Roll Back Malaria Case Management Working Group (CMWG)

WHO, Geneva 8-9 July 2009

Meeting Report

1 Background

The Roll Back Malaria (RBM) Case Management Working Group operated successfully for two years from 2003 to 2004. It played a key role in generating consensus around the push for ACT adoption by countries as first-line treatment. It then, however, ceased to be convened regularly for several reasons.
In 2009 the RBM Partnership Board recognizes emerging challenges in case management and has strongly endorsed the revitalization of the working group to address these issues.

The Case Management Working Group role is to coordinate partners for achieving access to treatment. It creates a valuable forum for technical experts to:

- Discuss key issues in expanding access to effective treatment
- Develop new strategies and methods for scaling up
- Identify and document the best practices from field experience
- Disseminate information and implementation updates
- Identify key scale-up gaps, priorities for action, and if needed organize workstreams to address them

Some critical current areas requiring coherent and concerted action by the Case Management Working Group are:

Progress to scale-up and a strong commitment to meet global targets has created new challenges in case management, including:

- Scaling up malaria diagnosis, including in the context of changing transmission intensities. The CMWG has been asked to address how to strengthen implementation to increase access. Countries need more detailed operational plans.
- Preventing and managing the spread of artemisinin resistance. The RBM Board has requested a strategy paper on this issue.
- Access and delivery systems including quality of services and case reporting
- Quality and safety of drugs and diagnostics

This meeting was convened to discuss and take forward the restarting of the CMWG. The agenda and list of participants are attached in Annexes 1 and 2 respectively.

2 Objectives of the Meeting

The objectives of the meeting were:

1. To identify key bottlenecks and opportunities in implementing case management where coordinated action is needed, including implementation of the strategy for prevention and management of drug resistance and access to, and quality of, diagnostics and medicines

- Identify priority areas for action and modalities including workstreams
- Develop one-year action plan and outline budget

2. To map the actors and activities on treatment access issues globally
3. To review and revise the Terms of Reference and composition (membership, chairs and secretariat) for the Case Management Working Group to submit to the next RBM Board Meeting

3 Objective 1. To identify key bottlenecks and opportunities in implementation where coordinated action is needed

A series of presentations were made on key issues for scaling up access to effective case management, outlining current status and gaps. Discussions followed on the action needed from the partnership. The presentations will be made available for reference on the RBM website.

3.1 Malaria Diagnosis

The goal is to have all treatment based on parasitological diagnosis, but there is still much to do to achieve this goal. The approach should include a complementary microscopy and Rapid Diagnostic Test (RDT) strategy, and needs to address the context of changing transmission intensities and patterns.

The conclusions of a recent meeting organised by the Mérieux Foundation and WHO were that:

- The quality of routine microscopy was as poor in hospitals and health centres as in dispensaries
- Routine RDT implementation minimized over-diagnosis and significantly reduced artemether lumefantrine consumption
- Without appropriate diagnosis the true burden of disease cannot be estimated
- Well-trained clinicians with adequate supportive supervision comply with RDT results and improve on practice
- RDTs should be used as first-line diagnostic tool for malaria in all settings and all health facility levels, including hospitals where the potential for saving lives is the greatest

Some of the operational issues presented in relation to extending use of RDTs were procurement and distribution, training and supervision, QA/QC, monitoring and evaluation and private sector use. The importance of diagnosis in measuring the impact of control was noted. It was suggested that manufacturers should be requested to keep their RDTs standard, as changes to the operating procedures undermine training and learning materials.

Areas identified for CMWG action:

- Help to prioritise implementation approaches
- Consider diagnostics of multiple diseases
- Incentives for using diagnostics in private sector
- Consideration of subsidised RDTs in AMFm. It was proposed this may be after 2010

- Consider role of pharmaceutical companies in encouraging RDT use in the private sector
- Support more attention to user and patient perceptions
- Tracking feasibility of community level RDT use
- Inclusion of diagnosis as an epidemiological tool as well as a case management tool (it was agreed that this topic fits best in this Working Group even if it goes beyond case management, but would engagement in discussions with MERG). It would include use of diagnostic data to track progress, discussions on Active Case Detection, infection versus case detection
- Develop a framework for scaling up diagnosis
- Outline a package of what is needed for good diagnosis to advise the GFATM TRP and other donor mechanisms what to look for (including training, supervision etc)

3.2 Malaria treatment – policy and practice

The goal of malaria case management encompasses early detection and prompt effective treatment to cure the infection and prevent progression to severe disease, proper management of severe disease to prevent death, prevention of drug resistance and reduction of malaria transmission.

Current priority needs were highlighted as:

- Greater support from adoption to implementation of safe and effective ACTs
- Strategic approach to increase parasite based diagnosis and ACT coverage through facilities, home and community management and private sector
- Effective drug supply and management systems at country level
- Improved quality of care and service delivery
- Monitoring performance and progress through strong routine HMIS and sentinel surveillance

WHO has two important forthcoming publications, which will provide a basis for the work of the CMWG. One is the Second Edition of the WHO Guidelines for the Treatment of Malaria, which has three significant changes (recommendation of parasitological diagnosis before treatment for all suspected cases, addition of dihydroartemisinin-piperaquine to the list of recommended ACTs for uncomplicated malaria and addition of rectal artemisinin and RDTs where applicable to community treatment packages). The second is the Case Management Operations Manual to support national malaria control programmes to efficiently and effectively organize malaria case management service delivery at all levels of care. This publication aims to provide basic information for best practices for successful programme management including assessment of capacity, programme planning for service delivery, logistical management for regular supplies, quality control and assurance of services and programme supervision, monitoring and information systems.

