

IMPLEMENTING UNIVERSAL MALARIA DIAGNOSIS IN NATIONAL PROGRAMMES

The 2010 WHO guidelines for the treatment of malaria recommend that “prompt parasitological diagnosis on all patients suspected of malaria should be carried out wherever possible before initiating treatment”¹. This implies a move away from presumptive treatment of all suspected (fever) cases of malaria, that has been the cornerstone of national malaria programmes’ policies for the last twenty years, towards parasitological confirmation. This will mean an increase in the use and a need to strengthen malaria diagnostic services.

This shift in viewpoint has occurred in response to a growing need for more accurate parasitological diagnosis to assure improved patient case management as malaria prevalence declines due to the scaling up of effective prevention and control measures. When confirmatory diagnosis is used and results adhered to, not only will malaria case management be improved as patients with a positive test (malaria) will receive effective antimalarial treatment but for those with a negative test, an alternative diagnosis can be sought and treated appropriately, thereby improving overall health practices.

National programmes are starting to incorporate this recommendation into their national policy documents. The challenge is to transform policy into wide scale implementation; a high coverage and quality assured diagnostic service in parallel to the access and availability of artemisinin combination therapies. Difficulties persist in assuring a quality service due to access and availability issues, lack of resources and guarantee that those seeking and providing services adhere to new guidelines. Therefore, to successfully implement such a service, a systematic and holistic approach to planning, implementation and monitoring and evaluation is required.

The two methods in routine use for parasitological diagnosis are light microscopy and rapid diagnostic tests (RDTs). Their diagnostic accuracy is comparable², if procedures are followed correctly, and the extent of use of either method will depend on local circumstances. Microscopy is the established standard for malaria diagnosis and offers advantages in parasite quantification and species identification, and the ability to assess response to treatment. Generally, microscopy will be used where adequate laboratory facilities, supplies and trained personnel are available. RDTs require less training and institutional support thereby allowing the malaria diagnostic service to expand and decentralize to peripheral health facilities and community health workers where good quality microscopy is impractical or difficult to maintain.

Before an implementation plan can be drawn up, it is important that clear malaria case management policy documents and guidelines are endorsed that clearly define who will be performing the tests, which tests will be performed, when they will be performed, and at which level of the health service. This will depend on availability of resources and systems currently in use which can be determined by a situation analysis of existing malaria laboratory services. Involvement of all stakeholders in this process and in particular, the national laboratory service, will help ensure successful implementation.

Other areas that need to be addressed are the development and implementation of a quality control/quality assurance scheme for both microscopy and RDTs that is operationally feasible in the

¹ WHO Guidelines for the treatment of malaria -- 2nd edition, 2010.

² D’Acremont V, Lengeler C, Mshinda H, Mtasiwa D, Tanner M, et al. (2009) PLoS Med 6(1): e252. doi:10.1371/journal.pmed.0050252

country context. Overly ambitious targets and plans can lead to reduced motivation and commitment, causing the scheme to fail to operate successfully and provide necessary information to continuously improve the diagnostic service.

Implementation plans must also take into account training not only of existing health personnel and laboratory technicians but also of new cadres, to guarantee the availability of sufficient personnel to perform diagnostic services at all levels of the health service, including the private sector. These trainings must have available materials such as manuals, job aids and Standard Operating Procedures and must be reinforced with continuous supportive supervision to monitor the use of diagnostic results in patient management. Health education on the reasons for changes in diagnostic and treatment practices to both the health provider and community members will promote confidence in the system and adherence to test results.

Fundamental to the implementation plan is the logistics management of laboratory supplies including their quantification of needs, procurement, storage and distribution. Without sufficient supplies of quality products, available when required, health providers will return to previous prescribing practices. To provide technical and practical guidance to National Malaria Control Programs and other stakeholders in this area, documents have been produced such as the recent WHO/FIND evaluation of Rapid Diagnostic Tests for malaria³, the *WHO information note on interim selection criteria for procurement of malaria RDT*⁴ and advice on *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests at Central and Peripheral Storage Facilities*⁵. Guidance from these documents represents elements of a quality assurance program for malaria RDTs.

An example of a national implementation plan for malaria diagnostic services is shown below. This provides a step wise guide on what steps are required to implement universal parasitological diagnosis at a country level; scope of reach and timelines will be dependent on the availability of resources. It is expected that this plan will be modified based on the requirements of different country programmes in agreement with implementing partners. Budgeting for all the components of the programme at the outset is vital. The budget must take into consideration all the major line items outlined in the plan. The plan should be reviewed and updated on a yearly basis based on the most recent evidence and information available.

³ <http://apps.who.int/tdr/publications/tdr-research-publications/rdt-performance/pdf/full-report-malaria-RDTs.pdf>

⁴ http://www.who.int/malaria/diagnosis_treatment/diagnosis/infoRDTinterimcriteria.pdf

⁵ World Health Organization-Western Pacific Regional Office (WHO-WPRO), USAID | DELIVER PROJECT, Foundation for Innovative New Diagnostics (FIND), Roll Back Malaria Partnership, President's Malaria Initiative (PMI), and UNICEF. July 2009. *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests at Central and Peripheral Storage Facilities*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3; and Manila: WHO-WPRO