/sites/rdt/using_rdts/training/main.htm
FIND: http://www.finddiagnostics.org/programs/malaria/find_activities/improving_rdt_use/training_materials.html

Sample supervision checklist
Adapted from iMAD (Malawi), AMREF – Kenya, PNLP – Senegal, and NMCP – Uganda

TASK 5: LABORATORY DOCUMENTATION AND REPORTING

Laboratory Documentation *(adjust to local/national requirements for M&E and stock management)*	**yes / no**
Registers	
1. Log book/record book located in the laboratory	
2. Patient's name and details recorded and organized in legible manner	
3. Date of test recorded	
4. Species identification recorded	
Forms	
1. Pathology request forms used	
2. Results /reports forms (daily, weekly, monthly, quarterly, yearly) completed correctly	
3. Referral forms used	
Analysis	
The laboratory prepares monthly analysis including at least the number of RDTs performed, positivity rate, percentage of species identified and subsequent management	

Diagnosis-specific Malaria Case Management Indicators

Adapted from new WHO malaria indicators and availability should be checked

1. Indicator — Confirmed malaria case rate

Calculation	**Numerator:** Number of confirmed malaria cases reported by health facilities over a given time (passive detection), by active detection or by community health workers **Denominator:** Mid-year resident population x 1000
Typical definitions of key terms	Malaria reporting should distinguish cases where parasitological tests have been used, from cases based only on symptoms: • *Probable (suspected) malaria*: signs or symptoms of malaria but without parasitological confirmation as no diagnostic test available, requiring antimalarial treatment • *Confirmed malaria*: signs or symptoms of malaria and laboratory confirmation of diagnosis A malaria case should be reported on the basis of clinical presentation, defined as: • *Uncomplicated malaria*: fever or recent history of fever with or without other signs or symptoms of several malaria • *Severe malaria*: requires hospitalization with signs or symptoms of severe malaria Data is also further divided (disaggregated) by age to distinguish childhood case: age: <5 years and all ages ***Health facilities:*** public (government or owned by local administration) or private (non-profit or for-profit organizations) ***Community case:*** reported by community health workers, administrators and other personnel operating at village and community levels ***Reporting completeness:*** percentage of health facilities reporting data within a nationally established time frame out of the total existing facilities expected to report
Purpose	To contribute to measuring trends of morbidity; a proxy of incidence rate in a defined area and during a defined period.
Data collection	

Method	*Tools*	*Level*	*Frequency*
Health management information service: data from community and active case detection should be added to the totals but identified as a separate subset. Absolute numbers for numerator and denominator and reporting completeness must be reported with the rate. Data from active case detection should be reported as a separate sub-set.	Registers from outpatient and inpatient departments; confirmed cases from outpatient registers or laboratory registers; community health forms	District, province, region, country	Annually (at global level)

Interpretation and use	The indicators allow comparisons of malaria burden between areas within country, between countries, and over time. This data supports planning allocation of resources and targeting interventions. The number of malaria cases is influenced by multiple factors, some directly related to intensity of malaria transmission and malaria control, others related to access to health services and completeness of health facility reporting.
References	WHO Expert Committee on Malaria. Twentieth report. Geneva, World Health Organization, 2000 (WHO Technical Report Series, No. 892), pp. 46-47 Guidelines for the treatment of malaria. Geneva, World Health Organization, 2010 *Framework for monitoring progress and evaluating outcomes and impact*. Geneva, World Health Organization/Roll Back Malaria, 2000 (HWO/CDS/RBM/2000.25), pp. 10-13 *World malaria report 2005*. Geneva, Roll Back Malaria/ World Health Organization/UNICEF 2005 (WHO/HTM/MAL/2005.1102), pp. 75-84, Table 13, p. 291

2. Indicator Malaria test positivity rate

<table>
<tr><td>Calculation</td><td colspan="4">Numerator: Number of malaria cases (uncomplicated and severe) with laboratory confirmation (rapid diagnostic test or microscopy), reported by health facilities and by community-level health workers over a given time

Denominator: Total number of suspected malaria cases tested. (Report data from active case detection as a separate subset)</td></tr>
<tr><td>Typical definitions of key terms</td><td colspan="4">Health facilities: public (government or owned by local administration) or private (non-profit or for-profit organizations)

Community case: reported by community health workers, administrators and other personnel operating at village and community levels