Areas identified for CMWG action:

- Use partners' communication capacity to support use of WHO publications (Case Management Operational Manual and Treatment Guidelines
- Provide feedback on the Case Management Operational Manual
- Support development of tools to measure quality of case management to show if there is progress
- Support systems to track drug availability

- Outline a package to guide countries and TRPs on what is acceptable in GFATM proposals and other donor mechanisms.

3.3 Preventing and containing drug resistance

It is recognised that emergence and spread of resistance to currently used antimalarials would be a major threat to the progress of malaria control. It would lead to increased morbidity, mortality and transmission, and would have a serious economic impact. WHO has developed a three part strategy for managing resistance, which includes:
1. Avoiding emergence of drug resistance
2. Monitoring drug efficacy
3. Containing of drug resistance

Support from partners is needed to invest more in monitoring antimalarial drug efficacy. The strategy includes improving access to early and effective treatment, removing the sale and use of monotherapies, supporting surveys on drug quality and supporting transmission reduction.

Following confirmation of artemisinin derivative resistance in Thailand and Cambodia the countries and partners are implementing a containment strategy. The strategy focuses on how to reach mobile and migrant populations, especially new economic migrants, surveillance and information systems, suppression of using monotherapies, private sector issues and understanding patient behaviour. There is strong support for joint action by Thailand and Cambodia.

Areas identified for CMWG action:
- Plan more broadly for policy intervention that can delay or contain resistance
- Consider mass screening and treatment, active case finding, deployment of new drugs where appropriate.
- Consider what to do when there is a choice of drugs – sequential, mosaic etc
- Gain consensus on strategy components
- Outline response scenarios for different regions
- Link actions such as banning monotherapy with operational context – ensuring reliable access to ACTs
- Advocate strongly for more efficacy monitoring
- Make it a requirement in GFATM proposals, but also follow up in performance monitoring
- Facilitate an efficient process to move new drugs and formulations along the development pipeline to prequalification.

3.4 Facility-based Case Management

Effective facility based case management requires:-
- Malaria case management as an integrated service delivery
- Skilled health workers
- Availability of quality assured malaria medicines and supplies
- Quality assured microscopy and RDTs
- Proper recording and reporting

Areas identified for CMWG action:

- Encourage joint work with child health
- Identify cross-cutting operational issues between malaria and Integrated Management of Childhood Illness including resource mobilisation

3.5 Community-based case management

Given that a large proportion of malaria cases (30-70%) are treated outside public health facilities and that a large proportion of childhood deaths occur after no contact with the public system the strategy of providing access to treatment through community agents has gained momentum. Home management of malaria (HMM) is a strategy to enhance access to appropriate and effective malaria treatment in the community or home through early recognition of, and prompt and appropriate response/treatment to malarial illness. More recently, the prospect of more integrated community case management (CCM) of common childhood illnesses has gained support, particularly given the need to have some response for children shown by introduction of RDTs not to have malaria.

Community case management is a delivery approach that should complement health facility delivery approach, and the two should be strengthened in tandem. The extent to which CCM should be viewed as a permanent delivery approach needs careful consideration. Substantial operational research is needed to develop feasible implementation models.

Areas identified for CMWG action:

- Support more consideration of links between public health system and community systems
- Support approaches to increased diagnosis
- Continue and communicate mapping of initiatives on community case management – include research and experiential evidence
- Review scaleability of primary health care approaches (not just malaria)
- Advocate support for multiple models led by countries and assessed for effectiveness taking into account local variability (seasonality, endemicity, economic incentives, RDTs)
- Highlight interim as well as final targets to assess progress

3.6 Case Management in the Private Sector

A number of the issues of delivering malaria treatment through the private sector were illustrated by the situation in Cambodia, where about two thirds of people with febrile illness report seeking treatment in the private sector (CMS 2007). Private providers range from trained medical providers practising at registered clinics to untrained mobile providers selling drugs alongside household products, and there is wide availability of monotherapies and sub-standard/counterfeit drugs.

The public sector is gradually being strengthened with the aim that the population will eventually mainly access affordable effective treatment through the public health facilities. However, the private sector continues to be an important and popular source of antimalarial treatment. Unfortunately, the quality of care is often inadequate with low

rates of diagnosis, low compliance to national guidelines and selling of fake and substandard drugs and artemisinin monotherapies. In addition, cases of malaria seen by the private sector are not reported to the health information system, making malaria surveillance and control very difficult.
It is vital that there is clear national strategy for the use of antimalarials in the private sector in order to maximise access to affordable effective diagnosis and treatment for patients with malaria, whilst limiting poor practice.

