



THE GLOBAL MALARIA ACTION PLAN

For a malaria-free world

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“ It is imperative that universal coverage of prevention and treatment for the millions of people who suffer and die from malaria is attained. The Global Malaria Action Plan will guide and unify the malaria community in its efforts to provide timely and effective assistance to endemic countries. With sufficient funding and political support, this plan will help us reap dramatic gains against malaria in the coming years. ”

Awa Marie Coll-Seck, Executive Director of the Roll Back Malaria Partnership

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Acronyms and Abbreviations

ACT	Artemisinin-based Combination Therapy
AI	Active Ingredients (refers to the four AI classes of pesticides)
AL	Artemether-Lumefantrine
ANC	Antenatal care
AS	Artesunate
BCC	Behavior Change Communication
CQ	Chloroquine
EPI	Expanded Program for Immunization
GMAP	Global Malaria Action Plan
HWG	Harmonization Working Group
IEC	Information, Education and Communication
IPTp	Intermittent Preventive Treatment in pregnancy
IRS	Indoor Residual Spraying
IVM	Integrated Vector Management
ITN	Insecticide-Treated Nets
LLIN	Long-Lasting Insecticidal Nets
MAWG	Malaria Advocacy Working Group
M&E	Monitoring and Evaluation
MDA	Mass Drug Administration
MDG	Millennium Development Goal
MIP	Malaria In Pregnancy
MEE	Middle East and Eurasia
MERG	Monitoring and Evaluation Reference Group
NGO	Non-Governmental Organization
NMCP	National Malaria Control Program
OR	Operational Research
PAR	Populations at risk of malaria
PSM	Procurement and Supply Chain Management
PQ	Primaquine
R&D	Research and Development
RBM	The Roll Back Malaria Partnership
RDT	Rapid Diagnostic Tests
RTS,S	Most clinically advanced vaccine against <i>P. falciparum</i>
RWG	Resources Working Group
SP	Sulphadoxine-pyrimethamine
SRN	Sub-Regional Networks
SSA	Sub-Saharan Africa
SUFI	Scale-Up For Impact
WHO	World Health Organization
WHOPES	WHO Pesticide Evaluation Scheme
WIN	Scalable Vector Control Working Group

Foreword

Many of us who have spent our lives working for human health and development understand the tremendous challenges that must be overcome to achieve impact at a global level. Yet, we are driven daily by the desire to alleviate the unnecessary suffering caused by preventable disease.

Malaria impacts the lives of 3.3 billion people in 109 countries each year, the majority of which are already among the world's most vulnerable. Current prevention and treatment tools have led to significant progress in malaria control. With rapid scale-up of these interventions and continued investment in malaria programs and research, we are confident that a malaria-free world will be achieved.

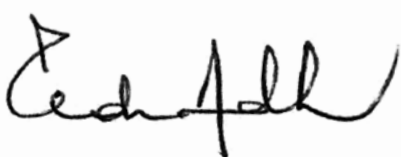
Greater attention, stronger leadership and more resources are being devoted to malaria control and elimination today than at any time in the past forty years. We are at a critical tipping point in the global fight against malaria. If we can bolster ongoing efforts, align leadership, build partnerships and leverage available resources, we can build the momentum needed to eliminate malaria in a number of countries. However, if this momentum is not sustained, progress stalls and funding wanes, our failure comes at the price of millions of lives needlessly lost.

The Global Malaria Action Plan presents a strategy to achieve our shared vision of near zero deaths from malaria and eventual eradication in the long term. A product of collaboration among hundreds of experts, this plan issues an urgent call for action, critical to making our vision a reality.

Every individual and organization reading this report has a vital role to play in building a world free of malaria. No single group is large enough, knowledgeable enough, or powerful enough to achieve such a goal alone. Malaria eradication worldwide will require leadership, management, resources and unwavering commitment at the community, national, regional and global levels. In addition, it demands public, private and civil society partnerships, aggressive research and development, strong health systems, coordination of commodities and services, and the harmonization of global support.

The Global Malaria Action Plan offers a strategic way forward for policy makers, advocates, health workers, donors, researchers and all those rallying against malaria. Working together, many countries have seen a significant reduction in malaria deaths in recent years. Looking ahead, this plan further equips us to tackle ambitious but achievable goals, including cutting malaria cases worldwide in half by 2010 and reaching near zero deaths from malaria by 2015.

With an unwavering commitment to end the scourge of malaria and stop the millions of senseless, preventable deaths from the disease, we challenge those standing alongside us to utilize the guidance and innovation of this comprehensive plan as we work together for a malaria-free world.



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Roll Back Malaria Partnership
Minister of Health, Ethiopia



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Executive Summary

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Introduction

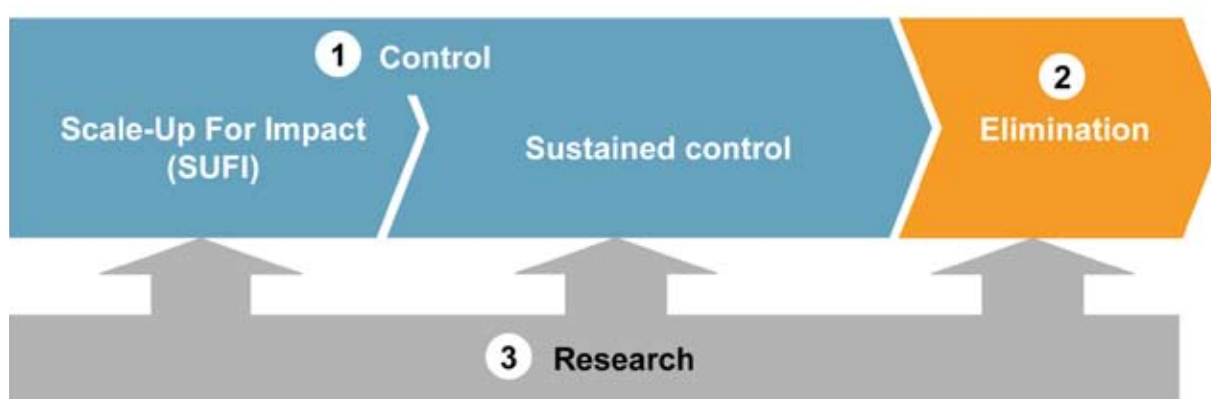
Sustained country leadership and commitment are essential in overcoming malaria. The Roll Back Malaria (RBM) Partnership has developed the Global Malaria Action Plan (GMAP) first and foremost to support countries. The GMAP provides a global framework for action around which partners can coordinate their efforts. Developed through an intensive consultative process, it consolidates the collective input of 30 endemic countries and regions, 65 international institutions and 250 experts from a wide range of fields. The GMAP presents (i) a comprehensive overview of the global malaria landscape, (ii) an evidence-based approach to deliver effective prevention and treatment to all people at risk and (iii) an estimate of the annual funding needs to achieve the goals of the RBM Partnership for 2010, 2015 and beyond. The GMAP is a *living* document: as approaches and tools evolve to fight malaria, so will the plan.

The GMAP outlines the RBM Partnership's vision for a substantial and sustained reduction in the burden of malaria in the near and mid-term, and the eventual global eradication of malaria in the long term, when new tools make eradication possible. To reach this vision, the targets of the GMAP are to:

- **Achieve universal coverage**, as recently called for by the UN Secretary-General, for all populations at risk with locally appropriate interventions for prevention and case management by 2010 and *sustain* universal coverage until local field research suggests that coverage can gradually be targeted to high risk areas and seasons only, without risk of a generalized resurgence;
- **Reduce** global malaria **cases** from 2000 levels by 50% in 2010 and by 75% in 2015;
- **Reduce** global malaria **deaths** from 2000 levels by 50% in 2010 and to near zero preventable deaths in 2015;
- **Eliminate** malaria in 8-10 countries by 2015 and afterwards in all countries in the pre-elimination phase today; and
- In the long term, **eradicate** malaria world-wide by reducing the global incidence to zero through progressive elimination in countries.

To achieve these targets, the GMAP outlines a three-part global strategy: **1) control** malaria to reduce the current burden and sustain control as long as necessary, **2) eliminate** malaria over time country by country and **3) research** new tools and approaches to support global control and elimination efforts. See Figure 1.

Figure 1: Three components of the global strategy



This executive summary highlights the key messages from the GMAP. More detailed information can be found within the full plan.

Part I: Malaria Today

- Malaria is a complex and deadly disease that puts approximately 3.3 billion people at risk in 109 countries and territories around the world. In 2000, there were between 350 and 500 million cases of malaria and at least one million deaths world-wide, most of them in African children.¹ In addition to its health toll, malaria places a heavy economic burden on many endemic countries, contributing to the cycle of poverty and limiting economic development. For example, Africa alone is estimated to lose at least US\$ 12 billion per year in direct losses (e.g. illness, treatment, premature death), and many times more than that in lost economic growth.
- Today, malaria can be prevented, diagnosed and treated with a combination of available tools. The primary tools used for prevention are long-lasting insecticidal nets (LLINs), indoor residual spraying (IRS) in which insecticides are sprayed on the walls of homes, and intermittent preventive treatment for pregnant women (IPTp) to prevent malaria infection in high transmission settings. Other vector control measures (e.g. larviciding and environmental management) are used when appropriate based on scientific evidence. Medicines and diagnostics are used for malaria case management. Malaria can be confirmed by parasitological diagnosis with either microscopy or a rapid diagnostic test (RDT). Artemisinin-based combination therapies (ACTs) are the recommended treatment against *P. falciparum* malaria. Chloroquine (CQ) and primaquine (PQ) are the treatment of choice against chloroquine-sensitive *P. vivax* malaria.
- Following an aborted Global Malaria Eradication campaign in the 1950s - 1970s, malaria received little attention until recently. Over the past decade, there has been substantial progress in raising awareness about malaria. Several countries have demonstrated that it is possible to substantially reduce malaria-related morbidity and mortality. For example, following expanded coverage with LLINs and ACTs, malaria cases and deaths in health facilities in Rwanda declined by more than 50%. Similar results were achieved in Eritrea, Sao Tome and Principe, and Zanzibar (United Republic of Tanzania).
- There is still much to do to achieve the RBM targets and bring the benefits of universal coverage to a wider range of countries. Country level capacity building and health systems strengthening will be critical to ensure countries can deliver the needed interventions to populations at risk. Data from the World Health Organization (WHO) World Malaria Report 2008 shows that many countries are far from meeting the universal coverage targets for key interventions. For example, across 18 African countries in 2006-2007, 34% of households owned an insecticide-treated net (ITN) and 23% of children under five slept under an ITN. In addition, UNICEF data on the number of ITNs produced shows an increase from 30 million ITNs in 2004 to 95 million ITNs in 2007, with further increases expected in 2008. Further, a number of partners and countries have been actively involved in boosting the utilization of indoor residual spraying in recent years.
- The trend in funding for malaria is positive. Unprecedented amounts of money have gone to malaria control since 2004, reaching an estimated US\$ 1.5 billion from all sources combined in 2007. Disbursements from international donors alone increased almost threefold from US\$ 250 million in 2004 to US\$ 700 million in 2007 and are expected to increase to US\$ 1.1 billion in 2008. However, to reach the RBM targets, funding will need to be increased to about four times the total current funding levels.

¹ The World Health Organization released its most recent WHO World Malaria Report 2008 (WMR) in September 2008. The WMR 2008 contains information on burden, policies, coverage and funding for 109 malaria endemic countries and territories. In the report, WHO uses a revised and updated methodology to estimate the incidence of malaria outside the African Region. This results in fewer malaria cases than previously estimated in the Americas, Eastern Mediterranean, Europe, Southeast Asia and Western Pacific regions. RBM Partners, including WHO, are continuing to improve and align estimates of malaria burden worldwide.

Part II: The Global Strategy

Control: Overcoming malaria

- The RBM Partnership's control strategy aims to reduce malaria morbidity and mortality by reaching universal coverage and strengthening health systems. The Global Malaria Action Plan defines two stages of malaria control: 1) *scaling-up for impact (SUFI)* of preventive and therapeutic interventions, and 2) *sustaining control* over time.
- **In scaling-up for impact**, the goal is to rapidly reach universal coverage for all populations at risk with locally appropriate malaria control interventions (i.e. LLINs, IRS, IPTp, drugs and diagnostics), supported by strengthened health systems. Delivery strategies may involve mass campaigns, distribution of interventions through existing public- and private-sector outlets, and by community health workers, for example. Strengthening health systems, including capacity building, for malaria control must begin during scale-up and continue beyond this. To achieve universal coverage by 2010, core malaria control interventions needed are:
 - 730 million LLINs globally (about 350 million for Africa). In Africa, approximately 50 - 100 million nets needed will be distributed in 2008, leaving 250 - 300 million new LLINs that need to be distributed in 2009 and 2010,
 - 172 million households sprayed annually with insecticides,
 - 25 million treatment courses of IPTp for pregnant women in Africa,
 - 1.5 billion diagnostic tests (microscopy or RDTs), and
 - 228 million treatments of ACTs (*P. falciparum*); 19 million doses of CQ and PQ (*P. vivax*).²
- **Sustaining control** is important to prevent the resurgence of malaria. After core interventions are scaled up, the malaria burden will drop and the need for case management is expected to fall dramatically. However, malaria control will not eliminate the mosquito vector, the parasite, or the favorable environmental conditions for transmission in many locations. To keep malaria at bay, countries must maintain high levels of coverage of preventative interventions even in the absence of a large number of cases. Relaxation of control – whether because of the decline in political will, a decrease in funding, or some other reason – increases the risk of resurgence in transmission and of epidemics.
- The goal of sustained control is to *maintain* universal coverage with interventions until countries enter the elimination stage. Sustained control will require strong political commitment at country level and a continued focus on the health systems activities started during scale-up (particularly communication and behavior change efforts and monitoring and evaluation). In addition, maintaining high coverage levels will require effective distribution approaches aimed at strengthening all routine delivery mechanisms and improving integration with other disease programs where appropriate. Strong inter-program collaboration, robust procurement and supply chain management systems and accurate forecasting capabilities are pre-requisites. Increased decentralization of decision-making and budgeting will facilitate strengthened community participation in the delivery of interventions.

Elimination and Eradication: Achieving Zero Transmission

- Elimination is defined as reducing to zero the incidence of locally acquired malaria infection in a specific geographic area as a result of deliberate efforts, with continued measures in place to prevent re-establishment of transmission. More than twenty lower burden countries around the world are already poised to eliminate malaria within their borders.

² Because *P. vivax* malaria is expected to respond more slowly to control efforts than *P. falciparum* malaria and the number of *P. vivax* cases may even increase with a decrease in *P. falciparum* cases, the quantities of CQ and PQ required may increase over time. However, it is also possible that more cases due to *P. vivax* will need to be treated with ACTs owing to increased resistance against CQ.

- The RBM Partnership promotes elimination efforts in countries where feasible, which will vary based on factors such as epidemiological feasibility, transmission intensity, country commitment and proximity to natural borders of the disease. The expert consensus is that elimination of malaria will require new control tools in traditionally high-transmission areas. Key components of elimination programs include cross-border initiatives, strong surveillance and case detection, significant and predictable government financial and political commitment, and communication and advocacy to prevent elimination fatigue. Many of these factors are also required during the scale-up phase. The RBM Partnership encourages international support of these elimination programs, as they will generate much-needed evidence to inform future efforts.
- Eradication is the permanent reduction to zero of the global incidence of infection caused by *Plasmodia* as a result of deliberate efforts, so that intervention measures are no longer needed. Eradication is a long-term goal. It can be achieved by eliminating malaria country by country as new approaches and tools expand the geographical range of where elimination is possible.

The Malaria Research Agenda

- Three types of research support effective malaria control and elimination: 1) research and development for new tools, 2) research to inform policy and 3) operational and implementation research.
- **Research and development** is needed to create new or improved anti-malarial interventions including drugs, vector control tools, diagnostics, and vaccines. For *control*, tools for both *P. falciparum* and *P. vivax* malaria are needed that increase operational ease of use and compliance, minimize the risk of emergence of drug-resistant malaria (especially artemisinin-resistant malaria) and insecticide-resistant mosquitoes, reach underserved populations, are less expensive and provide consistently accurate diagnosis. For *elimination*, tools are needed that support interruption of transmission and target asymptomatic carriers. To further define the research and development agenda for elimination, formal consultative processes are being established.
- **Research to inform policy decisions** will define the type of interventions and programs best suited for different contexts. For *control*, research is needed on parasitological diagnosis of children under 5 in high transmission settings, on the optimal use of LLINs and IRS (singly or combined), on the use of intermittent preventive treatment in infants and children (IPTi and IPTc) and on when preventative intervention coverage levels can be reduced. For *elimination*, research can help identify areas that would benefit most from a public health or economic standpoint, and the surveillance, prevention and case management tools that would be most suitable for those areas.
- **Operational and implementation research** is needed to understand the use and effectiveness of interventions in the field and improve the delivery and quality of prevention and treatment interventions. For *control*, health systems research is needed to improve delivery of interventions; behavioral research is needed to improve uptake, use and compliance; and research on new monitoring and evaluation technologies is needed to improve data for program management. To support *elimination*, operational research is needed, among others, on interventions to protect against the reintroduction of malaria across international borders and by transient populations, and on indicators and program approaches to guide the gradual withdrawal of universal coverage in formerly high transmission settings in favor of interventions that are targeted at high risk areas and seasons only.

Costs of Investment in Malaria Control, Elimination and Research

- To achieve the coverage targets for 2010, almost four times the funds currently available are needed. Increased funding by malaria-endemic countries themselves is critical, but international donors will also be called upon to fill the large resource gaps.
- The estimated needs, based on the costs of prevention, treatment and program strengthening in 109 malarious countries and territories over the next several years, are:
 - Approximately US\$ 5.3 billion and US\$ 6.2 billion in 2009 and 2010, respectively
 - From 2011-20, an average of US\$ 5.1 billion annually
 - From 2021-2030, an average of US\$ 3.3 billion annually
 - From 2031-2040, an average of US\$ 1.5 billion annually
 - Asia and Africa account for the majority of the costs (approximately US\$ 2.7 billion in Africa and US\$ 3.0 billion in Asia-Pacific in 2010)
- R&D investment is critical to ensure that the interventions to meet control and elimination objectives are developed. Through 2018, about \$750-900 million per year should be spent for new malaria control tools – vector control, drugs, vaccines and diagnostic technologies. See Table 1 for a summary of all costs.

Table 1: Summary of annual global costs

Cost (US\$ millions)	2009	2010	2015	2020	2025
Prevention cost	3,728	3,982	3,724	3,864	2,576
Case management cost	968	1,359	550	226	87
Program cost	638	839	764	787	714
Global control and elimination costs	5,335	6,180	5,037	4,877	3,378
Research & Development cost	759	759	800	681	460
Total Cost	6,094	6,939	5,837	5,559	3,838

Note: Detailed cost estimates are included in Part II - Chapter 5: Costs and Benefits of Investing in Malaria Control, Elimination and Research, Appendix 4 and Appendix 5.

Source: GMAP costing model.

Part III: Regional Strategies

- There are considerable differences between regions. Regions differ in the size of the populations at risk, the disease burden in terms of deaths and cases, the relative mix of malaria and vector species, the control strategies and interventions used and the level of funding available to fight the disease. Therefore, the global strategy includes regional strategies for Africa, Asia-Pacific, the Americas, and the Middle East and Eurasia. Following national and regional consultations, the plan outlines the epidemiology, burden and approach to combating malaria in each region, and then explores regional priorities, challenges and funding requirements.
- The highest number of malaria cases and deaths and the greatest challenge for control is in 30 countries in Africa and 5 countries in Asia-Pacific. These countries account for the bulk of the deaths and cases and the greatest economic burden from malaria. They also represent the leading priority for partner support to achieve universal coverage through scale-up, and will require the largest investment of financial and human resources. Emphasis is placed on supporting these countries as well as countries that have regional significance for malaria control and elimination efforts. In addition, the GMAP emphasizes that all malaria-endemic countries ultimately will be of importance in achieving the goal of global eradication.

Part IV: The Role of the RBM Partnership

The **Roll Back Malaria Partnership**, through its various mechanisms (e.g. Working Groups, Sub Regional Networks, Secretariat) and in collaboration with specific Partners, provides assistance at all levels, concentrating on areas with the greatest need and on tasks that benefit the most from collaboration and cooperation. These tasks, which complement and complete the plan, involve:

- Advocacy,
- Resource mobilization,
- Policy and regulatory support,
- In-country planning,
- Financing,
- Procurement and supply chain management,
- Communication and behavior change methodologies,
- Monitoring and evaluation, and
- Preparation and support for humanitarian crises.

RBM Partnership Working Groups already cover many of these topics. The Partnership intends to further expand its activities in the coming years to be ever more responsive to the needs of endemic countries and to reach its targets. In the near term, areas to be expanded include greater support for resource mobilization, assistance with communication and behavior change methodologies, and support for countries facing humanitarian crises (e.g. conflicts, natural disasters). In all areas, the Partnership will strengthen its links with regions outside of Africa. Ties will also be strengthened with research institutions to develop new tools, to inform policies and to improve implementation. These steps will enable the RBM Partnership to more effectively coordinate efforts to implement this plan.

The Bottom Line

The costs of fighting malaria are significant, but the benefits are far greater and the risks of inaction too large to ignore (e.g. lives lost, economic development stymied, resistance emerging).

- *Malaria control saves lives today and prevents deaths tomorrow.* Up to an estimated 4.2 million lives will be saved by 2015 in the 20 highest burden countries in Africa alone if the plan is put into effect.

- *Malaria control is highly cost effective, especially when compared to interventions for other diseases.* At a cost of \$2-24 per disability-adjusted life year (DALY) saved, the only intervention that is more cost effective is childhood immunization.
- *Research investment in new and improved interventions will improve malaria control, increase the cost-effectiveness of interventions and support efforts to eliminate malaria.* Estimates show, for instance, that developing preventative interventions (LLINs, IRS, etc) that achieve greater field effectiveness could decrease the costs for interventions by approximately US\$ 100 million per year.
- *A lower malaria burden yields positive economic benefits and can reduce poverty.* Malaria affects some of the poorest, most marginalized populations in the world. Minimizing the malaria burden means more people at work, more children at school and a break in the cycle of poverty.

“ I believe that if you show people a problem, and then you show them the solution, they will be moved to act. The Global Malaria Action Plan lays out an achievable blueprint for fighting malaria - now it's time for the world to take action. ”

Bill Gates, Co-Chair, Bill & Melinda Gates Foundation

In 2000, an estimated 350-500 million episodes of malaria led to the deaths of 1 million people, mostly children. Today, half of the world's population or 3.3 billion people are at risk of malaria.



PART I Malaria Today

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1. Introduction to the Global Malaria Action Plan

The Global Malaria Action Plan (GMAP) has been created by the Roll Back Malaria (RBM) Partnership, the global coordinating body for fighting malaria. The RBM Partnership comprises all malaria-endemic countries, bilateral and multilateral development partners, the private sector, nongovernmental organizations, community-based organizations, foundations, and research and academic institutions involved in malaria control as well as the RBM Secretariat, Working Groups, and Sub-Regional Networks.

The RBM Board recommended that a Global Malaria Action Plan be developed through an in-depth consultative process. Accordingly, the RBM Partnership developed the plan with the involvement of over 250 individuals from endemic countries, global partner organizations, and experts from a diverse set of fields ranging from economics to malaria control to epidemiology. The input and advice of these contributors have been invaluable in the creation and revision of the plan. A list of all contributors can be found in *Appendix 1*.

The purpose of the Global Malaria Action Plan is to foster agreement among all partners around the goals, strategy, and activities that the RBM Partnership will pursue, and to clearly lay out those goals, strategies, and activities. The plan will maximize the impact of the malaria community's work by guiding the prioritization of resources and by strengthening the alignment across and effectiveness of various initiatives. The GMAP may influence the activities of partners and countries by supporting the definition of normative policy, the creation of country plans, and the development of implementation plans of individual partners. However, those activities remain the responsibility of countries and partners.

Many areas of ongoing work are represented in this plan. As they evolve, they will further influence the way that the RBM Partnership addresses malaria. Therefore, this action plan is a living document: it will be updated with new information and will incorporate newly identified needs on an ongoing basis through the RBM website and through periodic revisions.

The plan is split into four parts.

- *Part I: Malaria Today* briefly describes the vision and targets of the RBM Partnership, the current global burden and the current funding.
- *Part II: The Global Strategy* articulates the near-term, mid-term and long-term strategy to overcome malaria. This section focuses on what needs to be done globally, and is intended to provide a global vision beyond what the RBM Partnership alone can do. This section also estimates the costs and benefits of the global strategy.
- *Part III: Regional Strategies* explores what the global strategy means for Africa, Asia-Pacific, the Americas, and the Middle East and Eurasia. It provides a short overview of malaria and malaria control in each region, and then outlines what it would take for each region to achieve the targets.
- *Part IV: The Role of the RBM Partnership* highlights what the RBM Partnership will do to achieve its targets.

2. The RBM Partnership's Vision and Targets

Our vision and targets are aspirational. They serve both as a call to action and as a challenge to all partners to work together to achieve them. They are intended for the world as a whole, acknowledging that there will be variation across countries in terms of feasibility. Some countries have already achieved the 2010 and even the 2015 targets. Other countries will be challenged to meet even the 2010 targets by 2015.

Our Vision

Our vision is of a world free from the burden of malaria.

By 2015, the malaria-specific Millennium Development Goal (MDG) is achieved, and malaria is no longer a major cause of mortality and no longer a barrier to social and economic development and growth anywhere in the world.

Beyond 2015, all countries and partners sustain their political and financial commitment to malaria control efforts. The burden of malaria never rises above the 2015 level, ensuring that malaria does not re-emerge as a global threat.

In the long term, global malaria eradication is achieved. There is no malaria infection in any country. Malaria control efforts can be stopped.

Our Targets

The RBM Partnership reaffirms the targets articulated in its *Global Strategic Plan 2005-2015*.

- By 2010, through targeting universal coverage:
 - 80% of people at risk from malaria are using locally appropriate¹ vector control methods such as long-lasting insecticidal nets (LLINs), indoor residual spraying (IRS) and, in some settings, other environmental and biological measures;
 - 80% of malaria patients are diagnosed and treated with effective anti-malarial treatments;
 - in areas of high transmission, 100% of pregnant women receive intermittent preventive treatment (IPTp); and
 - the global malaria burden is reduced by 50% from 2000 levels: to less than 175-250 million cases² and 500,000 deaths³ annually from malaria.

¹ Locally appropriate vector control should be based on scientific evidence whenever possible.

² Korenromp E. *Malaria incidence estimates at country level for the year 2004 - Proposed estimates and draft report*. Geneva, Roll Back Malaria, 2005. Estimates are in line with the range calculated by Breman JG et al. *Conquering Malaria*. In: Jamison DT, Breman JG et al, eds. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006. p 415 for 2002.

³ Year 2000 estimate of 1 million deaths globally extrapolated from 804,000 deaths in Africa estimated in Rowe AK et al. The burden of malaria mortality among African children in the year 2000. *International Journal of Epidemiology*, 2006, 35:691-704. This is aligned with estimates with Breman JG et al. *Conquering Malaria*. In: Jamison DT, Breman JG et al, eds. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006. p 415.

- By 2015:
 - universal coverage continues with effective interventions;
 - global and national mortality is near zero for all preventable deaths⁴;
 - global incidence is reduced by 75% from 2000 levels: to less than 85-125 million cases per year;
 - the malaria-related Millennium Development Goal is achieved: halting and beginning to reverse the incidence of malaria by 2015; and
 - at least 8-10 countries currently in the elimination stage will have achieved zero incidence of locally transmitted infection.

- Beyond 2015:
 - global and national mortality stays near zero for all preventable deaths;
 - universal coverage (which translates to ~80% utilization) is maintained for all populations at risk until local field research suggests that coverage can gradually be targeted to high risk areas and seasons only, without risk of a generalized resurgence; and
 - countries currently in the pre-elimination stage will achieve elimination.

In the long term, malaria will be eradicated worldwide. Today, no timeline has been set for achieving this target. As new tools and approaches are developed, the RBM Partnership will review its targets and determine when it will be possible to specify timelines for worldwide elimination and eradication.

⁴ Preventable death is defined as deaths from malaria that can be prevented with rapid treatment with effective medication. Non-preventable deaths represent an extremely low mortality rate for the most severe malaria cases and occur even with the best available and most rapid treatment. There is no precise guideline for near zero preventable deaths but it would be roughly <10 malaria deaths in small countries with a population of less than 10 million and <100 in countries with a population of 10-30 million people. Current estimates mortality estimates indicate that a substantial reduction in deaths is possible with even the existing field efficacy rates. With scaled-up communication and behavior change programs to enhance the field efficacy further, near zero deaths are possible. See *Part II - Chapter 5* and *Appendix 4* for more information.

3. Global Burden and Coverage Today

Key messages

- Malaria is a complex and deadly disease
 - Malaria impacts 109 countries and territories around the world, caused by four species of parasites and transmitted by multiple mosquito vectors
 - In 2000, there were an estimated 350 to 500 million cases of malaria and more than one million deaths, most of them occurring in Africa and Asia-Pacific
- Following the aborted Global Malaria Eradication campaign in the 1950s - 1970s, malaria received little international attention until recently
- Over the past decade, there has been substantial progress in raising awareness and increasing the production, adoption and distribution of existing, effective interventions
- However, there is still much to do to achieve the RBM targets of universal coverage
 - Existing data shows that coverage for all interventions is low in most countries, although there have been substantial gains in LLIN distribution in Africa
 - In particular, case management with diagnostics and treatments need to be significantly strengthened in Africa, the highest burden region

In 2000, malaria caused 350 to 500 million clinical episodes annually⁵ and resulted in over one million deaths,⁶ most of which affect children under 5 years old in sub-Saharan Africa.⁷ Malaria is the fifth cause of death from infectious diseases worldwide (after respiratory infections, HIV/AIDS, diarrhoeal diseases, and tuberculosis) and the second in Africa, after HIV/AIDS.⁸ Recent estimates show that as many as 3.3 billion people live in areas at risk of malaria in 109 countries or territories.⁹ In addition to its health toll, malaria puts a heavy economic burden on endemic countries and contributes to the cycle of poverty people face in many countries. For example, it is estimated to have in Africa alone contemporaneous costs of at least US\$12 billion per year in direct losses (e.g. illness, treatment, premature death), but many times more than that in lost economic growth.^{10,11}

⁵ Korenromp E. *Malaria incidence estimates at country level for the year 2004 - Proposed estimates and draft report*. Geneva, Roll Back Malaria, 2005. Estimates are in line with the range calculated by Breman JG et al. *Conquering Malaria*. In: Jamison DT, Breman JG et al, eds. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006. p 415 for 2002.

⁶ Year 2000 estimate of 1 million deaths globally extrapolated from 804,000 deaths in Africa estimated in Rowe AK et al. The burden of malaria mortality among African children in the year 2000. *International Journal of Epidemiology*, 2006, 35:691-704. This is aligned with estimates with Breman JG et al. *Conquering Malaria*. In: Jamison DT, Breman JG et al, eds. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006. p 415.

⁷ The World Health Organization released its most recent World Malaria Report (WMR) 2008 in September 2008. The WMR 2008 contains information on burden, policies, coverage and funding for 109 malaria endemic countries and territories. In the report, WHO uses a revised and updated methodology to estimate the incidence of malaria outside the African Region. This results in fewer malaria cases than previously estimated in the Americas, Eastern Mediterranean, Europe, Southeast Asia and Western Pacific regions. RBM Partners, including WHO, are continuing to improve and align estimates of malaria burden worldwide.

⁸ *Global Burden of Disease estimates*. Geneva, World Health Organization, 2002.

⁹ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

¹⁰ This effect is much larger than direct losses, perhaps even 1 percentage point of GNP per year, which can cumulate to tens or hundreds of billions of dollars of lost GNP over the course of decades. Sachs J, Columbia University, personal communication, 2008.

¹¹ Gallup JL and Sachs J. The economic burden of malaria. *American Journal of Tropical Medicine and Hygiene*, 2001, 64:85-96.

Four *Plasmodia* species infect human beings: *P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale*.¹² *P. falciparum* and *P. vivax* cause the significant majority of malaria infections. *P. falciparum*, which causes most of the severe cases and deaths, is generally found in tropical regions, such as sub-Saharan Africa and Southeast Asia, as well as in the Western Pacific and in countries sharing the Amazon rainforest. *P. vivax* generally is common in most of Asia (especially Southeast Asia) and the Eastern Mediterranean, and in most endemic countries of the Americas. *P. malariae* and *P. ovale* contribute to only a small number of malaria infections. *P. ovale* is found in Africa and sporadically in Southeast Asia and the Western Pacific. *P. malariae* has a similar geographical distribution to *P. falciparum* but its incidence is patchy and is probably underestimated.

The lack of acquired immunity makes infants and young children highly vulnerable to malaria. In areas of intense malaria transmission, most cases of severe malarial anemia and deaths occur in infants and young children. Pregnant women are also at high risk of malaria. Each year approximately 50 million women living in malaria endemic countries throughout the world become pregnant.¹³

In stable transmission areas, the major effect is malaria-related anemia in the mother and presence of parasites in the placenta resulting in low-birth weight which contributes substantially to child deaths. In unstable transmission settings, pregnant women have little or no immunity to malaria and their risk of developing severe disease as a result of malaria infection is two to three times higher than that of non-pregnant women living in the same area.¹⁴ Consequently, malaria during pregnancy contributes to maternal deaths in both stable and unstable transmission areas. Therefore, pregnant women require special attention and targeted policies.

History of Malaria Control

To understand malaria today, it is important to acknowledge the history of the disease and previous global efforts to control and eradicate it. In the mid-19th century, malaria was endemic in most countries and territories of the world, affecting about 90% of the world's population and stretching as far north as the Arctic Circle.¹⁵ After successful efforts to reduce malaria with DDT beginning in 1945, in 1955 the 8th World Health Assembly launched the Global Malaria Eradication campaign for all malarious countries except Madagascar and those of sub-Saharan Africa,¹⁶ using IRS, primarily with DDT, as a vector control tool together with case management. In all, 37 of the 143 countries that were endemic in 1950 were freed from malaria by 1978, of which 27 are in Europe or the Americas.¹⁷ The effort had a positive impact on malaria mortality and morbidity in almost all targeted countries. However, some of the countries were unsuccessful in interrupting transmission. By 1973 it was concluded that in some countries a "time-limited eradication program was impracticable",¹⁸ and strategies were shifted into long-term integrated control programs. The Global Malaria Eradication campaign was abandoned. Little attention was paid to malaria over the subsequent years. Despite the end of the official WHO campaign, a number of countries have successfully eliminated malaria since that period, including Tunisia (1979), Maldives (1984), and the United Arab Emirates (2007).

¹² *P. knowlesi* is a primate malaria species that occasionally infects humans in remote areas of Southeast Asia; however, it will not be dealt with in this report.

¹³ The estimate is based on a model developed by Snow and colleagues using Mapping Malaria Risk in Africa (Snow RW and al. Estimating mortality, morbidity and disability due to malaria among Africa's non-pregnant population, *Bulletin of the World Health Organization* 1999; 77, 624-640) and its application to UNICEF data on live births (UNICEF, *State of the World's children*, Oxford University Press, 1998) adjusted for the year 2000.

¹⁴ Luxemburger C et al. The epidemiology of severe malaria in an area of low transmission in Thailand. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 1997, 91 (3): 256-262.

¹⁵ Wernsdorfer. Historical review of the global malaria eradication program - Concept, achievements, shortcomings. Presentation at WHO Informal Consultation on Global Malaria Control and Elimination, January 2008.

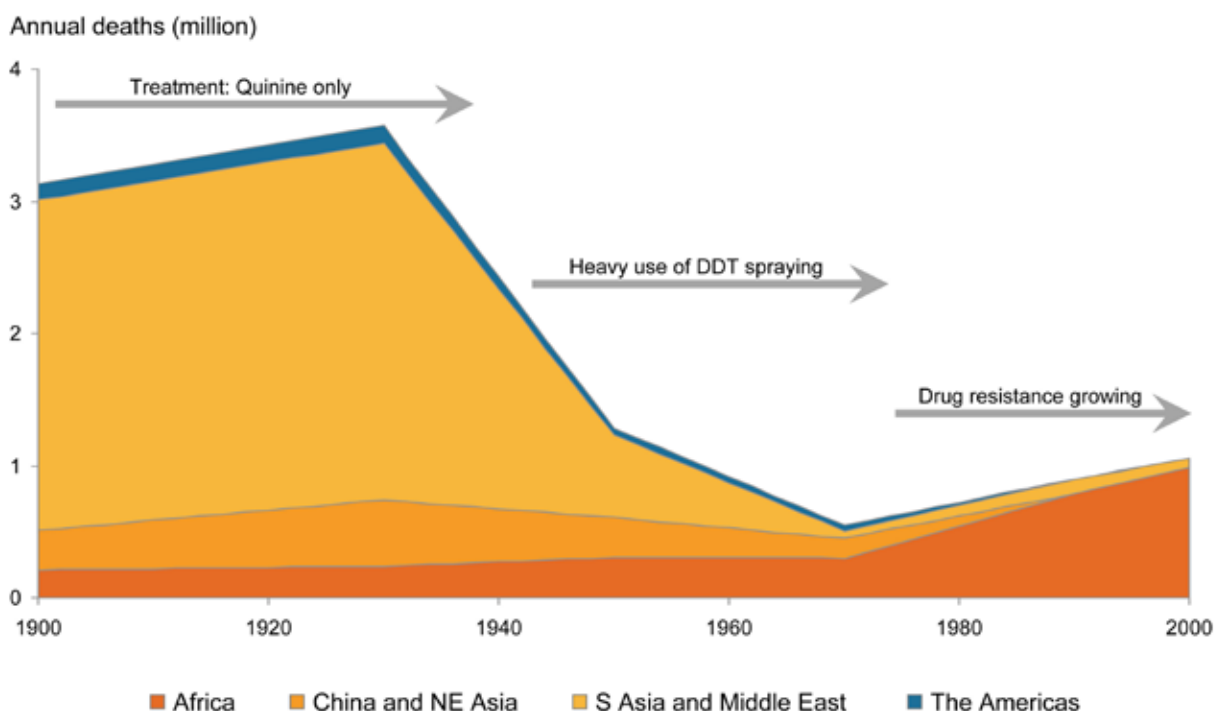
¹⁶ In these areas, malaria control was to remain the objective until suitable, economically feasible methods became available for elimination of the disease.

¹⁷ *Global malaria control and elimination: report of a technical review*. Geneva, World Health Organization, 2008.

¹⁸ *Malaria Control in Countries where Time-limited Eradication is Impracticable at Present: Technical Report Series 537*. Geneva, World Health Organization, 1974.

Malaria mortality and morbidity began to increase again in the 1980s due to a combination of factors such as the increase in parasite and vector resistance to the current anti-malarial drugs and insecticides, the weakening of traditional malaria control programs, rapid decentralization and integration into deteriorating primary health services, and the development of humanitarian crisis situations in many malaria-endemic areas (Figure I.1). This dramatic increase led to the adoption of the Global Malaria Control Strategy in 1992¹⁹ and to the creation, in 1998, of the Roll Back Malaria Partnership to coordinate global efforts in combating malaria.

Figure I.1: Evolution of malaria mortality



Source: R. Carter and K. Mendis. Evolutionary and historical aspects of the burden of malaria. *Clinical Microbiological Reviews*, 2002. 15(4): p. 564 - 594.

Progress in Malaria Control

In recent years, malaria has received greater international attention. Malaria has been included among major international development targets and acknowledged as a contributor to global poverty. The United Nations' Millennium Development Goals call for halting and reversing the incidence of malaria by 2015. In the Abuja Declaration in 2000, African leaders affirmed their commitment to halving malaria mortality by 2010. These initiatives have led to increased attention and funding to fight the disease in the past 10 years. In April 2008, the UN Secretary General has called for universal coverage by the end of 2010 to halt malaria deaths.²⁰

¹⁹ In October 1992, the Ministerial Conference held in Amsterdam convened by the WHO endorsed the Global Malaria Control Strategy.