Disaggregated analysis by (i) confirmed case and (ii) age: <5 years and all ages

Reporting completeness: percentage of health facilities reporting data within a nationally established time frame out of the total existing facilities expected to report</td></tr>
<tr><td>Purpose</td><td colspan="4">To monitor the impact of programme on malaria transmission.</td></tr>
<tr><td>Data collection</td><td colspan="4"></td></tr>
<tr><td colspan="2">Method

Health management information service: routine or integrated disease surveillance or malaria surveillance. Data from community should be added to the totals but identified as a separate subset.</td><td>Tools

Health facility records, registers and community health forms</td><td>Level

District, province, region, country</td><td>Frequency

Annually (at global level)</td></tr>
<tr><td>Interpretation and use</td><td colspan="4">This proportion indicates true malaria cases resulting from improved quality of services and efficiency. Both programme implementation and health system capacity influence this indicator.</td></tr>
<tr><td>References</td><td colspan="4">Malaria surveillance guidelines, WHO/GMP/SEE draft, 2010.</td></tr>
</table>

9 HMIS Reporting Form

Example of a weekly Health Management Information System reporting form, including for malaria, reformatted for use with SMS messaging
Modified from example developed by Uganda MoH

HEALTH UNIT WEEKLY EPIDEMIOLOGICAL SURVEILLANCE REPORT

Timing: Due in every Monday of the following week.

Objective: Report cases of notifiable diseases, malaria diagnosis and treatment, and malaria commodity stocks.

Copies: Three copies. One stays at the health unit, one is sent to the Health-Sub-District (HSD) Headquarters and the third is sent to the District Health Officer (DHO).

Responsibility: Staff in charge of unit.

Procedures:

1. All health units must report this information to district health office in hard copy.
2. SMS strings should be sent first to ######, in separate 4 strings with space between each number – in format shown in tables: Table 1 with each disease code followed by numbers in Table 1 (e.g. AF 1+0 AB 3+0 RB), Tables 2-4 following lower rows of each (e.g. TEST 78 50 49...)
3. The report should be clearly labeled to show the period covered, i.e. date for the first (Monday) and last day (Sunday) of the week for which the report is being made.
4. For each disease category, indicate the number of new cases during the week (cases this week), the number of deaths that occurred during the week (deaths this week).
5. The health unit reports every week throughout the year, whether or not there are cases. If no cases need to be reported, this should be indicated as "zero" report.

HEALTH UNIT WEEKLY EPIDEMIOLOGICAL SURVEILLANCE FORM

Date of Report: _____ For period (Date):_____ To (Date): _____

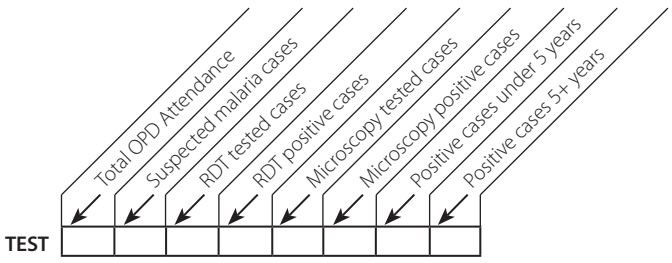
Health Unit: _____ Health Unit Code: _____ Sub-county: _____

HSD: _____ District: _____

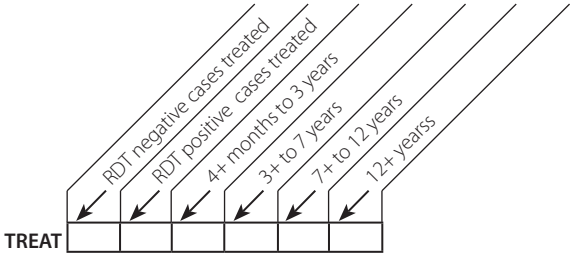
1. DISEASES

	REPORT	Code	Cases this week	+	Deaths this week
1	Acute Flaccid Paralysis	AF		+	
2	Animal Bites	AB		+	
3	Rabies	RB		+	
4	Cholera	CH		+	
5	Dysentery	DY		+	
6	Guinea Worm	GW		+	
7	Malaria	MA		+	
8	Measles	ME		+	
9	Meningitis (Meningococcal)	MG		+	
10	Neonatal Tetanus	NT		+	
11	Plague	PL		+	
12	Yellow Fever	YF		+	
13	Other Viral Hemorrhagic Fevers	VF		+	
14	Other Emerging Infectious Diseases	EI		+	