The nationally recommended ACT composes only 28% of reported sales in the private sector, even after several years of social marketing, which was hampered by stockouts. Monotherapies are still widely available in the private sector

A public-private mix (PPM) strategy is to be piloted including: mapping private sector providers, training providers on proper case management and reporting, conducting regular supportive supervision and monitoring trips and rewarding providers with good practices. Cambodia has also submitted a proposal for the first phase of AMFm.

The Affordable Medicines Facility for malaria (AMFm) co-finances ACT orders from public and private buyers with 95% paid directly to approved manufacturers. Any nationally registered first-line buyers in both public and private sectors may purchase subsidized ACTs. The co-payment applies to all ACTs that comply with Global Fund Quality Assurance policy. 12 countries have submitted on invitation proposals for phase 1 of the AMFm with expected arrival of drugs in 2010. There is a need for partner support and guidance during the phase 1. There is a RBM Harmonisation Working Group workstream having regular calls on AMFm, and it will be important to clarify the roles of the different RBM partnership working groups in relation to AMFm. The Procurement and Supply Management Working Group also may have a role. There is now an opportunity to target country support at new relevant issues and ideas on how to best do so, including improving coordination across existing partner efforts, are needed. It is important that AMFm operates in a coordinated manner with broader efforts to improve access to effective treatment and partners. Phase 1 of AMFm will be externally evaluated, and further roll out (phase 2) will be contingent on positive result s of this evaluation.

Areas identified for CMWG action:

- Ensure coordination with HWG AMFm workstream
- Training
- Guidance on adherence (packaging, patient information)
- Address issue of diagnosis price
- Promote operational research, for example on trade-offs

3.7 Supply and quality

There are several complex and dynamic issues in supplying quality antimalarials and diagnostics.
Quality Because of their inbuilt chemical instability, the requirement for observing stringent quality manufacturing standards is particularly important for artemisinin and its derivatives, for which manufacturers and national regulatory authorities have limited experience. Differences in product quality selection criteria create opportunities for sub-

standard artemisinin-based antimalarial medicines to access international funds for procurement, and discourage compliance with more stringent quality standards.

A set of harmonised selection criteria has been developed among international agencies for their procurement. These are 1) inclusion in WHO Treatment Guidelines, 2) prequalification (PQ) approved or Stringent Regulatory Authority (SRA)-registered, 3) dossier accepted by PQ or SRA, 4) Good Manufacturing Practice (GMP) compliance after inspection by WHO PQ or SRA.

Price There is considerable variability in price of ACTs and a steady decline in recent years.

Forecasting This has been a major challenge given timelags between adoption and procurement, but is essential given the long lead-time for production of artemisinin-based drugs.

For diagnostics the quantities procured has rapidly increased in recent years, and the number of manufacturers has proliferated. There have been recent developments in international quality assurance systems allowing purchasers to make more informed choices.

Areas identified for CMWG action:

It was considered that most of the issues of supply and quality were covered by the Procurement and Supply Management Working Group.

3.8 Measuring access to diagnosis and treatment

Monitoring and evaluation for case management are relevant both to the CMWG and to the RBM Monitoring and Evaluation Reference Group (MERG), so discussion covered how the two groups would ensure adequate communication and synergy and avoid duplication.

Information needs at global, country and local levels differ, so a range of methods of measurement is needed, including population-based surveys, routine reporting, administrative systems and special studies.

WHO has developed a recommended routine data package for high-burden African countries showing core indicators and data elements, analysis and use of data for decision making. It was noted that routine data are important to minimise stock-outs at health facility level and avoid wasted resources. Routine surveillance can monitor impact and contribute to monitoring drug resistance and fake drugs. While routine data systems are not difficult to establish, there is a need for technical assistance.

A major challenge in tracking progress towards the RBM targets is that the commonly used indicator of “Prompt effective treatment of children <5yrs old with fever or malaria” in population based surveys is difficult to interpret and depends on whether programmes promote diagnosis or not. So a better series of questions including diagnosis is needed.

Areas identified for CMWG action:

- A specific link between RBM-MERG and RBM-CMWG (possibly a small joint "task force") could allow the link between standards of programme advice and standards of programme monitoring. The task force could produce a paper on current and anticipated needs and approaches to measuring malaria diagnosis and treatment for both groups to review.
- Exploring ways to obtain reliable case management reporting data from the private sector and from community agents

3.9 Conclusions

As a result of the discussions on bottlenecks and opportunities the group proposed that the Case Management Working Group would set up four Workstreams for more intensive work in key priority areas. Their modus operandi is discussed in section 5. The proposed themes of these Workstreams are:

1. Scaling up parasitological diagnosis
2. Expanding access to treatment / service delivery
3. Strategic options for managing drug resistance
4. Monitoring and Evaluation of case management

4. Obective 2. To map the actors and activities on treatment access issues globally

During the meeting the participants briefly described their work related to scaling up effective malaria case management and their interest in the Case Management Working Group. Annex 4 summarises this information.

5. Objective 3. To review and revise the Terms of Reference and composition (membership, chairs and secretariat) for the Case Management Working Group

This objective was achieved through a group work session reviewing and updating the original Terms of Reference (TORs) from 2003.