²⁰ UN Secretary-General Ban Ki-moon, video message, World Malaria Day April 2008. The Secretary-General reiterated the UN vision for universal interventions coverage in order to end malaria deaths.

The RBM Partnership has made great strides in increasing awareness of malaria and global coverage with key malaria-control interventions. However, much remains to be done to achieve the ambitious targets of the RBM Partnership: by 2010, universal coverage with appropriate malaria interventions and 50% reduction in fatalities and cases from 2000 levels; and by 2015, near zero preventable deaths and 75% case reduction from 2000 levels.

Today, effective tools exist that make it possible to prevent and treat malaria in most settings, with the potential to substantially reduce the morbidity and mortality from malaria. The primary tools used today for prevention are: long-lasting insecticidal nets (LLINs), indoor residual spraying (IRS) in which insecticides are sprayed on the walls of homes, and intermittent preventive treatment for pregnant women (IPTp) to prevent infection.

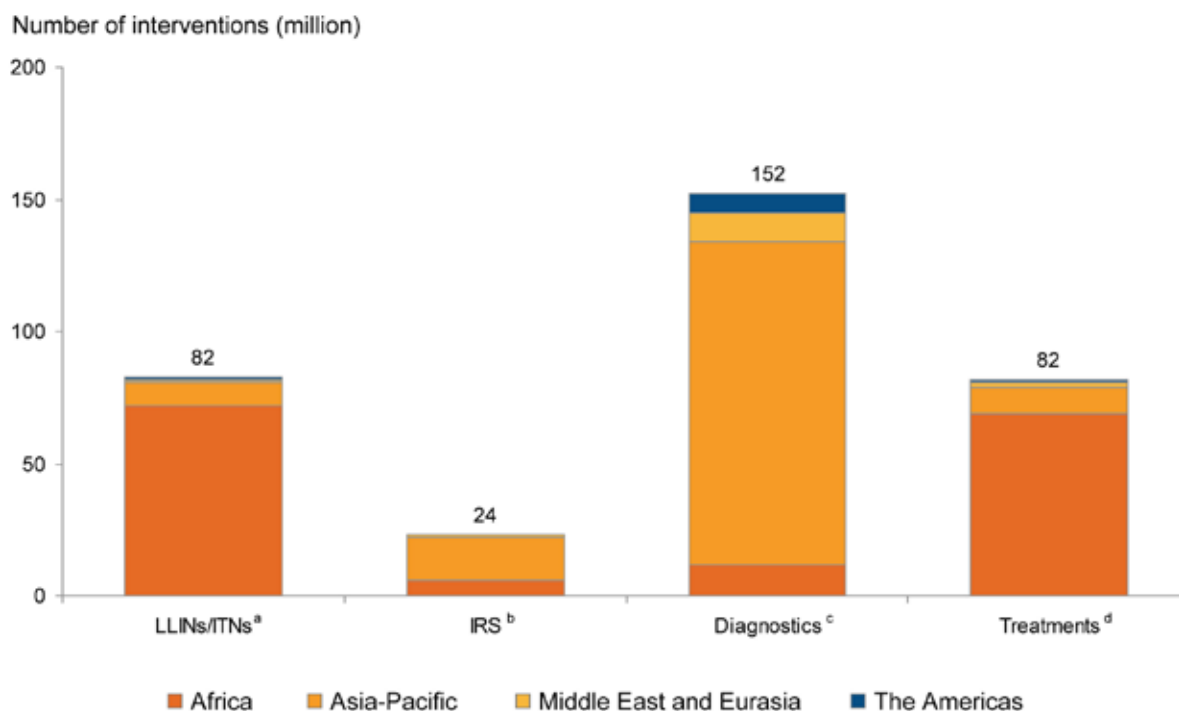
Drugs and diagnostics are used for malaria case management. Artemisinin-based combination therapies (ACTs) are the drug of choice against *P. falciparum*, the most deadly malaria species. Chloroquine (CQ) is still the treatment of choice in many places²¹ against other *Plasmodia* species (*vivax*, *malariae*, *ovale*).²² Malaria infections can be diagnosed clinically and confirmed by parasitological diagnosis with either microscopy, examining slides with a blood smear to identify the occurrence of parasites, or with rapid diagnostic tests (RDTs). Malaria RDTs assist in the diagnosis of malaria by detecting evidence of malaria parasites in human blood and can be used outside of health facilities.

The following paragraphs present the global progress in production, adoption and distribution of key malaria interventions for which data is available. Data comes from many sources. In addition to the WHO World Malaria Report 2008, data from household surveys, international donors, procurement agencies, product manufacturers and the RBM Commodity database were used. Most of the available data covers years up to and including 2006. Figure 1.2 presents estimates of LLINs, IRS, diagnostics and treatments reported in use globally as of end 2006 based on estimates derived from the WHO World Malaria Report 2008 and the RBM Commodity database. This is still far from what is needed to reach universal coverage. (See Figure II.6 in *Part II-Chapter 3*). In 2007 and 2008, with increased funds from international donor flowing to countries (Figure 1.6), many countries have begun broader scale-up of interventions than in previous years. This means that today many countries are likely closer to achieving universal coverage than is reflected in the GMAP.

Although substantial effort will be needed globally to reach universal coverage targets for all populations at risk, the size of the gap that needs to be filled varies widely from region to region and between countries. Many countries in sub-Saharan Africa and parts of Southeast Asia are still far from reaching universal coverage targets and need to gear up control efforts over the next months. In the Americas and in parts of Asia-Pacific, several countries have reached sufficient levels of control and are considering elimination. A regional analysis of progress achieved and gaps can be found in *Part III: Regional Strategies*. An explanation behind the estimates is provided in *Appendix 3: Assumptions behind Current Burden, Coverage and Funding Estimates*.

²¹ Amodiaquine is the treatment of choice in chloroquine resistant *P. vivax* malaria. According to WHO treatment guidelines, “there are relatively few data on treatment responses in chloroquine-resistant vivax malaria. Studies from Indonesia indicate that amodiaquine is efficacious, and there is some evidence that mefloquine and quinine can also be used. The artemisinin derivatives would also be expected to be highly effective, and artemether-lumefantrine could be an alternative treatment. However, there are insufficient clinical data to confirm this.”

²² The radical cure for *P. vivax* and *P. ovale* requires a 14-day treatment of Primaquine as well, except in certain conditions. See *Guidelines for the Treatment of Malaria*. Geneva, World Health Organization, 2006.

Figure I.2: Number of interventions by region

a) LLINs / ITNs: Number of effective ITNs (1 year lifespan) and LLINs (3-year lifespan) in circulation in 2006.

b) IRS: Number of households sprayed in 2006.

c) Diagnostics: Number of cases examined by microscopy or RDTs in 2006.

d) Treatments: Number of treatment courses with any first-line anti-malarial treatment (ACTs only for Africa) in 2006.

Source: World Malaria Report 2008. Geneva, World Health Organization, 2008; Roll Back Malaria (RBM) Commodity database

Long-lasting insecticidal nets (LLINs). Long-lasting insecticidal nets are recommended as a key vector control intervention to protect all populations at risk of malaria, and are particularly effective in areas where vectors primarily stay indoors. They provide both personal protection with the net and the insecticide, and community protection by reducing the vector population when implemented at very high coverage.

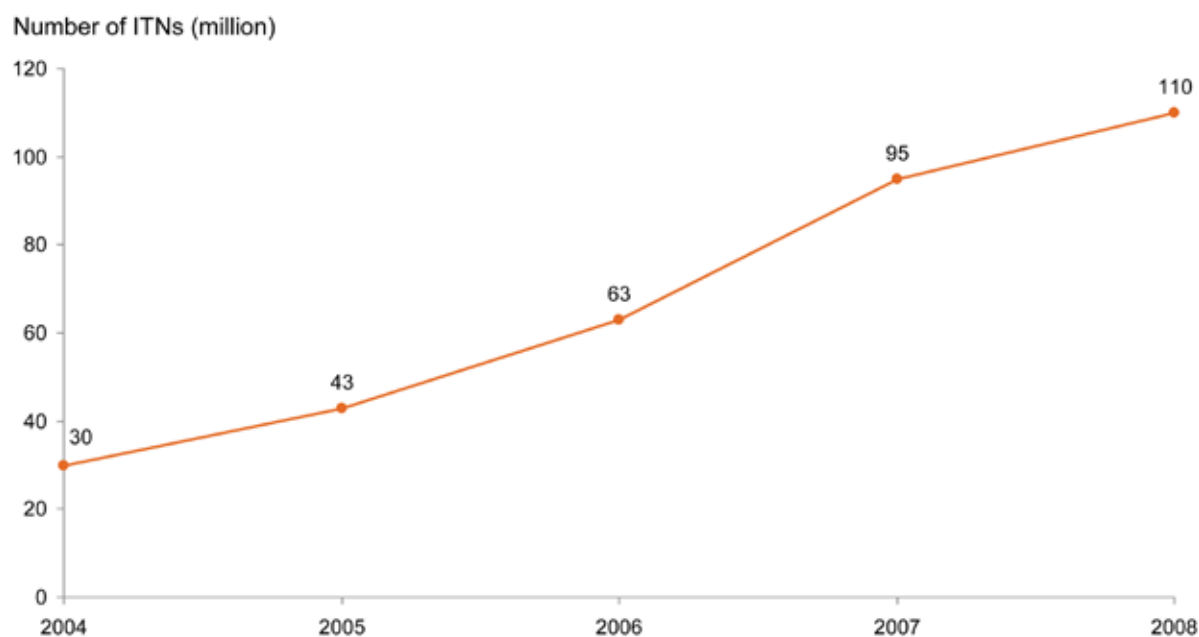
Progress achieved. Great progress has been achieved in manufacturing, funding and distributing LLINs over the past 5 years. Annual production of insecticide-treated nets (ITNs) almost tripled from 30 million in 2004 to 95 million in 2007²³ and is estimated to reach 110 million in 2008 (Figure I.3).²⁴ In addition, there has been a strong increase in funding and the subsequent procurement of nets. Funding from the Global Fund led to the procurement and distribution of 1.3 million nets in 2004, 18 million in 2006, and more than 30 million in the first 6 months of 2007.²⁵ The number of nets procured by UNICEF (the largest net procurement agent globally) more than tripled from 2004 to 2006 (from 7 million to 25 million).²⁶

²³ *Malaria and children: Progress in intervention coverage.* New York, UNICEF, 2007.

²⁴ Estimates provided August 2008 from UNICEF supply division.

²⁵ *Global Fund Helps Deliver Sharp Increases - Over 1 Million on AIDS treatment, 30 Million Malaria Nets Distributed.* Geneva, The Global Fund to fight AIDS, Tuberculosis and Malaria, Press release, May 2007.

²⁶ *Malaria and children: Progress in intervention coverage.* New York, UNICEF, 2007.

Figure I.3: Evolution of global insecticide-treated net production

Source: UNICEF Supply Division data, 2007, based on estimates from insecticide-treated net manufacturers.

In 2006, estimates suggest approximately 82 million effective LLINs / ITNs were in circulation around the world.²⁷ In 2007 and 2008, significant progress has been achieved in LLIN delivery, especially in sub-Saharan African countries (see Part III - Chapter 2: Africa). Despite the gains in production and distribution, end-user compliance is still a major challenge. A 2004 survey showed that of nets owned, only 56% had been slept under the night prior in Nigeria, 62% in Zambia, and 61% in Ethiopia.²⁸

Indoor residual spraying (IRS). IRS is an effective method of vector control aimed at killing mosquitoes that enter houses and rest on sprayed surfaces (e.g. walls and ceilings). IRS is widely used in areas of seasonal transmission, including epidemic-prone areas, and increasingly in more malaria-endemic areas. The most common insecticides used are DDT²⁹ and pyrethroids. IRS is appropriate in epidemiological settings where vectors mainly stay indoors and in countries where the necessary logistical capabilities can be deployed.

Progress achieved. Efforts are underway (led by the RBM Monitoring and Evaluation Reference Group - MERG) to harmonize indicators and data collection methods to monitor coverage of IRS programs. Depending on local conditions, IRS is being performed either as the main vector-control method or as a complement to LLINs. Twenty-five countries in sub-Saharan Africa are using IRS, although only 17 are using it routinely.³⁰

²⁷ Estimates based on an analysis of WHO World Malaria Report 2008 country program data and the RBM Commodities database for 2006. Numbers of nets in use derived from 3 years of LLINs distribution (2004, 2005, 2006) and one year of ITNs distribution (2006). See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates*.

²⁸ *Awareness, Ownership and Use of Mosquito Nets in Nigeria, Senegal, Zambia, Ghana and Ethiopia, Cross-country results from 2004 surveys*. Washington, D.C., NetMark, 2005.

²⁹ Concerns over the safety of DDT, a persistent organic pollutant, have also been comprehensively addressed in the framework of the Stockholm Convention on Persistent Organic Pollutants (POPs). The Convention bans the use of DDT, except for public health purposes. DDT can be used for IRS where it is indicated, provided that stringent measures are taken to avoid its misuse and leakage outside public health.

³⁰ *Implementation of Indoor Residual Spraying of Insecticides for Malaria Control in the WHO African Region*. Brazzaville, Congo, WHO-AFRO, 2007.

Countries in Southern Africa have implemented successful collaborative programs such as the Lubombo Spatial Development Initiative (LSDI) between Swaziland, Mozambique, and South Africa. LSDI started in 1999 and uses IRS as the main vector control intervention. IRS is commonly used in endemic countries outside Africa, especially in the Southeast Asian region. In total, approximately 24 million households (or ~118 million people) worldwide were sprayed in 2006.³¹ Despite its effectiveness, use of IRS is constrained by implementation and logistical difficulties, limited funding and the 1997 World Health Assembly resolution calling for a reduction in the use of insecticides in disease control.

Intermittent preventive treatment for pregnant women (IPTp). In high transmission settings, all pregnant women should receive at least 2 doses of IPT after fetal motion is first felt (known as the quickening) or in the 2nd and 3rd trimesters. WHO recommends sulphadoxine-pyrimethamine (SP) for IPTp in high transmission settings. This strategy has been adopted in high transmission areas of sub-Saharan African countries while research is ongoing to determine its applicability in other epidemiologic and geographic settings.

Progress achieved. IPTp has been adopted as policy in all 35 sub-Saharan African countries³² with stable malaria transmission where it is recommended³³ and is part of national malaria control strategies around the region. By the end of 2007, implementation had been initiated in all countries. However, as of 2007, only 20 countries had gone to scale and deployed it at the national level. In sixteen national household surveys conducted between 2006 and 2007, use of IPTp varied from 0.3% of pregnant women who received at least 2 doses of SP in Niger to 61% in Zambia.³⁴ These estimates are in line with reports from WHO-AFRO³⁵ that show coverage with the first dose (IPT1) ranging from 23-93%, and the second dose (IPT2) from 5-68%. See *Part III - Chapter 2: Africa* for a discussion of the challenges faced.

Diagnostics (microscopy or rapid diagnostic tests - RDTs). Parasitological diagnosis is recommended to confirm malaria cases (through quality-assured microscopy or, where unavailable, RDTs) before treatment is started (with the exception of children under 5 years of age in areas of high stable malaria transmission, who should be treated on the basis of a clinical diagnosis as the probability of fever in a child being caused by malaria is high).³⁶

Progress achieved. According to estimates based on the WHO World Malaria Report 2008 data, ~152 million cases of malaria were clinically confirmed, primarily with microscopy, in 2006.³⁷ The use of diagnostics is much stronger in Asia-Pacific, the Americas and the Middle-East and Eurasia than it is Africa, where most fever cases are treated presumptively as malaria. Although most cases were diagnosed by microscopy in 2006, the production of RDTs has increased significantly since 2000, from ~2.9 million RDTs in 2000 to an estimated 80 - 90 million for 2008.³⁸ In 2006, NMCPs reported the distribution of 15.6 million RDTs.³⁹ A comprehensive process to assess the quality of products in the market is being carried out⁴⁰ and could change the RDT market significantly in the coming years. However, the use of RDTs is still constrained by limited funding and training, as well as concerns about the variability of RDT quality.

³¹ Estimates based on an analysis of WHO World Malaria Report 2008 country program data and the RBM Commodities database for 2006. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates*.

³² *Africa Malaria Report 2006*. Geneva, World Health Organization, 2006.

³³ *A strategic framework for malaria prevention and control during pregnancy in the African Region*. Brazzaville, Congo, WHO-AFRO, Regional Office for Africa, AFR/MAL/04/01, 2004.

³⁴ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

³⁵ Presentation from WHO-AFRO, RBM MIP meeting, April 2008.

³⁶ *Guidelines for the Treatment of Malaria*. Geneva, World Health Organization, 2006.

³⁷ Estimates based on an analysis of WHO World Malaria Report 2008 country program data. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates*.

³⁸ Baik F and Bell D. Forecasting global procurement of malaria rapid diagnostic tests: estimates and uncertainties. WHO - Western Pacific Region, 2007 (www.wpro.who.int/sites/rdt). 2008 estimate extrapolated from trend line.

³⁹ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

⁴⁰ Project led by WHO - Western Pacific Regional Office, Foundation for Innovative New Diagnostics (FIND) and TDR - Initiative for Quality Assurance of Malaria Rapid Diagnostic Tests Outline of product testing and associated protocols.

Anti-malarial treatment (ACTs, chloroquine, primaquine and others). Appropriate treatment based on parasitological diagnosis should be provided within one day of the onset of illness. By only treating confirmed cases of malaria, the number of anti-malarial treatments needed is substantially reduced.

Progress achieved. Impressive progress has been achieved in product development, manufacturing, procurement and financial accessibility to treatments (especially ACTs), although prompt and widespread coverage with effective treatment is still low in many countries. In product development, a new formulation designed specifically for children has been developed to provide improved and safer access to ACTs. Production and procurement of ACTs have dramatically geared up recently - from 2004 to 2006, annual global procurement of ACTs increased from 4 million to ~100 million doses.⁴¹

The estimated global procurement for 2007 is ~125 million doses.⁴² World-wide, approximately 82 million doses of anti-malarial treatments were distributed in 2006, 69 million of these ACTs in Africa.⁴³

Outside of Africa, program data from the WHO World Malaria Report 2008 shows that ~13 million anti-malarial treatments were distributed through public health services in 2006.⁴⁴ While this amount may seem small, it could cover a sizable proportion of malaria cases outside Africa if all suspected malaria cases were first confirmed with parasitological diagnosis.

Coverage with ACTs was low within Africa as of 2006 and 2007. For instance, according to the WHO World Malaria Report 2008, eighteen household surveys conducted in 2006-2007 in the African region showed that an average 38% of children under 5 years with fever took an anti-malarial drug, 19% on the same or the next day. Just 3% of children were given ACTs (at any time). The low coverage in high-burden countries is due to limited access to or availability of ACTs in public health facilities, and the fact that in many endemic countries, most treatments are obtained through the private sector, where ACTs are often too expensive for most patients to buy. Instead patients often purchase less expensive - and ineffective - treatments. On a more positive note, recent surveys showed use of CQ in Africa declined from 2000-2001 to 2006 in 10 of the 11 countries surveyed.⁴⁵

Efforts are underway to increase access to ACTs in many places. Investments have been made in scaling up ACT delivery in the public sector through introductions of pre-packaged, low price ACTs targeted to children, and innovative financing mechanisms (such as the Affordable Medicines Facility for malaria, or AMFm) that could potentially decrease the cost of ACTs to patients substantially, making them as affordable as less-effective treatments, even in the private sector.

⁴¹ RBM Commodity database, 2007.

⁴² 2007 ACT forecast presented by WHO on June 2007 in an Medicines for Malaria Venture / WHO meeting in Bangkok (www.artepal.org).

⁴³ Estimates based on an analysis of WHO World Malaria Report 2008 country program data and the RBM Commodities database for 2006. See Appendix 3. *Assumptions behind Current Burden, Coverage and Funding Estimates*.

⁴⁴ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

⁴⁵ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

4. Funding for Malaria Today

Key messages

- Funding for malaria has increased significantly over the past 5 years, reaching an estimated US\$ 1.5 billion in 2007
 - Approximately half of the funds are provided by international donors, which have increased their financial support threefold between 2004 and 2007
 - National government spending is low in countries with the highest burden; 90% of African countries spend less than 15% of government expenditures on health
- To reach RBM targets, funding will need to be about four times the current level

Funding is still a key factor limiting malaria control for many countries. For most countries, achieving the RBM targets for 2010 and 2015 and sustaining a high level of control will require a substantial increase in funding from both the international community and endemic countries. The current funding of US\$ 1.5 billion is equivalent to less than 50 cents per person at risk. Recent studies by Snow et al comparing international funding commitments to populations at risk of stable *P. falciparum* transmission show significant variations in funding levels across regions and countries, with some high burden areas receiving relatively low international support.⁴⁶

Endemic countries and the international community are making strides toward controlling malaria: all countries have started to implement their control programs and many have achieved at least partial successes. Awareness of malaria has risen significantly over the past decade, leading to unprecedented levels of funding.

However, a significant gap must be overcome between the current coverage with malaria interventions and what is needed to achieve the goal of universal coverage. The funds required to purchase and deliver these interventions are approximately 4 times the current world-wide malaria funding. While ambitious, this increase in funding is achievable if we continue to build on the positive trends of the past years.

Current Funding for Malaria Implementation

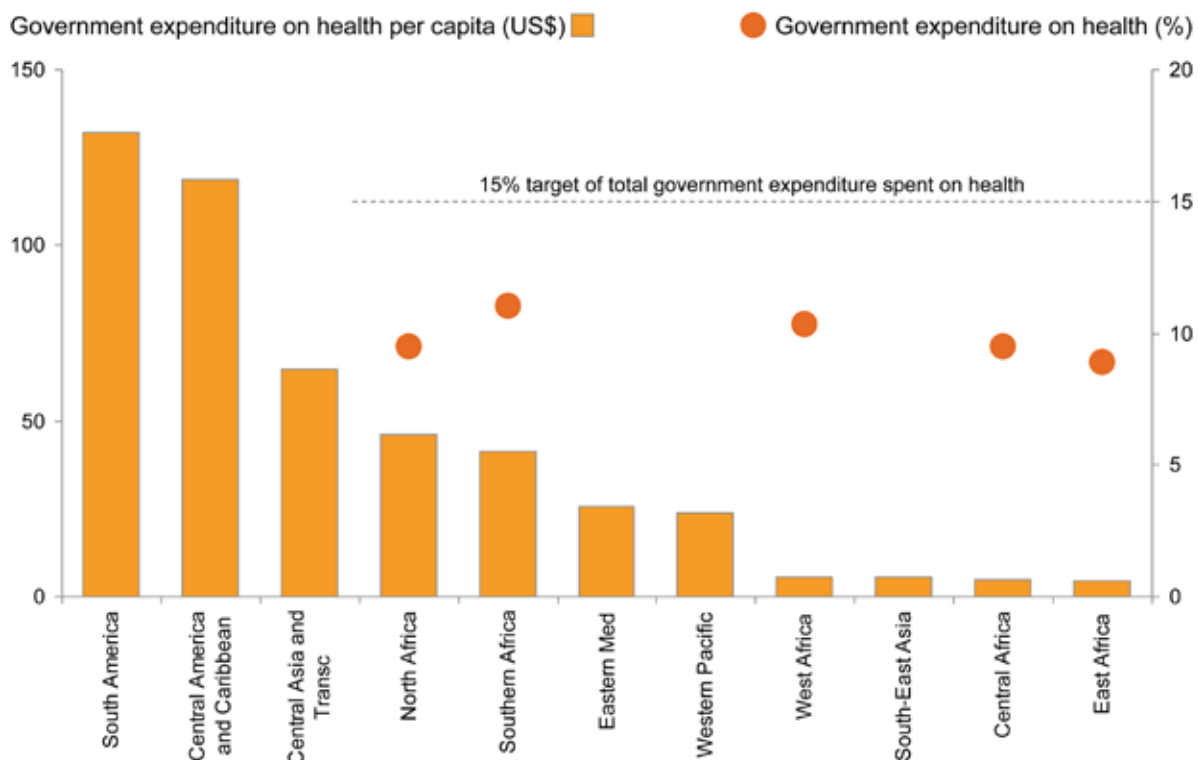
Limited national resources in high burden countries. Although the situation varies widely by region and by country, current national funding covers only a fraction of what is needed for the implementation of malaria control programs, especially in high burden countries. This is particularly true in Africa, where government budgets represent only 18% on average of total malaria funding.⁴⁷ In 2003, African leaders affirmed in the Maputo Declaration their commitment to increase financial support for the health sector to 15% of total government expenditure. Today, however, 90% of African countries remain below the 15% threshold.⁴⁸ Even if countries were to achieve the 15% target, their expenditures on key malaria interventions would still be substantially less than the estimated need. As shown in Figure I.4, government expenditures on health per capita are the lowest in regions with the highest malaria burden.

⁴⁶ Snow RW et al. International funding for malaria control in relation to populations at risk of stable *Plasmodium falciparum* transmission. *PLoS Med*, 2008, 5(7):e142.

⁴⁷ Excluding private household spend. Based on total spending coming from government and international donors. See Appendix 3. *Assumptions behind Current Burden, Coverage and Funding Estimates*.

⁴⁸ *Malaria Landscape Report 2007*. Geneva, the Roll Back Malaria, 2007.

Figure I.4: Government expenditure on health in malaria-endemic regions



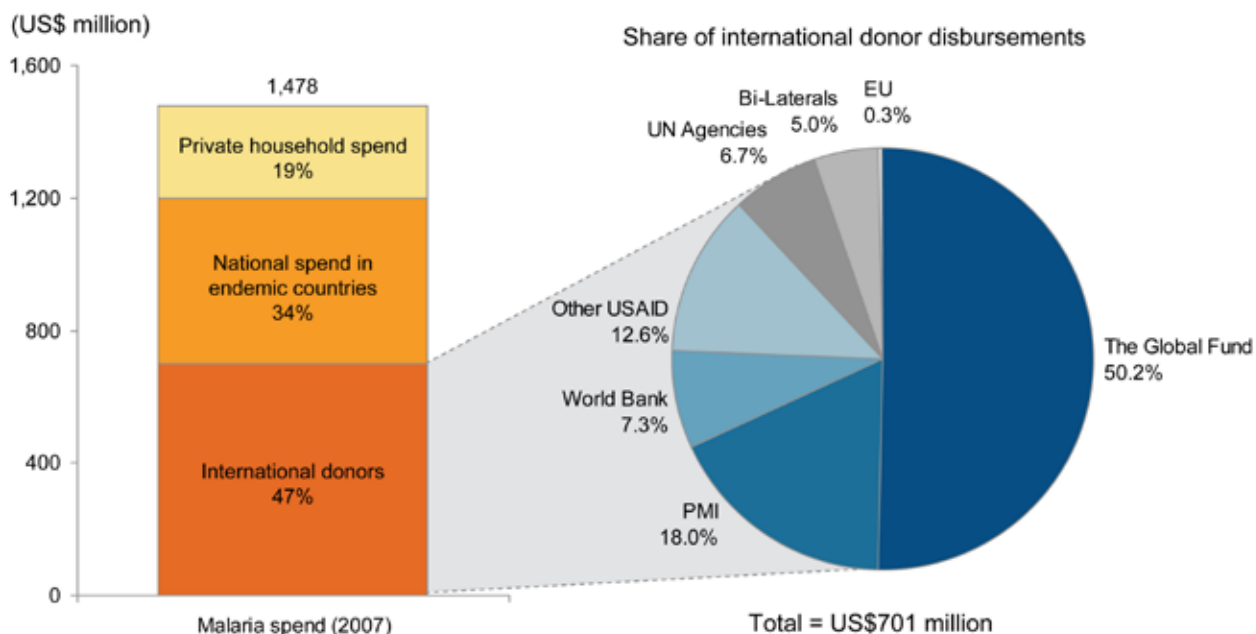
Note: Government expenditure on health per capita as regional weighted average; % of government expenditure on health as arithmetical average, 15% target agreed by African countries in Maputo Declaration (July 2003).
 Source: Analysis based on WHO Health Statistics 2008; 2005 data.

According to data from WHO and the main donor organizations, the share of government budget spent on malaria is substantially higher in Asia-Pacific than in Africa and represents the largest source of malaria funding in the Americas and in the Middle East and Eurasia. Detailed regional analyses of funding for malaria are presented in *Part III: Regional Strategies*.

Major sources of malaria funding. Money spent on malaria in 2007 amounted to an estimated total of -US\$ 1.5 billion (see Figure I.5). One fifth of these funds came from household purchases of malaria products (such as anti-malarial drugs or long-lasting insecticidal nets) principally through the private sector. Approximately 34% of funds came from national government expenditures dedicated to malaria, and the remaining funding came from international donors, which disbursed an estimated US\$ 701 million. The Global Fund contributed to half of the disbursements from international donors.⁴⁹

⁴⁹ As described in *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates*, these figures take into account actual disbursements as opposed to commitments.

Figure 1.5: Current sources of funds spent on malaria

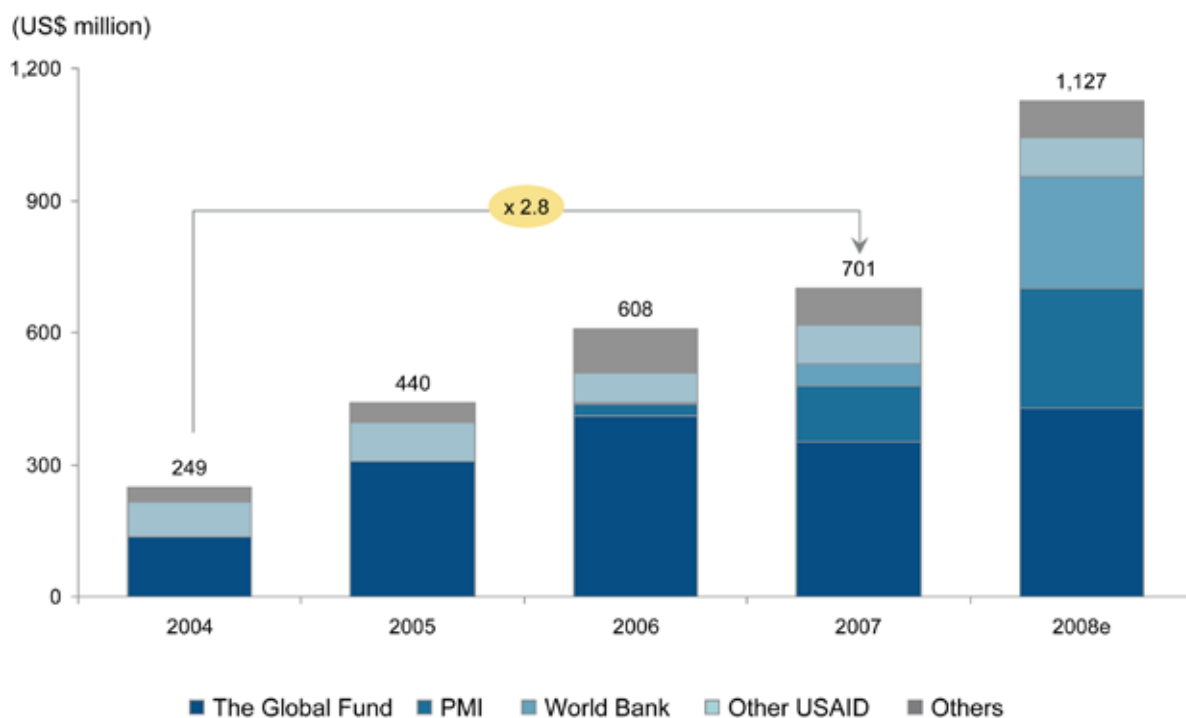


a) Regional funding estimates not available for private household spend and other USAID. Therefore, summing regional funds presented in Part III - Regional Strategies only adds up to approx. US \$1.1 billion, see Appendix 3 for methodology.

Source: World Malaria Report 2008. Geneva, World Health Organization, 2008 (Government, UN Agencies, Bilaterals, EU); the Global Fund website; PMI operational plans; USAID website; World Bank Booster Program (see appendix on methodology); 2007 data.

The trend is positive for international funding. As Figure 1.6 illustrates, unprecedented amounts of money have poured into malaria control since 2004. Disbursements from international donors increased threefold from 2004 to 2007. Commitments for coming years are promising. 2008 disbursements are estimated to be ~US\$ 1.1 billion, (more than four times 2004 amount) thanks to expected payouts of previous Global Fund rounds, increased scope of the U.S. President’s Malaria Initiative (PMI) (from 10 countries in 2007 to 15 countries supported in 2008) and the disbursements of money committed in Phase I of the World Bank Booster Program (~67% of Phase I commitments are expected to be disbursed by the end of 2008).

Figure I.6: Evolution of international funding disbursements for malaria



Source: World Malaria Report 2008. Geneva, World Health Organization, 2008 (Government, UN Agencies, Bilaterals, EU); GFATM website; PMI operational plans; USAID website; World Bank Booster Program (see appendix on methodology).

Both the Global Fund (US\$ 9.7 billion for 2008-2010)⁵⁰ and the World Bank (US\$ 41.6 billion for the International Development Association's 15th replenishment)⁵¹ have been highly successful in advocating for replenishments. While G8 donor countries are still far from reaching the aid pledges made to Africa in 2005 in Gleneagles, individual governments have increased their pledged funds and other donations for malaria. In April 2008, Prime Minister Gordon Brown announced the United Kingdom's government's pledge to donate 20 million bed nets. In July 2008, the President of the United States signed a reauthorization act that could increase US malaria funding to US\$ 5 billion over the next five years.⁵² The World Bank is preparing Phase II of its Booster program with an aspirational lending target of at least ~ US\$ 1.2 billion for sub-Saharan Africa. In addition, the World Bank's Board of Executive Directors has just approved over US\$ 500 million for a project to support India's efforts against malaria and other diseases, for which the amount for malaria could reach US\$ 200 million,⁵³ making it the largest single disease control investment in the history of the World Bank.

⁵⁰ Funding shared with the two other diseases. *Donors provide US\$9.7 billion to the Global Fund; Initial Pledges for 2008 - 2010 Enable the Global Fund to Triple In Size*. Geneva, The Global Fund to fight AIDS, Tuberculosis and Malaria, Press release, September 2007.

⁵¹ Estimate as of December 2007. Funding shared with other diseases and development priorities will finance projects over the three-year period ending June 30th, 2011.

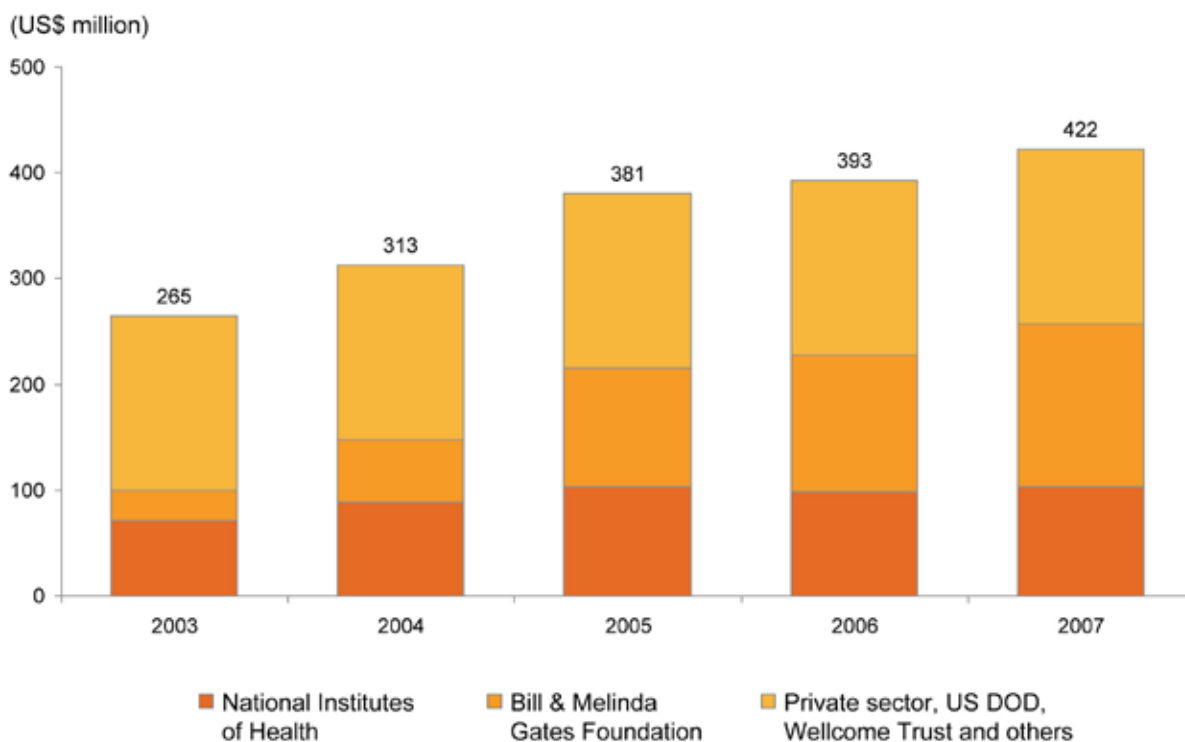
⁵² The Tom Lantos and Henry J. Hyde United States Global Leadership on HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008.

⁵³ US\$ 121 million for malaria specific activities, US\$ 52 million for management and policy strengthening (including significant inputs for malaria), and US\$ 37 million not yet allocated potentially available for malaria.

Increased Funding for Malaria Research and Development

Figure I.7 shows the steady increase in funding for malaria research and development over the past five years. In 2007, funding for malaria research and development is estimated at ~US\$ 422 million. The two major donors (United States’ National Institutes of Health and the Bill and Melinda Gates Foundation) account for ~40% of estimated current funding for R&D. More than 60% of funds are directed to drugs and vaccines.

Figure I.7: Evolution of spending on malaria research and development



Note: Estimated US \$165 million in funding from “other” donors based on Malaria R&D Alliance estimate for 2004; assumes all BMGF malaria funding is for R&D.

Source: Bill & Melinda Gates Foundation; National Institutes of Health website; Malaria R&D Alliance (2005).

There are three main stages of activities in defeating malaria:

- 1. control malaria to reduce the current burden and sustain control as long as necessary;*
- 2. eliminate malaria over time country by country; and*
- 3. research new tools and approaches to support global control and elimination efforts.*



PART II The Global Strategy

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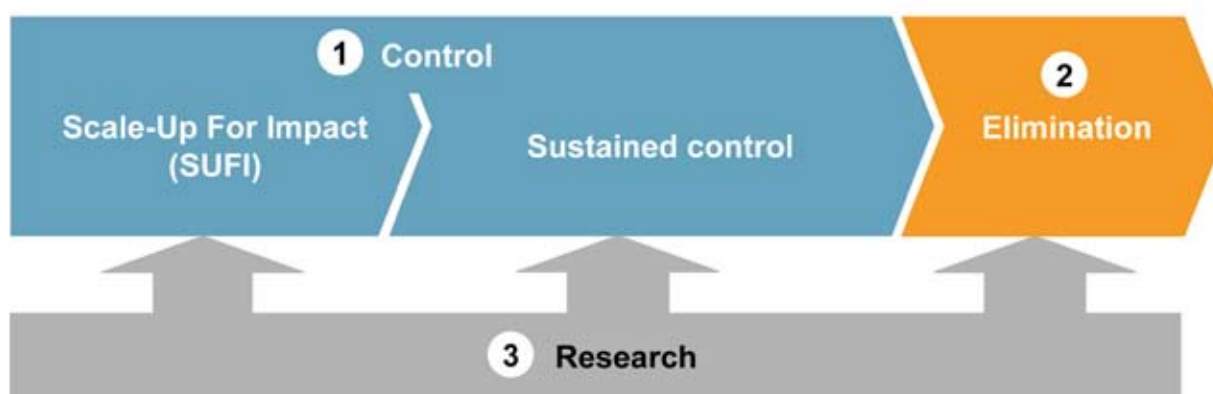
1. Introduction to the Global Strategy

Malaria occurs in 109 countries around the world. A strategy combating malaria should be both country-led and internationally supported. *Individual countries* are often best positioned to know which actions are most appropriate depending on the populations at risk, the level of transmission, the degree to which interventions are in place, and the capacity of countries' health systems to take these efforts further. The *international community*, on the other hand, plays a critical role by supporting countries and providing tools. Through cooperation, countries and international partners can achieve the near-term goals of mortality and morbidity reduction by 2010 and 2015 as well as the longer-term vision of worldwide eradication.