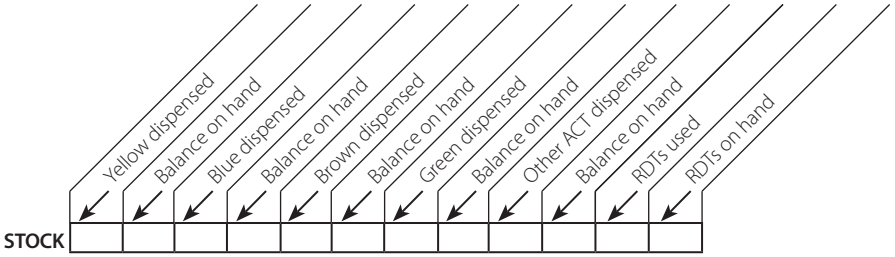
2. CONFIRMATION OF MALARIA CASES



3. SUMMARY OF MALARIA CASES TREATED



4. STOCK DATA



Submitted on (Date): _____ By:_____ Receipt No. _____

10 Integrated Action Plan for Fever Case Management

Example of a coordinated implementation process (Uganda). This is a plan for implementing a malaria RDT training program at the peripheral. It assumes that RDTs are en route or already dispatched up to the district storage centres, awaiting training.
Source: Malaria Diagnostics Task Force work plans for 2009 - National Malaria Control Program, Ministry of Health Uganda

DAY	ACTIVTIES AT NATIONAL LEVEL	ACTIVITIES DISTRICT LEVEL	ACTIVTIES AT TRAINING SITE (Hospital or Health Centre Level IV)	ACTIVITIES AT RDT IMPLEMENTATION LEVEL (Health Facility)
1	1. National Trainer of Trainers debriefing and receiving logistical information 2. Travel to districts/ provinces for training	District coordinator contacts scheduled trainees to confirmation invitations sent out earlier	Preparation to host trainings	In-charges alert health workers and group them for the two training schedules
2	1. National coordinator liaises with training team and district managers to ensure organisation 2. Coordinator liaises with Central Medical Stores to confirm RDT supply	1. Debriefs between national trainers and district health leadership 2. Sensitization and advocacy meeting with non-technical leadership at the peripheral level		
3		Sensitize district leadership (political, administrative and maternal and child health promotion departments)	Representative hospital managers attend sensitization meeting	
4-6		District-based trainings of trainers (2.5 days)		
6.5		1. District coordinator manages training process 2. National and District Trainers work together to plan for downstream training	Trained district trainers travel to training site to deliver RDT training of health workers	First half of the health workers travel to the training sites
7-8			Training of first batch of health workers	
8.5			Trained health workers receive start-up RDTs, job aids and user manuals, travel back to own health facilities	The second half of the health workers travel to the training site
9-10			Training of second batch of health workers	
10.5			District trainers discuss training and administrative plans before closure	
11-13	Reporting back to national coordinator	Immediate follow up to support integration of RDT in routine patient management		Malaria RDT use at health centre begins

11 QA/QC Testing of Malaria RDTs

Establishing a short-term procedure for QA testing of malaria RDTs
Adapted from NMCP, MoH, Uganda

QA/QC - Central purchase of RDT

Tasks (RDT Implementation Coordinator)

1. Review manufacturers QC data *(Action: Regulatory Authority, Central Stores, QA focal nodes record data)*
2. Record:
   - Purchase date
   - Expiry date
   - Lot number
   - Storage records (°C)
3. Send RDT test samples to Reference Lab *(Action: QA focal nodes send 100 tests via District Health Laboratory to central laboratory)*
4. Pre-distribution of external QC results – *(Action: Regulatory, Central Stores or designated QA focal point records lot testing results)*
5. RDT distribution records:
   - Date when RDT sent out
   - To whom
   - No. of kits
   - Transport conditions (°C, Humidity)
6. Keep record for any returned or failed kits; include details. Contact supplier about failures or anomalies.