The rationale for updating the TORs was to account for changes in critical issues for scaling up access to effective treatment and changes in the global partnerships in case management. The group identified that the most significant changes since 2003 include:

- The increasing importance and role of diagnosis
- The evolving resistance profile
- Further emphasis on community-based and private sector roles in expanding delivery
- The need to harmonize among the many new partners working in case management. Many initiatives are developing in various countries; it is important to determine how to take advantage of the lessons learned by coordination and integration of best practices.

CMWG will act as an alignment or advisory body for the RBM Partnership on case management. As an alignment group, it will feed recommendations for actions via the Harmonisation Working Group (HWG), which is an implementation group.

The revised TORs are attached as Annex 3. The membership is shown in the TORs. Dr. Kamini Mendis of WHO Global Malaria Programme and Dr. Larry Slutsker of Centers for Disease Control and Prevention, Atlanta USA (CDC) were elected as co-chairs, and the Malaria Consortium was elected as Secretariat.

6. Next Steps

1. Obtain feedback from the RBM Board on reconstitution of the CMWG
2. Participate in RBM two year planning to incorporate workplan of the CMWG
3. Submit a strategy paper on partnership roles in prevention of development and containment of spread of artemisinin resistance
4. Initiate operation of the four workstreams

Meeting of the RBM Case Management Working Group
8-9 July 2009 - Geneva, SWITZERLAND

PROVISIONAL AGENDA

Wednesday, 8 July

08.30 - 09.00	Registration	
09.00 - 09.20	Welcome to participants Opening remarks	*Associate Director, G MP/WHO* *Executive Secretary RBM*
09.20 - 09.30	Introduction of participants	
09.30 - 09.40	Background, objectives and expected outcomes	Chairpersons
09.40 - 09.50	Presentation of meeting agenda	
09.50 - 10.30	Current case management landscape & discussion	*Moderated by Thomas Teuscher*
10.30 - 10.45	***Coffee break***	

Session 1*:Issues pertaining to scaling-up malaria diagnosis and treatment, monitoring and controlling drug resistance, service delivery at facility and community levels, and in the private sector will be discussed with a view to identifying gaps, and priority partnership activities needed. The session will consist of a brief presentation of the state-of-the art implementation and critical challenges and gaps, followed by a directed discussion to agree on partnership action.*

Malaria diagnosis: Operational issues

10.45 - 10.55	Summary of outcomes of the Annecy Diagnostics Forum, June 2009	*Sergio Spinaci*
10.55 - 11.05	Introduction to operational issues	*Mark Perkins/Jane Cunningham*
11.05 - 11.15	Principal Discussant	*Larry Barrat*
11.15 - 11.50	Discussion	

Malaria treatment: Policy and practice

11.50- 12.05	Introduction of issues including the WHO Operational Manual for Case Management	*Peter Olumese*
12.05 - 12.20	Principal Discussants	*George Jagoe & Ricki Orford*
12.20 - 13.30	***Lunch***	
13.30 - 14.00	Discussion on Malaria Treatment	

Drug resistance

14.00 - 14.15	Introduction: Strategy for containment of resistance	*Pascal Ringwald*
14.15 - 14.25	Containment of artemisinin resistance at the Cambodia-Thailand border	*Sylvia Meek*
14.25 - 14.35	WorldWide Antimalarial Resistance Network (WWARN)	*Philippe Guerin*
14.35 - 15.15	Discussion	

Facility-based case management

15.15 - 15.30	Presentation of issues	*Wilson Were*

15.30 - 15.45	Principal discussant	*Soce Fall*
15.45 - 16.15	Discussion	
16.15 - 16.45	***Coffee break***	

Community-based case management

16.45- 17.00	Introduction of issues	*Wilson Were*
17.00 - 17.15	Principal discussant	*James Tibenderana*
17.15 - 17.45	Discussion	
18.00	Welcome Cocktail	
	End of Day 1	*All*

Thursday 9th July

Session 1 continued*: : Priority areas for action identified from the previous days' deliberations will be presented and discussed. Issues pertaining to scaling-up malaria diagnosis and treatment, and service delivery in the private sector will be discussed with a view to identifying gaps, and priority partnership activities needed. The session will consist of a brief presentation of the state-of-the art implementation and critical challenges and gaps, followed by a directed discussion to agree on partnership action.*

09.00 - 09.20	Summary of previous days deliberations and priority areas for case management working group activities	*Malaria Consortium (Rapporteur)*

Case management in the private sector

09.20 - 09.35	An overview of issues	*Duong Socheat*
09.35 - 09.50	Discussant: focus on AMFm	*Allen Manser*
09.50 - 10.15	Discussion	

Supply and quality of antimalarial medicines and diagnostics

10.15 - 10.30	Introduction of issues	*Rima Shretta*
10.30 - 10.50	***Coffee break***	
10.50 - 11.05	WHO Prequalification of medicines	*Lembit Rago*
11.05 - 11.25	Discussion	

Measuring "access to diagnosis and treatment"

11.25 - 11.40	Introduction of issues	*Rick Steketee*
11.40 - 11.55	Discussant: focus on routine country surveillance	*Mac Otten*
11.55 - 12.25	Discussion	
12.25 - 13.30	***Lunch***	