Three Components of the Global Strategy: Control, Elimination and Research

The Global Strategy consists of three components (Figure II.1) that will ensure these ambitious goals can be achieved: 1) Controlling malaria, 2) Eliminating malaria and 3) Research into new tools and approaches.

Figure II.1: Three components of the global strategy



1. **Control.** The majority of malaria-endemic countries can make a substantial impact on their malaria burden by controlling it with existing tools. By first *scaling up* appropriate interventions for all populations at risk and then *sustaining control* over time, malaria will cease to be a major source of deaths world-wide.
2. **Elimination.** Reducing to zero all locally-acquired infections within a country will bring the world closer to the ambitious goal of global eradication. Some countries are currently engaging in elimination and more will transition to elimination after achieving control provided there is strong rationale for this move. In high transmission settings, complete interruption of malaria transmission will require additional, new control tools.¹
3. **Research.** Malaria control and elimination efforts will require continued research to be successful. International research is needed to create new tools, as well as inform policy and improve operational implementation of strategies. Then, national and local health systems must focus on how to use the tools and sustain the gains.

¹ *Global malaria control and elimination: report of a technical review.* Geneva, World Health Organization, 2008.

Targeted Efforts for Big Impact

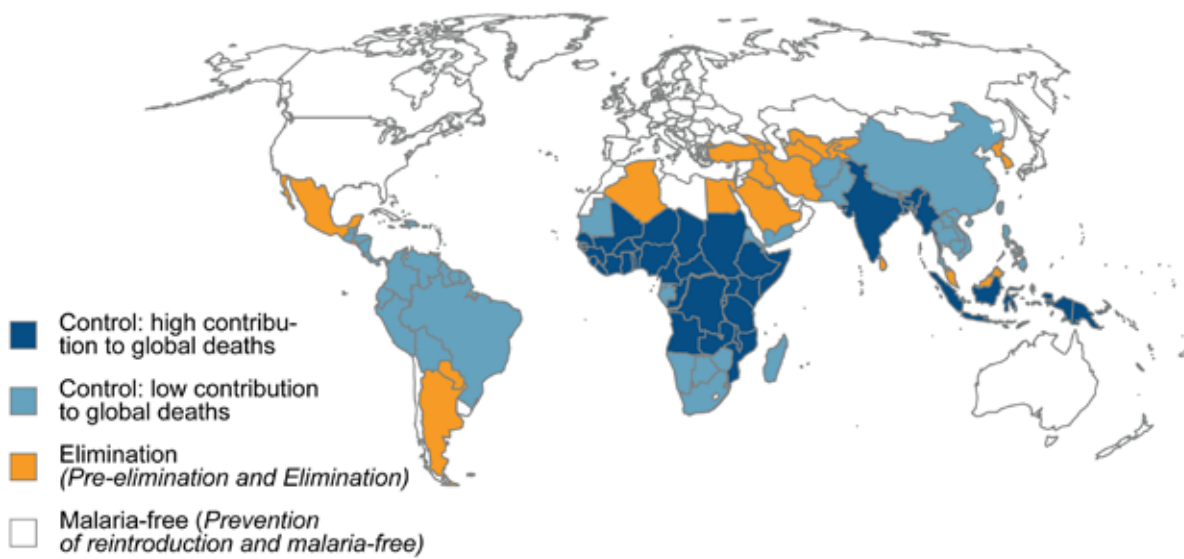
All countries are an important part of the global strategy and will contribute to the success of the world-wide objectives against malaria. However, in a resource constrained environment, global resources may not be sufficient to support all countries at the same time. To achieve the 2010 and 2015 global targets, scale-up efforts in at least the highest burden countries are essential.

As illustrated in Figure II.2, countries can be grouped into the following categories:

1. **High contribution to global deaths in the control stage.** 35 countries are responsible for the majority of the total deaths world-wide. The 5 main contributors (Nigeria, Democratic Republic of Congo, Uganda, Ethiopia and Tanzania) amount to 50% of global deaths and 47% of cases. Many of these 35 countries have high transmission of *P. falciparum* malaria and are located in sub-Saharan Africa; others have very large populations at risk, especially in Southeast Asia.
2. **Low contribution to global deaths.** 74 countries bear a lower share of the malaria burden. There are two main groups, depending on the objective of their current national anti-malaria program.
 - a. **Low contribution in the control stage:** Forty-seven countries bear a smaller share of the global deaths and cases attributable to malaria. They have malaria control as their current objective. Most of these countries have low to moderate transmission of *P. falciparum*, mixed transmission, or *P. vivax* transmission only. They are mainly located in South America, in Africa or in Asia-Pacific. A few countries (e.g. Haiti, Dominican Republic, Timor-Leste) have high transmission but, because of their small size, contribute little to the global death toll.
 - b. **Low contribution in the elimination stage:** Twenty-seven countries have very low burden levels and are currently in various stages of the elimination process as reported by WHO. As more countries transition out of the control stage and into the elimination stage, greater international emphasis will be placed on elimination. They are mainly located in the Eastern Mediterranean region, in North Africa, in the Americas or in the Western Pacific region

The Global Strategy chapters that follow will describe how countries and global players can work together on control, elimination and research to fight malaria. The final chapter highlights the costs and financial considerations to implement the control and elimination strategies within countries, to conduct the R&D needed for control and elimination tools, and the health systems research required for scale-up, sustained control and elimination strategies. It concludes by illustrating the economic and epidemiological benefits of malaria control.

Figure II.2: Country categorization by malaria control status and burden



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008; 2006 data.

2. Control: Overcoming Malaria

Key messages

- RBM's malaria control strategy aims to permanently reduce malaria mortality and morbidity by
 - Strengthening health systems to enable malaria control
 - Reaching universal coverage with appropriate interventions
- This will require many countries to
 - First, **scale-up** their health systems and delivery capabilities
 - Second, **sustain control** for years until they move to elimination
- Because of the variation between countries in epidemiology and control programs, no one global approach is recommended.
 - Appropriate interventions will differ by transmission levels, parasite type and vector behavior
 - Delivery strategies will need to be adapted to existing control programs and integrated with other disease and development programs
- However, best practices in health system strengthening and delivery can provide guidance to countries and highlight areas where global support is needed
 - In the short term, substantial global support is needed to help the highest contributors to global burden scale-up rapidly to meet the 2010 targets
 - In the longer term, all countries will need support in moving towards elimination
- Global support is needed to provide tools and resources required for malaria control and in the following capabilities: policy and regulatory, planning, financing, procurement assistance and supply chain management, communication and behavior change methodologies, monitoring and evaluation, management of humanitarian crises and appropriate research and development

Malaria control can be defined as reducing malaria morbidity and mortality to a locally acceptable level through deliberate efforts using the preventive and curative tools available today. WHO classifies 82 of the 109 countries or territories with malarious areas in the Control stage.

Malaria control relies on effective *prevention* and *case management*. Prevention with vector control interventions aims to reduce transmission and thus decrease the incidence and prevalence of parasite infection and clinical malaria. Prevention with intermittent preventive treatment for pregnant women reduces the impact of placental malaria infection and maternal malaria-associated anemia. Early and effective case management of malaria will shorten its duration and prevent complications and most deaths from malaria.²

Malaria Control: Different Settings, Different Approaches

Since most countries will contain multiple settings, countries need a tailored approach to control malaria with tools appropriate for the various settings.³ The decision of which intervention (or combination of interventions) to use depends heavily on epidemiological and logistical factors. Therefore the package of interventions to be implemented in each district is first and foremost a country decision, informed by WHO malaria control recommendations.⁴

² *Malaria Control Today - Current WHO Recommendations, working document*. Geneva, World Health Organization, 2005.

³ An initiative called the Malaria Atlas Project (MAP) is working to develop a detailed model of the spatial limits of *P. falciparum* and *P. vivax* malaria at a global scale and its endemicity within this range. This information will be helpful to inform country burden estimates as well as the appropriate interventions (see <http://www.map.ox.ac.uk/index.htm>).

⁴ See WHO website (<http://www.who.int/malaria/>) and *Appendix 6 Compilation of WHO references*.

As summarized below, different interventions are required for areas of high transmission of *P. falciparum*, areas of low to moderate transmission of *P. falciparum*, and areas with a high proportion of *P. vivax* or mixed transmission. See *Part 3: Regional Strategies* for a more detailed description of which interventions are appropriate within regions.

High transmission of *P. falciparum*. In areas of high transmission of *P. falciparum* as occurs in many sub-Saharan African countries, at least one of the two core vector control interventions (LLINs, IRS) should cover people at risk. IPTp is recommended to protect pregnant women; at present, this intervention is only recommended for sub-Saharan Africa, however, in highly endemic areas in Asia-Pacific, this intervention could also be appropriate, but its role still needs to be clarified. Where IPTp is not being implemented in a high transmission area, routine screening of pregnant women for malaria infection and appropriate treatment could be done. In areas of high stable malaria transmission⁵, the probability of fever in a child being caused by malaria is high. Children under 5 years of age should therefore be treated on the basis of a clinical diagnosis of malaria. In older children and adults including pregnant women, a parasitological diagnosis (by quality-assured light microscopy or where unavailable RDTs) is recommended before treatment is started.⁶ Artemisinin-based Combination Therapies (ACTs) are the recommended first-line treatment against *P. falciparum* infections.

Low to moderate transmission of *P. falciparum*. In places where transmission is seasonal or localized in select areas, the use of targeted vector control measures such as IRS or other vector population reduction methods (environmental management, larviciding etc.) can be appropriate. LLINs can also be used. IPTp for pregnant women is currently not recommended. Prompt parasitological confirmation of the diagnosis is recommended before treatment is started in all age groups⁷ (microscopy or, where unavailable, RDTs).

***P. vivax* or mixed transmission.** When both *P. falciparum* and *P. vivax* are prevalent (e.g. in Asia-Pacific, in the Americas or in the Middle East), diagnosis should distinguish *P. falciparum* from non-*falciparum* parasites, as the appropriate treatment differs. In many areas, chloroquine is still effective for *P. vivax*, but must be combined with primaquine to ensure clearance of liver-stage infection. If infections are mixed, then ACTs must be used to treat *P. falciparum* (which is widely resistant to chloroquine). In addition, the patient should receive primaquine for treatment of *P. vivax* liver-stage parasites.

Reaching and Sustaining Universal Coverage: Two Stages, Two Objectives

Malaria control in countries is a continuum consisting of two main stages with different, although complementary, objectives (Figure II.3):

- **Scale-up for impact:** in this stage, the goal is to *rapidly reach* universal coverage for all populations at risk with locally appropriate malaria control interventions, supported by strengthened health systems.
- **Sustained control:** in this stage, the goal is to *maintain* universal coverage with interventions by continued strengthening of health systems until universal coverage is made irrelevant by elimination or until field research suggests it can be reduced without risk of resurgence of malaria.

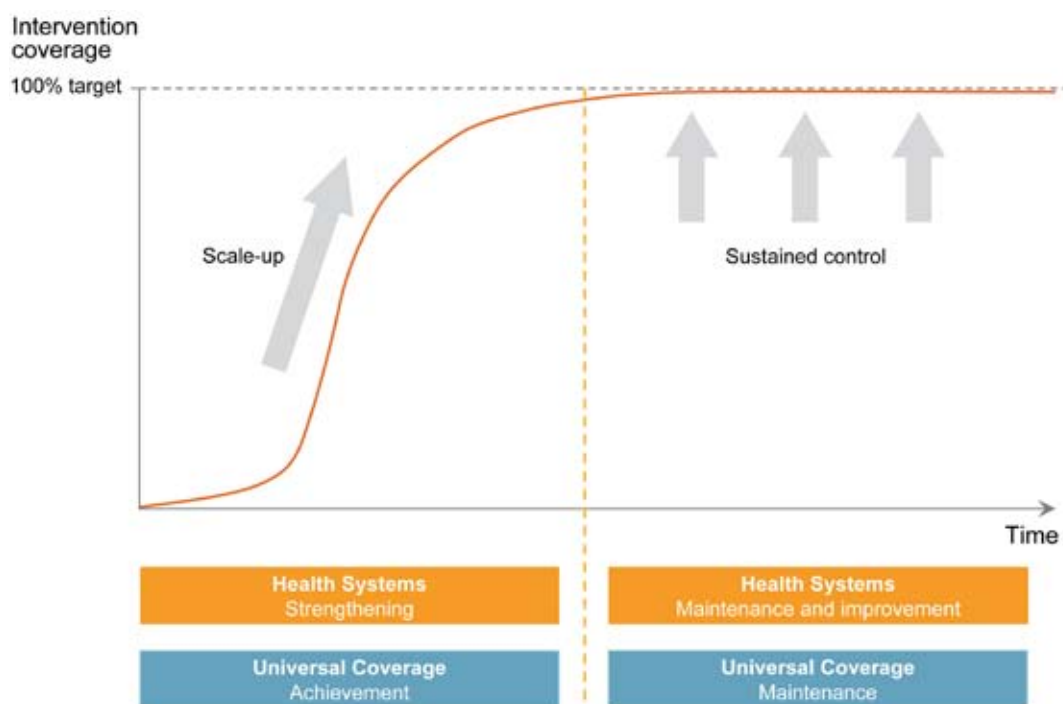
Both the scale-up and sustained control stages share two primary activities: strengthen health systems to enable malaria control and scaling up and maintaining universal coverage with appropriate interventions. Both of these cross-cutting activities begin in the scale-up stage but continue in the sustained control stage to ensure that reduction in mortality and morbidity continues.

⁵ There is as yet no consensus on criteria for determining the thresholds between high and low to moderate transmission settings. Suggested criteria include: the proportion of all children under 5 years of age with patent parasitaemia, and the incidence of individuals with the spleen palpable below the umbilicus in children aged 2-9 years. The IMCI guidelines recommend that areas in which fewer than 5% of young children with fever have malaria parasitaemia should be considered as low-transmission settings.

⁶ *Guidelines for the Treatment of Malaria*. Geneva, World Health Organization, 2006.

⁷ *Guidelines for the Treatment of Malaria*. Geneva, World Health Organization, 2006.

Figure II.3: Two primary activities supporting scale-up and sustained control



Strengthen health systems to enable malaria control. Controlling malaria through universal coverage is not only about increasing spending and the delivery of malaria interventions. It also requires building, expanding and continuously improving health systems supporting all interventions.

A health system is defined by WHO as the sum of all organizations, institutions, people and resources whose primary purpose is to improve health (Box II.1). It requires adequate staff, funds, information, supplies, transport, logistics, communication, overall guidance and direction. Strengthening health systems is not only a malaria specific issue: it is a global development issue deserving the support of the international donor community. Improving health systems related to malaria control is likely to benefit other diseases and contribute heavily to the achievement of development targets.

Box II.I: WHO Framework for Health Systems Strengthening

The framework for health systems strengthening defined by WHO comprises six major components:⁸

1. *Leadership and governance.* This includes strong **political commitment** backing malaria efforts, clear definition of **policy** and financing frameworks in line with international recommendations, **regulation**, leadership and stewardship from national authorities to lead **planning efforts** and to coordinate and align all partners.
2. *Sustainable financing and social protection.* It is essential for malaria control programs to have access to **adequate and timely resources** for activities planned, in ways that ensure populations at risk are covered by the required interventions without bearing undue personal cost.
3. *Health workforce.* **Sufficient, well trained**, fairly distributed and productive **staff** is required to deliver interventions with the highest possible quality.
4. *Medical products, technologies, infrastructure and logistics.* Efficient and cost effective tools for malaria prevention and case management need to be available for all populations at risk.
5. *Service delivery.* Good health services are those which **deliver effective, safe, quality interventions** to those that need them, when and where needed, with minimum waste of resources.
6. *Health information system.* The health **information system** ensures the production, analysis, dissemination and use of reliable and timely information. It includes monitoring and evaluation, disease and mortality surveillance, disease mapping and information technology.

Reach universal coverage with appropriate interventions. Scaling up and sustaining universal (100%) coverage of appropriate malaria interventions for the entire population at risk with a target of at least 80% utilization⁹ will lead to a dramatic reduction in malaria morbidity and mortality.

Prevention. Universal coverage for prevention means that 100% of the population at risk is provided with locally appropriate preventive interventions. For these interventions, coverage is defined as follows:

- Long-Lasting Insecticidal Nets (LLINs): A household owns one long-lasting insecticidal bed net for every two people living there
- Indoor Residual Spraying (IRS): The interior walls of every house are routinely sprayed at appropriate intervals with an effective insecticide
- Intermittent Preventive Treatment (IPTp): A pregnant woman living in a high transmission setting receives at least 2 doses of an appropriate anti-malarial drug during her pregnancy¹⁰
- Other vector control measures: Other targeted approaches (e.g. larviciding, environmental management, etc.) are applied wherever appropriate based on scientific evidence

Case management. Universal coverage means that 100% of patients receive locally appropriate case management interventions. For these interventions, coverage is defined as follows:

- **Diagnosis:** A patient receives prompt parasitological confirmation by microscopy or rapid diagnostic tests (RDTs) of malaria diagnosis (with some exceptions)¹¹

⁸ *Everybody's business: Strengthening health systems to improve health outcomes - WHO's framework for action.* Geneva, World Health Organization, 2007. The framework presented is the generic WHO framework for Health Systems Strengthening. However the concrete examples for the 6 pillars presented here have been adapted to malaria.

⁹ This is in line with the Roll Back Malaria Harmonization Working Group's recommendations that countries should budget for universal coverage of all populations at risk with interventions to achieve 80% utilization as there will be a gap between coverage and utilization.

¹⁰ Recommended for high transmission settings in sub-Saharan Africa only. At least two doses of IPTp need to be taken for complete treatment. IPTp is offered as part of a comprehensive ANC package for pregnant women.

¹¹ With the exception of children under 5 years of age from areas of high stable transmission where treatment is based on clinical diagnosis. *Guidelines for the Treatment of Malaria.* Geneva, World Health Organization, 2006.

- Treatment: An infected person receives appropriate anti-malarial drugs for uncomplicated or severe malaria within one day of onset of illness

Particular attention is required to ensure that interventions reach the most vulnerable populations, and that gender, socio-economic status or geographic location are not barriers to access.

Strengthening health systems to enable malaria control and reaching and maintaining universal coverage both require substantial effort. The two following sections A. *Scale-up for Impact: Achieving Universal Coverage* and B. *Sustained Control: Maintaining Coverage and Utilization* focus on strategies to answer the following questions:

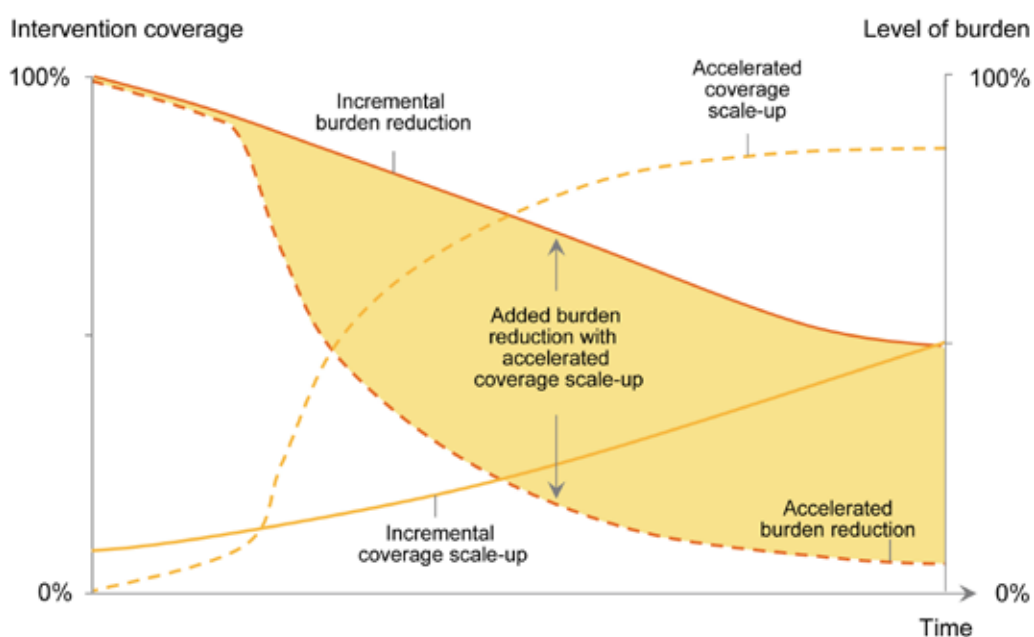
- How can health systems strengthening activities be tailored for malaria to help countries scale-up and sustain control?
- Which delivery strategies for each intervention are the most appropriate to scale-up and maintain universal coverage?

A. Scale-up for Impact: Achieving Universal Coverage

As illustrated by the limited levels of coverage described in *Part I: Malaria Today*, it will be a major challenge to achieve universal coverage with even one intervention for all populations at risk. When countries can scale-up a package of preventive and curative interventions together, the resulting benefits will have a dramatic impact on the global malaria burden.¹² This concept, known as scale-up for impact (SUFI), is one of the biggest opportunities to have a major impact on global mortality and morbidity.

Figure II.4 illustrates the difference in impact of gradual increases in coverage (red lines) and the dramatic impact that results from rapid scale-up (blue lines).

Figure II.4: Intervention coverage scale-up and burden reduction



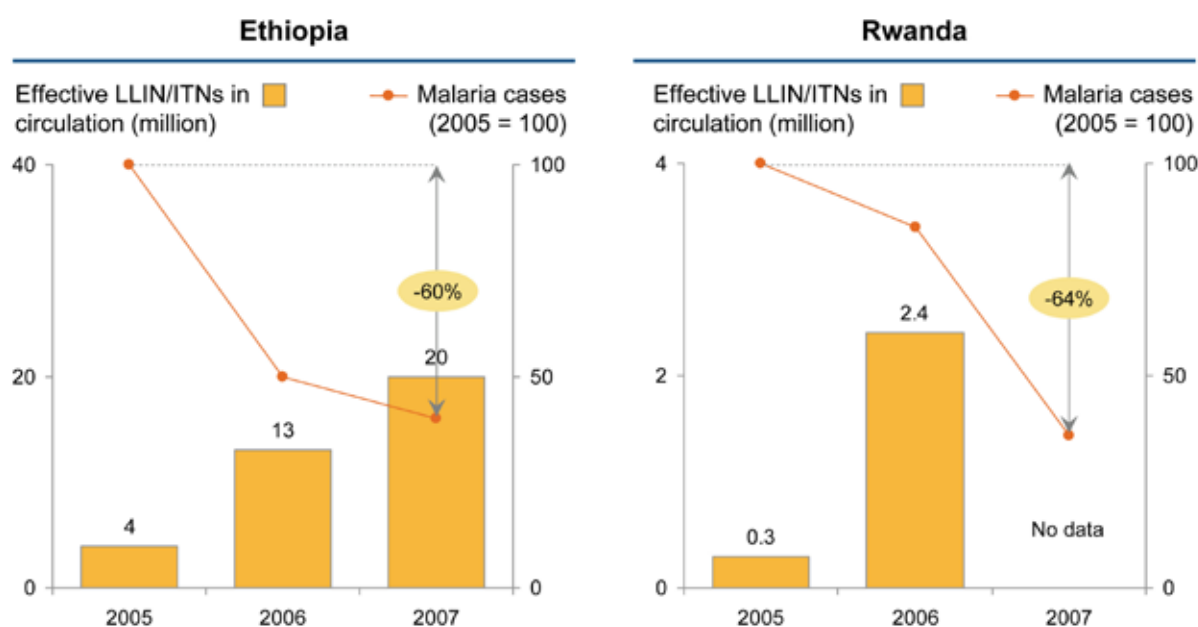
Source: Based on Steketee R, Lennon A, "Scaling Up for Impact Through Comprehensive Program Improvement", Malaria Control Partnership (MACEPA), June 2007.

¹² Rowe AK and Steketee RW. Predictions of the impact of malaria control efforts on all-cause child mortality in sub-Saharan Africa. *American Journal of Tropical Medicine and Hygiene*, 2007, 77 (Supplement 6).

Rapidly scaling up to universal coverage for populations at risk is critical to achieve the targets of 50% mortality and morbidity reduction by 2010 and a 75% reduction in morbidity and near zero mortality by 2015. The principle of scale-up has been promoted since 2005 by the RBM Partnership. This commitment has been reaffirmed by the UN Secretary-General's call on World Malaria Day in April 2008 to "put a stop to malaria deaths by ensuring universal coverage by the end of 2010" through the use of vector control and case management tools and strengthening of community-level efforts.¹³

After expanded coverage of malaria interventions, principally LLINs (distributed through a combination of approaches, reaching over 60% coverage of populations at risk in both countries)¹⁴ and ACTs in Ethiopia and Rwanda, results are promising: malaria cases in Rwanda decreased by 64% and deaths by 66% between 2005 and 2007 among children under 5 years; in Ethiopia, cases decreased by 60% and deaths by 51% in the same age group¹⁵ in the health facilities selected for the study.

Figure II.5: Impact of increased LLIN and ACT distribution in Ethiopia and Rwanda



- a) Numbers calculated assuming three year lifespan of LLINs delivered and one year lifespan for ITNs delivered.
 b) In-patient malaria cases in children <5 years old, January-October 2003-2007, 7 in-patient facilities, Ethiopia.
 c) In-patient malaria cases in children <5 years old, January-November 2005-2007, 19 in-patient facilities, Rwanda.

Source: Intervention data based on World Malaria Report 2008. Geneva, World Health Organization, 2008; Impact data based on Impact of long-lasting insecticidal-treated nets (LLINs) and artemisinin-based combination therapies (ACTs) measured using surveillance data, in four African countries. Geneva, World Health Organization, Global Malaria Program, 2008.

Several other studies demonstrate similar results, including those in Eritrea, Madagascar and Zanzibar. In the latter, high coverage with ACTs and insecticide-treated nets resulted in drastic mortality and morbidity reduction.¹⁶ Strengthening health systems lays the groundwork to reach universal coverage. While improving health systems is critical to reaching the universal coverage targets, these efforts will have the biggest impact

¹³ UN Secretary-General Ban Ki-moon, video message, World Malaria Day April 2008. The Secretary-General reiterated the UN vision for universal interventions coverage in order to end malaria deaths.

¹⁴ Coverage levels have continued to increase in these countries since the completion of the study.

¹⁵ Impact of long-lasting insecticidal-treated nets (LLINs) and artemisinin-based combination therapies (ACTs) measured using surveillance data, in four African countries. Geneva, World Health Organization Global Malaria Program, 2008. These results are preliminary and further evidence is needed over time to confirm sustainability of successes due to control efforts. This study is based on results in a limited number of health facilities and therefore not necessarily nationally representative.

¹⁶ Bhattarai A et al. Impact of Artemisinin-Based Combination Therapy and Insecticide-Treated Nets on Malaria Burden in Zanzibar, *PLoS Medicine*, 2007, 4:e309.

when they are focused on concrete actions related to malaria control. Therefore, we focus on core elements of health systems needed to enable the scale-up of malaria interventions and not a comprehensive review of all health system strengthening activities.

The sections below describe what is needed from key stakeholders and the components of the health systems to scale-up universal coverage and the support these changes may require from the international community. Many of these activities, while begun during scale-up, will need to be continued once scale-up is complete to sustain control.

Key Stakeholders of the Health System

To strengthen health systems, countries will need strong support from political leaders and coordinated efforts from those who work within the health system at the national, district and local levels. Support required from the international community will be essential.

Strong leadership and governance from political leaders. Success at the country level requires strong, sustained political and budgetary commitment to malaria control. High-level officials (head of state, prime minister, ministries of finance and health) need to support the malaria control programs and their health systems to provide the necessary resources (human and financial), help resolve bottlenecks in countries (remove taxes and tariffs, provide free treatment etc.), accelerate procedures (administrative or regulatory procedures) and affirm governmental leadership in planning and coordinating all partners active in the country to reach rapidly the universal coverage targets. Zambia and Ethiopia, which achieved substantial progress in malaria control, are prime examples of strong political support behind malaria control programs. For instance, the Zambian government has supported the establishment and implementation of the 6-year strategy and has taken the lead on coordinating all partners. The Ethiopian government has demonstrated its commitment by establishing joint steering committees at the national and regional levels to strengthen accountability by removing taxes and tariffs on malaria preventive tools and by promoting demand through communication efforts.

Support required. Advocacy efforts targeted to political leaders to raise malaria on the national agenda of endemic countries are required. Strong emphasis should be placed on the need to create an enabling environment for malaria control by removing bottlenecks to scale-up at the national level. See *Part IV - Chapter 1: Advocacy* for more detail.

Adequate and well-trained health workforce. Human resource capacity is one of the major concerns in most malaria endemic countries. Scale-up corresponds to a substantial increase in the delivery of malaria interventions and will require bold efforts to match human resources with planned activities. The national malaria control program needs to be structured adequately to match needs, and efforts will be conducted to increase the recruitment, motivation and retention strategies of key personnel (e.g. program managers, logistic or monitoring experts, accountants, entomologists, health workers). Emphasis will be put on developing skills through intensive capacity building and training programs at all levels (national, regional and local). See *Part IV - Chapter 4: In-Country Planning*.

Support required. Countries need technical assistance to develop comprehensive human resource plans. Increased support for capacity building is needed to increase management skills (program or financial management), technical knowledge (e.g. entomology, monitoring and evaluation, procurement and supply chain management) and knowledge of the delivery of interventions (for community-based health workers and other health care providers).

Components of Health Systems that Enable Scale-up

The key components of the health systems to enable scale-up are presented below. More detail is provided on each of these topics and on the role the RBM Partnership will play in coordinating partner activities around them in *Part IV: The Role of the RBM Partnership*.

Policy and regulations in line with international guidance. National regulatory bodies register products, ensure quality assurance and enforce mechanisms for quality control of interventions. National policy processes establish treatment and prevention guidelines. National authorities ensure that adopted policies are adopted and implemented throughout the country. Ideally all these national decisions are aligned with international recommendations. The adoption of international regulatory decisions could reduce critical time-delays during the scale-up stage.

Support required. New international recommendations need to be developed (e.g. on RDTs) and current international recommendations (such as WHOPEs and prequalification of ACTs) need advocacy in countries to avoid delays in the scale-up stage. Policies that reduce the risk associated with resistance should be strongly encouraged. See *Part IV - Chapter 4: Policy and Regulatory* for more detail.

Detailed and accurate planning. A clear understanding of local needs will form the basis of accurate planning for each district.¹⁷ This is best created through a multi-partner, consensus-based effort, involving the public sector, the private sector, civil society, the main donors, technical and implementation support partners, the research community and neighboring countries. To achieve the ambitious 2010 targets for universal coverage, countries will need detailed, district-by-district planning based on district needs assessments. These should be translated into month-by-month plans of who will do what and where. This will lead to a clear understanding of the major bottlenecks, resource needs and delivery capacities of the country.

Support required. Countries need technical assistance support in developing their health plans and proposal (especially for applications to major donors such as the Global Fund or World Bank). They need to be supported in capacity strengthening to run such processes. The development and dissemination of best-practices of successful scale-up programs will be essential to inform planning. See *Part IV - Chapter 5: In-country Planning* for more detail.

Timely access to resources. Available resources should be matched to planned activities. Once resource gaps are identified, strong plans should help to build the case for additional funding, and resource mobilization activities should be conducted to fill these gaps. For scale-up, reprogramming of existing grants and accelerating country resources disbursement is a key opportunity: countries and fund recipients need to take advantage of the flexibility offered by major donors,¹⁸ such as the Global Fund (frontloading of product purchases, acceleration of phase 2 negotiations and disbursements etc.) or the World Bank (acceleration of commitments for Booster Phase 2, leverage of amendments to previous projects etc.). Mechanisms such as direct payment of grants to procurement agents or manufacturers can be considered to accelerate financing processes.

Support required. An international resource mobilization strategy must be in place to raise funds for all in-country activities and international support required to reach universal coverage. To meet rapidly the scale-up targets, disbursement mechanisms of international donors need to be accelerated. Capacity strengthening at the country level to respond to Technical Review Panels and to resolve disbursement bottlenecks is essential to ensure the availability of resources. Equally important is the political will and accountability within country governments and ministries of finance to ensure the release of funds to malaria control programs. Countries need assistance in completing high-quality procurement and supply management and M&E plans. Besides, innovative financing and procurement mechanisms could be established for ACTs and LLINs. See *Part IV - Chapter 6: Financing* for more detail.

¹⁷ For instance the main vector control method chosen depends highly on epidemiological conditions and on logistical in-country capabilities.

¹⁸ *Funding and procurement challenges facing rapid scale-up of LLINs to reach the 2010 targets.* World Bank, Presentation at RBM 14th Board Meeting, May 2008.

Effective distribution systems. Expanding distribution to reach universal coverage with interventions requires managing large amounts of products for which adequate forecasting, quality control, procurement and supply chain management systems need to be in place. Strengthening the public health system procurement and supply chain is essential. Quick resolution of implementation bottlenecks and capacity building in procurement and supply chain management are critical to ensure that the short term goals can be achieved while countries manage the long term expansion of these distribution systems.

Support required. Countries need technical assistance to resolve implementation bottlenecks impeding scale-up, especially linked to procurement and supply chain management (PSM) issues. For instance, they need to be supported in using available PSM capabilities of the public sector, the private sector or NGOs and in strengthening mechanisms to improve logistics. To strengthen forecasting capabilities, comprehensive needs assessments are being carried out in sub-Saharan African countries. In the longer term, a process will be established to help identify the best approaches to forecasting for all interventions. Countries may also need to be supported for their tendering systems, contracting out, building and financing supply chains. Updated procurement guidelines will also be prepared. See *Part VI - Chapter 7: Procurement and Supply Chain Management* for more detail.

Strong communication and behavior change methodologies. Service delivery is not only about delivering products; it is also about ensuring they are used properly. Communication and Behavior Change Methodologies are essential to ensure the appropriate use of interventions. These programs need to be designed with the active participation of both service providers and intervention-users and will aim for improving health-seeking and care-providing behaviors. At the individual level, they will develop strong messages to improve recognition of malaria symptoms and risk groups as well as correct use of interventions (use of LLINs, acceptance of IRS, correct diagnosis to demonstrate parasites before treatment, full compliance with ACTs etc.). They will be designed to create opportunities for people to discuss malaria issues, especially at the community level. Whatever communication channel is chosen, messages need to be tailored to address specific regional and community needs and to involve local leaders (political, religious and traditional) to increase identification and participation of the population.

Support required. To increase utilization rates of interventions, countries need help developing and disseminating consensus-based guidelines and best practices for approaches to Information, Education and Communication / Behavior Change Communication (IEC / BCC) methodologies during the scale-up stage. See *Part IV - Chapter 8: Communication and Behavior Change Methodologies* for more detail.

Monitoring and Evaluating (M&E). M&E information systems measure the coverage, utilization and health impacts of interventions, with a view to making informed adjustments in future planning. Every country should have a costed malaria M&E plan addressing national and local need. Increasing staff dedicated to M&E and building capacity are essential to track the indicators that are essential for the scale-up stage, especially levels of coverage and utilization of the interventions (including equity in access), which can be measured through regular surveys (e.g. the Multiple Indicator Cluster Survey, the Demographic and Health Surveys and the Malaria Indicator Survey) and through strengthened routine health information systems. For example, additional information will be needed to monitor new approaches such as the AMFm and the prices of ACTs. Once information is collected and analyzed, countries will share it with all major stakeholders to enable global tracking of progress.

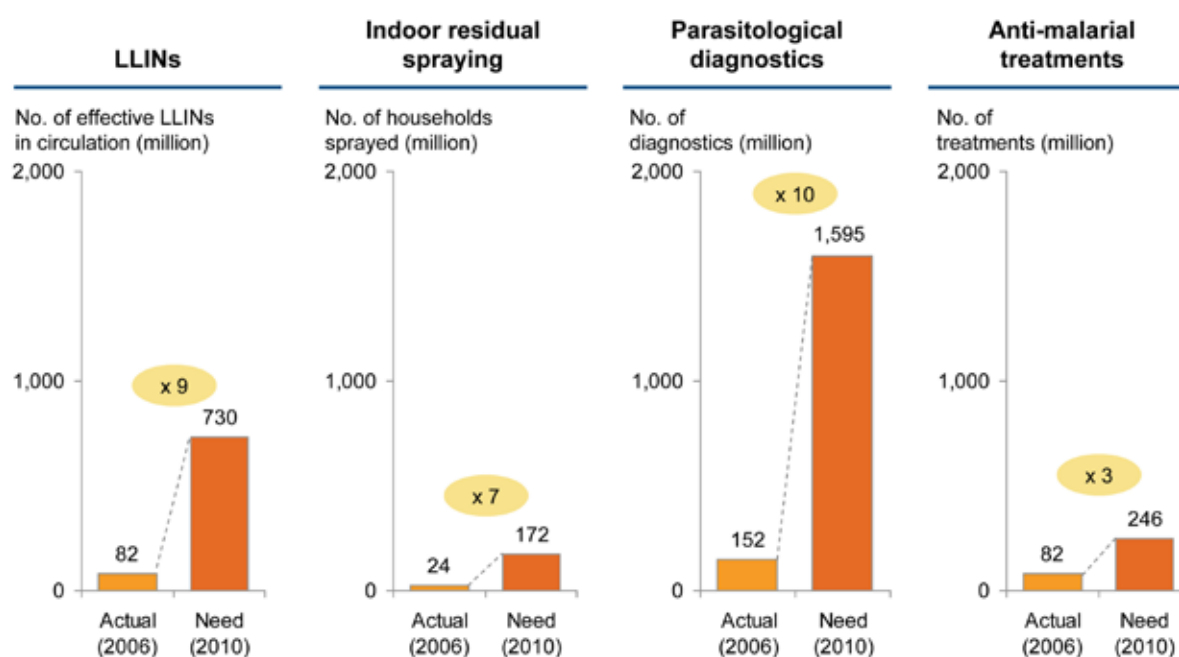
Support required. Countries in the scale-up stage need assistance in developing their national M&E plans. They need support as they increase M&E dedicated staff and roll out frequent population-based surveys. Support is also needed to integrate efforts with wider health sector M&E to enable efficiency. International tracking of progress in malaria control needs to be organized and coordinated internationally. See *Part IV - Chapter 9: Monitoring and Evaluation* for more detail.

Effective Delivery Strategies Required to Reach Universal Coverage

Most countries are still at low levels of coverage. To reach targets of universal coverage, a substantial amount of interventions need to be funded and delivered globally:

- Globally, an estimated 730 million LLINs are needed to protect populations at risk for whom nets are appropriate. Approximately 50 to 100 million nets already distributed (mostly in sub-Saharan Africa) will remain effective for the next two years. Approximately 315 to 340 million new LLINs are needed annually in 2009 and 2010. For Africa alone, 250 - 300 new LLINs are needed to reach universal coverage by 2010.
- Globally, ~172 million households need to be covered with IRS every year.
- ~25 million pregnant women annually are expected to require IPTp. This estimate is only for high transmission areas in sub-Saharan African countries where IPTp is currently recommended.
- The global annual need for diagnostics (by microscopy or RDTs) based on fever cases is ~1.5 billion.
- Target treatment coverage, assuming diagnosis with microscopy or RDTs, is estimated at ~247 million treatments: 228 million treatments of ACTs and 19 million treatments of chloroquine and primaquine for treatment of *P. vivax*. Without diagnosis, the number of treatments needed would be much higher due to over treatment of fever cases as malaria.

Figure II.6: Global scale-up in interventions from 2006 to 2010



a) Estimate based on number of nets that should be in use. Because of 3-year lifespan, fewer new nets are needed each year than the number in use.

b) Today, actual use is likely not matching confirmed malaria cases.