QA/QC at Health Centre

Tasks (Programme and partners)

1. Pre-training assessment (e.g. staff availability, location, needs) *(Action: situation analysis by QA focal node, NMCP)*
2. Establish a training procedure prior to use of RDT and maintain record of trainees (at national, district levels) and dates of instruction. Use a step acceptance training method (pre & post-tests, concordance test)
   (Action: Adapt training, photographic guide, user manuals and guides, and 12. *Adapt evaluation forms of initial on-site training [this may take place at a central location])*
3. Record training details *(Action: NMCP M&E office)*
4. Record receipt of RDT at health centre:
   - Date
   - Lot number
   - Expiry date
   - Storage conditions
5. Conduct quarterly support supervisory activities (evaluation forms, concordance tests, anomalies and report to health sub-district)
   (Action: NMCP M&E office)
6. Label and retain all cassettes for future possible review by Central Public Health Laboratory
   (Action: Health Centre to keep used cassettes for inspection)

Possible samples available for use in local QC procedure during supervisory visits

Tasks (Supervisors and QA focal nodes)

1. Compare RDTs with blood smear from same patient (random selection) *(Number determined by programme, see Section 2.9.1 of this manual)*
   (Action: Health Centre transfers blood smears to reference laboratory for analysis: invalid cassettes, false negative, false positive tests)
2. Refer blood slides to bigger lab (central QA lab) for blind comparison with RDT. Keep records of all these internal QC results.
   (Clinics transmit QC data upstream with feedback expected)
3. In case of anomalies:
   - Return suspect kits to purchasing centre immediately (through existing support supervision/reporting structures)
   - Receive replacement kit / accessories from a different batch as soon as possible
   - Do not use suspect batch until checked