Session 2*. The proceedings of the meeting will be discussed with a view to developing a workplan and budget for the Working Group. The broad outline of the structure and modalities of the Working Group and a workplan and budget for the next year will be agreed on.*

13.30 - 14.30	Discussion on priority activities and budgets	
14.30 - 15.30	Structure and modus operandi of the Working Group	*Moderators: Thomas Teuscher Elodie Genest*
15.30 - 16.30	Plenary session: recommendations, and closure of meeting	*Chairs*

Annex 2. List of Participants

RBM Partner Organization	Names	
Bilaterals & Multilaterals		
CDC	Larry Slutsker	Patrick Kachur
CIDA	Phedra Moon Morris	
GLOBAL FUND/AMFm	Olusoji Adeyi	
TDR	Andrew Kitua	Jane Cunningham
UNITAID	Ambacheew Yohannes	
USAID/PMI	Lawrence Barat	
WHO AFRO	Dr Socé Fall	
WHO HQ CAH (IMCI)	Were Wilson	
WHO HQ GMP	Andrea Bosman	Marc Otten
	Kamini Mendis	Pascal Ringwald
	Peter Olumese	Sergio Spinaci
	Andrei van Zeen	
World Bank	Noel Chisaka	
Endemic countries		
Benin MoH	Yacoubou I. Karimou	
Cambodia National Malaria Center	Duong Socheat	
Vietnam, National Inst. of Malariology, Parasitology & Entomology	Le Xuan Hung	
NGOs, Consortia, Research & Development organizations		
ACT Consortium	David Schellenberg	
INESS	Khatibu	
ACT Watch/PSI	Gunther Baugh	Ricki Orford
DNDi	Graciela Diap	Florence Camus-Bablon
	Jean-René Kiechel	
FIND	Mark Perkins	David Bell
Malaria Consortium	Sylvia Meek	James Tibenderana
MMV	George Jagoe	Penny Grewal
	Ambrose Talisuna	
MSF	Martin de Smet	Jean-Marie Kindermans
Welcome Trust	Dejan Zurovac	
WWARN	Philippe Guerin	
Private Sector		
Novartis	Heiner Grueninger	Rebecca Stevens
Ajanta Pharma	Mani Kuriakose	
RBM Working Groups		
MERG	Rick Steketee	
RBM Secretariat	Thomas Teuscher	Caroline Ndiaye
	Jan Van Erps	

Roll Back Malaria Partnership Secretariat

Malaria Case Management Working Group

Revised Terms of Reference July 2009

I. Background[1]

In accordance with the Operating Framework of the Roll Back Malaria (RBM) Partnership, the malaria Case Management Working Group (CMWG) has been re-established by the Board on ? date of the July meeting, or the Board meeting date to advance the work programmes of partners during Phase II. The Working Group will be supported by the Secretariat to fulfill its terms of reference as noted below. The Working Group will aim at achieving consensus on complex strategic issues concerning scaling up implementation of policies for malaria case management, and on synthesizing and disseminating evidence-based best practice, but not duplicate the essential responsibilities of WHO expert committees and consultations, which are to advise on norms and standards for products and services and their appropriate use. Recommendations to the Board from the Working Group should be useful and adaptable to local situations (bearing in mind inter-country and within country differences in needs and context, and existing local mechanisms for securing such advice). The Working Group is further guided by the overall commitment of the RBM partners to: (i) partnership and capacity building, (ii) harmonization, accountability and transparency in scaling-up actions; and (iii) bridging the gaps between technical and programmatic support needs at country level.

II. Rationale

One of the four essential elements of the RBM strategy is access to prompt and effective treatment for malarial disease. Increasing drug resistance, warranting the use of new treatments, combined with weak health systems has made it difficult to ensure that prompt, effective treatment is available and affordable to those who need it. Scaling up access to effective treatment of malaria cases will be contingent on well coordinated, multi-disciplinary action towards defined objectives, systems, services and products. In September-October 2002, RBM partners met in Geneva to discuss access to treatment issues. This meeting endorsed the formation of a Working or Reference Group and identified some of the questions and issues that such a group should address. Following a period of relative inactivity, the CMWG was re-established in July 2009 at a meeting at which the TORs were revised and updated to be consistent with the new demands and challenges.

III. Role and Functions of the Malaria Case Management Working Group

[1] Ref.: Minutes of the RBM Steering Committee Meetings/Teleconferences, June – December 2002; and the Proposed Operating Framework for the RBM Partnership (Revised Draft of 9 December 2002)

Annex 3

The Malaria Case Management Working Group is mandated by the RBM partnership board to make recommendations on steps needed for scaling up implementation of national and international policies and recommendations in the field of malaria case management. Decisions and recommendations from the Working Group would be ratified by the Board for implementation, which will be coordinated and monitored by the Secretariat.

The CMWG will act as an advisory body for the RBM Partnership on case management. For the purposes of the Working Group, case management is defined broadly to allow consideration of all issues critical to prompt and effective malaria treatment. Such issues include use of diagnostic methods, improving drug provision, ensuring access to affordable quality drugs and quality treatment advice in both the public and private sectors, improving provider and patient use of malaria drugs, mitigating the risks of antimalarial drug resistance, and measuring the impact of implementation scale up on morbidity.