Source: Need based on GMAP costing model; actual based on analysis of World Malaria Report 2008. Geneva, World Health Organization, 2008 and Roll Back Malaria Commodities database.

Global production capacities need to be increased substantially to be able to reach global scale-up targets. The production issue needs to be addressed for all interventions and could be even more acute for ACTs due to withdrawal of artemisinin producers from the market in 2007-2008 after the substantial decrease of artemisinin prices. Alternative artemisinin produced through bio-technology from yeast culture will not become available before 2010. Global support and effort is needed to address the issue of adequate supplies.

To achieve universal coverage, countries must go beyond the procurement and financing of interventions to ensure that the products can reach every person at risk. Countries can scale-up interventions to reach the largest populations at risk based on best practices demonstrated by other countries.

Gender and socio-economic status should not determine access to interventions. Against the background of universal coverage for all populations at risk, dedicated strategies will need to be put in place to make sure that the most vulnerable and isolated populations are covered by the interventions, especially those in the poorest economic quintiles, populations living in remote areas and women.

For several interventions, using the skills of the private sector proves to be efficient in scaling up interventions. Commercial networks can be used for the delivery of some products (e.g. LLINs or treatments) provided that adequate information and training are provided, enabling access into even remote areas where health facilities might not be accessible. Private companies or consortia could also be contracted out for conducting programs such as IRS. Private sector competencies to foster demand generation or provide capacity building within countries can enable successful malaria control.

Vector control scale-up. Both long-lasting insecticidal nets (LLINs) and indoor residual spraying (IRS) can dramatically reduce malaria morbidity and mortality. They both provide community protection at high levels of utilization (>80%).

- *LLIN scale-up.* In the early years of mosquito net distribution, nets were primarily promoted through social marketing largely through the private sector and subsidized distribution approaches as a personal protection tool for vulnerable groups.¹⁹ Since 2003, a global consensus has been building towards the scaled up distribution of LLINs at no cost to the end-users. WHO endorses this approach and recommends that all targeted populations are 100% covered with LLINs to exploit the community protective effect of insecticide-treated nets (ITNs) that is observed at high coverage levels. For this purpose, distribution to all populations at risk (not only vulnerable groups) with free LLINs is generally considered to be the most rapid and cost effective way to reach universal coverage, and is the approach used successfully in Ethiopia (see Box II.2) and other countries.

Several factors contributed to the success of the Ethiopian LLIN distribution campaign, including the use of a third-party procurement agent, donor flexibility in use of funds which allowed rapid disbursement, and the utilization of multiple delivery methods including enhanced outreach, health facilities and the strong network of 30,000 health extension workers to reach the population.

Using the competencies of the private sector and outsourcing the mass campaigns could also be an effective way to reach the coverage targets, while helping national authorities to focus on their core activities, such as strengthening of routine health services or monitoring and evaluation.

Distribution systems for LLINs should not be viewed as competitive or fighting for “market share”, but as complementary approaches to achieving a single goal: a comprehensive LLIN distribution strategy,²⁰ including both campaign and routine distribution mechanisms supported by both the public and private sectors, to create a “net culture” in which the use of LLINs becomes a societal norm.²¹ Mass campaigns, often integrated with other health interventions such as immunization and vitamin A supplementation are good for initiating high coverage levels rapidly, and routine systems – e.g. distribution during antenatal or infant immunization services – are very efficient for maintaining coverage between campaigns and ensuring that vulnerable populations (such as pregnant women and children under 5) are reached.

¹⁹ Teklehaimanot A et al. Malaria Control needs mass distribution of insecticidal bednets. *The Lancet*, vol. 369, issue 9580, pp. 2143-2146, 2007.

²⁰ Lengeler C et al. Program diversity is key to the success of insecticide-treated bednets. *The Lancet*, 2007.

²¹ *Scaling-up Insecticide-treated netting programs in Africa, RBM-WIN and Insecticide-treated mosquito nets: a WHO position statement.* Geneva, World Health Organization, 2006.

Box II.2: Success of LLIN mass distribution in Ethiopia²²

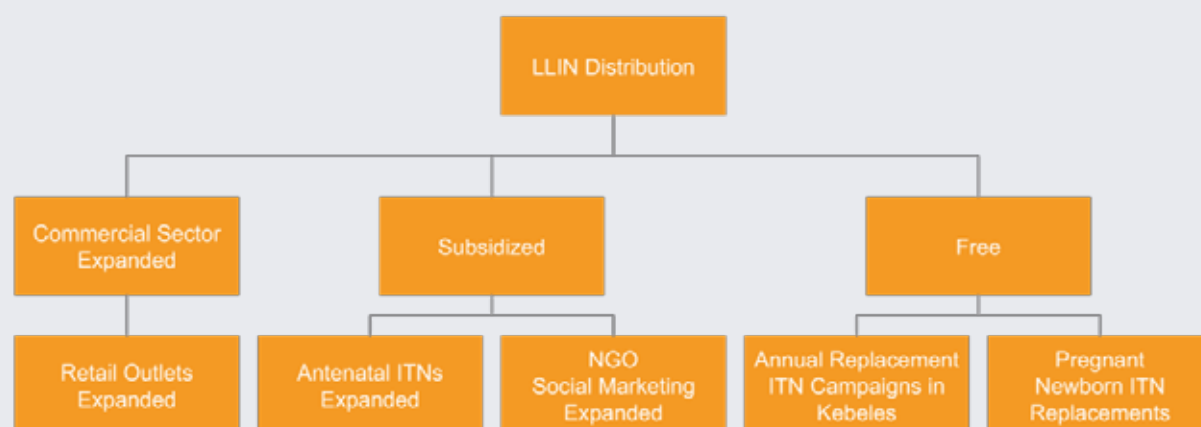
Between 2005 and 2007, one of the most ambitious LLIN delivery programs ever attempted was implemented in Ethiopia, where nearly 20 million nets were distributed across the country (two nets for each of the 10 million households targeted).

After its worst malaria epidemic in 2003, Ethiopia made a bold proposal to international donors in 2005: to deliver 20 million LLINs in 3 years. Ethiopia made a strong case for the budget required (US\$ 160 million, 3 times the previous national malaria budget). Donors responded positively, with over US\$ 200 million coming from the Global Fund, World Bank, DFID, the Carter Center and others. Ethiopia took advantage of flexibility built into both the Global Fund and World Bank processes to frontload funding. Rather than disbursing its grants over 5 years, the country drew down on the pledged funds to finance its ambitious distribution program in 1-2 years.

Ethiopia used UNICEF as a third-party procurement agent to increase procurement speed and reduce transaction costs. Funds flowed directly from the Global Fund to UNICEF, avoiding the need to disburse funds from the Global Fund to the government and then on to a procurement agent. At the same time, significant investments were made by the government and partners to build in-country procurement capacity for the post scale-up stage.

A combination of distribution channels were used to achieve a high level of coverage, especially the Enhanced Outreach Program and the network of 30,000 Health Extension Workers in communities (see Box II.6 later in this chapter), as well as distribution from health facilities. UNICEF has also been supporting the development and implementation of a community based social communication program (toolkits, training of health workers and community volunteers) to ensure high utilization rates of the nets delivered. Ethiopia is developing communication programs to improve usage and developing strategies to provide continued access to additional LLINs to maintain 100% coverage, as presented in Figure II.7 below:

Figure II.7: Targeted distribution channels in Ethiopia



Analysis conducted by the WHO-GMP show that the combined delivery of LLINs and ACTs in Ethiopia was very successful: the weighted average percentage decline for children under 5 in in-patient facilities visited in Ethiopia was 60% for cases and 51% for deaths between 2005 and 2007²³ with coverage of LLINs of approximately 60% at the time of the study. While great successes have been achieved, opportunities still exist to improve utilization. Additionally, monitoring over time will determine the sustainability of the initial gains.

²² Ministry of Health of Ethiopia, personal communication, 2008; Chambers, Gupta, Ghebreyesus. Responding to the challenge to end malaria deaths in Africa. *The Lancet*, 2008; *Factsheet Malaria in Ethiopia*. New York, UNICEF, 2007.

²³ *Impact of long-lasting insecticidal-treated nets (LLINs) and artemisinin-based combination therapies (ACTs) measured using surveillance data, in four African countries*. Geneva, World Health Organization Global Malaria Program, 2008.

- *IRS scale-up.* IRS has proved to be an efficient vector control measure for reducing malaria burden, as was the case with the Lubombo Spatial Development Initiative (LSDI) between Swaziland, Mozambique and South Africa, and in countries targeted by the President's Malaria Initiative (10 African countries in 2007-2008 and 15 targeted in 2008 and beyond). In the LSDI initiative, intensive IRS campaigns markedly reduced *P. falciparum* malaria prevalence and between 1999 and 2005, the number of confirmed malaria cases was reduced by 95% in Swaziland and by 96% and 78% in two adjacent provinces of South Africa.²⁴ IRS is also widely used in Southeast Asia and contributed largely to overall burden reduction during the malaria Eradication campaign from 1950-1970 in countries such as India²⁵ or Sri Lanka.²⁶

IRS can be scaled up provided that the logistical structures are in place (equipment, well-trained staff), local epidemiology and transmission patterns are well known, and capacity for regular supervision and quality monitoring exists. Even countries which previously did not have this capacity, such as Mozambique pre-LSDI, can implement programs with the appropriate support and commitment. Generally, IRS programs were clearly separated from other programs in the national control strategy and this autonomy was a success factor. National malaria control programs such as in Botswana, Namibia or South Africa have their own teams of spraying operators composed of government-employed public health workers. In other examples, spraying campaigns were outsourced to private sector consortiums or companies. Success of IRS scale-up campaigns is very much linked to the ability to deploy well-trained spraying teams, to manage the logistics of the insecticides (safe storage, handling etc.) and to be able to monitor and map sprayed structures.

- *Scale-up of other vector control interventions.* Other more targeted vector control interventions, such as larviciding or environmental management, can be used where they are proved to be efficient and cost-effective. One of the key elements of success for these interventions is the participation of local communities, as was the case in India²⁷ or in a regional program in Mexico and Central America²⁸ where local communities worked to reduce breeding sites.

Diagnostics scale-up. In parallel to increasing access to treatments, parasitological diagnosis (with microscopy or, where not possible, with Rapid Diagnostic Tests) should be made available to populations at risk when appropriate²⁹ (see Box II.3). The use of parasitological diagnosis is still limited overall and needs to be expanded to inform treatment choice and make more rational use of anti-malarial treatments. Microscopy and RDTs are both part of laboratory systems. They need their own supervision and quality control. Their use will necessitate strong algorithms to interpret the results and allow appropriate decisions to be made on both malarial and non-malarial febrile illness, and appropriate supply and logistics to support these decisions.

- *Microscopy scale-up:* increasing the use of quality-assured microscopy requires strengthening capabilities in health facilities. This includes providing microscopes along with strong training programs on microscopy, quality monitoring systems and increasing attendance at equipped facilities. In Indonesia, the use of microscopy has recently expanded to a wide network of local health facilities.

²⁴ Sharp et al. Seven years of regional malaria control collaboration - Mozambique, South Africa and Swaziland. *American Journal of Tropical Medicine and Hygiene*, 76(1), pp. 42-47, 2007.

²⁵ Incidence reduction from 75 million cases to 100,000. Sharma VP. *The Malaria Eradication Experience of the Indian Sub-Continent*. Presented at the WHO Informal Consultation on Malaria Control and Elimination, 2008.

²⁶ Child mortality was reduced by 50% between 1946 and 1956. Newman P. *Malaria Eradication and Population Growth, with Special Reference to Ceylon and British Guiana*. *Bureau of Public Health Economics*, University of Michigan, School of Public Health, Research Series No. 10, 1965.

²⁷ Lindsay et al. *Environmental Management for Malaria Control in the East Asia and Pacific (EAP) Region*. *HNP discussion paper*, Washington, D.C., World Bank, 2004.

²⁸ Regional Program of Action and Demonstration of Sustainable Alternatives to DDT for Malaria Vector Control in Mexico and Central America (DDT-GEF). Available on (<http://www.amro.who.int/English/AD/SDE/ddt-home.htm>).

²⁹ *Guidelines for the Treatment of Malaria*. Geneva, World Health Organization, 2006.

- *Rapid Diagnostic Test (RDT) scale-up:* RDTs can be used in public health facilities that do not have access to microscopy services. They are also well suited for community case management and for private sector distribution. As with microscopy, assurance of quality is essential and concerns have been raised over the quality of many RDTs. An initiative to assess quality assurance of RDTs is being carried out by WHO - Western Pacific Regional Office, WHO - the Special Programme for Research and Training in Tropical Diseases (TDR) and Foundation for Innovative New Diagnostics (FIND) and should inform policies in the near-term future. Proper storage and transport are critical for RDTs and need to be closely monitored since the tests can be damaged by high temperatures and freezing. Therefore, countries that want to scale-up RDTs need to have in place cold chains for transport and storage (i.e. avoiding any exposure to temperatures outside manufacturer's recommendations), quality control testing procedures, and clear treatment algorithms to clarify actions following the results of the test.

Box II.3: Parasite-based Diagnostics for Malaria

Parasite-based diagnosis, based on light microscopy or RDTs, is recommended by WHO for management of all malaria cases, with the exception of children under five in high transmission settings (where evidence of benefit over cost is unclear) and certain specific situations such as epidemics proven to be malaria in low-resource situations. Providing the febrile patient with a correct diagnosis will reduce delays in the correct management of non-malarial febrile illness, and may improve adherence to anti-malarial therapy, thus reducing morbidity and allowing better targeting of resources.

However, the introduction and maintenance of diagnosis through the use of microscopy and RDTs requires considerable investment in training, supervision, logistics and education of health workers and the community. This must be included in program budgets, together with provision for non-malarial febrile illness, as most fevers will not be due to malaria. While this is essential, access to effective anti-malarial medicines must not be delayed, and in some cases may need to be deployed on the basis of clinical diagnosis while capacity for parasite-based diagnosis is rapidly scaled up in such areas.

Anti-malarial treatment scale-up. Universal coverage with anti-malarial treatments (such as ACTs) is a daunting challenge because three-quarters of all anti-malarial treatments are currently obtained outside the public health system,³⁰ many of the most affected populations live in remote areas with limited access to public facilities, and many cannot afford ACTs at current prices, especially in the private sector. A combination of several strategies can be used to expand treatment coverage:

- *Make better use of existing professional resources.* Improving the availability and quality of interventions delivered in existing health facilities is the first step to increase effective coverage. This includes improving forecasting and logistical management at all levels, including the local level, to avoid stock outs or expiration of drugs and other supplies, offering training programs for care providers, and using program management to improve the quality of interventions delivered.³¹ To avoid overburdening the current health systems, new tasks could be integrated within existing responsibilities, but outsourcing certain activities could also be considered, such as in Bangladesh where the delivery of several interventions was successfully outsourced to NGOs. Every health facility should have adequate drug storage facilities with proper record-keeping procedures.
- *Expand the reach of the health system into the community.* This can be done by providing access to treatment through community providers, supplying medicines and diagnostics to community workers, and implementing community education and communication programs to ensure proper use of drugs. In Ethiopia, malaria control interventions are integrated with the Health Extension

³⁰ AMFm Technical Design. RBM Resources Working Group, 2007. More information available on (<http://www.rbm.who.int/globalsubsidytaskforce.html>).

³¹ *Scaling Up Home Based Management of Malaria*. Geneva, World Health Organization, 2004.

Program, which is staffed by more than 30,000 trained, salaried, community-based Health Extension Workers (HEW) and is coordinated by the Ministry of Health. See *Box II.6: Health Services Extension Program and Health Extension Workers in Ethiopia*. Ghana has put in place a Community-based Health Planning and Services (CHPS) program based on ~3,000 Community Health Officers who are assisted by community volunteers in delivering a broad package of health services, including the provision of insecticide-treated nets, IPTp and case management for uncomplicated malaria.³² This program has been implemented in 104 of the 110 districts in the country.³³

- *Increase geographical access through the private sector.* Ensuring convenient, affordable high-quality anti-malarial treatments in the private sector, and providing information on how to use them are essential steps. Strategies include training and monitoring private sector drug sellers (market sellers and shop-keepers) in parasite-based diagnosis (such as RDTs) and appropriate treatment. Efficient examples of private sector involvement include franchising or accrediting private pharmacies to provide high quality management, contracting out malaria management to private practitioners, and delivering subsidized, affordable ACTs through retail networks are examples that could increase access. Ideally, the public sector will provide overall stewardship to private providers, including training for diagnosis, drug handling, dispensing, advice giving and referral of severe cases, and monitoring of the management of both malarial and non-malarial febrile illness. Careful planning is necessary to ensure that standard management policies are followed, and that providers have appropriate incentives to maintain good targeting of, and adherence to, therapy.
- *Increase financial access and pool health risks:* Increasing the financial access is important so that all people at risk of malaria can receive appropriate prevention and treatment regardless of their socioeconomic status. There are several ways to increase financial access. One is to reduce the cost of treatments upstream before they enter countries, as is the case with the innovative financing mechanisms currently being considered (such as the Affordable Medicines Facility - malaria which has been endorsed by the RBM Board). Another is to ensure free delivery of treatment and other health services associated with treatment such as consultation and diagnostic tests. Experience in countries such as Mali shows that making health services free for children under five can have substantially higher impact than delivery of free malaria treatment alone.³⁴ However, this will require sustained financing to cover the costs of providing treatment. See *Part IV - Chapter 6: Financing*, especially *Box IV.2: Affordable Medicines Facility - malaria*. The challenge for many malaria endemic countries is to protect individuals from high out-of-pocket payments for malaria and other diseases. In addition to decreasing the costs of interventions and services, countries can institute mechanisms to pool health risks and provide financial protection to the population. Four main health insurance mechanisms are used to pool health risks, promote prepayment, raise revenues, and purchase services. These are state-funded systems through ministries of health or national health services, social health insurance, voluntary or private health insurance or community-based health insurance.³⁵
- *Design, implement and evaluate interventions to reach the poorest and underserved populations:* Countries need to identify strategies to expand uptake by those who are not currently accessing any malaria treatment. In general the poorer groups are less likely to have treatment and have lower quality treatment than those who are better off. There is insufficient evidence on how best to reach the poorest and underserved groups. The evidence that does exist shows that a variety of approaches can work, depending on how well they are designed and implemented.³⁶ However, there is very little evidence specifically on how best to reach the poorest with malaria treatment as most studies have not looked at who is benefiting from treatment.³⁷ This should be assessed in future studies to see which strategies are most cost effective.

³² *Community Based Health Planning and Services (CHPS), The operational policy*. Ghana Health Services, 2005.

³³ Nyonator et al. The Ghana Community based health planning and services initiative for scaling up service delivery innovation, *Health policy and planning*, 2005.

³⁴ Médecins sans Frontières, personal communication, 2008.

³⁵ *Health Financing Revisited, A Practitioner's Guide*. Washington, D.C., World Bank, 2006.

³⁶ *Reaching the Poor with Health, Nutrition and Population services, What works, what doesn't and why?* World Bank, 2005. Available from: <http://siteresources.worldbank.org/INTPAH/Resources/Reaching-the-Poor/summary.pdf>.

³⁷ *Second interim report on progress against outstanding AMFm implementation challenges*. RBM AMFm Taskforce, August 2008.

Malaria in Pregnancy (MIP) interventions scale-up³⁸ including IPTp. Since at least 70% of pregnant women in Africa seek antenatal care at least once during pregnancy, antenatal care services provide a platform for the delivery of interventions for the prevention and control of malaria during pregnancy (IPTp, LLINs, effective case management and other interventions for ensuring healthy pregnancy outcomes and maternal and child survival such as iron supplementation against anemia). Malaria in Pregnancy programs work best with strong cooperation between national malaria control programs and reproductive health programs. Distribution channels through antenatal care (ANC) clinics are already in place in many countries; today, several challenges impede scale-up of MIP interventions among which are the availability of MIP interventions in ANC clinics as well as the regular and timely attendance clinics throughout pregnancy.

- *Minimize missed opportunities.* Despite high ANC utilization, IPTp coverage remains low in countries with stable malaria transmission, reflecting missed opportunities for reaching ANC attendees with effective interventions for malaria control. A significant proportion of pregnant women attend ANC clinics only once in their pregnancy, whereas WHO recommends four visits, three visits after quickening each time with IPTp delivery. Zambia has effectively used antenatal clinics to deliver IPTp, reaching 61% of pregnant women with two doses; in Zambia, 94% of pregnant women attend ANC clinics once and 71% attend them at least 4 times. In several countries of sub-Saharan Africa, IPTp coverage is substantially lower than ANC coverage, clearly demonstrating the extent of missed opportunities in the delivery of IPTp and LLINs through antenatal care services. Scaling up IPTp and other MIP interventions will require concerted efforts to minimize missed opportunities and ensure that all women attending ANC clinics in high transmission settings receive the necessary interventions for malaria prevention and control.
- *Challenges to MIP scale-up.* Main challenges to MIP interventions include persistent stock-out of drugs for IPTp, inadequately trained personnel, poor supervision and tools for effective monitoring and evaluation of program effectiveness. Success in this regard requires strong collaboration between national malaria control and reproductive health programs and concrete actions to strengthen the health system to support the delivery of these interventions. Specific health systems strengthening aspects include improved availability of drugs, supplies and commodities, joint planning and capacity building of health workers, improved capacity of laboratories with sensitivity for comprehensive care of the pregnant woman and her unborn baby and strong supervision, monitoring and evaluation tools. Of critical importance is the need for communication and behavior change methodologies and support for engaging communities in the prevention and control of malaria during pregnancy. Such engagement ensures that the community develops an appreciation of the need for skilled care during pregnancy and that women receive all the interventions they need in a timely manner with community support.

Scale-up of interventions in humanitarian crises. Some countries that need to scale-up malaria control interventions are experiencing humanitarian crises situations where the appropriate interventions and the delivery strategies need to be adapted. Countries experiencing chronic crises (e.g. Sudan and the Democratic Republic of Congo) require tailored technical support. See *Part IV - Chapter 10: Humanitarian Crises*.

Rapid and Coordinated Global Support Needed to Reach the 2010 Targets

The Partnership's main objective is to reduce malaria mortality and morbidity by 50% compared to 2000 by the end of 2010. To support countries in successfully achieving these targets, all partners (donors, politicians, local officials, NGOs, etc.) will need to work in coordination and align themselves behind a single strategy, as outlined in the Organization of Economic Cooperation and Development (OECD) Paris Declaration on Aid Effectiveness.³⁹ If some countries do not meet the 2010 deadline, they will continue to strive for the achievement of the universal coverage scale-up targets.

In addition to strategies to strengthen health systems and increase coverage of interventions, global support is needed to speed up financing, planning and distribution if the RBM Partnership is to be successful by 2010. In particular, three main steps are needed.

³⁸ *A strategic framework for malaria prevention and control during pregnancy in the African region.* WHO-AFRO, 2004.

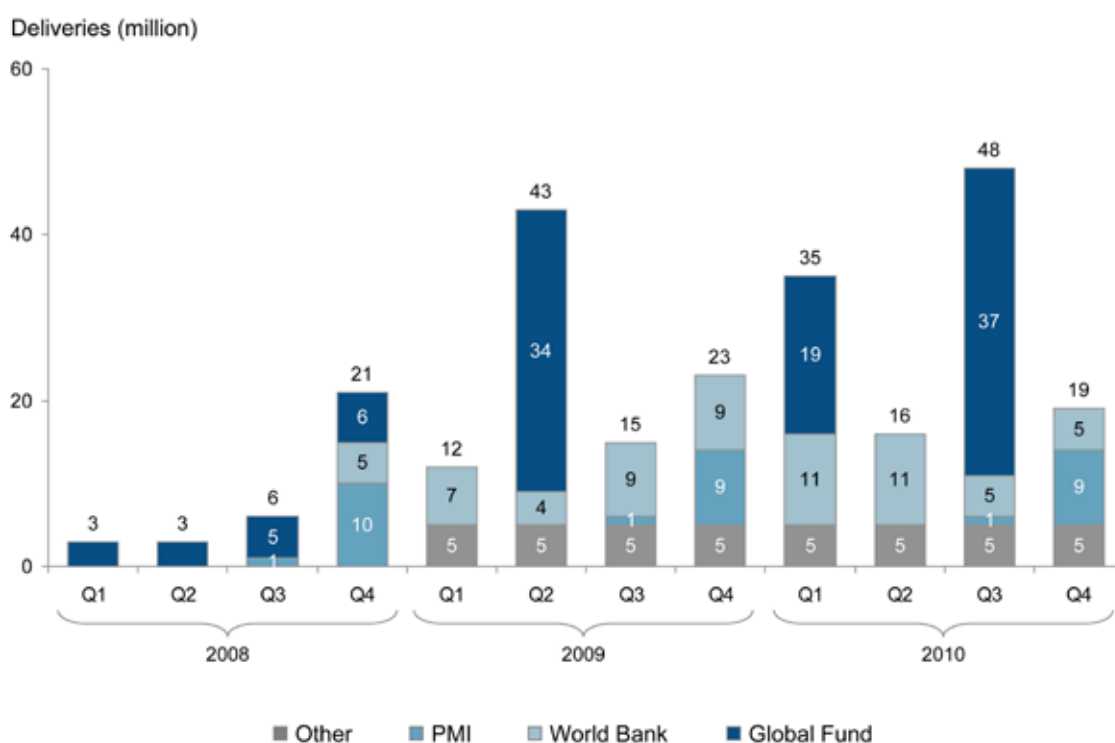
³⁹ *Paris Declaration on Aid Effectiveness: Ownership, harmonization, alignment, results and mutual accountability.* Paris, OECD, 2005.

Conduct robust country planning. A roadmap analyzing quarter-by-quarter⁴⁰ delivery needs and funding availability will be developed at the country level based on a country Needs Assessments. These plans will be developed with local RBM partners including governments, NGOs, multilateral and bilateral partners, civil society, NGOs, academia and others.

Accelerate and expand financing. An RBM Harmonized Working Group (HWG) analysis of country needs versus donor funding timelines indicates that funding will not be available for earliest distribution windows, even if the major donors (such as the Global Fund and the World Bank) accelerate their disbursements. New national and international funding sources are needed for the near term to cover this gap.⁴¹

Speed up procurement and distribution. There are several ways to speed up procurement and distribution of interventions. For instance, the use of third-party procurement agents for LLINs proves to be 2-3 times faster than country-led procurement mechanisms⁴² and will be a key success factor in achieving the 2010 targets for LLINs. See Figure II.8 for preliminary estimates of delivery needs aggregated for sub-Saharan Africa.⁴³

Figure II.8: Projected LLIN deliveries in Sub-Saharan Africa to reach universal coverage



Source: Achieving the Roll Back Malaria Partnership 2010 targets and fulfilling the United Nations SG’s Call to Action - A Roadmap for reaching the LLIN target as part of a comprehensive package of malaria control interventions; RBM Harmonization Working Group.

As interventions are rolled out, increased focus by countries and partners on communication, behavior change, monitoring and evaluation activities becomes all the more essential to ensure interventions are reaching those who need them and are being used appropriately.

⁴⁰ Quarterly as an example; other time frames could be more appropriate depending on the objective.

⁴¹ Update from the Harmonization Working Group presented at the RBM 14th Board Meeting, May 2008.

⁴² Funding and procurement challenges facing rapid scale-up of Long-lasting insecticidal nets to reach the 2010 targets. World Bank, Presentation at RBM 14th Board Meeting, May 2008.

⁴³ A roadmap for reaching the LLIN target as part of a comprehensive package of malaria control interventions, RBM, June 2008.

B. Sustained Control: Maintaining Coverage and Utilization

When scale-up is achieved globally, the lives of approximately 75% of children under 5 who would have died from malaria will be saved annually, and the global malaria case load will be reduced drastically. On the African continent, hospital beds will be freed-up and billions of dollars of gross domestic product (GDP) will be recovered annually in endemic countries. Success in malaria control is likely to contribute substantially to the achievement of the other Millennium Development Goals and to play a strong role in reducing the burden of poverty world-wide.

Even if parasite prevalence falls to low levels, malaria control will not eliminate the mosquito vector, the parasite, or the favorable environmental conditions for transmission in many locations. To keep malaria at bay, countries need to maintain high levels of coverage even in the absence of a large number of cases.⁴⁴ Relaxation of control—whether because of the decline in political will, decrease in funding, or some other reason—could lead to resurgence in transmission and to epidemics.

Only by sustaining control will countries maintain the benefits they gained through universal coverage. This will require that countries continue the use of the preventive interventions, keep monitoring in place for early signs of clinical disease, increasing parasite prevalence or resistance to drugs or insecticides, and diagnose and treat the remaining cases with appropriate case management tools.⁴⁵ One result of scale-up may be the loss of acquired immunity among people no longer continually infected with malaria parasites. Pregnant women in particular are more likely to have increased susceptibility to malaria infection during this stage and to suffer from severe disease with the risk of death. For infants and children protected from exposure entirely, protective partial immunity will never develop. Thus, if malaria makes a comeback, the whole population will be at risk of clinical symptoms and more severe cases.

In Sri Lanka in the late 1960s, relaxation of control measures after control led to a resurgence of malaria cases and more serious outcomes, which provides a powerful illustration of the importance of sustained control. (See Box II.4)

Box II.4: Malaria Resurgence in Sri Lanka

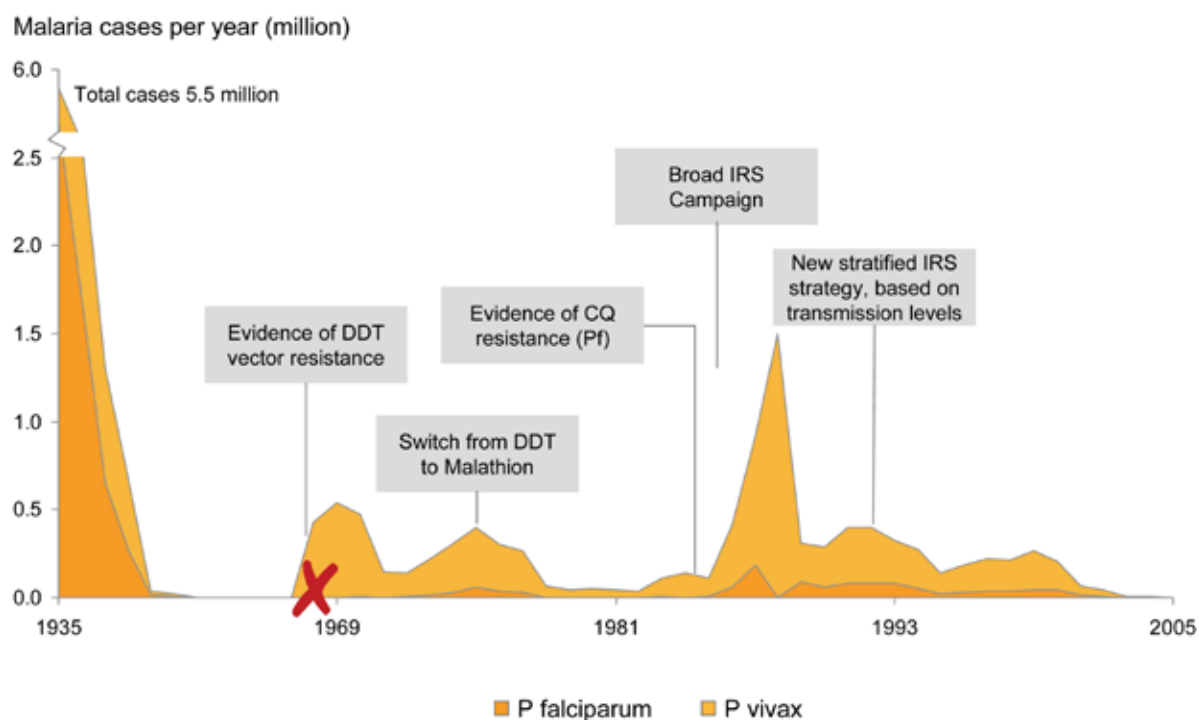
From 1945 until 1963, the number of reported malaria cases in Sri Lanka declined from 1.3M to a mere 17. Credit goes to widespread DDT campaigns in endemic areas and increased access to government health services. Following this success, the government stopped the DDT spraying program in 1964, relaxing their main vector control tool.

The DDT program was restarted, but by then resistance to DDT was widespread in the mosquito population and a switch to Malathion was made. In the 1980s and 1990s, river development projects created new breeding grounds for vector mosquitoes and at the same time, spurred population movements. Outbreaks in previously non-malarious areas and another significant resurgence occurred. IRS was used in the early 2000s to bring malaria under control once again. Both *P. falciparum* and *P. vivax* cases have declined to low numbers but the risk of resurgence remains if its control measures are relaxed. See Figure II.9: Resurgence of malaria in Sri Lanka.⁴⁶

⁴⁴ *Global Malaria control and elimination: report of a technical review*. Geneva, World Health Organization, Geneva, 2008.

⁴⁵ This assumes that vector or parasite behavior does not change, which would make current tools less effective.

⁴⁶ In 1935, the number of cases reported is extremely high, equivalent to 97% of the population. Explanations include: one individual treated more than once or # of visits, not cases, reported. Sources: Wijesundera M. Malaria Outbreaks in New Foci in Sri Lanka. *Parasitology Today*, vol. 4, no. 5, 1988; Mendis K et al. The neglected burden of *Plasmodium Vivax* malaria. *Am. J. Trop. Med. Hyg.*, 64 (1, 2)S, 2001, pp. 97-106; Briet O et al. Malaria in Sri Lanka: one year post-tsunami. *Malaria Journal*, 5:42, 2006.

Figure II.9: Resurgence of malaria in Sri Lanka

Source: Wijesundera (1988); Mendis et al (2001); Briet et al (2006).

The goal of the sustained control stage is to maintain universal coverage and ensure high utilization with appropriate malaria interventions for all populations at risk, until it is made irrelevant by elimination or until field research suggests coverage by some tools can be reduced without risk of resurgence of malaria.

At the global level, the 2015 RBM targets state that global and national mortality is near zero for all preventable deaths,⁴⁷ that global incidence is reduced by 75% from 2005 levels which will contribute substantially to the achievement of the malaria-related Millennium Development Goal (halting and beginning to reverse the incidence of malaria).

It is estimated that countries with natural high transmission settings will need to sustain high levels of control for at least 15-20 years or more, until new tools enabling elimination are available. Countries with lower transmission settings may move from sustained control to elimination more rapidly, provided that they have addressed other factors (e.g. strong health infrastructure, good management of malarious borders and epidemiological milestones).⁴⁸

To be successful, the sustained control stage requires a continued focus on the health systems activities started during scale-up and a sustained commitment from both endemic countries and the international community during years in which, if control is sustained successfully, few cases and deaths will occur. In addition, distribution channels for malaria products will need to be adapted and expanded to ensure that universal coverage can be continued. Below we discuss approaches to ensure this sustained and enhanced focus is achieved.

⁴⁷ Preventable death is defined as deaths from malaria that can be prevented with rapid treatment with effective medication. Non-preventable deaths represent an extremely low mortality rate for the most severe malaria cases and occur even with the best available and most rapid treatment.

⁴⁸ Epidemiological milestone is slide positivity rate (SPR) <5% in fever cases, see *Part II - Chapter 3: Elimination and Eradication: Achieving Zero Transmission*.

Sustained Commitment Needed from Key Stakeholders of the Health System

Maintain political support and sustained international funding. The continued support of external donors and national political leaders is critical to maintaining financial support. In the face of a greatly decreased malaria burden, attention will naturally shift to other priorities. However, universal coverage with interventions needs to be maintained until the beginning of the elimination stage, requiring long-term political commitment and high and predictable funding. Communication programs between the NMCP and other sectors within the country as well as at the local level are essential.

Support required. When the burden of disease is substantially decreased, strong advocacy efforts will need to be directed towards international donors, partners and endemic country leaders to emphasize the importance of continued malaria support. See *Part IV - Chapter 2: Advocacy*.

Expand human capacity in countries. Countries need more on-the-ground service providers, program managers, technical staff (logisticians, statisticians, accountants, etc.), scientists (e.g. entomologists, epidemiologists), researchers and skilled workers for monitoring and evaluation programs. An analysis of the objectives and needs of the NMCP should be carried out to build an adequate NMCP structure to coordinate partners. This structure will vary based on partner roles, degree of decentralization, public / private compositions, management styles, etc. As case management activities and some delivery circuits for preventive tools become more decentralized and malaria interventions become more integrated with other programs (such as reproductive health or child health programs), there is a crucial need for capacity building in management and technical skills down to the district and local level and also outside the traditional malaria system.

Support required. Countries need to be strongly supported in their efforts to plan for medium term human resource needs and in the expansion of capacity building programs especially through elaboration of adapted trainings and the creation of training networks.

Components of Health Systems that Sustain Universal Coverage

Improve policy and regulatory processes. Regulatory processes at the country level need to be continuously improved and accelerated. Regional regulatory processes could be considered for some countries where the limited size of the market could discourage manufacturers to enter into the national process. Strong governance structures need to be in place to strengthen policy-making processes and ensure that decisions are unbiased and based on scientific review.

Support required. International recommendations for regulatory and policy issues need to be updated taking into account changes in the malaria environment that might occur after scale-up. Countries need to be supported in capacity development of governance structures to strengthen national policy-making processes. See *Part IV - Chapter 4: Policy and Regulatory Priorities* for more detail.

Adapt planning for more effective decentralization. As the objective of the sustained control stage is to keep-up universal coverage of appropriate interventions, it will require a new round of planning to organize partners around the best-suited distribution systems for maintenance. This includes redefining the priorities of the control program around the strengthening of health systems in relation to malaria, including human resource capability and capacity building, equipment, infrastructure, logistics and supplies, supervision, monitoring and evaluation and improved communication / behavior change efforts as well as increased advocacy to ensure there is continued support for the malaria control efforts. The move from nationwide scale-up (thanks to national plans and implementation of mass distribution campaigns) to maintenance of control programs and strengthening of routine health systems and community health services is accompanied by a decentralization of authority. To ensure that strategies are adapted to local needs, it is even more important to develop local plans and to increase local political empowerment, leadership and budgeting power. In addition, regional malaria control initiatives should be encouraged in sustained control, which would require cross-country planning efforts. Strong inter-program and inter-sector collaboration are critical at this stage.

Support required. Countries need technical assistance in developing plans and funding proposals for the sustained control stage. These plans will also need to include the scale-up of new interventions. Support for collaboration on regional projects and the development and dissemination of best practices on approaches should be provided. See *Part IV - Chapter 4: In-country Planning*.

Maintain predictable and long-term access to resources. The magnitude of costs to sustain control are similar to the cost of SUFI, with two main differences: 1) the mix of costs will change with lower treatment costs and higher program costs due to stronger surveillance systems and higher preventive costs due to population growth and 2) funding flows need to be prolonged for a long period of time. Therefore, long-term and predictable funding will be needed to maintain the appropriate level of control required. To improve predictability, tools or frameworks for medium term planning for financing such as the Medium Term Expenditure Frameworks could be used. See *Part IV - Chapter 6: Financing*.

Increasing in-country funding. Countries should be encouraged to increase the level of internal resources spent on malaria to a point where they can sustain their own programs. Increasing national health budgets and the share allocated to malaria will make funds and funding gaps more predictable. As economic growth in high-burden countries will likely rebound after incidence goes down,⁴⁹ it is important that this is translated into increased national health spending for malaria and used to advocate for in-country inter-sector (education, agriculture etc.) funding. Private sector financing should be promoted.

Continued need for external funds. However, it is unlikely for many countries, especially the lower income countries, that internal financing alone can cover their needs. Countries will need to continue to seek external financing from international donors. As long-term commitments will be essential in this stage, a shift towards performance-based management will be important. In order to sustain interest from the donor community, increased financial reporting capabilities need to be in place by implementing, for instance, Malaria Sub-Accounts which will help better identify financial flows and therefore economic impact.

Support required. An international resource mobilization strategy with medium- and long-term goals is required to fund in-country implementation activities and international support needed, coming from external and increased domestic resources. Countries need to be supported in their efforts to improve medium-term planning for financing to clarify requirements for the future. This will help the donor community and national budget allocations for malaria to be more predictable during sustained control. International guidance is required on the use of tools to increase accountability of funding flows such as Malaria Sub-Accounts.

Adapt distribution systems to maintain coverage. Maintaining high coverage levels requires a combination of adapted distribution approaches to strengthen all routine delivery mechanisms and to improve integration with other disease programs where appropriate. Strong inter-program collaboration and robust procurement and supply chain management systems and accurate forecasting capabilities are prerequisites. Increased decentralization of decision-making and budgeting will also be accompanied by strengthened community participation in the delivery of interventions.

Sustain quality of interventions. Sustained control is the time when quality of interventions needs to be maintained and improved continuously. With the decreasing burden, care providers might reduce the attention required and quality of services they deliver. Capacity building especially through continuous training programs is critical to maintain the level of quality required for interventions as countries move towards elimination. If control is successful and incidence goes down, some of the diagnostic and treatment interventions will be less frequently used. To ensure their continued quality, adequate quality control testing programs need to be in place. The need for strengthened collaboration with other programs such as reproductive and child health programs to ensure prompt effective diagnosis and treatment for all cases would be critical at this stage.

⁴⁹ Malaria control is only one enabler to economic growth among numerous other factors.

Support required. Procurement and supply chain management capacities within countries need to be strengthened during the sustained control stage. Manufacturers of products in malaria- endemic countries need to be supported to meet the international standards. As new tools become available, adequate procurement and supply systems to roll them out need to be in place. International guidance and mechanisms should be established for quality control monitoring of all major interventions. Countries need to be supported in their efforts to strengthen forecasting capabilities. See *Part IV - Chapter 7: Procurement and Supply Management*.

Develop communication and behavior change methodologies. As the burden of malaria decreases, people may let down their guard: they may stop sleeping under nets or delay health seeking treatment. Health workers might decrease focus on malaria. Strong education and communication programs need to be in place to educate communities about the continuing risks of malaria. In addition, community-based communication programs aiming at increasing use of the various interventions also need to be maintained.

Support required. In-country communication programs are essential to maintain high levels of utilization of the interventions deployed. Countries need to determine what human resources are needed to conduct in-country communication programs in a sustainable way. Technical assistance will then be needed to train these workers. Standardized M&E indicators aimed at measuring progress in in-country communication programs will need to be developed. See *Part IV - Chapter 8: Communication and Behavior Change Methodologies*.

Strengthen Monitoring and Evaluation (M&E). Monitoring and evaluation takes on even greater importance in sustaining control. M&E systems should be able to routinely track coverage and utilization levels of interventions, as well as the quality of interventions delivered. Staff needs to be increased and M&E capabilities strengthened at the local level (districts and communities), along with the implementation of new mapping and communication tools, to track and respond locally to intervention gaps and malaria infections in a prompt manner. For this purpose, national support systems will increasingly move to sub-regions. M&E activities need to be more integrated into routine health information systems. If routine and local monitoring mechanisms are strengthened sufficiently so that they provide robust and timely data on coverage and impact, the need for national, population-based surveys could decrease. To ensure continued support for malaria control, regular reporting to all stakeholders for global tracking of progress and advocacy is essential.

Support required. Countries need to be supported to follow international guidance on the shift and enhancement of M&E capabilities for sustained control. In particular, they need support in capacity building and technology development (mapping or communication tools) at the local level. See *Part IV - Chapter 9: Monitoring and Evaluation*.

Ensure cross-border collaboration. Cooperation between countries becomes even more important once countries have scaled up and are sustaining control. Adjacent countries often have similar epidemiological settings, including transmission intensities and levels of resistance. It is therefore advantageous for countries to work together to harmonize intervention strategies as well as approaches to insecticide and drug tracking and reporting. Frequent communication between different malaria control programs facilitates best practice sharing and gathering of information regarding epidemiological changes which may require changes in policy.

Support required. The international community can support countries within regions by providing funding and institutional support for regional coordination meetings and regional coordinators. See *Part III: Regional Strategies*.

Box II.5: Scaling Up and Sustaining Control in Brazil⁵⁰

Brazil's Amazon region—where 13% of the country's population lives—is where virtually all malaria transmission takes place in the country. After decades of on-and-off control, the Brazilian government is applying proven interventions to control the disease. Migration throughout the multi-country region makes elimination an unrealistic short-term goal, but sustained control can be achieved and can keep the malaria burden low and manageable for the 24 million people in Brazil's Amazon region.

Since the last disease peak in 2006, Brazil has:

- Instituted uncomplicated *P. falciparum* malaria treatment with ACTs in an expanded network of diagnostic laboratories,
- Stepped up distribution of free LLINs and
- Maintained high levels of IRS and other forms of site-specific environmental management.

The pool of malaria control personnel has been expanded continually since 1999, which has improved the dissemination of control interventions and increased the capacity for operational research and monitoring. A powerful information management system captures the information collected and provides a clearer picture of changes, closer to real time than ever before.

Brazil's stepped-up control program is still new, but the results are promising. After the first year (2006), total malaria cases were down 17% and falciparum cases down 37%. Hospital admissions for malaria were cut by one-third, and there were only 73 deaths.

Brazil has identified the next challenges, concentrating on continued scale-up and sustaining control. With these measures, Brazil is on a path to meet the RBM 2010 goals and, thereafter, continuing control and documenting further declines in its malaria burden.

Adapted Delivery Strategies are Critical to Sustain Universal Coverage

To ensure ongoing universal coverage, the interventions must be provided on a regular basis during sustained control. The fabric and effectiveness of LLINs last for approximately 3 to 5 years.⁵¹ IRS can be effective for 3-6 months depending on the insecticides used and the surfaces sprayed.⁵² Drugs and RDTs are used up and expire. To maintain the coverage, the delivery systems set up during the scale-up stage should be continued, including the mass distributions if indicated.

There are multiple ways to maintain universal coverage of malaria interventions. Some intervention-specific success factors are presented below, but two key enablers apply to across interventions: integration with other programs and the enhanced use of the private sector.

While standalone interventions sometimes put additional pressure on health systems, integrated delivery mechanisms benefit from synergies between various programs that often target the same populations or the same areas. Although integrated mechanisms may be more difficult for some interventions (e.g. indoor residual spraying), countries need to make the best use of those which proved to be effective. The use of routine delivery systems (such as antenatal or immunization visits) and integration with the routine distribution programs of other diseases (e.g. Expanded Program for Immunization) need to be strengthened as they prove to be a cost effective way to maintain coverage levels. Expanding and strengthening malaria interventions, such as quality-assured microscopy, can also have a positive impact on other diseases.

⁵⁰ Presentation from Dr. Jose Ladislau, Ministério de Saúde: Secretaria de Vigilância em Saúde Programa Nacional de Controle da Malária. Geneva, 2nd Consultation Global Malaria Business Plan Meeting, July 2008.

⁵¹ Time of efficacy of LLINs could be lower in certain field conditions.

⁵² Even if some insecticides such as DDT can be effective for up to 9-12 months in certain conditions. *Policy Brief, Malaria Global Fund Proposal Development*. Geneva, World Health Organization Global Malaria Program, March 2008.

Reaching beyond the public sector to partner with the private sector for service delivery can be an effective way of sustaining coverage. Among other things, the private sector can assist with improving demand generation for malaria services, reaching isolated populations through expanded commercial networks, or even giving trainings to increase logistical, procurement and supply chain management skills within countries.

Maintenance of vector control. Vector control is important to sustain control and includes LLINs, IRS, and a variety of other interventions.

Maintenance of LLINs. The combination of approaches chosen during the scale-up will continue. If mass distribution campaigns were used to reach universal coverage, these campaigns need to be continued regularly to renew the installed base of nets. Routine services such as ANC and immunization visits should complement the distribution system by continuously distributing nets between the mass campaigns. Ethiopia, which has reached high coverage with LLINs, is developing a plan to maintain this coverage level through a combination of replacement campaigns (through the Health Extension Workers and other community-based agents) and routine delivery in health facilities and antenatal clinics.⁵³ Private sector distribution coupled with voucher mechanisms could complement these efforts.

Maintenance of IRS. As for scale-up, rounds of spraying will be performed once or twice a year, depending on the seasonality of malaria transmission and the insecticide used. In areas of stable malaria transmission where IRS is used routinely, long-term and predictable commitment from donors and authorities is needed to avoid gaps in coverage. In areas of unstable transmission, IRS will be increasingly needed to reduce transmission in residual foci or new active foci and to control outbreaks.

Maintenance of other vector control interventions. Other vector control interventions (larviciding, environmental management etc.) are of greater importance in sustained control as the burden goes down and targeted approaches towards breeding sites can be very effective in reducing vector populations. Their sustainability relies on the ability to conduct continuously reliable surveillance and mapping activities to identify areas where these interventions are most appropriate.

Maintenance of diagnostics. As mentioned earlier, universal access to parasitological diagnosis (by microscopy or RDTs) to confirm clinical diagnosis needs to be maintained for all populations at risk. For the moment, WHO recommendation is based on parasitological diagnosis for all age groups, except for children under 5 in areas of high transmission who should be treated on the basis of clinical diagnosis.⁵⁴ As the number of fevers due to malaria decreases, the use of parasitological confirmation will be extended to all age groups. During the sustained control stage, microscopy capabilities need to be extended substantially to prepare for elimination. For microscopy, quality assurance controls need to be in place. At a local level, when skilled workers are not available to conduct microscopy, RDTs as a community or home case management tool will be essential to ensure prompt and effective treatment.

Maintenance of anti-malarial treatment. As outlined in the scale-up chapter, the main pillars of universal coverage in treatment are improving the use of existing professional resources, expanding the reach of the health system especially through the development of community health workers networks, increasing financial access through subsidies or cost sharing mechanisms, and expanding geographical access with enhanced private sector distribution. These pillars continue to be critical to sustaining control.

Community-based access to treatment aims at giving community members the opportunity to participate in malaria control, for example through community health worker programs (see Box II.6). These programs are usually not malaria-specific and cover a broad range of health interventions such as management of diarrhea and promotion of breastfeeding. Maintaining high levels of training and expanding these community health worker programs could be an effective way to maintain treatment coverage over time, and are one of many potential successful solutions. Community-based access programs must consider human resource factors related to motivation and compensation to prevent burnout and encourage retention. Additionally, the number of tasks required per health worker must not be so high that the quality of care delivered suffers. As incidence diminishes and as treatment occurs more at the community level, forecasting capabilities need to be further strengthened to avoid stock-outs and expiration of drugs.

⁵³ Ministry of Health of Ethiopia, personal communication, 2008; *PMI Malaria Operational Plan - Ethiopia*. 2008. Also see PMI webpage (http://www.fightingmalaria.gov/countries/ethiopia_mop-fy08.pdf).

⁵⁴ *Guidelines for the Treatment of Malaria*. Geneva, World Health Organization, 2006.

Box II.6: Health Services Extension Program and Health Extension Workers in Ethiopia⁵⁵

The health service extension program (HSEP) provides primary health care service to prevent major communicable diseases that account for 80% the health, hygiene and environmental sanitation, maternal and child health problems. The program is developed to deliver preventive, selective and curative health care services in all the 15,000 kebeles⁵⁶ of the country.

The program started in 2003 with training and deployment of 33,200 Health Extension Workers (HEW) to all kebeles and the establishment or upgrading of 3,153 health centers in order to strengthen referral exchanges and supportive supervision to HEW for the attainment of equitable essential health care service at all levels.

HSEP contains 5 main package programs: disease prevention and control (malaria, tuberculosis, and HIV/AIDS), family health (maternal and child health, family planning, Expanded Program on Immunization - EPI, adolescent reproductive health and nutrition), hygiene and environmental sanitation, and health education. These package programs are implemented at household and health post level in each kebele. On average a kebele consists of 5,000 people and gets the service by two trained female HEW.

Malaria prevention and control is one of the programs which benefited most from HSEP. It improved case management by making diagnosis and treatment services available at a walking distance. In Integrated Vector Management, HSEP contributes to the successful distribution and proper utilization of LLINs, prompt IRS operation and continued environmental intervention. Finally it started community dialog on the malaria burden, prevention and control strategies tailored to the community need.

Maintenance of Malaria in Pregnancy (MIP) interventions. Interventions for malaria in pregnancy are delivered through antenatal clinics. During sustained control, continued work is required to integrate maternal health and malaria services and to build the capacity of the maternal health workforce around malaria issues. Among other things, communication programs need to promote regular antenatal visits for all pregnant women.

Risks Must be Managed

Despite the many benefits, global control also brings risks. In particular, three risks need to be planned for during the sustained control step: the fatigue among key stakeholders, the wide-spread emergence of resistance to insecticides and drugs and the increased risk of epidemics and severe malaria.

Risk of malaria fatigue. As successful control efforts reduce the burden of malaria, there is a strong risk that interest in malaria could drop amongst key stakeholders (e.g. donors, politicians, health officials and the public). If not addressed, this fatigue could lead donors to lower funding for malaria control, governments and health ministers to place less emphasis on malaria control and the public to reduce utilization of preventive and treatment measures. Strategies to combat fatigue are discussed above when discussing key stakeholders of the health system above and in *Part II - Chapter 3: Elimination and Eradication: Achieving Zero Transmission*.

Risk of increased resistance. Sustained universal coverage means that parasites and vectors will be exposed to large amounts of anti-malarial drugs and insecticides over a long period of time. There is still some debate whether the spread of malaria resistance is faster in high versus low transmission areas. It seems that generally it is increased in areas of high transmission, but for some drugs it also spreads rapidly in low-transmission areas.⁵⁷

⁵⁵ Ministry of Health of Ethiopia, personal communication, 2008.

⁵⁶ Smallest administrative unit of Ethiopia.

⁵⁷ Talisuna AO. Intensity of Malaria Transmission and the Spread of Plasmodium falciparum-Resistant Malaria: A Review of Epidemiologic Field Evidence. *American Journal of Tropical Medicine and Hygiene*, 77 (Supplement 6), 2007.

However, there is little debate about the fact that resistance to chemicals widely used in prevention and treatment will likely emerge. It is essential that countries create robust programs aiming at monitoring resistance while putting in place the adequate policies to mitigate it, such as the use of combination therapies, emphasis on targeting treatment and maximizing adherence, insecticide rotation for vector control, and the universal use of diagnosis where transmission diminishes. The international community must have strong operational research programs to develop new approaches to mitigate resistance, as well as research and development to create new formulations of drugs and insecticides that will replace current ones. Good policies are essential, such as banning the use of artemisinin monotherapies. To improve international tracking of resistance, regional collaborative networks could be built, as is the case in South Asia with the South-Asia Surveillance Network for Malaria Drug Resistance. In addition, ensuring procurement of high-quality medicines and insecticides is necessary to manage resistance.

Risk of epidemics and severe malaria. In areas of natural high transmission, frequently exposed populations at risk develop acquired immunity over time, resulting in low levels of severe clinical illness for adults (adults can be infected without symptoms – thus creating asymptomatic reservoirs of parasites). A strong decrease in incidence due to successful control measures in scale-up will likely decrease immunity and therefore increase the severity of malaria in adult populations. Pregnant women in particular become at increased risk of severe clinical illness and death as pregnancy increases a woman's susceptibility to malaria infections, and protective acquired immunity is lost in low prevalence situations. Therefore, targeted communication will be required among adult populations to explain the increased risk of severe illness and deaths, as well as stronger epidemics management, with surveillance systems to promptly detect risks of epidemics and to rapidly deploy adequate response systems.

Countries in Sustained Control Must Prepare for Elimination

In sustained control, countries also prepare the move to elimination. Country efforts to strengthen health systems and maintain a low level of burden are important pre-conditions for pre-elimination and elimination. By building the capacity to plan at the national, regional and local level, to reach remote populations, and to conduct advanced M&E activities, a country will build the groundwork for the health systems required to conduct successful elimination programs.

3. Elimination and Eradication: Achieving Zero Transmission

Key messages

- Elimination is officially defined as reducing to zero the incidence of locally acquired malaria infection in a specific geographic area through deliberate efforts.⁵⁸
- The RBM Partnership endorses elimination efforts in countries where appropriate, based on factors specific to the country context. For example, elimination would be more appropriate in countries:
 - that meet epidemiological criteria for low burden;
 - that lie near the natural borders of disease;
 - whose leaders are politically and financially committed to elimination;
 - whose health systems and surveillance capacity are sufficient to manage an elimination program; and/or
 - where parasite and vector species and technical factors make elimination feasible.
- The RBM Partnership encourages support of countries pursuing elimination through collection and dissemination of best-practice approaches, R&D for new tools, and funding and technical assistance by individual partners as desired.
- Eradication, or reducing the global incidence of malaria to zero, is the long-term goal for RBM and will be achieved through progressive elimination in countries where feasible.

Since the global malaria eradication campaign ended in 1969, several countries have embarked on programs aimed at elimination, and some have succeeded in achieving or nearing that goal. For example, the Maldives, Tunisia, and most recently the United Arab Emirates (UAE) have eliminated malaria from within their borders. Successes can be credited to intense national commitment to achieving zero incidence of infection, together with coordinated efforts by partners.

More recently, a growing number of countries have adopted malaria elimination as a goal. The African Union's 2007 "Africa Malaria Elimination Campaign", the recent declaration by Bill and Melinda Gates reinstating global eradication as a long-term objective, and its reiteration by Margaret Chan, Director General of WHO, all have reinforced goals of local elimination in some settings, as well as global eradication as a feasible long-term vision.

Elimination is a worthwhile goal in many countries today. It is epidemiologically feasible in more settings than previously thought, specifically in areas of unstable transmission, where over 1 billion people are at risk.⁵⁹ The RBM Partnership endorses elimination efforts in countries where it is feasible with current preventive and curative interventions, and where reintroduction from neighboring countries can be prevented or managed. The RBM Partnership also encourages partners to support countries pursuing elimination through the development of best-practice approaches, research and development of new tools, and funding of country programs by individual donors and partners as desired. This section describes the elimination stages, the recommended short- and long-term international strategy for elimination, and individual countries' approaches and challenges relating to elimination.

⁵⁸ Dowdle W. The principles of disease elimination and eradication from the 1997 Dahlem Workshop. *WHO Bulletin*, 1998, 76 (supp2). The definition has been adapted to acknowledge that disease from imported cases will still occur in countries which have achieved elimination (based on WHO and other expert opinion).

⁵⁹ Guerra CA et al. The limits and intensity of *Plasmodium falciparum* transmission: implications for malaria control and elimination worldwide. *PLoS Medicine*, 2008, 5(2):e38.

Elimination: A Definition, Targets, and Examples

Elimination entails reducing to zero the incidence of locally acquired malaria infection in a specific geographic area as a result of deliberate efforts, with continued measures in place to prevent re-establishment of transmission.⁶⁰ After three years in this state, countries can request malaria-free certification from WHO; however, they are not required to do so.

While the RBM Partnership's long-term objective is for all countries to eventually eliminate malaria to achieve global eradication, it is premature for the Partnership to set formal international targets specifying when countries should achieve elimination. However, it is expected that 8-10 countries in the elimination stage today may be able to achieve zero locally acquired cases by 2015, with malaria-free certification at least three years later, if their current trajectory is continued.

Regional organizations also have set specific objectives regarding elimination. In 2007, the African Union launched the "Africa Malaria Elimination Campaign" to focus countries on reducing their malaria burden through universal free access to prevention and treatment interventions. Targets for 2015 are to "stop transmission" in low-transmission countries (Algeria, Botswana, Namibia, South Africa, Swaziland, Comoros, Sao Tome and Principe, and Cape Verde), while reducing malaria morbidity and mortality in high transmission countries by 75 percent.⁶¹

The Southern African Development Community's (SADC's) Council of Ministers of Health approved a regional elimination strategy, which states that by 2012 at least five SADC countries will implement elimination strategies and by 2015 at least six SADC countries will have eliminated malaria (though not achieved malaria-free certification).⁶² Achieving the elimination target by 2015 with current tools and approaches in some of these transmission settings will require intensive control (including optimal implementation of current tools), improvements in health systems, and cross-border collaboration.

Several countries have achieved success in their pre-elimination and elimination campaigns. In 2005, Morocco and Syria reported zero locally acquired malaria cases. On the other hand, some countries have experienced setbacks: the Russian Federation and Jamaica had been considered non-malarious, but subsequently experienced local outbreaks. Oman has requested malaria-free certification, but because of a recent outbreak will have to wait at least three additional years for certification. Mauritius, while still considered malarious, reported its last case in 1997.⁶³

According to WHO, 21 countries or territories fall within the pre-elimination and elimination stage, with an addition 6 countries in the prevention of reintroduction stage.⁶⁴ Additionally, according to experts in the Malaria Elimination Group (MEG),⁶⁵ 11 countries on the natural borders of malaria, explained later in this section, have either embarked on elimination programs or are contemplating doing so.⁶⁶

⁶⁰ Dowdle W. The principles of disease elimination and eradication from the 1997 Dahlem Workshop. *WHO Bulletin*, 1998, 76 (supp2). The definition has been adjusted to acknowledge that disease from imported cases will still occur in countries which have achieved elimination (based on WHO and other expert opinion).

⁶¹ *Africa Malaria Elimination Campaign by the African Union Advocacy Strategy Document*. African Union, April 2007.

⁶² *SADC Malaria Strategic Plan*. 2007. Includes Botswana, Swaziland, South Africa, and Namibia. Lesotho is already designated malaria-free. While Mauritius was certified malaria-free in the mid-1970's, a cyclone led to an outbreak. Mauritius has reported 0 locally transmitted malaria cases for several years.

⁶³ See WHO website (<http://www.who.int/ith/countries/mus/en/>).

⁶⁴ According to the WHO *World Malaria Report 2008*, 11 countries fall into the pre-elimination stage: Mexico, Iran, Azerbaijan, Georgia, Kyrgyzstan, Tajikistan, Turkey, Uzbekistan, DPR Korea, Sri Lanka, and Malaysia. 10 countries fall into the elimination stage: Algeria, Argentina, El Salvador, Paraguay, Egypt, Iraq, Saudi Arabia, Armenia, Turkmenistan, and the Republic of Korea. While Egypt is officially categorized in the elimination stage according to the WHO *World Malaria Report 2008*, its last reported case was in 1998, and the country is awaiting verification of malaria-free status to enter into the prevention of reintroduction stage. 6 countries are in the prevention of reintroduction stage: Mauritius, Jamaica, Morocco, Oman, Syria, and the Russian Federation. Country status can change. For current status, check with WHO or the country's malaria control program.

⁶⁵ The Malaria Elimination Group (MEG) is a group of over 40 experts that supports countries which are embarking, or are considering embarking on, a pathway to malaria elimination.

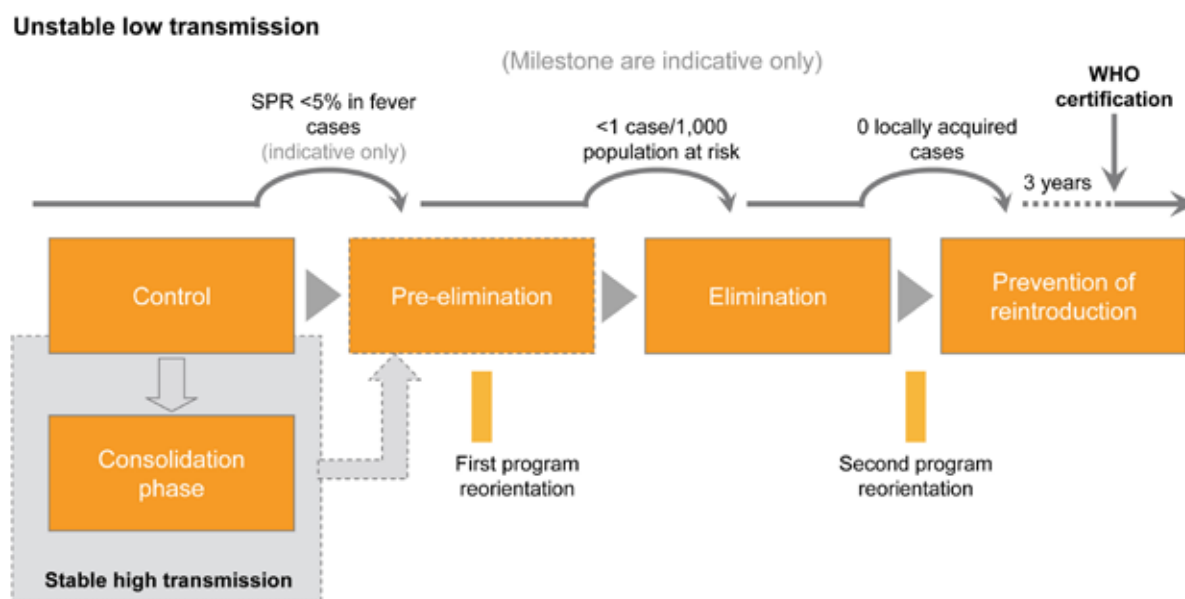
⁶⁶ In addition to some of the countries designated pre-elimination or elimination by the WHO *World Malaria Report 2008*, other countries are the island nations of the Comoros, the Philippines, Sao Tome and Principe, Solomon Islands, and Vanuatu; Asian countries of Bhutan and China, as well as the sub-Saharan African countries of Botswana, Namibia, South Africa, and Swaziland.

Elimination Readiness

Several factors indicate when countries are ready to begin to pursue elimination as a goal. The RBM Partnership recommends that countries assess their own readiness on the basis of the combination of factors most relevant to their situation. Although there is no agreed-upon set of criteria that definitively determine a country's readiness, experts agree that initiation of an elimination campaign must be driven by the country.⁶⁷ Furthermore, every successful national elimination effort requires significant political will to focus on malaria elimination over the long term, as well as significant financial commitment. Below are some of the key considerations in the quest for elimination. Please note that this list is neither exhaustive nor intended to serve as a checklist.

Epidemiological milestones. WHO recommends indicative epidemiological milestones for determining when a low- or medium-transmission country has an incidence low enough to begin the rigorous surveillance required during elimination. When the slide positivity rate (SPR) of all febrile patients with suspected malaria is less than 5% or the incidence is less than 5 per 1000 people at risk⁶⁸, the country, or district in some cases, could consider transitioning into "pre-elimination" if other factors are in place as well. The ability of a country to measure and know definitively its incidence rate is in itself an indication of the country's readiness to enter pre-elimination. This is the stage where the control program reorients itself to further emphasize surveillance, reporting and information systems. (For more details, see *Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries*; Geneva, World Health Organization, 2007).

Figure II.10: Epidemiological milestones



Source: "Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries" World Health Organisation, 2007.

According to Figure II.10, after program reorientation enables a country to achieve an incidence rate of less than 1 per 1000 people-at-risk, the country enters into the elimination stage. Here the goal is to halt local transmission and eliminate foci. Once surveillance shows a reduction of locally acquired cases to zero (all remaining malaria cases being positively identified as from imported origin), the program enters

⁶⁷ Based on experts present at the RBM Working Group Consultation Meeting, Washington DC, April 2008.

⁶⁸ A "manageable" case load for the intensive follow-up required per case during this phase.

the “prevention of reintroduction” stage. A country can be declared malaria-free by the WHO after proving there has been no local transmission for at least three years.

The milestones prior to zero incidence are not rigid, but rather serve as guidelines to indicate when a country might be able to aggressively monitor and track every case. The incidence level at which it would be appropriate to transition between stages may vary, depending on each country’s situation. For example, if a country in pre-elimination has more than 1 case per 1,000 people-at-risk per year, but the cases are very concentrated and easily tracked and treated, the country may be able to move into elimination. On the contrary, if another country has less than 5% slide positivity rate (SPR), but the cases are widespread and difficult to track, that country may want to wait until it achieves an even lower incidence or improves its readiness systems before considering an aggressive pre-elimination campaign.

Formerly or naturally high transmission areas that have achieved a low incidence thanks to successful control efforts are encouraged to enter a “consolidation phase” between sustained control and elimination. During this period, the area sustains its gains while assessing the feasibility of reorienting its program to elimination. Once feasibility is confirmed, the country is encouraged to move into pre-elimination.

Malarious borders. Another criterion on which a country’s ability to eliminate malaria is assessed is its location relative to the endemic borders of the disease. Many countries along the geographic borders of the endemic zone are more likely to eliminate malaria with today’s tools due to latitude, altitude, climate, and other factors making transmission less efficient and malaria less prevalent.⁶⁹ The edges of endemic regions have lower vulnerability to reintroduction of malaria due to fewer malarious borders, minimizing chances for reintroduction compared to areas surrounded by malaria. For example, historically elimination in the United States was the precursor to beginning elimination in Mexico, as elimination in South Africa today prepares the way for elimination in Zimbabwe and Mozambique.

For today’s highest-burden countries to eventually embark on elimination, it will be necessary for elimination to have occurred in many of the countries at the endemic borders. Shrinking the malaria map is an important dimension of moving toward elimination in the heartland and eventually to global eradication.

If incidence levels of neighboring countries are significantly higher, a country should initiate cross-border initiatives where appropriate or wait until its neighbors have controlled malaria to avoid risk of reimportation. For example, Rwanda has reached low incidence levels, but because it is surrounded by countries with high transmission rates and low control, elimination would likely not be sustainable. Cross-country collaboration can help achieve sustainable malaria control and elimination.

Strength of health systems and surveillance. Countries must also have strong surveillance systems to facilitate immediate detection, notification and response to all foci as well as outbreaks, epidemics, and individual malaria cases. Such systems work in tandem with strong health systems and developed infrastructure to enable appropriate preventive measures (e.g. spraying in foci) and prompt case management (including appropriate diagnosis with microscopy, treatment with ACTs, and follow-up of each case). This includes having skilled human resource capacity to effectively manage and deliver programs. Many experts recommend that countries not attempt elimination until the intensive surveillance systems needed to track each case are in place.

Population movement. Countries with porous borders, as well as islands that experience an influx of people from high transmission settings, are continuously at risk for reimportation of malaria. In these situations, countries need to institute initiatives addressing foreign carriers before embarking on elimination campaigns. Such initiatives could include malaria screening at borders or ports of entry, as is the case with Oman and the airport screening of foreigners from malaria-endemic regions.

Parasite species.⁷⁰ In regions with *P. falciparum*, but where *P. vivax* is the predominant species (e.g. the Middle East), elimination of *P. falciparum* is likely achievable with current tools. While *P. vivax* elimination has been achieved in some settings (e.g. in the United Arab Emirates), it may require different tools and

⁶⁹ Feachem R, Sabot O. A new global malaria eradication strategy. *The Lancet*, 2008, 371: 1633.

⁷⁰ Lines J, Whitty CJM, Hanson, K. *Prospects for Eradication and Elimination of Malaria: A Technical Briefing for DFID*. December 2007.

approaches to reach this goal in other settings. Countries with both species must also consider the relative increase in *P. vivax* cases once *P. falciparum* has been eliminated.

Intervention effectiveness in targeted area.⁷¹ Some areas have factors such as drug and/or insecticide resistance or vectors with outdoor and/or early biting, which make current interventions less effective and elimination more difficult (e.g. in Southeast Asia). New and improved interventions may be needed for elimination to be feasible in these settings.

Country commitment. As introduced above, countries must assess their own readiness to undertake an elimination campaign. To be successful, countries should demonstrate success of prior control efforts and experience significant decreases in incidence. However, it is critical that governments understand and are committed to an elimination campaign from a financial and policy/regulatory standpoint over the long term, even when changes are not so drastic. That commitment includes collaboration across several ministries including health, finance, agriculture, industry and education.

In tandem with commitment, countries should consider the portfolio of health problems they are facing and their ability to tackle multiple issues simultaneously. They may need to determine new ways to justify high levels of spending on malaria, which by this time accounts for only a few cases, when other diseases still comprise significant morbidity and mortality in the country.

Elimination Program Components⁷²

Once a country has decided to move forward with an elimination campaign, the country must maintain the improvements achieved in sustained control while reorienting the health system toward elimination. The challenges to elimination should not be underestimated. Reorientation requires developing or strengthening several program elements, particularly surveillance and responsiveness to malaria cases.

Surveillance. The cornerstone of a successful elimination campaign is strong surveillance of foci and disease. WHO recommends the creation of an elimination database during the pre-elimination stage to aid in the efficient monitoring and reporting of malaria cases. Additionally, a national register of foci should be set up to organize information relating to the identification, treatment and monitoring of foci and potential outbreaks.⁷³ More details regarding specific surveillance activities are listed in the “Vector Control” and “Case Management” sections below.

Vector control in active foci. All foci should be identified and intensely monitored for potential malaria transmission. Targeted, customized vector control interventions should be used to control outbreaks and protect areas receptive to transmission, including areas exposed to importation of malaria parasites.⁷⁴ In many areas, current interventions such as long-lasting insecticidal nets, indoor residual spraying, and larviciding would be appropriate.

In areas of outdoor and/or early biting (e.g. forest fringe areas), traditional interventions such as LLINs are not as effective but can still be employed. Further operational research is needed to understand best approaches for elimination in these and other areas with challenging technical situations such as pesticide resistance. R&D for new tools in these situations will also be beneficial.

Case detection and management. All people who carry malaria parasites need to be identified and treated to reduce transmission. Entire populations, including nationals, migrants and citizens of neighboring countries, should have access to timely malaria diagnosis and treatment. All suspected cases of malaria should be confirmed through parasite-based diagnosis. WHO recommends microscopy for confirmation of parasitaemia. Prophylaxis should be readily available for residents who travel abroad to malarious areas.

⁷¹ Lines J, Whitty CJM, Hanson, K. *Prospects for Eradication and Elimination of Malaria: A Technical Briefing for DFID*. December 2007.

⁷² *Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries*. Geneva, World Health Organization, 2007.

⁷³ *Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries*. Geneva, World Health Organization, 2007.

⁷⁴ *Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries*. Geneva, World Health Organization, 2007.

Changing epidemiology due to successful sustained control efforts will have an impact on case management strategies. Previously high transmission districts which may have been organized to target populations under 5 (as these carried most of the burden), will have to reorient their program as more adults (who will have less and less immunity) get the disease. Another consideration is that reduced immunity could lead to a higher percentage of cases turning into severe cases, making immediate detection even more important.

Although not recommended by WHO, Mass Drug Administration (MDA) has been attempted in the past with mixed outcomes. In some instances, it has had poor long-term results and undesired consequences, including exacerbation of drug resistance. However, some believe that MDA can be used effectively to eliminate parasites in asymptomatic carriers. For instance, primaquine is used for mass chemoprophylaxis in DPR Korea against *P. vivax*. More operational research is needed to determine when and where MDA is appropriate and which drugs work best while minimizing resistance.

National steering committees. Countries may want to consider organizing a national malaria committee to oversee and guide progress towards elimination goals.⁷⁵ This should be separate from the National Malaria Control Program, which manages day-to-day program operations and implementation of the elimination campaign. One of the key responsibilities of the committee could include the ongoing monitoring and evaluation of the program against objectives, and revising overarching strategies to fit changing epidemiological settings. A second key responsibility would be to ensure the continued financing and support for the elimination campaign.

Optimizing public and private sector roles. While the private sector often plays a crucial, albeit less formal, role during the scale-up and sustained control stages, more formal integration with the national control program is necessary to ensure that all cases are identified and responded to appropriately. Countries should consider ways to involve the sectors that are most effective for delivering malaria control (for example, outsourcing elements of the program to the private sector when appropriate). Countries should strive to ensure full reporting of all malaria cases to one centralized source: WHO recommends that final reporting be maintained within the public sector. An example of a successful public-private sector collaboration enabling central reporting is Oman. The government in Oman requires all malaria treatment to be provided by the public sector for tracking purposes.⁷⁶ Although many people are still diagnosed in the private sector, they are then referred for treatment to a public-sector facility, which is thereby able to conduct the appropriate surveillance and reporting.

Advocacy and IEC / BCC⁷⁷ to combat elimination fatigue. As is the case with sustained control, political fatigue is one of the most difficult challenges to overcome. During elimination, malaria is no longer a public health burden, but it still requires significant financial and human resources. Gaining the political support to provide significant funding despite minuscule reductions in incidence, especially when other diseases such as HIV/AIDS and tuberculosis may have high burdens, will be challenging. International and national advocacy will be essential to set expectations regarding the duration and challenges of elimination (including the risks of relaxing control), and to help government leaders and donors understand the importance of maintaining support.

As with government leaders, support among populations at risk for malaria control may also dwindle as the burden declines. As cases become rarer, the use of preventive measures (LLINs and IRS) and the prompt detection and reporting of new cases may decrease. Significant communication and education are necessary to ensure that populations understand the ongoing risk and support case management activities while malaria is still present.

Similarly, educational programs and continuous re-training of health workers will also be necessary to ensure health workers are well versed in preventive and curative measures. Particularly essential is the continuing ability to rapidly diagnose malaria through microscopy and / or RDTs, and provide the recommended treatment, particularly when cases are rare. Ensuring workers have constant access to diagnostic tools and drugs for immediate treatment is part of this.

⁷⁵ *Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries*. Geneva, World Health Organization, 2007.

⁷⁶ Dr. Majed S. Al-Zedjali, Director, Directorate of Malaria Eradication, Ministry of Health, Oman, personal communication, 2008

⁷⁷ Information, Education and Communication/Behavior Change Communication.

Cross-border initiatives to lower the risk of reintroduction. Another major challenge to sustaining elimination is addressing the potential reintroduction of cases, either via border areas or from migrant populations. Although the United Arab Emirates has achieved elimination, vigilant surveillance is necessary to minimize re-importation via immigrants from Pakistan and India. Continued arrival of cases from mainland Tanzania has kept Zanzibar from maintaining low incidence levels in the past, and re-importation of cases is also seen on South Africa's border with Zimbabwe and Mozambique.

It is important to take a two-pronged approach, focusing both internally (on cases that have been imported) and externally (on cross-border initiatives). Oman has been able to reduce imported cases through mass screening of individuals arriving at the airport from East African countries;⁷⁸ those who test positive are treated for free and monitored for two weeks. Both Oman and the United Arab Emirates provide free treatment to everyone who tests positive, whether they are nationals or foreigners.

While cross-border collaboration should be considered early in the control process, its importance in managing re-importation is highly evident in the elimination stage. This is particularly critical in areas with significant population movement from areas of high transmission intensity. One example of a cross-border initiative is the Lubombo Spatial Development Initiative (LSDI), initiated in 1999 among South Africa, Swaziland, and Mozambique. The LSDI has since pushed the frontiers of malaria almost completely out of Swaziland and South Africa; an area in KwaZulu-Natal that previously had a malaria prevalence of over 90 percent now reports 0.89 percent. In addition, significant reductions in malaria prevalence have been achieved in southern Mozambique.⁷⁹

Another example is the Korean peninsula. Malaria was eliminated from the Korean peninsula in the 1970's but re-emerged in the Democratic People's Republic of Korea (DPR Korea) due to changing agricultural practices and energy problems.⁸⁰ Malaria then spread south to the Republic of Korea. The Republic of Korea instituted early case detection and mass chemoprophylaxis for soldiers, as well as financial contributions to DPR Korea and other support facilitated by China. As a result both countries have seen dramatic reductions in incidence.⁸¹

Other cross-border initiatives include China's Global Fund Round 6 program with Myanmar, the collaboration between Bhutan and India, and between Bhutan and China, the WHO Mekong Malaria Programme (a cooperation of all 6 Greater Mekong Subregion countries), the cooperation between Cambodia and Thailand to contain artemisinin tolerance in the border area, and the Pacific Malaria Initiative involving Papua New Guinea, Solomon Islands and Vanuatu.

Prevention of Reintroduction⁸²

Preventing reintroduction of malaria, particularly cases that lead to re-establishment of local transmission, is key to sustaining elimination efforts. As mentioned earlier, Mauritius, Jamaica, Morocco, Oman, Syria, and the Russian Federation currently fall within this stage.

If an area's receptivity⁸³ and vulnerability to malaria is zero, the probability of reintroduction of malaria is zero. However, risk varies across regions and can change seasonally or with other factors such as population movement and development projects (such as irrigation projects, mining, and forest clearing) that create favorable conditions for vectors and increase human-to-vector contact.

⁷⁸ Dr. Majed S. Al-Zedjali, Director, Directorate of Malaria Eradication, Ministry of Health, Oman, personal communication, 2008.

⁷⁹ Presented by Rajendra Maharaj, Trans-Zambezi RMCC Meeting, January 2008.

⁸⁰ *Update on WHO in DPR Korea*. Geneva, World Health Organization, November 2003.

⁸¹ Han ET et al. Reemerging vivax malaria: changing patterns of annual incidence and control programs in the Republic of Korea. *Korean Journal of Parasitology*, December 2006, Vol. 44, No 4: 285-294.

⁸² *Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries*. Geneva, World Health Organization, 2007.

⁸³ Even if receptivity alone is zero, risk of reintroduction is zero.

Prevention programs must therefore be geared specifically to each region. Suggested actions based on regional characteristics are detailed in the WHO publication “Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries.” Key findings are described in Table II.1:

Table II.1: Suggested actions for prevention of reintroduction programs

Regional characteristic	Suggested actions
Areas of low receptivity and vulnerability	Use early case detection, epidemiological investigation of every case and appropriate curative and preventive measures
Areas of increasing levels of receptivity and vulnerability	Conduct activities recommended for areas of low receptivity and vulnerability, and consider active case detection
Areas of high vulnerability	Continued use of vector control measures (IRS, LLINs, or larviciding)

Source: *Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries*, World Health Organisation.

Preventing reintroduction is the responsibility of the general health services in collaboration with other relevant sectors (e.g. agriculture, environment, industry, tourism). A country’s success in maintaining zero locally acquired transmission for at least three consecutive years is required for WHO malaria-free certification.

Eradication

Eradication is the permanent reduction to zero of the global incidence of infection caused by *Plasmodia* as a result of deliberate efforts, so that intervention measures are no longer needed.⁸⁴ Malaria will be eradicated when transmission of all four types of human malaria in every country of the world ceases.

As stated in *Part I - Chapter 2: The RBM Partnership’s Vision and Targets*, malaria eradication is the long-term goal of the RBM Partnership. This will be achieved through the three-part strategy detailed in *Part II: The Global Strategy*, which includes 1) Controlling malaria, 2) Eliminating malaria, and 3) Research into new tools and approaches. While this does not mean that resources flow equally to the three parts of the strategy simultaneously, it does mean that every part is essential and needs adequate investment and attention.

Once elimination is proven possible in all countries, the international community will assess the feasibility of a global eradication campaign to assist the last countries in achieving elimination. This will be helpful to garner the financial and political support needed to sustain the campaign until malaria is officially eradicated.

International Strategy to Support Elimination and Eradication

To support its long-term goal of eradication, the RBM Partnership encourages individual countries where malaria elimination is feasible today to move toward elimination. This stance includes endorsement of the financing and support of these efforts by individual partners if so desired. Countries nearing elimination today will be an important source of evidence concerning the programmatic and scientific challenges and solutions in elimination programs, which will benefit all countries. Organizations are beginning to support these efforts. The Malaria Elimination Group (MEG), mentioned earlier, is one group supporting countries with intellectual and practical guidance to assist with the embarking on or consideration of embarking on a malaria elimination program. MEG will produce *A prospectus on malaria elimination* in 2009 which will contain a collection of information relevant for countries and partners interested in malaria elimination.

⁸⁴ Dowdle W. The principles of disease elimination and eradication from the 1997 Dahlem Workshop. *WHO Bulletin*, 1998, 76 (supplement 2).

The RBM Partnership will increase its direct involvement in elimination and eradication work post-2010 and when most countries have achieved their coverage targets. Suggested roles are described in *Part IV: The Role of the RBM Partnership*, but will be defined more specifically in the future, and will be based on elimination practices and knowledge gaps that will be identified.

The high-level list of activities below details some of the elimination priorities during the short term for RBM partners.

Research for new tools. Most experts agree that elimination is not feasible in all settings with current tools and approaches. In order to maximize chances for achieving elimination across a variety of countries and settings, several gaps need to be filled. New tools, including vaccines, interventions targeting *P. vivax*, and those that interrupt transmission, will be needed to achieve elimination in all transmission settings. *Part II - Chapter 4: The Malaria Research Agenda* discusses R&D for new tools more specifically.

Research for elimination strategies and approaches. Research into multiple elimination approaches across a variety of transmission and geographical settings will be necessary to gain greater understanding of programmatic and scientific challenges and solutions. Mechanisms for sharing best practices should also be instituted, so that best practices can be used by other malarious countries embarking on elimination campaigns and by the international partners supporting those efforts.

Research should also be undertaken to help define priority areas where dramatic reductions in malaria would benefit the global community for public-good reasons (e.g. areas where historically initial onset of resistance has been seen). See *Part 2 - Chapter 4: The Malaria Research Agenda* for more specific information on research for elimination strategies and approaches.

Advocacy and education for elimination. Advocacy and education about elimination campaigns should be coordinated. This includes the dissemination of information regarding elimination feasibility and best practices, as well as increasing awareness of elimination strategies, challenges and country readiness. See *Part IV - Chapter 2: Advocacy* for more information.

Technical support for elimination efforts. As knowledge of elimination is being generated, technical support will likely be of great benefit to countries in elimination campaigns. This effort would include on-the-ground support for all elements of the program (surveillance, reporting, mechanisms for case detection, etc.), as well as feasibility and cost-effectiveness studies prior to starting a program. Documentation of these experiences, along with the operational research proposed above, will be a valuable resource for countries beginning elimination campaigns in the future.

Funding for elimination efforts. Elimination will be costly. International funding support will be needed not only by some of the countries choosing to pursue elimination, but also to support the global support activities listed above: R&D, operational research, advocacy, and technical support. New financing mechanisms that support and facilitate regional and cross-border initiatives will also be needed. See *Part IV - Chapter 3: Resource Mobilization* and *Part IV - Chapter 6: Financing* for more information.

4. The Malaria Research Agenda

Key messages

- Three categories of research are needed for effective malaria control and elimination:
 - 1) **Research and development (R&D)** for new or improved anti-malaria interventions including drugs, vector control tools, diagnostics and vaccines.
 - For control, tools for all types of malaria are needed which:
 - Increase operational ease of use and compliance,
 - Delay the emergence of resistance,
 - Serve underserved populations, including those in emergency situations,
 - Remove cost barriers, and
 - Provide consistently accurate diagnosis.
 - For elimination, tools are needed which:
 - Interrupt and sustain interruption of transmission, and
 - Address asymptomatic reservoirs.
 - 2) **Research to inform policy** decisions to define the type of interventions and programs best suited for the global, regional and country context.
 - 3) **Operational and implementation research** to understand use and effectiveness of interventions in the field and improve the delivery and quality of prevention and treatment.
- Formal consultative processes are being established to define the R&D agenda for tools for elimination and eradication.
- A similar consultative process is recommended for research to inform policy and for operational and implementation research.

Despite the efficacy of today's tools, achieving near-term goals of reducing incidence and reducing mortality as well as the longer term goals of elimination and eradication will require new and improved tools that are effective across a variety of settings and populations. Strategies for scaling up, sustaining control and elimination cannot be discussed without acknowledging the crucial role that research plays in enabling these strategies' success. Lessons learned from the field will feed back into the R&D process, thus informing new research directions.

Three kinds of research are needed to achieve both the near-term and long-term goals

1. **Research and development** to improve and develop new anti-malaria interventions, including drugs, vector control tools, diagnostics, and vaccines
2. **Research to inform policy decisions** at international and country levels
3. **Operational and implementation research** designed to understand the use and effectiveness of interventions in the field, and to improve the delivery, quality, equity and effectiveness surrounding malaria prevention and treatment.

A. Research and Development for New and Improved Tools

New and improved tools are needed to control and eliminate malaria. This chapter will discuss current and future interventions, identifying what is working well today, and what may be needed for the scale-up, sustained control and elimination stages.

R&D in the Control Stage

The purpose of scaling up and sustaining control is to rapidly bring down burden of disease through high, compliant, and sustained coverage of key preventive and curative interventions. When used appropriately, current interventions offer significant protection against malaria infection; however, gaps in existing interventions still hamper progress in these stages. Research is needed for vector control, treatment, diagnosis, and vaccines.

Opportunities to improve vector control. Vector control interventions can make a significant impact on morbidity and mortality today. However, several opportunities to improve on existing interventions might be addressed by research and development.

- *Costs and challenges of Indoor Residual Spraying (IRS):* While IRS can be a very effective form of vector control, it is cumbersome to apply and requires strong systems to execute correctly. Vast improvements in the application equipment, which has not changed in 50 years, are necessary to improve execution and protective impact. The ‘final step’ in IRS, the actual application of the insecticide to the wall, is entirely dependent on the spray operator’s diligence in maintaining the correct pump pressure, distance to the surface and speed of application. The difficulty of this job is compounded by personal protective equipment (masks, coveralls, gloves, etc.), the heat, salary and other factors. Additionally, cost is a challenge, which ranges from US\$ 7.50 to more than US\$ 20 per household per round, and high, perennial transmission areas may require multiple applications per year. Longer-lasting IRS formulations may ease this challenge by enabling less frequent sprayings.
- *Distribution and practicality of long-lasting insecticidal nets (LLINs):* The bulkiness of nets makes distribution a challenge. Even when LLINs are distributed, utilization rates may be low for several reasons: aesthetics, discomfort sleeping under net due to high temperature and reduced air flow, lack of awareness of proper use and/or the benefits associated with reduced biting and infection by mosquitoes and lack of a bed or adequate household structure to accommodate use of a net. Additionally, there are limited suitable active ingredients that are safe for use in settings with significant human contact.
- *Delaying resistance to pesticides:* Resistance to pesticides is a significant threat to current interventions. Resistance to DDT and pyrethroids is already emerging, although the extent in many parts of the world is not known. There is evidence that this becomes even more dangerous in later stages of control when decreasing transmission potentially facilitates faster emergence. Implementation of specific R&D strategies to discover new active ingredients (detailed below) and monitoring technologies could delay the emergence and potential impact of resistance for all products, as well as improve the ability to respond to resistance.
- *New chemistries and targets for killing vectors:* As there are only four active ingredient classes suitable for vector control, research that includes the development of new chemistries, targets and a wider range of classes could help pre-empt or combat resistance. Unfortunately, R&D surrounding pesticides brings particular challenges. Developing a new active ingredient requires an investment of more than US\$ 175 million over 12 years.⁸⁵ The public health market for pesticides is very small compared to that of the agriculture market, and therefore receives much less investment and research focus. While public health has benefited previously from agriculture, as all previous ingredients are offshoots from agriculture, crop trends such as genetically modified seeds and systemic pesticides are limiting the future pipeline of pesticides which may have public health benefits.

⁸⁵ Interviews with topic experts

- *Larvicides for use in multiple settings and inexpensive biologics:* Biologics are expensive (2-3 times more expensive than traditional insecticides), while larviciding is not feasible in many high burden areas due to the large number of breeding sites. Research is needed to develop opportunities for less expensive biologics and more operational research indicating where larviciding may be feasible (or applications where larviciding can be feasible in regions previously thought inappropriate).
- *Novel mechanisms for killing vectors:* Consumer products such as sprays, repellants and coils are being purchased and used by private buyers primarily for nuisance-abatement. However, current evidence shows that these products are not effective against malaria control. Additionally, there is potential for greater impact through other evidence-based barriers to biting, such as spatial repellents, novel toxins and others. Housing modification interventions such as screening could also be evaluated further. Merging nuisance-abatement and anti-malarial properties into combination products will likely enable pull-through from buyers and increased impact on transmission.
- *Control methods and personal protection measures for outdoor biting vectors:* The major forms of vector control today, IRS and LLINs, are almost ineffective at addressing outdoor-biting vectors. While other impregnated materials (e.g. blankets, insecticide-treated hammocks and nets for hammock) are more promising in these environments, there is still a gap in tools which effectively target these vectors.

Status of the Research. Many researchers are working to increase the breadth and depth of the vector control pipeline, mostly in the pesticide category. For example, the Innovative Vector Control Consortium (IVCC) brings researchers together to develop new and improved products to control transmission of vector-borne diseases.⁸⁶ Several products aimed at addressing two of the opportunities outlined above, targeting resistance and improving IRS, include:

- Two new formulations for LLINs to reduce reliance on pyrethroids;
- Tools to monitor pesticide resistance in Africa, to launch in early 2009; and
- Five new formulations for longer-lasting IRS to launch in the near term.

The current vector control pipeline is detailed in Figure II.11. Only programs in the public domain are illustrated (IVCC, Bill & Melinda Gates Foundation, National Institutes of Health, etc). While some private developments are active, they are not shown for reasons of intellectual property protection and confidentiality.

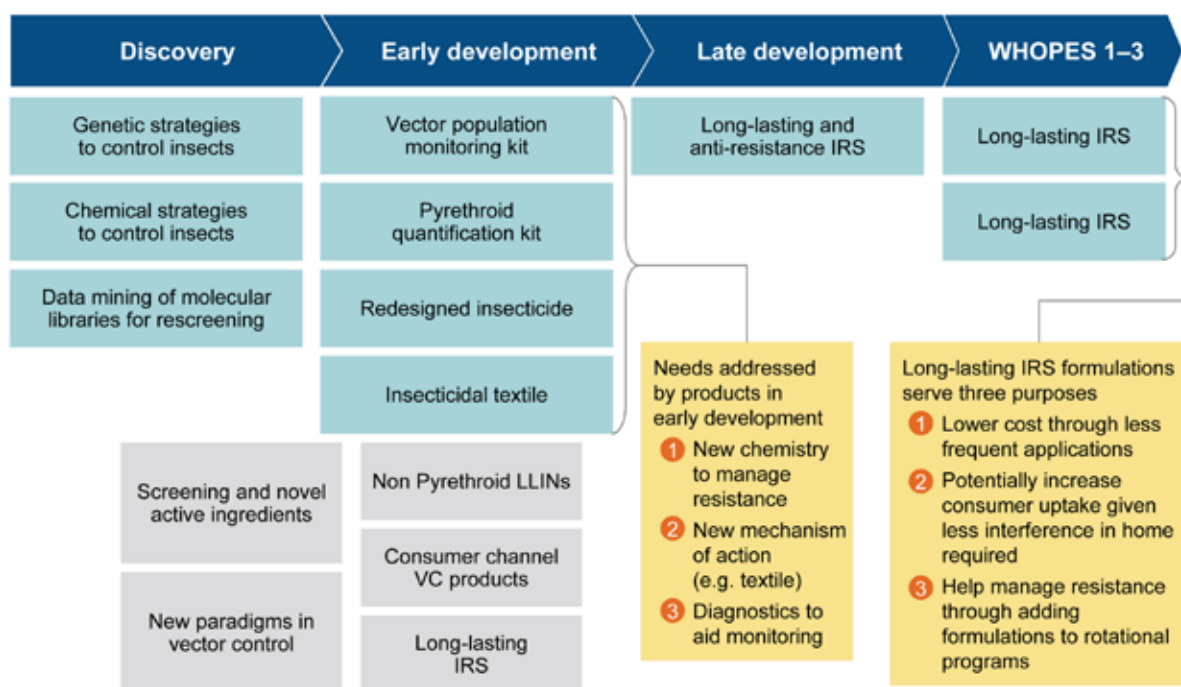
Proposed Recommendations. R&D opportunities for improving vector control include:

- New chemistries and targets for killing vectors (including development of new active ingredient classes to stave resistance);
- Research into safe, longer-lasting, insecticides for IRS and LLINs;
- Development of less expensive but still highly effective pesticides and biologics;
- Interventions targeting outdoor-biting vectors; and
- New mechanisms for application and use, such as new tools for spraying or fogging, consumer products with evidence-based efficacy, and other impregnated materials (curtains, wall-paper, mosquito-proofing).⁸⁷

⁸⁶ See Innovative Vector Control Consortium website (<http://www.ivcc.com>).

⁸⁷ Information taken from presentation by Guillet P at the 2008 WHO Informal Consultation on Global Malaria Control and Elimination, 2008; Lines J, Whitty CJM, Hanson, K. *Prospects for Eradication and Elimination of Malaria: A Technical Briefing for DFID*. December 2007; Interviews with topic experts.

Figure II.11: Current vector control pipeline and opportunities



Note: Only program in the public domain are illustrated (Sponsored by IVCC, BMGF, NIH etc). While some private developments are active, they cannot be shown for reasons of IP protection and confidentiality.

Source: Innovative Vector Control Consortium.

Opportunities to improve treatment. Effective treatment is an essential part of Malaria Control Programs. The only drugs recommended currently by WHO for the treatment of uncomplicated *P. falciparum* malaria are artemisinin-based combination therapies (ACTs). (The drug combinations include artemether-lumefantrine, artesunate + amodiaquine, artesunate + mefloquine, artesunate + sulphadoxine-pyrimethamine). Chloroquine and primaquine are recommended for uncomplicated *P. vivax*. Opportunities that might be addressed with research and development include the following:

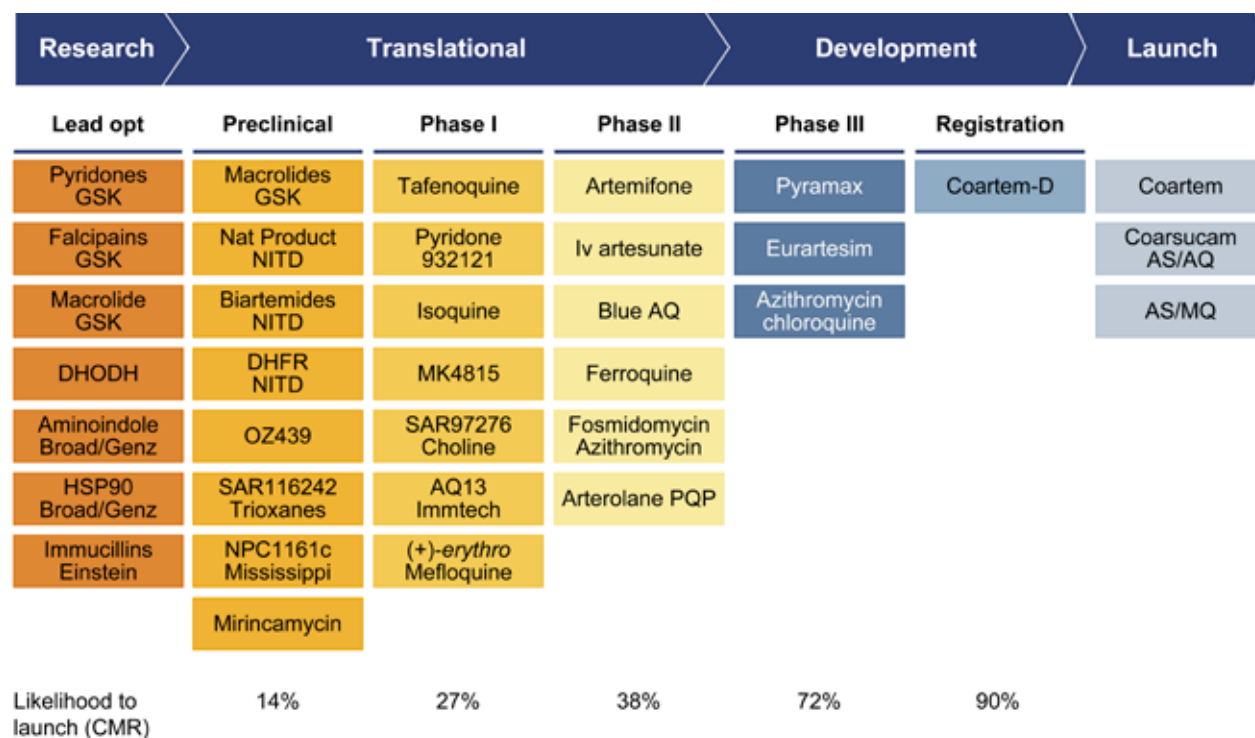
- *Reducing the costs of treatments.* While ACTs are highly effective against *P. falciparum*, price is a significant barrier to widespread uptake. At costs ranging from 50 cents to more than US\$ 5 depending on the manufacturer,⁸⁸ more work is needed to bring the cost of treatment for all ACTs down to an affordable level for both public sector purchase and individual access. Active ingredients with lower cost of goods for treatment of *P. falciparum* malaria are needed.

⁸⁸ Board on Global Health (BGH). *Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance*, 2004.

- *Increasing compliance with drug regimens.* Unusual dosing regimens of some earlier ACTs are cited as barriers to compliance which not only lead to treatment failures but could potentially increase drug resistance. Three ACTs now have once daily dosing: Amodiaquine Artesunate, Dihydroartemisinin - Piperazine and Pyronaridine - Artesunate.⁸⁹ A single-dose cure would be even more advantageous, and this is part of the optimal target product profile for any novel *P. falciparum* therapy.
- *Improving the shelf life of ACTs.* ACTs have a relatively short (~2 year) shelf life, which is particularly challenging in developing world settings. Currently one drug in the pipeline, Pyronaridine-artesunate, is addressing this gap, and is projected to have a 3-year shelf life. Other non-ACT combinations will need to be developed with an ultimate objective of a 5-year shelf life.
- *Treatments for small children and expectant mothers.* New formulations and dosages for the treatment of small children (less than 12 months) and expectant mothers are needed. A deepened understanding of the pharmacokinetics of medicines is key, since metabolism in these patient groups is very hard to predict. In addition, new medicines are needed for intermittent preventive treatments of infants and of expectant mothers.

Status of the research. Several companies and organizations, including the Medicines for Malaria Venture (MMV), are investing to increase the breadth and depth of the drug pipeline to address the gaps. The current drug pipeline is detailed in Figure II.12. Key products in the pipeline include five late-stage ACTs; each use different companion drugs in order to reduce selection pressure and help minimize risk of resistance development. Another product is Tafenoquine, which is being developed as a radical cure for *P. vivax*. Artemisinin products for severe malaria are also in development, and include suppositories and intravenous formulations. Intermittent preventive treatment is being pioneered with non-artemisinin combinations (Azithromycin-Chloroquine) as well as those which contain artemisinin (Eurartesim: Dihydroartemisinin Piperazine). The early stage pipeline contains a wide variety of drugs targeting new mechanisms, which although higher risk from a development viewpoint, will ensure as wide a protection as is possible against the emergence of resistance.

Figure II.12: Current drug pipeline



Source: Medicines for Malaria Venture.

⁸⁹ Their brand names are Coarsucam, Eurartesim and Pyramax, respectively.

Challenges. Effective treatment of all populations, especially infants and expectant mothers is a priority. Given the relative lack of pharmacovigilance, accurate monitoring and reporting of safety and adverse event profiles are essential.

- *Risk of emergence to artemisinin.* Potential emergence of resistance to artemisinin is one of the major dangers to treatment effectiveness. Historically, resistance to anti-malarial drugs has emerged to all drugs used for treatment. Patients with delayed parasite-clearance times have already been detected, and it is only a matter of time before artemisinin-resistant strains will emerge. To combat this, a robust pipeline of new medicines is needed, including non-artemisinin-based combinations with novel mechanisms of action. Ideally, a radically new treatment should be ready for launch into the community every 5 years. More artemisinin combinations and perhaps “combinations of combinations”, though costly, may be necessary to slow emergence and build-up of resistance.⁹⁰ Separate drugs specifically tailored for IPT and mass drug administration (MDA) should also decrease pressure on the drugs that are used for standard case management. Diversifying the number of tools used may enable the renewed use of drugs previously lost to resistance (e.g. chloroquine, SP), especially where clinically synergistic effects (such as with Azithromycin and chloroquine) are seen.
- *New interventions for certain populations.* Another challenge is that ACTs cannot be used by pregnant women in the first trimester. Other options which can be used in all stages of pregnancy should be developed and evaluated. These studies will take considerable time to minimize risk to mother and unborn child, but also to optimize the dose based on an understanding of pharmacokinetics. In pediatrics, treatments for use in infants of less than 12 months need to be optimized to ensure correct dosing. Treatments also need to take account of variations in nutritional status of the child. Additionally, two aspects of the immune status need to be allowed for - firstly, the immune status of the patients can be modified by co-infections (such as HIV/AIDS), and then, increasingly with vaccination post-launch. Given that vaccination is only estimated to protect a percentage of the population, careful study of the therapy for breakthrough infections will be needed.
- *New approaches to intermittent preventive treatment.* This work needs to proceed along two lines. First are the clinical studies to test the hypothesis of intermittent preventive treatment with combinations of medicines which already exist. Looking longer term, new medicines are needed with the appropriately long half lives for such IPT regimes. Given the propensity of long half-life drugs to induce resistance, new medicines with unprecedented mechanisms will be a priority.
- *Interventions for patients with severe malaria.* More interventions are also needed for patients with severe malaria. Nearing completion of development, rectal artesunate will be for patients too ill to take oral medications and too far from health facilities to receive an injection.⁹¹ A temporary solution until patients reach a hospital, it has been shown to clear parasites faster than parenteral quinine.
- *Implementation studies of new medicines.* Given the challenges of health care in malaria-endemic countries, it is important to have studies on the implementation of new medicines within the local healthcare systems. Here, important data on compliance and uptake can be gathered, along with accurate data on safety and adverse events. See *Section II - Chapter 4C: Operational and Implementation Research*.

Recommendations. R&D opportunities for improving treatment include:

- Development of drugs with improved stability and a longer shelf life, dosing regimens that promote compliance (e.g. single dose for uncomplicated malaria), and lower price;
- New, improved interventions for patients with severe malaria;
- New curative and preventive treatments for under-served populations at high risk of the disease (e.g. infants, children, pregnant women, immune-compromised patients); and
- New drugs which pre-empt emergence and impact of resistance.

⁹⁰ Interviews with topic experts.

⁹¹ Gomes A. Rectal artemisinins for malaria: a review of efficacy and safety from individual patient data in clinical studies. *BMC Infectious Diseases*, 2008, 8:39.

Opportunities to improve diagnosis. Improved case management requires accurate diagnosis, either through microscopy or rapid diagnostic tests (RDTs). RDTs can be used for populations at risk for *P. falciparum* and *P. vivax* in all malarious areas today, and are especially suitable for areas with little or no infrastructure. Over 100 RDTs from 50 different manufacturers exist today. However, several performance and quality issues surrounding some RDTs should be addressed in order to gain the full benefit from their use.⁹²

- *Improved reliability of diagnostics.* The sensitivity and stability of RDTs are often inconsistent and sometimes unreliable. Field microscopy has also been demonstrated to be of poor quality in many endemic areas. Consequently, there is considerable evidence that health care providers do not use the results of diagnostic tests, even when they have them. RDTs with improved effectiveness, sensitivity and stability are needed in order to increase trust within the health care sector (both of patients and providers) and improve case management. This will be even more important as the proportion of malaria cases among all febrile illness declines.⁹³
- *Quality assurance:* Quality assurance systems are often inadequate or non-existent. Systems for both microscopy and RDTs need to be strengthened in order to improve the accuracy of, and confidence in diagnosis for case management and for monitoring of disease burden. There are currently quality tests under development, specifically designed for use by community health care workers in low-resource environments. Launch is expected in 2009, and the priority will be ensuring rapid scale-up and use of these to confirm the effectiveness of batches of RDTs.
- *Diagnostics for identifying different risk factors.* Lastly, some experts recommend development of diagnostics to identify at-risk groups (e.g. G6PD deficiency) where drugs may do more harm than good.
- *Lower cost RDTs:* The cost of RDTs, which is similar to that of a treatment course, is also cited as a barrier to use, and often leads to presumptive treatment. More affordable yet still highly accurate tests will be needed to facilitate widespread diagnosis.

Proposed Recommendations. The key R&D opportunities for improving diagnostics are:

- Low cost, consistently accurate RDTs for both *P. falciparum* and *P. vivax* and
- Quality assurance systems for RDTs and microscopy.

Vaccine opportunities. Effective malaria vaccines would be useful in the sustained control stage to reduce morbidity and mortality.⁹⁴ From 2005 to 2006, more than 230 experts representing 100 organizations participated in the Malaria Vaccine Technology Roadmap Process.⁹⁵ This collaboration led to two stated goals: by 2015, to develop and license a first-generation *P. falciparum* malaria vaccine with a protective efficacy against severe disease and death of more than 50% and which lasts longer than one year; and by 2025, to develop and license a malaria vaccine with a protective efficacy against clinical disease of more than 80% and which lasts longer than four years.

Status of the Research. The new tools at the disposal of the malaria vaccine research community, combined with the decoding of the *P. falciparum*, *P. vivax* and other experimentally relevant animal model parasite genomes (e.g. *P. knowlesi* and rodent malaria parasites) and the infusion of significant financial resources, are making possible new advances in malaria vaccine development. Categories of vaccines under development include those which prevent, delay or diminish infection, those which interrupt transmission and those which decrease anemia and other severe symptoms in persons infected with parasites.

⁹² P. Ringwald. *Antimalaria Medicines and Diagnostics: Strengths and Limitations*. Presented at the WHO Informal Consultation on Malaria Control and Elimination, 2008.

⁹³ Frost L. *MRDTs: Global Scaling up and Introduction of new diagnostic method for malaria*. Harvard School of Public Health.

⁹⁴ Lines J, Whitty CJM, Hanson, K. *Prospects for Eradication and Elimination of Malaria: A Technical Briefing for DFID*. December 2007.

⁹⁵ This effort was called for by the Malaria Vaccine Advisory Committee to the WHO, coordinated by the WHO Initiative for Vaccine Research (IVR) and sponsored by the Bill and Melinda Gates Foundation, PATH Malaria Vaccine Initiative (MVI), and the Wellcome Trust.

The most clinically advanced vaccine candidate, RTS,S, has been shown to be safe and efficacious when administered to children aged one to four years, reducing infection, mild and severe disease over an 18-month period. More recently, it has been shown to be safe in young infants, reducing infection by 65% over a three-month follow-up period and episodes of clinical malaria by 35% percent over a six-month follow-up period starting after the first dose.

Worldwide, there are about 40 *P. falciparum* candidate malaria vaccines or vaccine components in the pipeline⁹⁶ and only a few for *P. vivax*. Only one vaccine for *P. vivax* (the Duffy Binding Protein, Region II) is heading towards clinical trials. Experience with vaccine development, in general, shows that perhaps one in ten will make it through the development process and into use. As yet, however, it is not known whether this success rate will hold true for malaria vaccines. The overall vaccine portfolio is characterized by a legacy of blood-stage candidates, more recent pre-erythrocytic candidates and reflects the entry of new platforms (such as viruses) into the pipeline.

Challenges. While considerable progress has been made in malaria vaccine development, developers will need to overcome significant challenges to arrive at a vaccine with at least 80% efficacy, the 2025 goal described above.⁹⁷ First, no human vaccine has ever been developed against a parasite: all vaccines currently in use target either viruses or bacteria. Second, the malaria parasite is extremely complex, which may require unique approaches to target the different stages in its lifecycle. Third, the ability of the pathogen to quickly mutate and evade the immune system makes it a more challenging target. Fourth, evasion of even a few pathogens from a vaccine has the potential to cause serious illness, especially in malaria-naïve individuals.

To address these challenges, new antigens, platforms and adjuvants, are needed⁹⁸ as well as additional assays and other evaluation technologies to inform decision-making. Figure II.13 provides a simple illustration of the four areas of research seen as crucial to developing a vaccine of at least 80 percent efficacy by 2025.

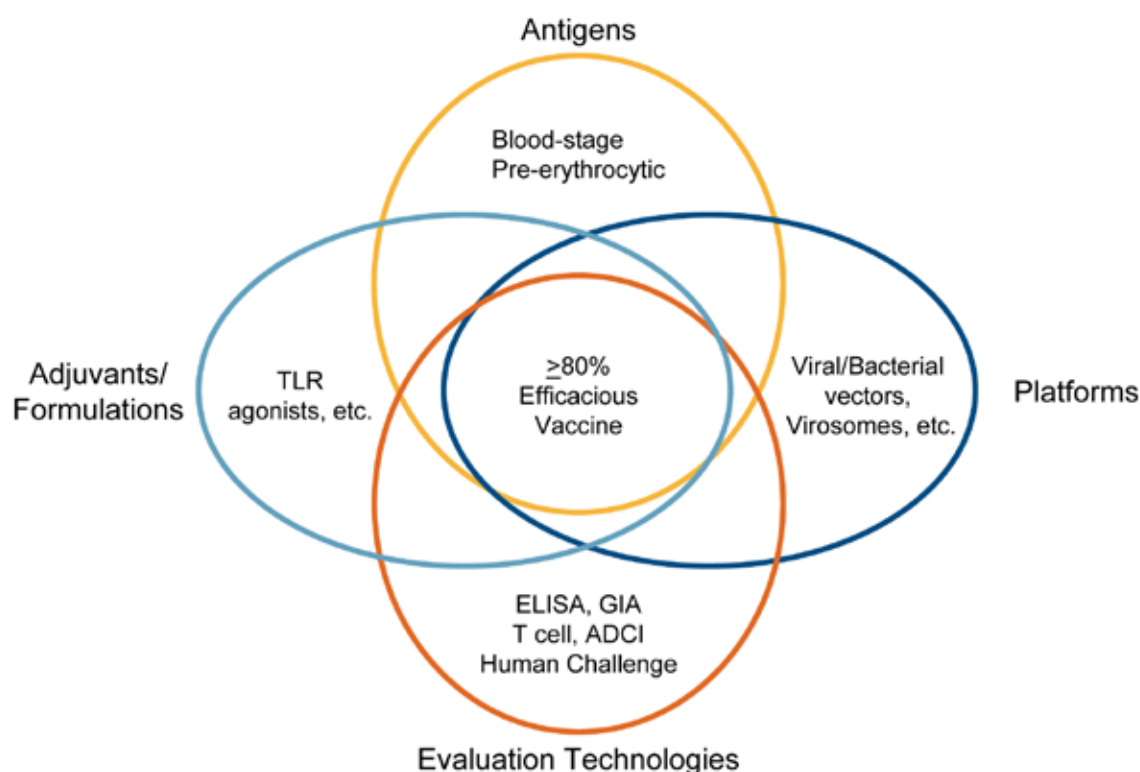
- **Antigens.** Antigen discovery remains a crucial area of research within the malaria vaccine field, given the limited number of antigens – whether blood-stage or pre-erythrocytic – currently under development and the strong likelihood that a more effective, next-generation vaccine will need to combine vaccine components and approaches.
- **Platforms.** Viruses, bacteria, virosomes, and nanoparticles are among the *platforms or delivery vehicles* under exploration in the malaria vaccine R&D field. As with antigens, platforms may be used in combinations to induce a larger number of more robust specific responses including increased breadth, magnitude, and duration of induced immunity.
- **Assays and evaluation technologies.** Enhancing methods for *in vivo* and *in vitro* assessment of candidate vaccines is another critical need in malaria vaccine R&D. Investments to develop and refine *evaluation tools*, such as *in vitro* assays and human as well as non-human primate challenge models, and the support of reference and service centers, are needed to capitalize on the prospective value that can be generated from the comparative assessment of candidate vaccines. Success in this area would yield a significant return over the long-term by providing robust data to inform development decision-making and reduce development investment risk.

⁹⁶ *The Malaria Product Pipeline: Planning For the Future*. The George Institute for International Health, September 2007.

⁹⁷ Interviews with personnel from the Center of Disease Control (CDC), National Institute of Allergy and Infectious Disease (NAID) and National Institutes of Health (NIH).

⁹⁸ Interviews with personnel from the Malaria Vaccine Initiative (MVI); Malkin E, Dubovsky F, Moree M. Progress towards the development of malaria vaccines. *Trends in Parasitology*, 22, 2006.

Figure II.13: Areas of research for vaccines



Source: Malaria Vaccine Initiative.

As necessary scientific advances are being made, vaccine access strategies should be addressed. Cost and cost effectiveness will be key to enabling broad population access to the vaccine. Additionally, effective distribution strategies (e.g. including a vaccine within existing Expanded Program for Immunization (EPI) schedule or alternative distribution systems) and proactively dealing with potential cold chain and scalability issues will be important. Regarding EPI, operational research should be conducted on inclusion of a partially protective malaria vaccine into the program, and its impact on mothers' perceptions of the EPI program and vaccines in general when mothers are accustomed to completely preventive vaccines. (See *Section II - Chapter 4C: Operational and Implementation Research*).

Proposed Recommendations. R&D opportunities for vaccine development include:

- A "next-generation," highly-efficacious vaccine that combines vaccine approaches and targets *P. falciparum*; and
- Vaccine access strategies that address policy and regulatory challenges, introduction and roll-out, advocacy and communications, and ongoing distribution.

R&D for Elimination/Eradiation

Most experts believe elimination is not possible in high transmission areas with today's tools. In order to facilitate a consensus-driven approach to address tools needed specifically for elimination and eradication, the Bill and Melinda Gates Foundation hosted "The Consultation on R&D for Malaria Eradication" in March 2008. The meeting engaged an ad hoc group of experts across all malaria interventions to develop a framework for considering R&D issues and to lay out a process to organize these efforts. The outcome of the future consultation process will be strategies and target product profiles needed to achieve the goal of eradication, focusing on the following seven themes: drugs, vaccines, vector control, modeling, M&E/surveillance, integration strategies, and health systems/operational research/diagnostics. Although the priorities are still to be developed, some of the preliminary questions and hypotheses regarding the tools needed are listed below.

Opportunities to improve vector control. In addition to the gaps in control listed previously, there are opportunities to improve vector control.

- *Increased emphasis on Integrated Vector Management (IVM):* As defined by WHO, IVM is a "rational decision-making process for the optimal use of resources for vector control" across all vector-borne diseases including malaria.⁹⁹ Important attributes of IVM include employing the most cost-effective methods for a particular setting, leveraging inter-sector approaches (e.g. involving health, agriculture, transportation and other government sectors) and ensuring effective decision-making processes at all levels. Unfortunately, stakeholders often are not able to take such a comprehensive, holistic view. This limited approach then results in the use of interventions and approaches which may not be effective for a particular transmission setting.

While these concepts are important during the initial control stages, they also fit well within the elimination stage. IVM relies on sustaining and consolidating the public health achievements achieved during the scale-up stage through an inter-sector approach, which are key components of elimination programs.

- *Larval source and environmental management:* Historically, environmental management was the key to elimination in many environments, including the U.S., and is key to the elimination programs of several low- to moderate-transmission countries including the United Arab Emirates and Oman. In Africa, however, the ecology of the malaria vectors, especially the ubiquity of breeding sites, their relatively long flight range, and high vectorial capacity make them extremely difficult to control through larval source management. While recent projects in urban Dar es Salaam and the African highlands are encouraging, more work is needed before this can be considered on par with LLINs and IRS.¹⁰⁰

Proposed Recommendations. The key opportunity for improving vector control for elimination is:

- Additional research into applications of larviciding and environmental management in various transmission settings.

Opportunities to improve treatment. Treatment becomes even more important when regions strive for elimination, as areas change from high- to low-transmission settings and as incidence and, consequently, natural immunity decline. Some of the key research questions and needs involving treatment relate to drugs which interrupt (and sustain the interruption of) transmission and those targeting asymptomatic reservoirs of disease.

- *Interventions which interrupt transmission.* With elimination as a goal, new strategies to interrupt transmission from humans to mosquitoes will be essential. New medicines which target the gametocyte stages will be especially important in reducing transmission in areas where there is already a partial immune reaction to the parasite. Given that these patients will be asymptomatic, then particular attention has to be paid to the safety profile.

⁹⁹ *Position Statement on Integrated Vector Management.* Geneva, World Health Organization, 2008.

¹⁰⁰ Michael MacDonald, USAID, personal communication, 2008.

- Currently, primaquine and tafenoquine (in development) kill gametocytes more effectively, but carry a risk of haemolysis¹⁰¹ which can be dangerous if populations have a prevalence of G6PD deficiency, as is common in malaria-endemic populations.¹⁰²
- *Targeted interventions for P. vivax.* Medicines specifically targeting *P. vivax* must be considered, especially for the elimination stage. Primaquine and tafenoquine, as well as chloroquine, are available to treat *P. vivax*. However new protocols are needed: primaquine is currently once per day for 14 days, and chloroquine resistance is common. *P. vivax* has the dormant liver stage hypnozoite form, and medicines which kill hypnozoites will be essential to prevent relapses after the primary infection.
- *Drugs and approaches which target asymptomatic carriers.* Asymptomatic reservoirs, parasite-positive individuals who contribute to the transmission pool but have no malaria symptoms themselves and are therefore not treated, is another issue that should be addressed. Mass screening and / or mass drug administration (MDA) may be considered in later stages to minimize or eliminate infectiousness of asymptomatic reservoirs.

MDA has been attempted in the past with mixed outcomes. In some instances, it has had poor long-term results and undesired consequences, and could potentially exacerbate drug resistance. However, some experts believe that MDA can be used effectively to eliminate parasites in asymptomatic carriers. More research is needed to determine when and where MDA is most appropriate, and which drugs work best while minimizing resistance. A preliminary target product profile for MDA includes safe, effective drugs that have a long half life and simple dosing; they would be different from the first-line recommended treatment to minimize risk of resistance development.

Proposed Recommendations. R&D opportunities for improving drugs for elimination include:

- Interventions and approaches which target asymptomatic reservoirs;
- Drugs which interrupt and sustain interruption of transmission;
- Treatments which target liver-stage disease; and
- More treatments which target *P. Vivax*.

Diagnostic opportunities. Many of the recommendations listed for control are also relevant for elimination. For example, lower-cost, higher accuracy diagnostics will play an important role as more active case detection is undertaken. One requirement more relevant for elimination is the identification and targeting of asymptomatic reservoirs of disease. Targeting, diagnosing, and treating these individuals will be essential to interrupting transmission.

Proposed Recommendations: R&D opportunities for elimination include:

- RDTs which target asymptomatic reservoirs of disease.

Vaccine opportunities. Many scientists believe that the development and implementation of effective malaria vaccines, especially against the predominant species *P. falciparum* and *P. vivax*, will be critical to achieve malaria eradication. With malaria vaccines potentially within reach, it is important that the international community continue to support and increase investments in malaria vaccine research.

- *P. vivax:* A vaccine for *P. vivax* is increasing in development priority. Vaccines which target *P. vivax* may in fact prove to be necessary to achieve elimination and eradication.¹⁰³ *P. vivax* is genetically distant from *P. falciparum*, and scientific evidence strongly suggests that vaccines targeting each species will be required. All four human malaria species in fact have their unique biological characteristics, which could prove to be relevant for targeting their ultimate eradication with malaria vaccines or drugs, along with other intervention tools. *P. vivax* and *P. ovale*, for example, both have dormant ‘hypnozoite’ forms in the liver.

¹⁰¹ Destruction or dissolution of red blood cells with subsequent release of hemoglobin.

¹⁰² Lines J, Whitty CJM, Hanson, K. *Prospects for Eradication and Elimination of Malaria: A Technical Briefing for DFID*. December 2007.

¹⁰³ Lines J, Whitty CJM, Hanson, K. *Prospects for Eradication and Elimination of Malaria: A Technical Briefing for DFID*. December 2007.

- Very little is understood about these dormant forms, which can reinitiate blood-stage infections at a later point in time, in the absence of reinfection by the bite of an infected mosquito. The presence of these dormant forms is an added challenge, which adds epidemiological complexities and will require scientific investigation to devise special hypnozoite-specific interventions that will target these forms of the parasite.
- *Transmission-blocking*: As with treatment, a vaccine that can interrupt and sustain interruption of transmission would be a valuable tool in the arsenal for achieving elimination.

Proposed Recommendations. R&D opportunities for vaccine development for elimination include:

- Greater emphasis on developing and testing vaccine candidates that target *P. vivax*, whether alone or in combination with a *P. falciparum* vaccine component; and
- Vaccines that block transmission.

Delivery Research in All Stages

In ensuring successful control and elimination, the effective delivery of interventions is just as important as discovery and development to ensure the full potential impact of interventions is realized. In fact, inefficient rollouts have caused delays of up to 3 years for developing country populations awaiting interventions. Strategies to improve access and delivery should be developed, including for difficult-to-reach groups, and built into product characteristics when possible. These are described in more detail in other sections and include:

- Approaches to ensure policy and regulatory approval at global and country levels (See *Part IV - Chapter 4: Policy and Regulatory* and *Part II - Chapter 4B: Research to Inform Policy*);
- Plans to facilitate rapid introduction, roll-out, and scale-up of interventions (See *Part II - Chapter 2: Control* and *Part II - Chapter 4C: Operational and Implementation Research*);
- Advocacy and communication plans to ensure appropriate use and demand generation (See *Part IV - Chapter 8, Communication and Behavior Change Methodologies*);
- Advocacy and financial instruments to increase resources for R&D (See *Part IV - Chapter 3: Resource Mobilization* and *Part IV - Chapter 6: Financing*); and
- Approaches to enable effective, sustainable, distribution through all appropriate channels (See *Part IV - Chapter 7: Procurement and Supply Management*).

Additional Research in All Stages

Significant early-stage research is needed to enable later-stage drug development and understand mechanism of disease, disease targets, genome sequencing, mixed infections, biomarkers, transmission dynamics, vector biology and basic epidemiology. A better understanding and new discoveries of the basic biology of the malaria parasite and host will contribute to the development of the most appropriate, effective new tools and approaches (e.g. genetically-modified mosquitoes).

For example, the sequencing of the *Plasmodium* genomes allows a jump start on identifying new targets for anti-malarial drugs. It is possible to specifically identify new target classes, or members of well known target classes which are significantly different. In addition, the development of miniaturized assay formats and image processing enables the study of the effects of large collections of compounds on specific stages of the parasite life cycle. Over 5 million compounds have recently been tested this way, including using high content screening approaches. Taken together these approaches will be useful in identifying the novel starting points which are the basis of the new therapies required for malaria elimination.

Other research and modeling. Combinations of tools will be needed in the battle to control and eventually eliminate malaria; however there is a knowledge gap regarding the impact of combinations of interventions, in particular, whether intervention benefits are synergistic or additive. Therefore, more research should be conducted on the impact of using a portfolio of tools, not just on single interventions. See *Section II - Chapter 4C: Operational and Implementation Research*.

Modeling can also be used to predict the potential impact of combinations of tools, such as the impact of vaccines of different efficacy levels on the amount and type of treatment needed. In addition, models can help predict optimal product profiles to inform the R&D agenda.

Additionally, as transmission declines, more knowledge will be needed on the impact of drugs in the context of decreasing immunity and the consequential increase in adult disease.

Table II.2: Overview of R&D opportunities for control and elimination

Intervention	Control	Elimination
Vector control	<ul style="list-style-type: none"> • New AI classes not vulnerable to resistance • Additional safe, longer-lasting, less-expensive insecticides for IRS and LLINs • Less expensive, highly effective pesticides and biologics • New mechanisms for application and use, e.g., <ul style="list-style-type: none"> – new tools for spraying or fogging – consumer products with evidence-based efficacy – other impregnated materials (curtains, wall-paper, mosquito proofing) 	<ul style="list-style-type: none"> • Research to understand broader applications of larviciding and environmental management in contexts other than low transmission settings
Drugs	<ul style="list-style-type: none"> • Drugs with <ul style="list-style-type: none"> – longer shelf lives – dosing regimens that promote compliance – lower costs • More interventions for patients with severe malaria • Interventions for under-served populations at high risk of disease, e.g., <ul style="list-style-type: none"> – pregnant women – infants – malnourished patients – immune-compromised patients • Drugs which pre-empt emergence and impact of resistance 	<ul style="list-style-type: none"> • Interventions which target asymptomatic reservoirs and interrupt transmission • Drugs which target the dormant liver-stage hypnozoite forms of <i>P. vivax</i> (and <i>P. ovale</i>)
Diagnostics	<ul style="list-style-type: none"> • Low cost, highly accurate RDTs • Quality assurance systems for RDTs • Lower cost RDTs • RDTs to identify different risk factors 	<ul style="list-style-type: none"> • Diagnostics for targeting asymptomatic carriers
Vaccines	<ul style="list-style-type: none"> • Efficacious <i>P. falciparum</i> vaccines that reduce burden of disease 	<ul style="list-style-type: none"> • Efficacious vaccines which can interrupt transmission • Vaccines targeting <i>P. vivax</i>

B. Research to Inform Policy

Research to inform policy defines the type of interventions and programs best suited for the different regional, country and local settings and plays an important role in policy decisions at international and national levels. Of all of the preventive and therapeutic interventions available, only a subset may be appropriate for a particular country or district. What is appropriate can also change as transmission declines and epidemiology changes with improved control measures. Evidence is therefore necessary to guide decisions for Essential Drug Lists, WHO policies, international guidelines (for example the recommendation against artemisinin monotherapies) and country-level policies (e.g. whether LLINs and / or IRS appropriate for the country setting). This research is sponsored by several large international partners, e.g. World Health Organization, Multilateral Initiative on Malaria / Research and Training in Tropical Diseases (MIM / TDR),¹⁰⁴ the Global Fund, the Bill and Melinda Gates Foundation, and several bilateral organizations.

Key Challenges

The challenges facing research to inform policy include insufficient resources, lack of replicable studies, and gaps in the understanding of health systems research.

Insufficient resources. While many recognize the importance of evidence in informing policy decisions, insufficient resources at international and country levels are devoted to research to help guide policy-makers. Policies often need to be specific to be useful. However, policies are sometimes applied more broadly than appropriate to large regions when it may actually only be relevant to a particular setting within the region. Specific issues related to scale-up, control, and elimination are detailed below.

Study replicability. Another overarching issue is the lack of replicability of studies across countries with similar settings. Studies should be designed so that their results can be compared and applied across multiple countries with similar epidemiological and systems settings, informing policy decisions across countries, rather than only those of an individual country. Certainly some studies are context-specific and may only apply to one country; however, opportunities exist to encourage synergies between current research efforts where appropriate. Additionally, ministries of health and malaria control programs need to be engaged on research conducted to enable faster acceptance of results and new drugs once they have been launched.

Health systems research. Another major gap in knowledge is health systems research to inform cross-disease policy issues. Some health systems policies can have significant impacts, positive and negative, on a malaria control program's effectiveness, and can vary by setting. Research related to costs, clinic user fees, human resources policy, taxes and tariffs on public health interventions, and country health expenditure and how these influence uptake and impact of control efforts will be helpful for policy-makers.

Control stage. There are several research needs which directly relate to the ability to scale-up and control the disease.

Diagnostic research. There is currently disagreement regarding guidelines for diagnosis in children under 5 in high transmission settings. Clinical diagnosis alone has been widely accepted in areas of high transmission and where laboratory access is poor; however some experts feel that this is outdated and that parasitological diagnosis should be encouraged. This change emerges from 1) declining transmission making differential diagnosis more useful, 2) high drug costs and risk of resistance, making presumptive treatment less viable, and 3) improvement of and increased access to diagnostic technology with RDTs. Research to understand the implications of this change in policy should be undertaken, in order to inform local practices.

¹⁰⁴ MIM / TDR is embedded in the UNICEF / UNDP / World Bank / WHO Special Program for Research and Training in Tropical Diseases. MIM / TDR evaluates research grant applications from African malaria scientists and awards funds via a competitive peer-review process.

Vector control. Unclear evidence and recommendations regarding the settings in which IRS and LLINs are most useful are issues. For example, some experts feel IRS is better suited for urban settings where it may be more operationally feasible, while others feel IRS may have more impact in rural settings. Additionally, some believe LLINs can be used more broadly than previously thought. While country circumstances are unique and should inform policy, more research to help guide these decisions is necessary. Additionally, there are questions regarding the impact of combining LLINs and IRS, and the settings in which their combined use could increase effectiveness.

Intermittent preventive treatment (IPT). There is also a gap in knowledge, and hence policy, on intermittent preventive treatment for infants and children, as well as the extent of the appropriateness of IPT for pregnant women in high transmission areas outside of Africa. More research is necessary to create definitive recommendations in this area.

Preventive coverage in sustained control. As countries become successful with control programs and incidence declines, a greater understanding of the required level of preventive coverage to sustain control is needed. Countries in lower transmission settings may be able to relax preventive coverage, but this is hypothetical and unknown. Regarding high transmission settings, it is currently assumed that high levels of coverage must be sustained for long periods of time, but this will vary across settings and levels have not been confirmed by research. If lower coverage levels were sufficient to sustain control, significant costs could be saved.

Resistance monitoring. Ongoing genetic monitoring of resistance rates in mosquito populations is needed to inform policy. Specifically this would include frequent and widespread monitoring of sodium channel mutations (knockdown resistance) in mosquito populations.

Elimination stage. While interest and research on elimination are increasing, elimination still represents a small proportion of total research efforts; some priorities are detailed below.

Elimination readiness research. General indicative recommendations regarding when countries should embark on elimination exist, but further real-world evidence is needed to help diverse countries understand the implications of starting such a program.

Broad-based benefits to elimination. Related to this is the need for a greater understanding of the broad-based benefits of a country or region eliminating malaria. For example, should eliminating malaria in areas historically responsible for resistance be a global priority? More research, and perhaps modeling, should be conducted to understand this impact.

Economic benefits of elimination. There is currently no economic research on the costs and benefits of elimination in different settings. The Malaria Elimination Group is developing a prospectus, to be published in 2009, that will address this issue, but a greater understanding of this area will be helpful in guiding countries in initiating an elimination campaign.

Deployment of policies for new tools and approaches. As R&D results in the development of new and improved tools, there will be a suite of research needed to inform global and country-level policy on their deployment. Related to this are the cost of new interventions and the need for cost effectiveness studies showing where new interventions would be most appropriate. For example, RTS,S is expected to be launched in 2013, and clear policy is needed to determine which locations may be most suitable for this first generation vaccine considering its efficacy levels and cost.

Related to the use of new tools, there are some interventions and approaches which are historically controversial but could benefit elimination campaigns and need more research. Mass drug administration is a controversial approach that may have potential applications in some settings but lacks sufficient evidence for definitive recommendations.

Priorities

General priorities. Based on the challenges above, the overarching priorities should be:

- a) Advocacy to increase financial resources devoted to policy-informing research at national and international levels;
- b) Increasing training opportunities for those involved in research, especially within endemic countries;
- c) Increasing replicability of research at international levels for multiple settings and regions through greater coordination across stakeholders and engagement of RBM Working Groups and Sub-Regional Networks; and
- d) Increasing health systems research.

Priorities in the scale-up and sustained control stages. Research to help inform policies relevant to immediate scale-up of interventions are needed for all regions. The key priorities are as follows:

- e) Research regarding the use of parasitological diagnosis in children under 5 in high transmission settings;
- f) Greater understanding of settings in which IRS and LLINs may be most effective and appropriate, as well as the impact of combining IRS and LLINs (and where this could be most advantageous);
- g) More research resulting in clear recommendations for Intermittent Preventive Treatment for infants (IPTi) and children (IPTc) as well as a greater understanding of all the settings in which IPTp is appropriate; and
- h) Research on minimum required preventive intervention coverage levels to sustain control for low and high transmission settings after achieving certain levels of incidence.

Priorities in the elimination stage.

- i) Research should be undertaken to define priority areas where elimination would benefit the global community for public-good reasons (e.g. eliminating malaria in areas of Southeast Asia which have been historically the first to encounter emergence of resistance).
- j) Economic research on the cost and benefits for different settings to pursue and achieve elimination.
- k) Research to define policy for new tools and approaches (e.g. vaccines, mass drug administration).

Organization Implications: Developing the Agenda for Research to Define Policy

While there have been some collaboration in the past, a group that includes all major stakeholders should be convened regularly to revisit the research agenda in light of increased impact from current control efforts and new strategies. This will include coordinating existing research efforts and planned work, and defining gaps in coverage of specific topics and in the resources to support high-priority projects. An initial focus will be projects needed to accompany scale-up in the 2010 timeframe. The group will also define a sustainable process and a focal body to regularly update the research agenda based on findings and new circumstances and to act as a forum for reviewing and disseminating results.

Additionally, further engagement of RBM Working Groups (WGs) and Sub-Regional Networks (SRNs) in setting the research agenda should be prioritized. They should be involved in the above convening, while researchers should be included in WG and SRN meetings. Creating a focal point within the RBM Secretariat will also help ensure this collaboration occurs.

C. Operational and Implementation Research

Operational and implementation research inform decisions about the effective implementation of scale-up, sustained control and elimination activities at country and district level. As with research to inform policy, significant additional financial resources and human capacity are needed.

WHO defines operational research (OR) as “the use of systematic research techniques for program decision-making to achieve a specific outcome. OR provides policy-makers and managers with evidence that they can use to improve program operations.”¹⁰⁵ The purpose of implementation research, as stated by WHO - the Special Programme for Research and Training in Tropical Diseases (TDR), is to “significantly improve access to efficacious interventions against tropical diseases by developing practical solutions to common, critical problems in the implementation of these interventions”.¹⁰⁶

Operational and implementation research helps to identify solutions to bottlenecks that limit program quality, efficiency and effectiveness, or to determine which alternative service delivery strategy would yield the best outcomes. At its best, the results of this research increase the performance of programs on both country and global levels. Operational and implementation research, while separate and distinct, links closely with M&E, described in more detail in *Part IV - Chapter 9: Monitoring and Evaluation*. Generally speaking, M&E is the routine tracking of program performance and the periodic evaluation of this performance, including outcomes and impact.

Historically, limited funding has made it difficult for operational and implementation research to keep pace as control measures has been scaled up, both for malaria and other health conditions. For example, current intervention field effectiveness is often much lower than its potential and varies significantly based on setting. Non-adherence to challenging drug regimens, improper use of LLINs and washing walls post IRS, are just some of the causes of the lower effectiveness that need to be assessed.

Operational research in malaria is sponsored by several large international partners, such as the World Health Organization, Multilateral Initiative on Malaria / Research and Training in Tropical Diseases (MIM / TDR), Bill and Melinda Gates Foundation, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and several bilateral organizations. WHO-TDR and the Global Fund have recently developed an operational framework to standardize the operational research carried out in countries. The Global Fund will be compiling a database of past and ongoing operational research activities¹⁰⁷ that are funded by Global Fund grants. All of this should add to lessons learned and best practices for malaria control.

Key Challenges

Challenges in the control stage. Several key questions and challenges exist in scaling up interventions which could be addressed by operational research.

Delivery of LLINs. Debate still exists surrounding the most effective mechanisms for delivering LLINs. While many approaches can be successful depending on the context and sophistication of a country’s control program and health system, greater understanding is needed of the appropriateness of campaigns vs. routine distribution (public and/or private), in initial scale-up and in replacement while sustaining control.

¹⁰⁵ *Framework for Operations and Implementation Research in Health and Disease Control Programs*. WHO-TDR and the Global Fund to fight AIDS, Tuberculosis and Malaria, 2008.

¹⁰⁶ *Framework for Operations and Implementation Research in Health and Disease Control Programs*. WHO-TDR and the Global Fund to fight AIDS, Tuberculosis and Malaria, 2008.

¹⁰⁷ Joint WHO-TDR/TGF Consultative Technical Meeting on the Framework for Implementation/Operational Research in Health and Disease Control Programs, Geneva, April 2008.

Insufficient health systems research. Research into general health systems that is relevant across diseases should be a priority: understanding the key bottlenecks to achieving universal coverage and utilization, and defining optimal solutions for minimizing them will be very important, particularly as countries move into sustaining control. Research into effective integrated, multi-disease programs which incorporate malaria will be helpful. Testing alternative and improved delivery strategies (e.g. community health workers, mobile clinics, mass campaigns) will also help program managers achieve universal coverage. For example, questions exist regarding optimal roles for the public and private sector in improving access and how the roles evolve as the control program reaches certain milestones. This would be impacted by public and private sector capacity in the country and the types of populations targeted. Economic analysis is also needed to assess how different delivery systems affect cost effectiveness.

Operational research on which mechanisms enable interventions to reach the poor and vulnerable groups, including women and young children, is also needed. Currently evidence is limited: small scale projects have been undertaken, but there is much less experience sustaining quality services on a large scale over time (e.g. sustaining drug supplies, or the motivation and quality of care among community health workers).

Behavior change research. Behavioral research will be necessary to help ensure preparedness for implementation of strategies, particularly surrounding those of new interventions and approaches. For example, increasing focus on parasitological diagnosis in more transmission settings across age groups will require significant behavior changes. Research focused on optimizing behavior change communication (BCC) and information, education and communication (IEC) approaches, which can improve intervention uptake, usage, and adherence, and on mechanisms for sharing best practice approaches should be developed.

Research for monitoring and surveillance technologies. Lastly, research is needed on the feasibility of new monitoring and surveillance systems. Several new applications utilizing mobile phone, SMS and PDA technology have the potential to increase frequency and accuracy of data collected. A greater understanding of which tools are most applicable in which settings will be helpful, particularly as surveillance becomes more critical.

Current activities. Several groups have begun defining key operational and implementation research for malaria. The RBM Malaria In Pregnancy Working Group (MIP) has developed a list of questions related to pregnant women and malaria, while the WHO Special Programme for Research and Training in Tropical Diseases (TDR) has done similar work for case management. Box II.7 contains an example from the RBM Scalable Malaria Vector Control Working Group (WIN) of its proposed operational and implementation research agenda for vector control.

Challenges in the elimination stage. Very little operational and implementation research exists for countries in elimination.

High transmission settings. There is currently little knowledge on elimination approaches for higher-transmission settings. For countries currently in elimination, more operational research is needed to identify best practice approaches in these and other diverse geographical settings. As higher transmission countries reduce burden to levels where elimination becomes feasible, specific research should be undertaken to understand how elimination programs can be successfully implemented. Countries which have pockets of higher transmission may be good candidates for such studies, such as South Africa, Swaziland and Botswana.

Additionally, as cross-border collaboration becomes more important due to porous borders and transient populations, greater understanding of best practice approaches will be helpful to countries. This includes guidance on assisting adjacent countries which may have lower resource levels and/or humanitarian crises which make malaria control, particularly with population movements, even more challenging.

Box II.7: An Example - Operational and Implementation Research Needs for Scalable Vector Control

From the RBM Scalable Malaria Vector Control Working Group (WIN)

The RBM WIN Working Group has identified a set of questions that could be answered by operational and implementation research. While questions must still be prioritized, they are listed below:

- What are the barriers to effective universal coverage and use of LLINs (system, political, operational, cultural, household, etc.) and how do we mitigate them? (includes reasons for sub-optimal use)?
- What are the optimal LLIN replacement strategies and thresholds, and how do we forecast needs for achieving and sustaining high coverage levels?
- What are the marginal costs and benefits of combining IRS with LLINs under varying strategies?
- What are the marginal costs and benefits of two versus one annual round of IRS in perennial transmission settings?
- Why is LLIN use low among pregnant women and how can use be improved?
- How can we better measure the useful life of LLINs under real life conditions?
- What options exist to strengthen and streamline national regulatory systems and regional support and how well do these work?
- What is the entomological and epidemiological impact of scaled-up LLINs and/or IRS (incl. social acceptability)?
- Can combined full coverage of LLINs and IRS push transmission to zero in highly endemic areas of sub-Saharan Africa (under what time frames and strategies)?

Priorities

General priorities.

- a) Significant additional financial resources and human capacity are needed to address all of the operational and implementation research priorities.

Priorities for scaling up and sustaining control. Several activities should be started in the short-term to help with the immediate needs of scale-up as well as the medium-term goals of sustaining control:

- b) Research surrounding mechanisms for replacement of LLINs and best practice recommendations based on setting and country capacity;
- c) General health systems research to identify approaches for reaching hard-to-reach populations, determine optimal roles for different sectors, increasing access to treatment, etc;
- d) Behavioral research to inform effective practices for improving uptake, usage and compliance with interventions; and
- e) Research on new M&E technologies.

Priorities for elimination. Increased operational research related to elimination would significantly benefit countries currently in this stage, as well as help define objectives and strategies for countries that could embark on elimination in the medium- to long-term. Priorities include:

- f) Greater understanding of and solutions to common elimination challenges, such as the control of malarious borders and transient populations; and
- g) Research on elimination approaches for formerly high transmission settings.

Organization Implications: Developing the Agenda for Operational and Implementation Research

Several research gaps exist around effective delivery of and access to available tools and treatments during the scale-up stage, including comprehensive approaches for difficult-to-reach populations. Many groups (e.g. the Scalable Malaria Vector Control Working Group, the Malaria in Pregnancy Consortium) have set operational research agendas for malaria and have identified operational research needs and opportunities that could be addressed. However, a common global agenda is still needed, as well as clear designations regarding who or which organizations should focus on specific research questions and a way to collate and disseminate findings.

As with the *Research to Inform Policy* recommendations, a group including all major stakeholders should be convened regularly to determine and refine the global operational and implementation research agenda. Additional RBM Working Group involvement could be coordinated through the RBM Secretariat-based focal point recommended earlier. Even if separate groups and mechanisms are created than those for research to inform policy, they should be closely linked.

5. Costs and Benefits of Investment in Malaria Control, Elimination, and R&D

Key messages

- The total cost of the global strategy (including both country implementation and R&D costs) is estimated to average US\$ 5.9 billion per year from 2011 to 2020.
 - Country implementation will cost approximately US\$ 5.3 billion in 2009, US\$ 6.2 billion in 2010 and average US\$ 5.1 billion annually from 2011 to 2020.
 - R&D will cost approximately US\$ 750 - 900 million per year through 2018 for new tools (vector control, drug, vaccine, and diagnostic technologies).
- The Global Strategy requires a long-term commitment: continued funding is essential in both country implementation and R&D to prevent a re-emergence of malaria.
- However, the investment is worthwhile.
 - Malaria control is cost effective, saving more lives per dollar spent than interventions for most other diseases.
 - R&D investment *today* in new and improved interventions can help countries eliminate malaria faster and reduce the need for longer-term R&D costs.

Investment in country implementation and R&D saves lives today and prevents deaths tomorrow. It is highly cost effective and results in lower treatment costs, lower R&D investment needs, and positive economic benefits in the future. This section describes:

- The cost of country implementation of malaria control and elimination strategies;
- The cost of R&D to develop new tools for these strategies; and
- The benefits of investing in malaria control, elimination and R&D.

These estimates are based on the best understanding of costs and benefits today, but will be continuously revised as part of ongoing activities of the RBM Partnership.

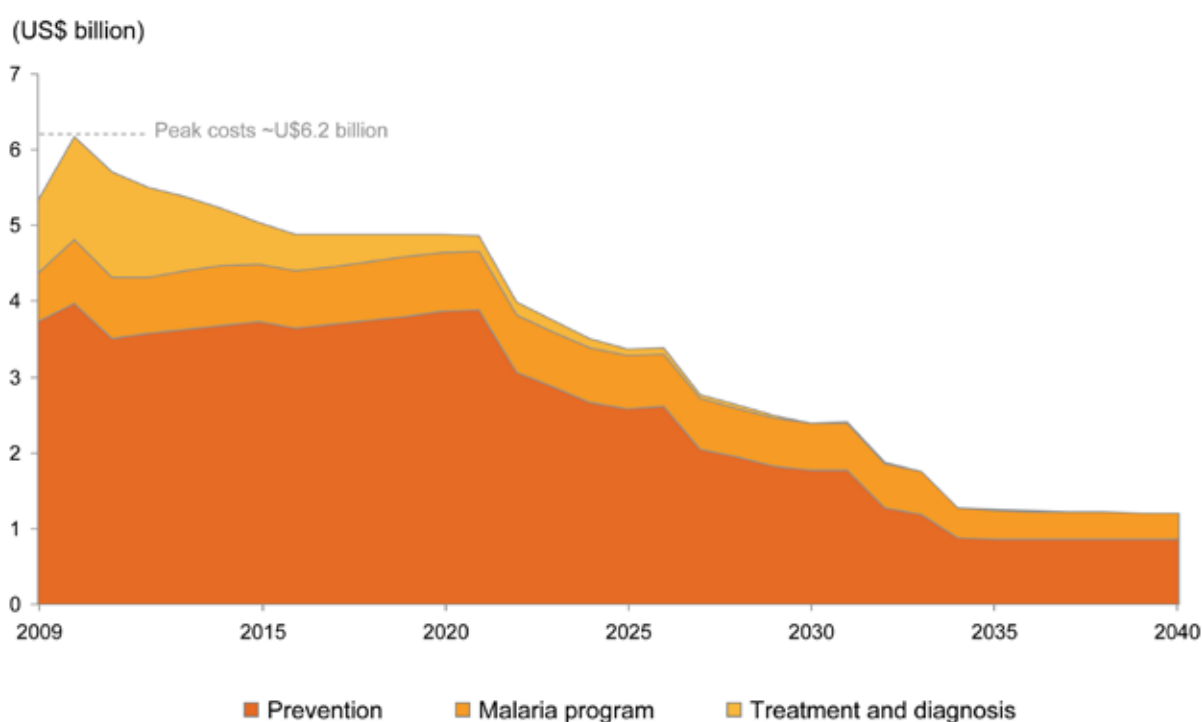
Cost of Country Implementation of Malaria Control and Elimination Strategies

We have estimated the full implementation costs for all 109 malarious countries to scale-up, sustain control, and eliminate malaria. Developed in consultation with experts from the RBM Resources Working Group and the London School of Hygiene and Tropical Medicine as well as experts from many other institutions, the costing model and estimates apply the most recent data and best approaches currently available.

Preliminary estimates¹⁰⁸ shown in Figure II.14 below indicate that

- Approximately US\$ 5.3 billion and US\$ 6.2 billion are needed in 2009 and 2010, respectively.
- From 2011-2020, an average of US\$ 5.1 billion is needed annually.
- From 2021-2030, average annual costs of US\$ 3.3 billion are expected.
- From 2031-2040, average annual costs of US\$ 1.5 billion are expected.

Figure II.14: Global cost for malaria control and elimination



Source: GMAP costing model.

Implementation costs include the costs of prevention, treatment and control programs. Estimates represent the fully loaded costs of preventive tools (LLINs, IRS, and IPTp)¹⁰⁹ and curative interventions (anti-malarial drugs, diagnostics, and severe case management), as well as malaria control program costs, for all 109 malaria endemic countries. Fully-loaded costs represent intervention costs plus distribution, warehousing and other delivery expenses based on published or expert sources. See Appendix 4: Assumptions behind Country Implementation Cost Estimates for more information relating to assumptions for the cost estimates. For more information on current funding from national and international sources, please see Part I - Chapter 4: Funding for Malaria Today.

¹⁰⁸ All estimates are nominal based on 2008 dollars. For projections based on potential inflation rates, please see *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates*.

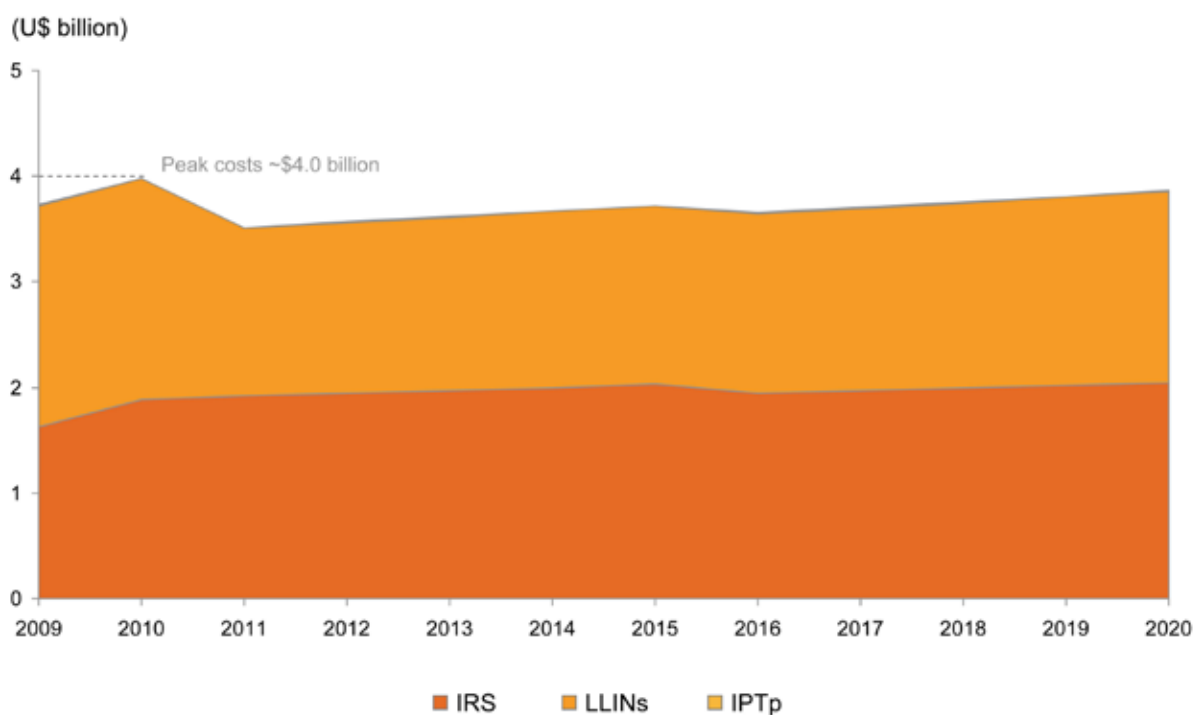
¹⁰⁹ Although important, the costs of environmental management were not included due to insufficient information.

Cost of prevention: LLINs, IRS and IPTp. The most substantial costs in malaria control are those of preventive interventions. This is because prevention will need to be sustained to prevent re-emergence of malaria in many areas even when burden declines. Prevention costs hover around 70% of total costs over time, creeping up slightly as countries sustain control after scale-up.

Covering the 3.3 billion people at risk globally with the appropriate preventive interventions will cost approximately US\$ 3.7 billion in 2009 and US\$ 3.9 billion 2010 (see Figure II.15). IRS represents 55%, LLINs represent almost 45%, and IPTp comprises less than 1% of total prevention costs. (See *Part II - Chapter 2: Controlling Malaria* for recommendations on coverage). From 2011 to 2020, preventive costs will average US\$ 3.6 billion annually due to the need to sustain control and to population increases.

Vaccines. The baseline projections and charts do not consider new interventions, including vaccines. Preliminary assumptions show that a 2013 launch and subsequent 2-year scale-up of a partially effective vaccine covering 80% of all children in Africa under 1 year of age would cost an additional ~US\$ 533 million per year.

Figure II.15: Preventive intervention costs

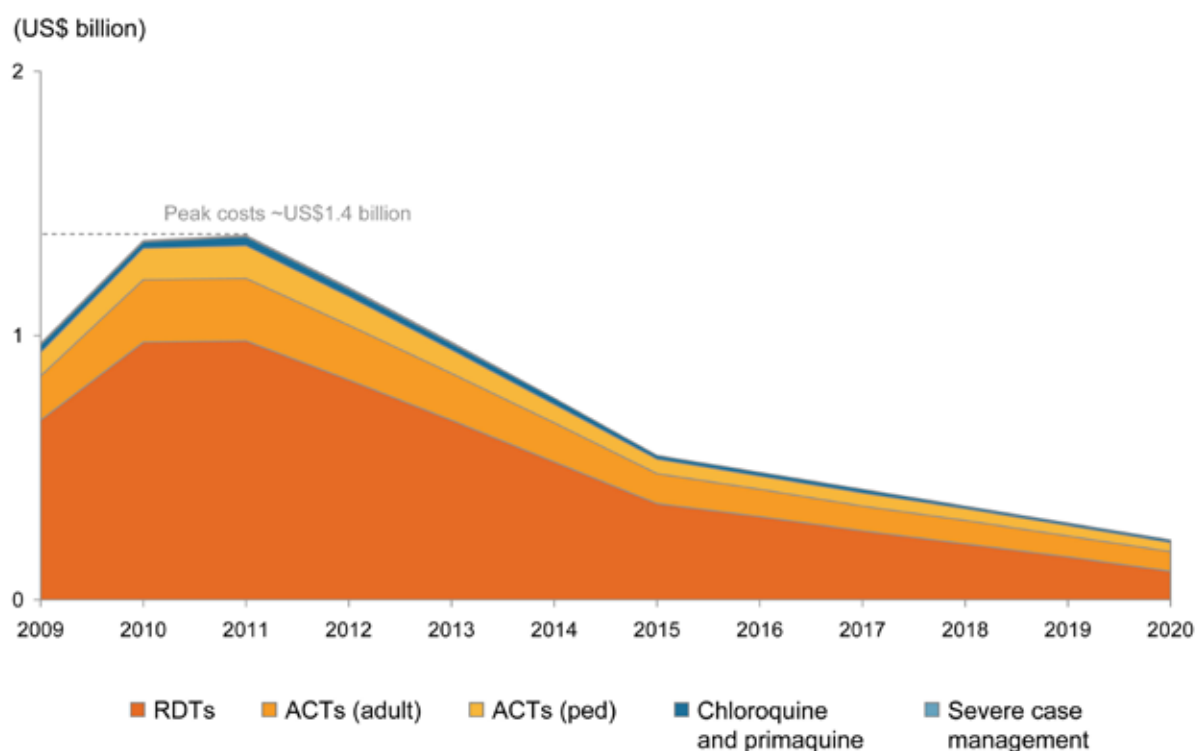


Source: GMAP costing model.

Cost of case management: RDTs, ACTs, Chloroquine, Primaquine and Severe case management. Case management costs, which include ACTs (for *P. falciparum*), RDTs, chloroquine and primaquine (for *P. vivax*) and severe case management are approximately 20% of total costs during the initial scale-up and early sustained control periods (see Figure II.16). RDTs comprise the bulk of costs due to the assumption that half of all fevers suspected of malaria are diagnosed with an RDT (the other half are assumed to be diagnosed via microscopy). Upon reaching a peak cost of about US\$ 1.4 billion in 2011, treatment costs decline significantly (to less than 10% of total costs) due to the impact of scaled-up preventive interventions on incidence throughout the sustained control period. In elimination, treatment will eventually decline to approximately 1% of total costs.

While in reality, there is often overuse of treatment, the baseline estimate takes an aspirational approach assuming wide-spread diagnosis and treatment of confirmed cases (plus an additional 25% to account for some over-treatment). However, a sensitivity analysis was conducted for Africa showing a 75% lower usage of RDTs than the baseline “aspirational” scenario and subsequent treatment of all fever cases. In this case, overall case management costs are ~40% higher. This makes a powerful argument for scaling up diagnostics, provided patients do not still seek anti-malarial treatment regardless of the diagnosis.

Figure II.16: Case management costs

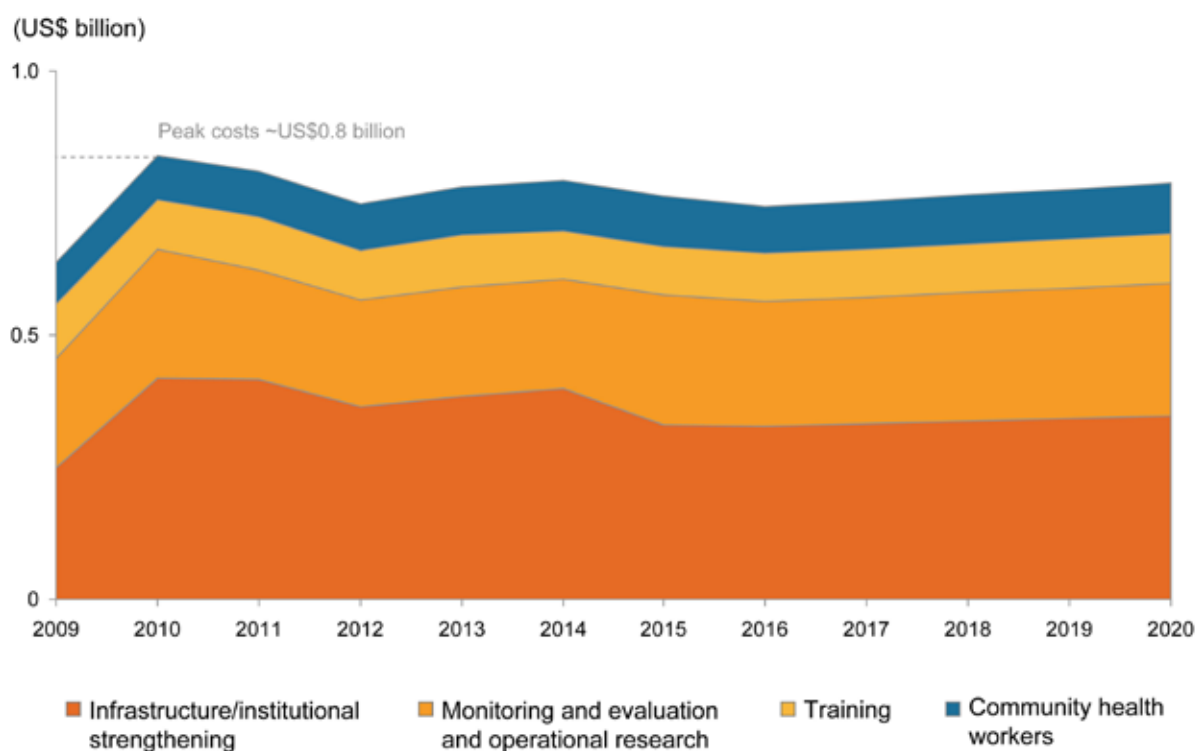


Source: GMAP costing model.

Cost of Malaria Programs: M&E, Operational Research, Training, Human Resources and Infrastructure. Program costs are country-level costs, and include local operational research, monitoring and evaluation, health infrastructure, training and community health workers, using country-specific estimates and methodology described by Kiszewski and Johns et al¹¹⁰ (see Figure II.17). These estimates do not include global costs such as R&D, operational research or monitoring and evaluation (M&E) at an international level.¹¹¹ Specific components of each of the four categories of costs are described in *Appendix 4: Assumptions behind Country Implementation Cost Estimates*.

Program costs are initially approximately 14-19% percent of the overall annual costs, and make up a greater relative percent as treatment and preventive intervention costs decline. During elimination, programs costs, except for surveillance, are slightly lower than during sustained control, as malaria control is integrated into broader, multi-disease control programs. Although declines in incidence may suggest even lower costs, intensive surveillance and vigilance require continued investment.

Figure II.17: Malaria program costs



Source: GMAP costing model.

When estimating delivery and program costs for malaria, there is a potential to over-estimate the shared delivery costs and/or the health systems costs which could be attributed to multiple diseases. While care was taken to minimize potential overlap by validating with experts and cross-referencing with multiple sources, some duplication may still exist due to the difficulty of differentiating malaria-specific costs, particularly in resource-constrained environments and across 109 countries. This highlights the need to understand better (and take advantage of) the synergies in malaria program costs with other disease programs.

¹¹⁰ Kiszewski A, Johns B, et al. Estimated global resources needed to attain international malaria control goals. *Bulletin of the World Health Organization*, 2007, 85:623-630.

¹¹¹ The model uses country estimates when available for costs, target interventions and coverage, etc., and global or regional assumptions when country-specific information was not available. Country-costs increased at the rate at which the country's population was projected to grow from 2005 to 2050. Other than this annual adjustment, no changes were made to reflect currency adjustments in the baseline. For estimates based on projected inflation rates, see *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates*.

Cost differences per stage. Annual costs decline as countries progress from scaling up to sustaining control to eliminating malaria. Estimates are based on differing assumptions and durations for each stage (which are detailed in *Appendix 4: Assumptions behind Country Implementation Cost Estimates*). The initial years between 2009 and 2011 will be the most expensive as most countries are scaling up malaria control. This stage requires significant investments across all intervention types. However, the short duration of the scale-up period means that in total this stage will be the least expensive relative to the others.

Annual costs begin to decline as countries focus on sustaining control over time since use of preventive interventions decreases the amount of treatment needed. However, while treatment costs decline, there is still significant expense required in maintaining preventive coverage. Hence sustaining control is expected to cost an average of US\$ 5.1 billion annually from 2011-20. Countries are assumed to stay within the sustained control stage between 5-20 years depending on natural-state transmission levels.

In the elimination stage, annual costs, while still significant, are expected to decline further. Country by country, all costs will vary depending on each country’s natural transmission level. During the time periods where more and more countries are expected to enter into elimination campaigns, preliminary estimates show costs could average US\$ 3.3 billion annually from 2021 to 2030, US\$ 1.5 billion annually from 2031-2040 and US\$ 550 million annually from 2041-2050. There is, of course, a likelihood that elimination will extend beyond 2050, which will extend the costs further.

To examine relative cost per stage more closely, one of the lower populations at risk (PAR) countries that is currently scaling up was examined to determine specific average costs per stage. Relative costs are shown in Figure II.18. Evaluation of higher PAR countries show a slightly lower decline in relative annual costs across each stage, meaning the program from start to finish would cost more.

Figure II.18: Average annual costs decline per stage

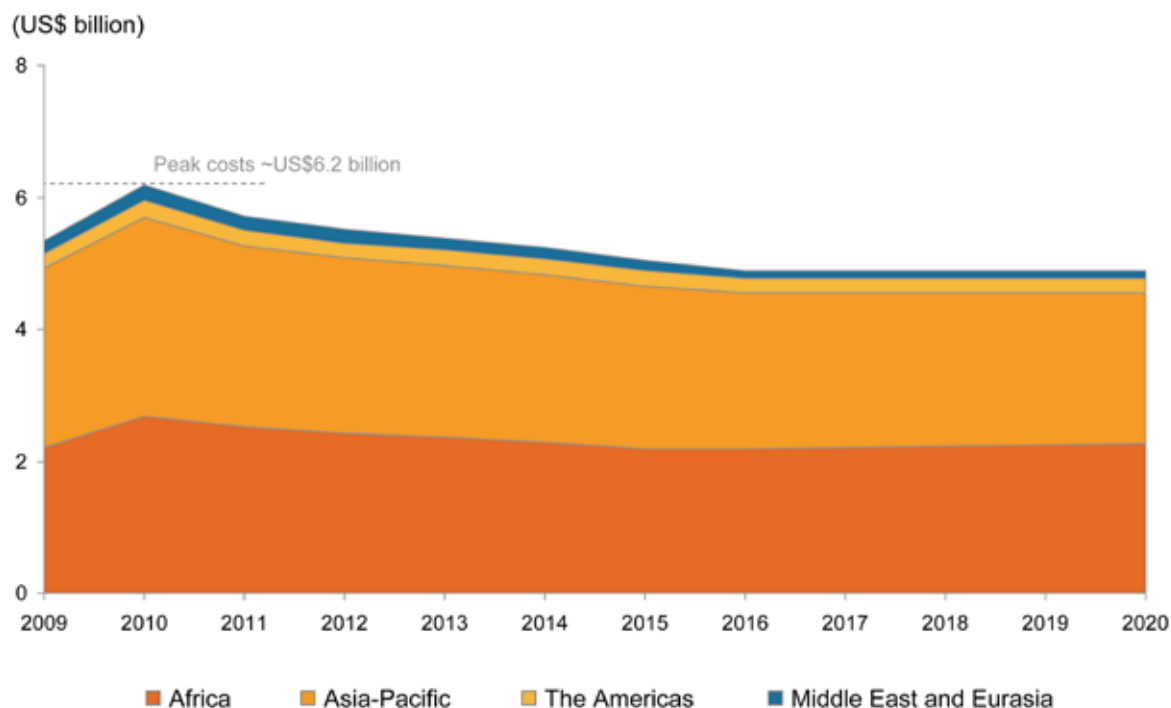


Note: Decreases shown are relative. In reality, cost declines are gradual.

Source: GMAP costing model.

Costs vary substantially by regions. Regions with high incidence and large populations at risk, such as Africa and Asia-Pacific, account for the largest portion of global costs throughout the duration of the program (see Figure II.19). Between 2009-10, approximately 43% of the annual costs are for Africa, and an addition 50% of the costs are from Asia-Pacific. Other regions, which consist of many countries in elimination and later stages of sustained control, have significantly lower malaria control costs. From 2011-20, approximate average annual control costs for regions are: Africa: US\$ 2.3 billion, Asia-Pacific: US\$ 2.5 billion, the Americas: US\$ 225 million, and Middle East and Eurasia (MEE): US\$ 120 million. Please see *Part III: Regional Strategies* for information on current national and international funding available to regions.

Figure II.19: Annual costs by region

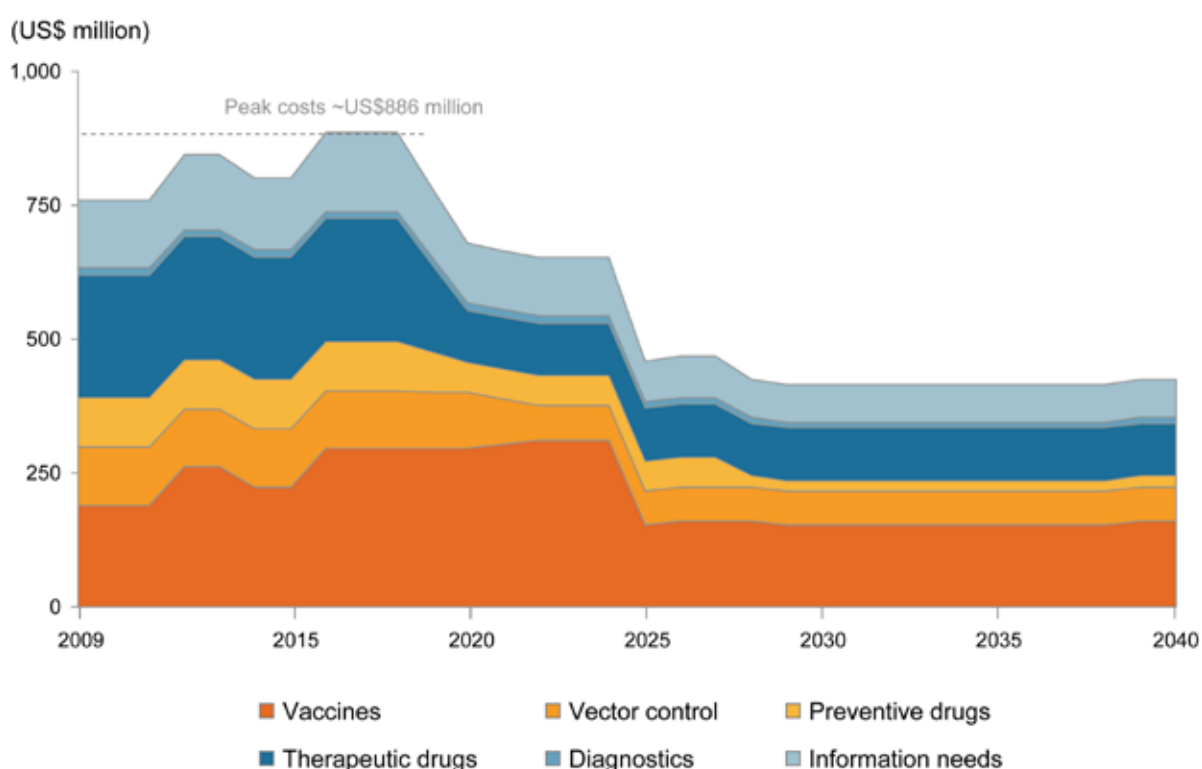


Source: GMAP costing model.

Cost of Research and Development

Based on preliminary estimates outlined in Figure II.20, malaria research and development will cost approximately US\$ 750 to US\$ 900 million per year through 2018 for new tools. This represents a total cumulative investment of more than US\$ 8.9 billion through 2018. Significant investment must be made into drugs, vaccines, vector control and diagnostics over the coming years to achieve the near-term goal of malaria control and prepare for elimination and eradication in the long-term. Of the US\$ 8.9 billion, about US\$ 1.2 billion is for vector control, US\$ 3.5 billion for drugs, US\$ 2.6 billion for vaccines, and US\$ 140 million for diagnostics. In addition to the direct cost of interventions, about US\$ 1.5 billion is needed for early research and for information needed to assess effectiveness and impact of new tools.

Figure II.20: Malaria research and development costs



Source: GMAP costing model.

These costs, while high, will lead to the introduction of important new tools. The R&D costs are based on today's thinking about the general classes of the preventive and therapeutic tools necessary to enable world-wide eradication. These tools were broadly discussed in the R&D section, but prescriptive estimates are necessary to model R&D cost projections.

Vaccines. With a sustained commitment to R&D, the world will have four different vaccines by 2028. Two vaccines will be developed for *P. falciparum*, however, the second vaccine will be more efficacious than the first. In addition, one *P. vivax* vaccine will be developed. One other vaccine that has the capability to target both *P. vivax* and *P. falciparum* simultaneously and/or block transmission and/or be used by pregnant women is anticipated.

Preventive and therapeutic drugs. By 2018, two IPT-specific drugs will be launched and four different types of therapeutic drugs will be developed: a next generation ACT for *P. falciparum*, a combination that targets *P. vivax* in the liver stage, and two therapeutics that separately block *P. falciparum* and *P. vivax* transmission. The transmission blocking drugs may also have the capability to treat the disease at the red blood cell stage. After launch of these drug products, it is estimated that two novel therapeutic drug combinations and one novel preventive treatment will be created every 10 years to avoid resistance build-up. In addition, new formulations for drugs will be created for pregnant women, children and infants, and different delivery modes will be created for severe malaria.

Vector control. For vector control, three new active ingredients and 15 formulations will be needed over the next 12 years to pre-empt pesticide resistance and integrate new paradigms such as larviciding and consumer products. Only one active ingredient and 10 formulations will be developed in subsequent decades for the same purposes.

Diagnostics. Reliable, robust and cost efficient microscopy and rapid diagnostic test technologies are necessary to enable malaria elimination. Over the next several decades, investments in microscopy, improvements in current diagnostic technology, developments of new monoclonal antibodies and innovative polymerase chain reaction (PCR) technology to increase diagnostic sensitivity, and inventions of non-invasive tests and broader diagnostic tools are necessary.

Timeframes and costs. These new tools require significant time and sustained investment. The cost to develop a vaccine ranges from US\$ 600 million to US\$ 1 billion and the project timeline is estimated to be 13 years. It takes approximately US\$ 250 million and 10 years to develop a new active ingredient for drug therapies and between two and six years and US\$ 25 million to launch a reformulation. For vector control, developing a new active ingredient requires a US\$ 175 million investment and 12 years whereas a reformulation is only US\$ 3 million over two to six years. Annual investments in developing new microscopic and diagnostic technologies range from approximately US\$ 10 to US\$ 15 million.

The R&D forecasts are uncertain and timelines are conservative. Though the model assumptions were vetted through interviews with industry experts, there is inherent uncertainty in the types of tools that are needed and the timelines to develop them. When in question, the current timeline estimates err on the side of conservatism. For example, we are assuming it requires development of two drugs to block transmission of *P. falciparum* and *P. vivax*. However, efforts are underway to simultaneously block both parasites with one product which would ultimately reduce overall cost and time spent on R&D. As a result, it will be necessary to continuously update this model over time. See *Appendix 5: Assumptions behind Research and Development Cost Estimates* for more information about the model inputs and assumptions.

Benefits of Investing in Malaria Control, Elimination, and R&D

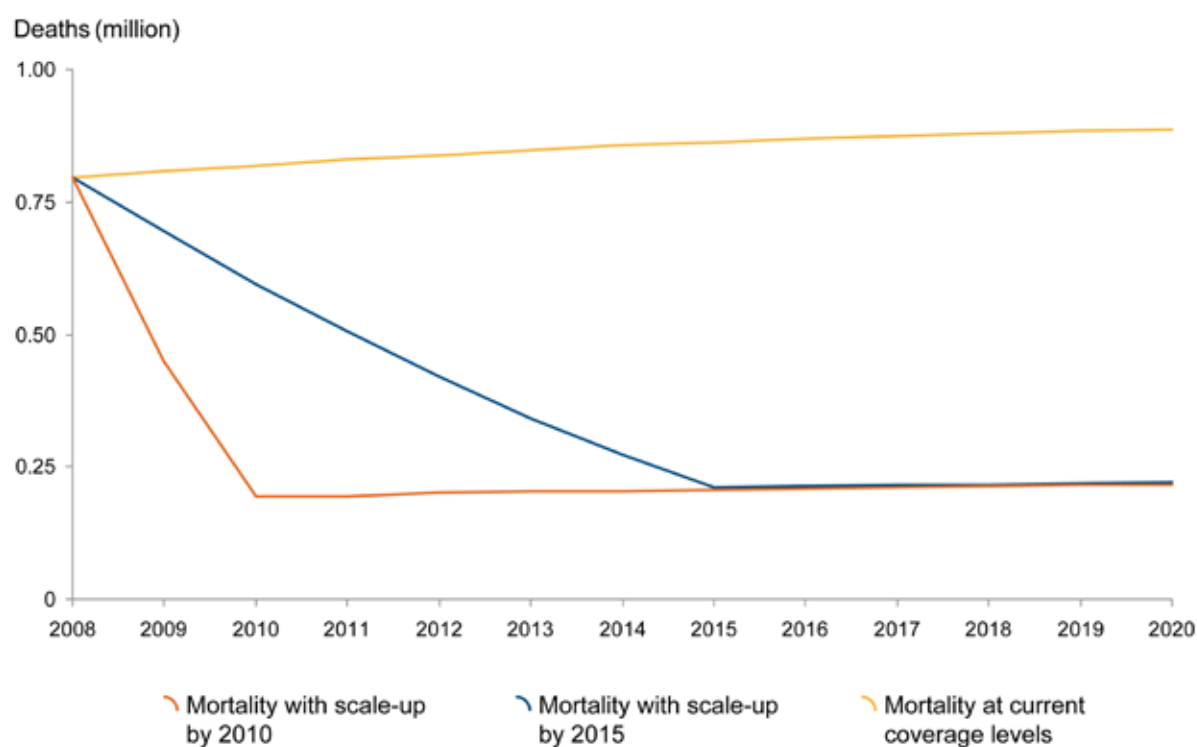
While the costs of fighting malaria are not low, the benefits are significant. There are several compelling reasons why malaria makes a good investment:

- Malaria control saves lives today and prevents deaths tomorrow;
- Malaria control is cost effective, especially when compared to interventions for other diseases;
- R&D investments save long-term control costs;
- Costs saved through rapid scale-up enable reinvestment in other health programs; and
- Lower burden yields positive economic benefits and can reduce poverty.

Malaria control saves lives today and prevents deaths tomorrow. Investing in rapid scale-up today and sustaining the achievements over the longer term will save several million lives. A consortium of organizations led by the Institute of International Programs at Johns Hopkins Bloomberg School of Public Health has developed an IMPACT model measuring child survival based on work by the Child Health Epidemiology Reference Group (CHERG) and using software developed by the Futures Institute. In Figure II.21, an indicative analysis of 20 high-burden African countries¹¹² shows that if 2010 coverage goals are met, over 4.2 million cumulative lives will be saved between 2008 and 2015. If scale-up targets are not achieved until 2015, only 2.8 million lives will be saved over that same period. See *Appendix 4. Assumptions behind Country Implementation Cost Estimates* for cost implications of slower scale-up.

The model bases child survival rates on the current effectiveness levels of preventive and curative interventions. These gains will likely increase as operational effectiveness increases and new tools are developed, making the goal of near zero deaths possible. Already, some countries have seen even greater reductions in mortality.

Figure II.21: Impact of scale-up on malaria mortality in 20 high burden African countries



a) Countries evaluated represent ~82% of global malaria mortality.

Source: Child Survival IMPACT model. Developed by a consortium led by the Institute of International Programs at Johns Hopkins Bloomberg School of Public Health. Based on work of the Child Health Epidemiology Reference Group (CHERG).

Malaria control is highly cost effective. In addition to the impact on morbidity and mortality, interventions to prevent and cure malaria have been shown to be very cost effective with high benefit-cost ratios in a number of studies. In Table II.3, a recent analysis of sub-Saharan Africa shows a package of malaria preventive interventions (including nets, IRS, and IPTp) to be the second most cost effective intervention compared to those of multiple diseases and conditions including HIV/AIDS and tuberculosis.¹¹³

¹¹² Countries evaluated represent ~82% of global malaria mortality: Angola, Burkina Faso, Cameroon, Chad, the Democratic Republic of Congo, Cote d'Ivoire, Ethiopia, Ghana, Guinea, Kenya, Madagascar, Mali, Mozambique, Niger, Nigeria, Senegal, Sudan, Tanzania, Uganda, Zambia. The model only looks at the impact on deaths due to *P. falciparum*.

¹¹³ Based on chapters in Jamison D et al. *Disease Control Priorities in Developing Countries*, 2nd edition, 2006, as summarized in Laxminarayan et al., 2006.

At a cost of US\$ 2-24 per DALY (disability-adjusted life year)¹¹⁴ averted the only intervention with higher cost effectiveness was childhood immunization. Using the same data, malaria interventions (including nets and ACTs) ranked among the top 7 of 315 health interventions analyzed based on a combination of benefit-cost and burden addressed.¹¹⁵

Table II.3: Cost-benefit ratios for major health care interventions

Health care intervention	Cost per DALY averted (\$)	Burden (in M of DALYs)
Childhood immunization	1 - 5	Not assessed
<i>Malaria prevention^a</i>	2 - 24	35.4
Surgical services & emergency care	7 - 215	25 - 134.2
Childhood illnesses	9 - 218	9.6 - 45.1
Cardiovascular disease	9 - 273	4.6
HIV/AIDS (prevention)	6 - 377	56.8
Maternal / neonatal care	82 - 409	29.8 - 37.7
HIV/AIDS (treatment)	673 - 1,494	56.8
Tuberculosis (treatment)	4,129 - 5,506	8.1

a) Includes insecticide treated bed nets, indoor residual spraying and IPTp in sub-Saharan Africa.

Source: Mills A. and Shillcutt S. Copenhagen Consensus Challenge paper on Communicable Diseases, 2004.

This confirms the findings of similar studies, including the 2004 Copenhagen Consensus, which showed that investments in ACTs and LLINs not only saved significant lives, but that the annualized net benefits and benefit-cost ratios are high compared to other diseases.¹¹⁶ This means that a dollar spent for malaria interventions may potentially have a larger impact on health outcomes than the same money spent on interventions against other diseases.

R&D investments save long-term costs. From a global cost standpoint, significant R&D investment made over the next decade is expected to yield highly effective tools which will decrease the need for R&D funding and expensive control efforts in future decades. For example, the launch of a successful vaccine would reduce long-term investment in drugs and other interventions. Over time, R&D investment will also permit development of more cost effective interventions and will therefore reduce ongoing in-country implementation costs. Until the launch of an efficacious tool that will help eliminate malaria, the annual R&D costs are projected to range from US\$ 750 million to US\$ 900 million through 2018. Ensuring these investments are made is integral to achieving the ultimate goal of malaria eradication.

Costs saved enable reinvestment. According to the costing model, most countries in the midst of control programs have an annual malaria control cost averaging US\$ 1.85 per person at risk, depending on several factors including regional differences, population size and density, number of interventions used simultaneously, etc. This expenditure will decline over time due to the savings generated through lower treatment needs. When compared to the average annual health expenditure of these countries, the costs are relatively low. Average annual health expenditures per person in Africa are US\$ 19, US\$ 30.5 in Asia, and US\$ 26.50 in the Americas.¹¹⁷

¹¹⁴ DALYs for a disease are the sum of the years of life lost due to premature mortality in the population and the years lost due to disability for incident cases of the health condition. One DALY represents the loss of one year of equivalent full health. Murray CJL, Salomon JA, Mathers CD, Lopez AD (eds.). *Summary measures of population health: concepts, ethics, measurement and applications*. Geneva, World Health Organization, 2002. See <http://www.who.int/healthinfo/boddy/en/> for more information.

¹¹⁵ Jamison D. Disease Control. In Lomborg B, eds. *Solutions for the World's Biggest Problems: Costs and Benefits*. Cambridge University Press, 2008.

¹¹⁶ Mills A and Shillcutt S. *Copenhagen Consensus Challenge Paper on Communicable Diseases*. 2004.

¹¹⁷ Kiszewski A, Johns B, et al. Estimated global resources needed to attain international malaria control goals. *Bulletin of the World Health Organization*, 2007, 85:623-630.

As malaria control expenditure decreases due to rapid declines in incidence, funding is freed up to fund other health initiatives.

Lower burden yields positive economic benefits and can reduce poverty. Malaria usually affects some of the poorest, most marginalized populations in the world. Minimizing the burden enables individuals to continue to go to work and school as well as lessens time away from work caring for the sick. This promotes economic growth and can diminish the cycle of poverty.

These investments in malaria control can have a significant positive impact on a region's economy. Some analyses have estimated the annual economic burden of malaria to be at least US\$ 12 billion per year of direct losses, plus many times more than that in lost economic growth. This means that if US\$ 2.3 billion is needed annually to control malaria in Africa, then every US\$ 1 invested into malaria control could enable more than a US\$ 5 gain¹¹⁸, taking only into account the US\$ 12 billion mentioned above. There are likely to be similar benefits in other parts of the world. Further research is being planned to evaluate the economic impact of malaria as well as the positive return seen when adequate investment in malaria happens. This document will be updated as this information comes available.

Table II.4: Summary of annual global costs

Cost (US\$ millions)	2009	2010	2015	2020	2025
LLINs/ITNs	2,091	2,091	1,689	1,807	1,035
IRS	1,632	1,883	2,026	2,047	1,531
IPTp	6	8	9	9	10
<i>Prevention cost</i>	<i>3,728</i>	<i>3,982</i>	<i>3,724</i>	<i>3,864</i>	<i>2,576</i>
RDTs	679	975	368	109	43
ACTs	257	356	164	107	41
Chloroquine and primaquine	5	5	2	1	0
Severe case management	27	23	16	9	4
<i>Case management cost</i>	<i>968</i>	<i>1,359</i>	<i>550</i>	<i>226</i>	<i>87</i>
Community health workers	79	82	97	96	75
Training	104	96	91	93	58
M&E and OR	207	242	245	251	298
Infrastructure / inst. strengthening	248	419	331	347	283
<i>Program cost</i>	<i>638</i>	<i>839</i>	<i>764</i>	<i>787</i>	<i>714</i>
<i>Global control and elimination cost</i>	<i>5,335</i>	<i>6,180</i>	<i>5,037</i>	<i>4,877</i>	<i>3,378</i>
Information needs	126	126	133	113	77
Diagnostics	13	13	13	13	13
Drugs	322	322	322	154	154
Vector control interventions	108	108	108	105	65
Vaccines	190	190	224	296	152
<i>Research & Development cost</i>	<i>759</i>	<i>759</i>	<i>800</i>	<i>681</i>	<i>460</i>
Total cost	6,094	6,939	5,837	5,559	3,838

Note: Diagnostic costs are covered both by RDTs in case management and by microscopy in infrastructure / institutional strengthening
Source: GMAP costing model; Johns B. and Kiszewski A. et al.

¹¹⁸ Extrapolated from loss of US\$ 12 billion of direct costs compared to the cost of achieving control in SSA. Gallup JL and Sachs J. The economic burden of malaria. *American Journal of Tropical Medicine and Hygiene*, 2001, 64:85-96.

People are at risk of malaria in 109 countries and territories around the world. The GMAP outlines strategies, targets and costs to control and eliminate malaria in Africa, Asia-Pacific, the Americas, the Middle East and Eurasia.



PART III Regional Strategies

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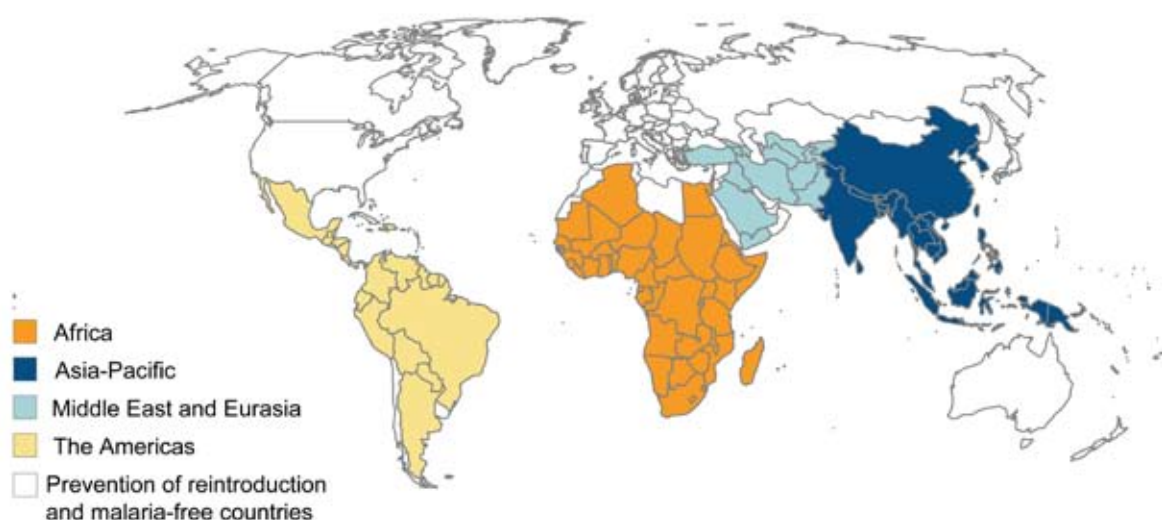


1. Introduction to Regional Strategies

Malaria varies greatly around the world in the level of intensity, in the vectors that transmit it and in the species causing the disease. In order for the global strategy to be relevant for countries around the world, it must be applicable to different settings. In this context, the purpose of the Regional Strategies chapters is to translate the global strategy into regionally-specific approaches for controlling and eliminating malaria, taking into account the differences between regions.

Figure III.1 shows how malaria-endemic countries have been grouped into four regions: Africa, the Americas, Asia-Pacific, and Middle East and Eurasia. This categorization aims to provide high-level clarity. Naturally, countries within the same region will differ substantially in important dimensions and will need to tailor their malaria control strategies beyond the recommendations offered in this section.

Figure III.1: Malaria-endemic countries divided into four regions



These regions differ in many ways: the size of the populations at risk, the disease burden in terms of deaths and cases, the relative mix of malaria species and the level of funds available to fight the disease. Africa is distinguished by having almost 100% of malaria caused by *P. falciparum*, a high number of cases and deaths per population at risk, the most external support and the lowest governmental spending of any region. On the other hand, the Americas and Middle East and Eurasia are dominated by *P. vivax*, have very few cases and deaths, and a high degree of governmental spending on malaria. Asia-Pacific falls between Africa and the other two regions. It has the largest populations at risk, largely mixed infections with *P. vivax* and *P. falciparum*, moderate number of cases and deaths, and two thirds of its funding from governments. These differences play an important role in determining what the strategy should be for each region.

Thirty-five countries are responsible for 98% of the total malaria deaths world-wide. They also contribute to ~96% of the total number of malaria cases. To achieve the 2010 and 2015 targets, support for these countries is essential:

- **30 countries in Africa:** Nigeria, Democratic Republic of Congo, Uganda, Ethiopia, Tanzania, Sudan, Niger, Kenya, Burkina Faso, Ghana, Mali, Cameroon, Angola, Côte d'Ivoire, Mozambique, Chad, Guinea, Zambia, Malawi, Benin, Senegal, Sierra Leone, Burundi, Togo, Liberia, Rwanda, Congo, Central African Republic, Somalia, and Guinea-Bissau
- **5 countries in Asia-Pacific:** India, Myanmar, Bangladesh, Indonesia, and Papua New Guinea

However, all countries are important in the global fight against malaria. The regional chapters address the needs of all malaria-endemic countries in each region, not just the countries with high contributions to global deaths. Table III.1 summarizes the funding required by region to meet the needs of all countries. As the burden decreases overtime, the distinction between high and low burden countries will become less important and regional and global cooperation to sustain control will increasingly become the focus.

Table III.1: Current spend and funding required by region

Cost (US\$ millions)	Spend 2007	GAP	Estimated funding required		
			2009	2010	2011-20 avg
Africa	622	1,577	2,199	2,686	2,291
The Americas	178	49	227	261	224
Asia-Pacific	217	2,504	2,721	3,008	2,467
Middle East and Eurasia	92	96	188	226	147
Total control & elimination cost	1,109	4,226	5,335	6,180	5,129

Note: The 2007 estimates include government and international donor spend. They do not include household spend.

Source: GMAP costing model, WHO, the Global Fund, the World Bank and the President's Malaria Initiative (PMI).

Each regional chapter follows a similar format. The upfront section, *Introduction to Malaria in the Region*, introduces the epidemiology and burden of malaria and reviews the current response against malaria (policies, number of interventions delivered, etc). The second section, *Recommended Regional Approach to Control and Eliminate Malaria*, translates the RBM targets into concrete regional targets, estimates the number of interventions needed, highlights region-specific challenges, outlines the strategic priorities for the region, and the type of support needed to achieve the strategy. Finally, each chapter will conclude by providing an estimate of funding required by intervention over time.

2. Africa

Africa is composed of 50 countries or territories with malarious areas. Forty-seven of these are located in sub-Saharan Africa, which bears most of the global malaria burden. The three malarious North African countries have only residual malaria transmission and occasional imported cases. Therefore, this chapter focuses mainly on the 47 countries of sub-Saharan Africa (SSA).

Central Africa (8): Democratic Republic of Congo (DRC), Cameroon, Chad, Congo, Central African Republic (CAR), Gabon, Equatorial Guinea and Sao Tome and Principe

East Africa (12): Burundi, Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Mayotte, Rwanda, Somalia, Sudan, Tanzania and Uganda

Southern Africa (11): Angola, Botswana, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, Zambia and Zimbabwe

West Africa (16): Nigeria, Niger, Burkina Faso, Ghana, Mali, Côte d'Ivoire, Guinea, Senegal, Benin, Sierra Leone, Togo, Liberia, Guinea-Bissau, Mauritania, Gambia and Cape Verde

North Africa (3): Algeria, Egypt and Morocco

Population at risk. Approximately 694 million people are estimated to be at risk of malaria in African countries, which represents 21% of the global population at risk. 30% of the total population at risk in this region is concentrated in two countries: Nigeria and the Democratic Republic of Congo.¹

Malaria transmission. Malaria transmission in sub-Saharan Africa is heterogeneous, both across and within countries. Many parts of sub-Saharan Africa have high transmission areas where infection is common and the population has developed immunity. In these areas, children and pregnant women are at high risk of developing severe symptoms or dying from malaria. Each year, approximately 25 million African women become pregnant and are at risk of *P. falciparum* malaria during their pregnancy.² Approximately 86% of Africa's total population at risk is located in areas of high transmission.³ Other parts of sub-Saharan Africa are epidemic-prone with unstable and low malaria transmission; in these settings, few people develop immunity so adults as well as children are at high risk of contracting malaria.

The size and intractability of the malaria burden in Africa is partly due to the dominance of the highly efficient *Anopheles gambiae* mosquito as the primary vector and of *P. falciparum*. Sub-Saharan Africa bears an estimated 93% of *P. falciparum* estimated cases in the world. Although *P. vivax* transmission should not be overlooked, about 98% of cases in Africa are estimated to be *P. falciparum*.

Malaria burden. Africa remains the region with the highest burden of malaria cases and deaths in the world. See Figure III.2. In sub-Saharan Africa, approximately 365 million cases occurred in 2002 and 963 thousand

¹ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

² *A strategic framework for malaria prevention and control during pregnancy in the African Region*. Brazzaville, Congo, WHO-AFRO, Regional Office for Africa, AFR/MAL/04/01, 2004. The estimate presented is based on a model developed by Snow and colleagues using Mapping Malaria Risk in Africa (Snow RW and al. Estimating mortality, morbidity and disability due to malaria among Africa's non-pregnant population, *Bulleting of the World Health Organization* 1999; 77, 624-640) and its application to UNICEF data on live births (UNICEF, *State of the World's children*, Oxford University Press, 1998) adjusted for the year 2000.

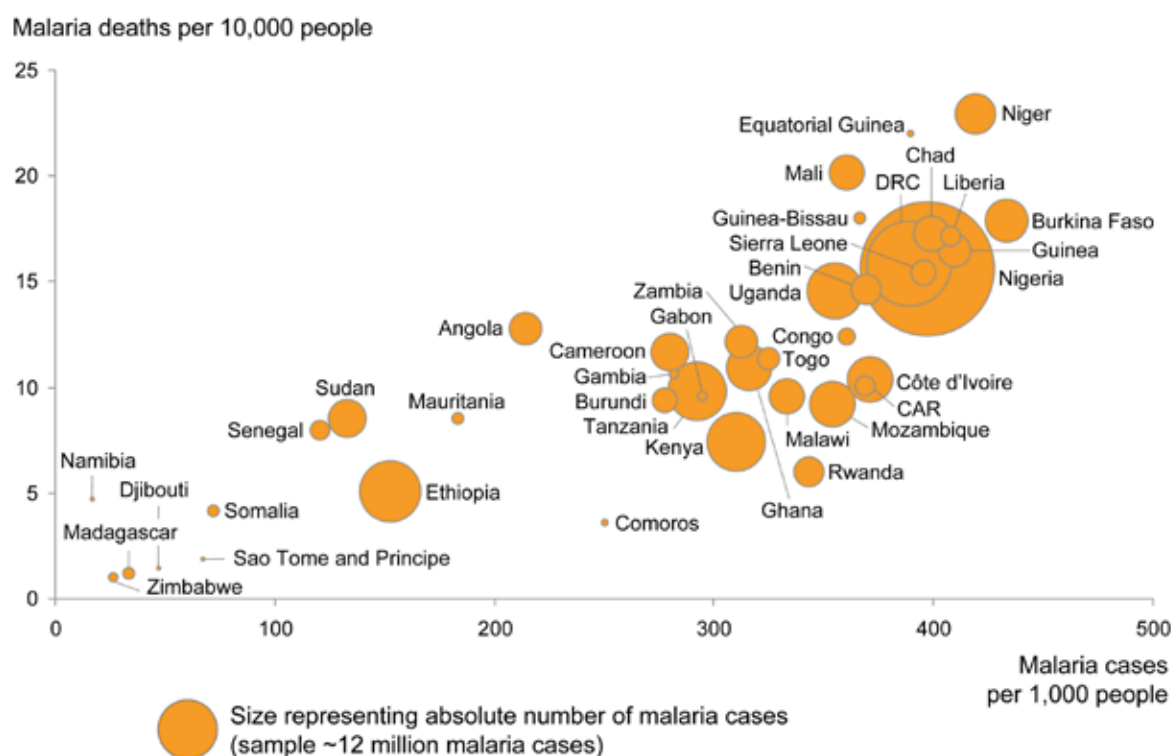
³ Where reported malaria case incidence is above 1 per 1000 population per year.

deaths in 2000, equating to 71% of worldwide cases and 85.7% of worldwide deaths.⁴ Almost 1 out of 5 deaths of children under 5 in Africa is due to malaria.⁵ In addition, malaria during pregnancy often contributes to maternal anemia, premature delivery and low birth weight thereby leading to increased child mortality. Severe maternal infection contributes significantly to maternal deaths in sub-Saharan Africa. Countries in North Africa have only a few imported malaria cases and no deaths.

Several factors have made malaria control difficult in sub-Saharan Africa and led to substantial increases in malaria burden on the continent during the 1980s and 1990s. The first was the widespread emergence of resistance of *P. falciparum*⁶ to chloroquine (CQ), then the most commonly used anti-malarial drug. This has been managed by changing treatment policy to ACTs in most sub-Saharan African countries.

Second, weaknesses in socioeconomic development, such as poverty, poor quality of housing and limited access to health care limit the feasibility and effectiveness of malaria control strategies. At the national level, there are often only limited financial resources for malaria-control interventions⁷ which, compounded with the human resource crisis in the public health sector, have led to fragmented implementation of control strategies that were limited in scale and in the populations targeted. The societal and health burden of the HIV/AIDS pandemic and numerous humanitarian crises during the past decades also contributed to the challenges of controlling malaria in the region.

Figure III.2: Malaria cases and deaths in Africa



Note: Countries with negligible burden are not shown (Algeria, Botswana, Cape Verde, Egypt, Eritrea, Mauritius, Mayotte, Morocco, South Africa, Swaziland).

Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008, 2006 data.

⁴ Breman JG et al. Conquering Malaria. In: Jamison DT, