

# Diagnosis Workstream

Update of Progress  
Aug 2010 – July 2011

Case Mgmt Working Group  
Geneva  
July 27 – 28, 2011

## Revised WHO Guidelines on Diagnostic Testing for Malaria, 2010

### Where malaria transmission is low-to-moderate and/or unstable

\*Parasitological confirmation of the diagnosis of malaria is **strongly recommended**. This should be provided by high quality microscopy or, where this is not available, by RDTs.

### In stable high-transmission settings

\*Parasitological confirmation of the diagnosis of malaria provided by high-quality microscopy or, where this is not available, by RDTs is **recommended** for all suspected cases of malaria.



# Diagnosis Workstream Work Plan Update

WG Sub-Activities	Milestones (Date)	Status
1. Assist the Procurement and Supply Chain Management Working Group in the forecasting of country requirements for RDTs	1. Technical assistance provided to PSM WG on technical aspects of RDT Procurement (2nd half 2010)	Draft Manual in Late Stage of Development. Projected completion Sept 2011.
2. Assist the PSM Working Group to develop a global forecast of RDT requirements	1. PSM Working Group assisted to develop a global forecast of RDT requirements	Funding recently identified. TORs under development.
3. Document best practices for scaling up diagnostics to national scale	1. Best practices documented in 1-2 countries (2nd quarter 2011)	No funding currently available.
1. Support the development, finalization, and dissemination of an inter-agency operational manual for program managers on key components of a malaria diagnostics program.	1. Draft operational manual developed (September 2010)	To be published Aug 2011
	2. Finalized manual disseminated through CMWG member networks (1st quarter 2011)	Dissemination to follow publication
2. Support provided to the development of a malaria diagnostics tool kit	1. Existing tools currently in operational use collected (June 2010)	Tools collected.
	2. Tools posted to an easily-accessible website with short descriptions of each tool (November 2010)	Funding identified. TORs to be developed. Target completion 4th quarter 2011.
3. Provide guidance to the Global Fund TRP on appropriate criteria for evaluating diagnostics components of applications for funding	1. Guidance document developed (July 2010)	Guidance provided July 2010. Recently updated.
	2. Document provided to Harmonization Working Group for dissemination to Global Fund TRP members and applicant country NMCPs (July 2010)	Dissemination completed August 2011. Revised version to be shared with WHO to be included in next update for TRP.
4. Develop a position statement promoting adoption by countries of the revised WHO guidelines for diagnosis of malaria	1. Position statement developed and vetted with CMWG (May 2010)	Completed July 2010.
	2. Position statement submitted to RBM Board for ratification (November 2010)	Resolution adopted by the Board Feb 2011.



**DECISION**

RBM/BOM/2010/SUB.1  
3 FEB 2011  
Draft document  
General distribution  
English Only

RBM Board Meeting – Electronic Vote - 10 Feb 2011

**Resolution on scaling-up implementation of the WHO revised recommendations on universal diagnostic testing for malaria**

**19<sup>th</sup> RBM Partnership - Final Version**

**Background**

The regular session of the 19<sup>th</sup> RBM Board meeting considered on 8 December 2010 a resolution on scaling-up implementation of the WHO revised recommendations on universal diagnostic testing for malaria. The RBM Board invited Board members to provide final wording on the Resolution to the Secretariat by mid January 2010. The Secretariat was invited to submit the final resolution text for Board approval by electronic vote as soon as possible.

**Final Version**

The RBM Board welcomes the recommendations laid out in the second edition of the WHO malaria treatment guidelines (2010) that prompt parasitological diagnosis is recommended, either by microscopy or by rapid diagnostic test (RDT), whenever possible before starting treatment with ACT.

Added advantages of systematic confirmation before treatment are that the inappropriate use of malaria treatments can be significantly reduced, thereby limiting drug pressure which may promote the spread of drug resistance and reduce irrational use of ACTs and costs to countries. Reducing inappropriate drug use will diminish the number of people experiencing side effects from these drugs. Confirming cases of malaria also will greatly improve the quality of malaria case reporting, providing countries with more accurate information on malaria burden by which to monitor the success of their control programmes. In addition, use of diagnostic testing for malaria is likely to improve detection and case management of other causes of fever, particularly childhood pneumonia and diarrhoea, and other haemo-parasitological infections, when microscopy is used for diagnosis.



## Operational manual on universal access to diagnostic testing of malaria – Table of contents

### **1. Programme planning and management**

- 1.1 TORs for national coordination group on malaria diagnosis
- 1.2 Situation analysis and gap identification
- 1.3 Roles and responsibilities

### **2. Policies and technical guidelines**

- 2.1 Update relevant national policies
- 2.2 Address regulatory issues
- 2.3 Prepare national guidelines
- 2.4 Prepare an implementation plan

### **3. Procurement and logistics of malaria tests**

- 3.1 Selection of products for malaria diagnosis
- 3.2 Quantification and forecasting of requirements malaria testing
- 3.3 Procurement of supplies for malaria testing
- 3.4 Distribution, transport and storage
- 3.5 Stock management
- 3.6 Maintenance of microscopes and other equipment

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### **4. Components of the quality management system**

- 4.1 Overview of quality management at different levels
- 4.2 Quality management activities at central level
- 4.3 Quality management activities at subnational level
- 4.4 Quality assessment at points of care
- 4.5 Action to be taken in cases of nonconformity with malaria testing
- 4.6 Country scenarios

### **5. Training of health workers and supervisors**

- 5.1 Sensitization
- 5.2 Organization of in-house training at all levels
- 5.3 Integration into pre-service training
- 5.4 Training in integrated management of fever

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

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### **7. Information, education and communication**

- 6.1 Preparing a communication plan
- 6.2 Roles and responsibilities

### **8. Monitoring and evaluating the programme**

- 8.1 Establishing indicators and monitoring
- 8.2 Trouble-shooting, investigation and response

### **9. Expected impact on malaria surveillance**

### **10. Diagnostic strategies in particular settings**

- 10.1 Advanced malaria control and pre-elimination
- 10.2 Areas in which malaria has been eliminated
- 10.3 Non-endemic areas
- 10.4 Endemic-prone areas
- 10.5 Complex emergencies

## Operational manual on universal access to diagnostic testing of malaria – List of Annexes

- Annex 1. Standard operating procedures for the use, care and maintenance of microscopes
- Annex 2. Specification sheet for laboratory equipment
- Annex 3. Maintenance service report for laboratory equipment
- Annex 4. Register for maintenance of laboratory equipment
- Annex 5. Standard operating procedures for storage of rapid diagnostic tests at points of care
- Annex 6. SOPs for management of wastes from malaria diagnostic tests
- Annex 7. Testing for proficiency in reading blood slides against reference slides
- Annex 8. Checklist for supervision of laboratories performing malaria testing
- Annex 9. Checklist for direct observation of laboratory technicians performing malaria microscopy
- Annex 10. Checklist for direct observation of health workers performing RDTs for malaria
- Annex 11. Case scenarios for training in use of rapid diagnostic tests in clinical management
- Annex 12. Checklist for supervision of malaria diagnostic testing in health facilities
- Annex 13. Checklist for supervision of clinical management of febrile children in health facilities

## Summary

- Much of the proposed activities on the work plan have been completed or are nearing completion.
- Funding identified for the tool-kit and the global RDT quantification. TORs to be developed.
- Assessment of best practices and bottlenecks to scaling up on-hold pending identification of funding.
- With multiple new tools now available, focus will have to shift to monitoring country-level implementation to identify and develop appropriate responses to gaps.