Because 90% of the burden of disease is located in Africa, the priority focus will be Africa; however, due attention will be given to issues from other regions when merited. Although the CMWG will assist the secretariat and partnership in ensuring partner support to countries, country-specific issues are not its primary mandate.

The activities of the CMWG will include, but not be limited to, the following:

1. Examining how effective case management, in accordance with country policies and WHO recommendations, can be most efficiently taken to scale, sustained and adapted for elimination in endemic countries.
2. Developing and maintaining consensus across partners and institutions around strategies for improved effectiveness of key components of case management.
3. Identifying critical strategic questions related to malaria case management and with the partnership secretariat organizing workstreams to address these, drawing on a wider range of expertise than is directly represented in the CMWG.
4. Liaising and coordinating with other relevant Working Groups, institutions, programmes, initiatives, networks and activities, towards RBM objectives to ensure work reflects changing needs.
5. Assisting the RBM partnership to develop an appropriate research agenda and promote research.
6. Identifying necessary expertise and experts to bring in on temporary, ad hoc basis to assist with addressing issues outside of the expertise of the CMWG itself
7. Accelerating flow of information to countries and others in the RBM partnership on developments within other programmes, institutions and initiatives, that may have relevance for RBM and case management, including progress in drug development.
8. Collaborate with other RBM Working Groups whose work is relevant to, or overlaps with case management to deal effectively with cross cutting issues pertinent to case management.
9. Advising the Board on allocation of resources and capacity building needs for achieving the objective of scaling up effective case management
10. Advocating for increased attention to and resources for effective malaria case management
11. Other activities as requested by the RBM Secretariat or Board within the scope of its expertise and functions

IV. Membership

The CMWG will have around 20 members, who will be drawn from endemic countries and relevant partners and institutions and will represent a broad range of disciplines. The RBM Secretariat will invite the members for the first meeting of the working group on the basis of the following criteria:

- balance of relevant disciplines (ex. Medicine, pharmacy, pharmacology, evaluation, health systems, paediatrics, clinical epidemiology, social sciences, economics, public health, programme management, training, communication etc.)
- expertise and experience in the area of malaria case management
- balance of scientific and practical public health experience
- balance of public, private, academic, and nongovernmental agencies
- geographic representation (especially Africa)

The CMWG will include representation from the following RBM partners. The partnership secretariat will communicate with the organizations invited to send representatives to ensure equitable representation of required competencies.

1. National Malaria Control Programme or MCH department from Africa/Asia (3 rotating)
2. National essential drug programme from Africa / drug regulatory board
3. National pharmaceutical regulatory authority from endemic producer country
4. USAID
5. Department for International Development, U.K.
6. Médecins sans Frontières
7. Medicines for Malaria Venture
8. Centers for Disease Control, and Prevention Atlanta, Georgia, USA
9. Malaria Consortium
10. United States Pharmacopoeia
11. Management Sciences for Health
12. UNICEF
13. TDR
14. World Bank and/or African Development Bank
15. Global Fund to fight AIDS, Tuberculosis and Malaria
16. WHO HQ/Global Malaria Program
17. WHO AFRO/CAH (Child and Adolescent health)
18. WHO AFRO/MAL
19. WHO AFRO/DSD (Health systems and essential drugs)
20. WWARN
21. PSI
22. Clinton Foundation
23. Others?

The CMWG may, within reasonable limits and subject to availability of funds, at any of its meetings, in consultation with the partnership secretariat decide to co-opt additional members *ad hoc* or long-term.

V. Structure

A chair and a co-chair will be elected to serve for two years, renewable. A rapporteur will be elected at each meeting. A Secretariat will be appointed.

VI. Working Procedures

1. The CMWG will meet twicea year initially, later less frequently with quarterly teleconferences for Workstreams. The proposed agenda of the first meeting will be prepared by the Partnership Secretariat in consultation with key partners.
2. Decisions of the CMWG are normally taken by consensus at a meeting or a teleconference.
3. If consensus cannot be established on an important issue, that must be reflected in the report.
4. At its meetings, the CMWG can set up sub-groups to deal with specific themes.
5. The CMWG as well as its sub-groups can set up task forces, which must be time-limited and focus on the accomplishment of specific products.
6. All sub-groups and task forces must have a focal point who is a member of the CMWG, but they, especially the task forces, are expected to recruit members from outside the CMWG.
7. Sub-groups and task forces may meet on an ad-hoc basis, but should to the extent possible work by telecommunication, taking into account the need to ensure full participation of all members.
8. Each sub-group must submit a progress report to each CMWG meeting. Between meetings they may produce interim reports; the chair and the co-chair will advise the secretariat on the use of these.
9. To the extent necessary and possible, the secretariat will arrange video and teleconferences for the CMWG, the sub-groups and the task forces.
10. The Working Group Secretariat will be responsible for meeting report preparation and distribution. A “final draft” approved by the chairman must be distributed by email to participants within 20 days after each meeting.
11. Meetings will be organized and financed by the partnership secretariat. To limit expenditures, partners (except endemic country representatives) will be invited to pay for their representatives.

VII. Implementation and Monitoring of CMWG Decisions

The decisions and recommendations of the Working Group are communicated to the RBM partnership board for endorsement. The implementation will be coordinated and monitored by the secretariat.

VIII. Dissolution of Working Group

The relevance of the CMWG and its terms of reference will be reviewed once a year at a meeting of the Working Group.

Presentations by Participating Organisations on their Interest and Experience Relating to the CMWG

WHO Headquarters
WHO sets norms and standards, provides technical guidance globally on all aspects of malaria case management.

WHO AFRO
WHO AFRO organises country support from WHO country offices, manages intercountry teams and regional office.
Supports countries for policy formulation – consensus with partners, policy implementation, pharmacovigilance and country case management reviews.

TDR
TDR fosters research on diseases of poverty with a pivotal role for developing countries. Policy and access are a focus, and it has undertaken a mapping exercise on access, and is planning a meeting on it. It develops operational research capacity in Ministries of Health. It supports implementation in CIDA project countries.

It has a Business Line BL7 on quality assured diagnostics.

World Bank
World Bank is a lender and donor, and provides country support. It works in countries work with the country partnership. It needs to make recommendations to its own board on its role in case management. Pillar 4 of the World Bank Booster programme for malaria is to increase access to ACTs. It has a focus on ACT procurement, and will procure 40-50 million doses in the next 2 years. It also supports RDTs and following ptotocols. It is interested in how to strengthen drug resistance monitoring. The Booster programme focuses on ten countries, including Nigeria and DRC given their huge burdent. World Bank also has a large support programme in India.

UNITAID
UNITAID's role is mainly financing, not implementation nor research, no presence in countries. Countries make proposals to UNITAID for achieving market impact in terms of affordability, availability and price. $210 million budget. Procurement of drugs of known quality

CIDA
The Canadian International Development Agency provides multilateral and bilateral support. It has a 100% focus on community- based delivery. It is supporting new programmes of PSI, Malaria Consortium, SCF, IRC as a catalytic initiative andintegrated packages through CRC and World Vision. It focuses on the poorest quintile, and has a strong M&E programme looking at impact on mortality. It hopes to feed into CMWG.

CDC
CDC undertakes work on optimising diagnosis and optimising client adherence. It participates in several consortia including the ACT Consortium, MIP and INESS. Together with USAID it oversees the US Presidential Malaria Initiative (PMI) in 15 African countries and supports two non African networks. It undertakes applied

research, for example with Malaria Consortium in Asia, MAC in Malawi, Ifakara in Tanzania and in Kenya.

USAID
PMI supports all areas of case management of malaria. Supply chain management is the biggest issue. It also focuses on community based case management. In diagnostics it looks at how to develop sustainable systems to make diagnostics available, including supply chain and quality issues

As well as the 15 PMI countries in Africa and the two non-African networks, USAID supports five other countries in Africa.

Benin
NMCP is responsible for access to ACT in the public sector and in the community with support from GFATM, World Bank and PMI, and for diagnosis and monitoring and evaluation. The challenge is that there are no ACTs in the private sector, so there is artemisinin monotherapy AMT, but the programme hopes AMFm will improve this.

Cambodia
A major focus of the programme is on containment of artemisinin resistance. Case management involved public and private sectors with PSI working on social marketing. Major problems are (1) that there is no GMP factory for artesunate-mefloquine and (2) the presence of counterfeit drugs. The government has issued a ban letter for artemisinin monotherapy (AMT) with initially positive results. The programme is expanding community based diagnosis and treatment with Village Malaria Workers (VMWs) as an alternative to the private sector. Avoidance of supply shortages is key for success of the strategy.

Vietnam NMCP
This is a successful programme with diagnosis and case management at facility and community level. First line treatment drug is artemisinin-piperaquine, and severe cases are referred to health centres. Drugs are free, and the private sector is not allowed to sell antimalarials. Malaria is mostly rural problem.
There is a malaria team in each province and a microscopist at community health centre level 3-4000 population. RDTs are only available from GFATM funds.

Clinton Foundation
Clinton Foundation is particularly engaged in AMFm, but also provides more holistic support on antimalarial drugs, as part of the Harmonisation Working Group. It undertakes operational research and work on safety of drugs, and is looking at how to play a role in the CMWG.

DNDi
DNDi is a Product Development Partnership, and has been responsible for developing the fixed dose combination (FDC) of artesunate-amodiaquine – AsAq, and in Brazil has supported artesunate-mefloquine FDC for implementation in Latin America and Asia. It has als undertaken a recent market and policy assessment in six countries. It has engaged in a significant pharmacovigilance initiative with MMV

FIND
FIND's focus is on diagnostics and developing appropriate products.

KEMRI WT
KEMRI Wellcome Trust undertakes laboratory, clinical and epidemiological research on malaria. It has worked on evaluating the quality of case management and policies into practice. Its main work is in Kenya with some in Uganda and Zambia. It plans to expand to other countries.

Malaria Consortium
Malaria Consortium helps countries in developing and implementing strategic plans for malaria control, policy formulation, health worker training and supervision in case management including severe malaria in the public and private sector. It works on home-based management of fever and integrated community case management and on the shift to parasitological diagnosis. It supports health systems strengthening in several African countries, including supply chain issues, is involved in monitoring and evaluation for case management, and is on several RBM WGs. In Asia it has a focus on monitoring, evaluation, surveillance, operational research and containment of resistance.

MMV
MMV works on public private drug development partnerships. It is involved in the largest pipeline in the history of the world. It has recently launched Coartem dispersible, and has two more products to launch in 2009: one with Sigma Tao and one with Shin Poon. MMV with the Uganda Ministry of Health and partners organized an intervention with subsidized ACTs in the private sector as a precursor to AMFm.

In the future the MMV access team hopes to find partners undertaking innovative work on community treatment and also on pushing diagnostics further down in areas with no health workers. Countries will need to choose among more drug options, so there is a need to work with WHO to present objective evidence to make decisions.

MSF
MSF is engaged in direct patient management in 40 countries, and has provided 1.3 million treatments in 2008. It advocates for a package including ACTs, RDTs and prevention measures. It has also undertaken operational research on access to treatment, efficacy and diagnosis. Its work is mainly in Africa and Asia with malaria control projects in Mali, Chad, Sierra Leone and Myanmar.

PSI, ACTWatch
PSI's interest is ACTs beyond the public sector, and it has distributed more than 20 million ACTs. Projects include Impact with KEMRI in Kenya, ACTWatch with London School of Hygiene & Tropical Medicine (LSHTM) and work with World Bank funds in India. PSI works in 35 countries in Africa, Asia and Haiti. It is on the Harmonisation Working Group. ACTWatch is a Bill & Melinda Gates Foundation funded project to monitor the market for ACTs looking at availability, price and quality of antimalarials in seven countries.

ACT Consortium
The ACT Consortium is a Bill & Melinda Gates Foundation funded project on deployment of ACTs. It is a research consortium led by the London School of Hygiene & Tropical Medicine. There are fourteen separate projects targeting antimalarials and investigating RDTs, health facilities, shops and community case management. It evaluates

approaches to access, includes a standardised approach to safety, studies interactions of anti-retrovirals and ACTs and has research on drug quality.

INESS
INESS is a Bill & Melinda Gates Foundation funded project with eight Demographic and Surveillance Sentinels (DSS) sites in Africa giving a platform to evaluate effectiveness and safety on ACTs. It will strengthen the health management information system (HMIS) to link with DSS data. It will create an opportunity to learn about operational issues of particular drugs before taking them to scale. It will be possible to trace patients with side effects. It will look at factors affecting safety and effectiveness. It will begin with existing ACTs

WWARN
WWARN is a network of scientists developing a central database on antimalarial resistance to include data from research groups and NGOs as well as MOH/WHO. The database will cover clinical efficacy, in vitro, molecular and pharmacokinetic data.

MERG
The RBM Monitoring and Evaluation Reference Group has areas of common interest with the CMWG.

Ajanta Pharma
Ajanta Pharma is a Mumbai-based pharmaceutical company. It works with 13 -17 countries with the private sector, and works with Clinton Foundation. It notes a major bottleneck is that we still do not know what is the basic requirement for ACTs, so cannot forecast raw material needs.

Novartis
Novartis is a Switzerland-based pharmaceutical company, which manufactures and supplies artemether-lumefantrine (AL). It is interested in quality of drugs. It wants to understand its role in the transition to parasitologically based diagnosis. It generates data on safety and efficacy providing phase IV trial support. It has training programmes and training materials, and produces 75 mill AL per year.

Annex 5

Proposed Memers of CMWG Workstreams

Name	Institution
Diagnosis	
MSF	Jean-Marie Kindermans
	Martin de Smet
FIND	David Bell
ACT Consortium	David Schellenberg
Wellcome Trust	Dejan Zurovac
Malaria Consortium	Elizabeth Streat
USAID/PMI	**Lawrence Barat**
CDC	Michelle Chang
CDC	Michael Aidoo
WHO/GMP	Peter Olumese
WHO/GMP	Sergio Spinaci
WHO	Andrea Bosman
Expanding Access to Treatment /Service Delivery	
Malaria Consortium	James Tibenderana
World Bank	Noel Chisaka
CDC	Patrick Kachur
CDC	Peter McElroy
MMV	Penny Grewal
ACT Watch	Ricki Orford
WHO/AFRO	**Soce Fall**
WHO/GMP	Peter Olumese
WHO/CAH	Were Wilson
WHO/AFRO	Jackson Sillah
WHO/AFRO	Josephine Nambooze
WHO/AFRO	Walter Kazadi
Containment of Drug Resistance	
World Bank	Noel Chisaka
WHO/GMP	**Pascal Ringwald**
WWARN	Philippe Guerin
CDC	Patrick Kachur
CDC	Jimee Hwang
Malaria Consortium	Sylvia Meek
LSHTM	Shunmay Yeung
WHO/GMP	Marian Warsame
Monitoring and Evaluation of Case Management	
MMV	Ambrose Talisuna
WHO/TDR	Andrew Kitua
ACT Consortium	David Schellenberg
Wellcome Trust	Dejan Zurovac
INESS	**R. Khatibu**
WHO/GMP	Kamini Mendis
CDC	Steve Yoon
CDC	Larry Slutsker