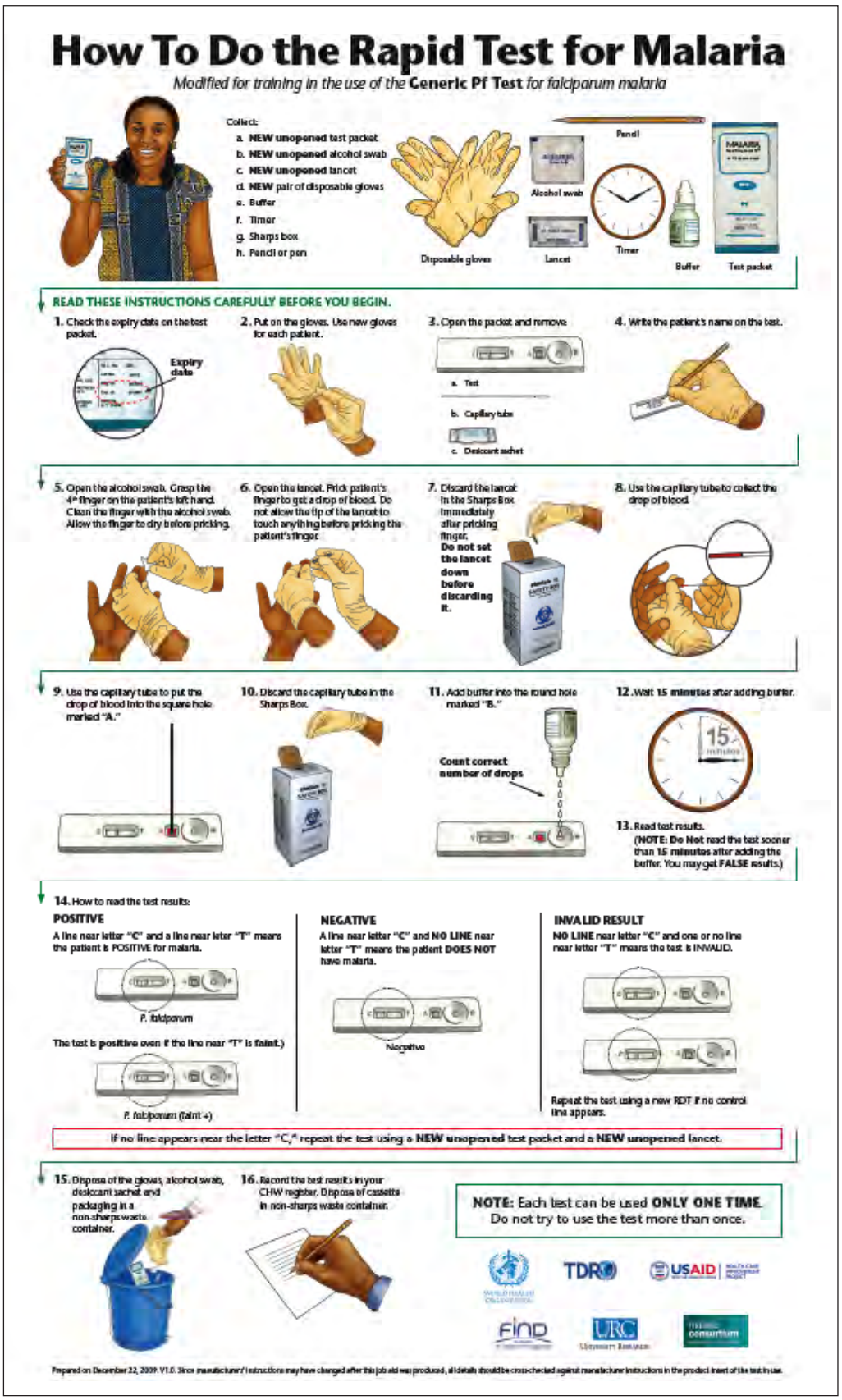
Managing anomalies at purchasing centre

Tasks (QA focal nodes)

- Check batch number and expiry date
- Notify other centres using same batch, withdraw all these through Central Public Health Laboratory
- Inform the supplier as soon as possible
- Receive, re-test and re-distribute fresh replacement batch
- Retest locally before distributing

Sample RDT training materials

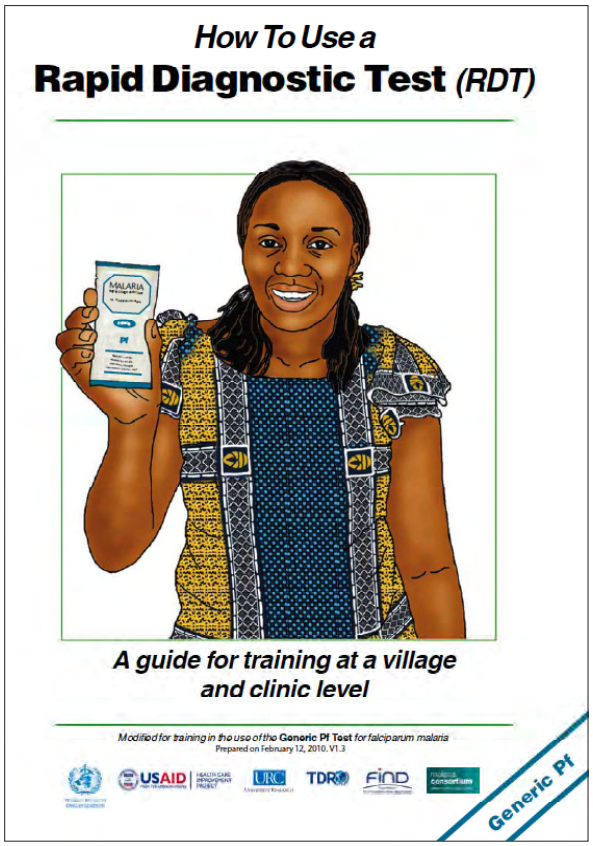
Source: How to use a rapid diagnostic test (RDT): A guide for training at a village and clinic level (Modified for training in the use of the Generic Pf Test for falciparum malaria). 2009.



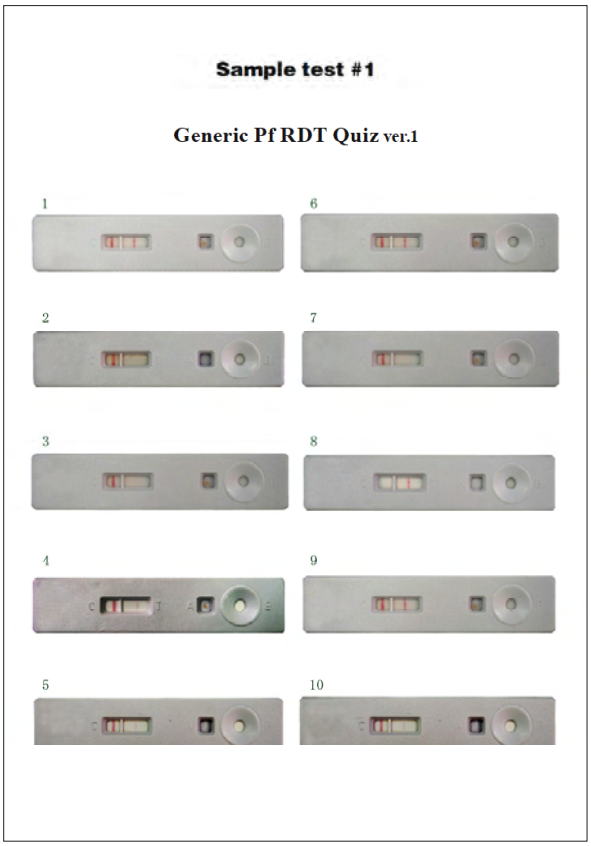
Job Aid

Sample RDT training materials

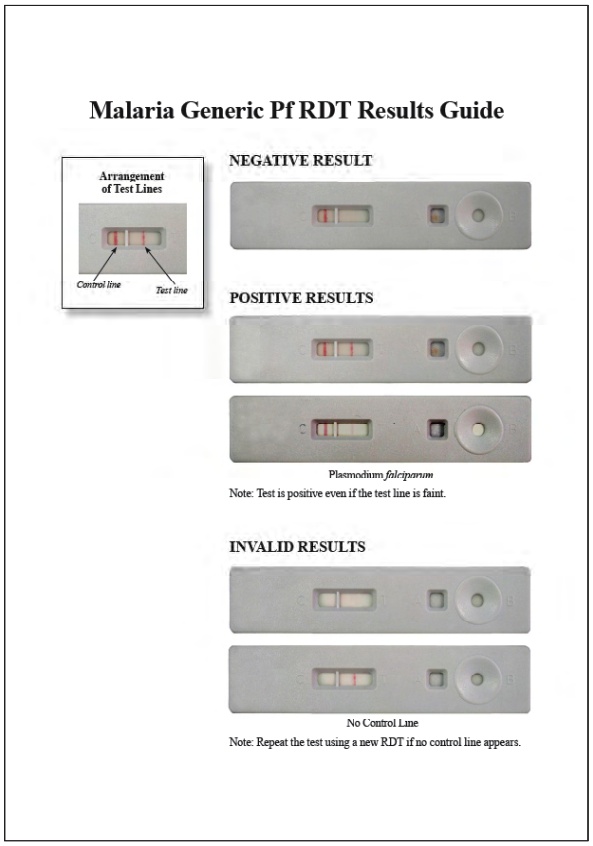
Source: How to use a rapid diagnostic test (RDT): A guide for training at a village and clinic level (Modified for training in the use of the Generic Pf Test for falciparum malaria). 2009.



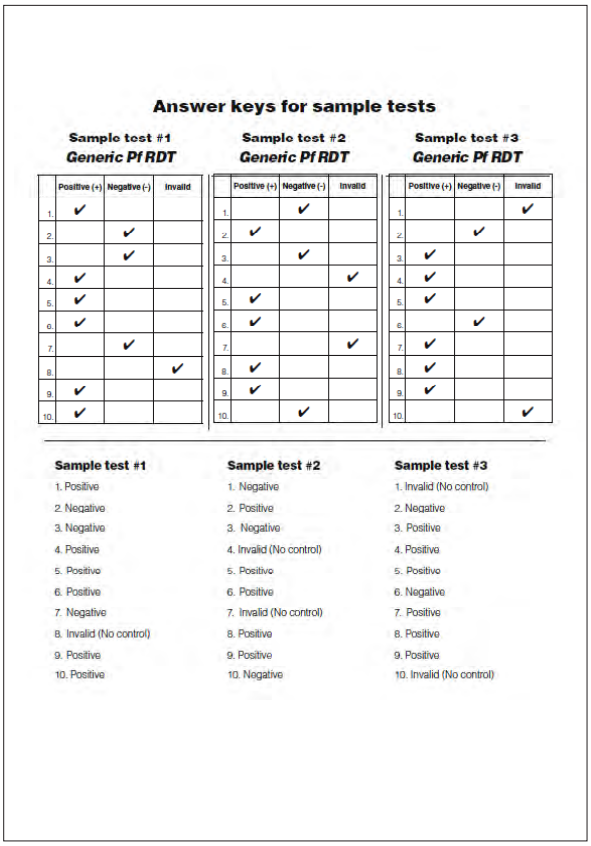
Training Manual



Sample Test



Results Guide



Answer Keys


CDC
USAID
FROM THE AMERICAN PEOPLE
President's Malaria Initiative


FIND
foundation
for innovative new diagnostics


UKaid
from the British people


malaria
consortium
disease control, better health


MCDI


AMREF
Better Health for Africa


ROLL BACK
MALARIA
PARTNERSHIP


KEMRIwellcome trust


PILIPINAS SHELL FOUNDATION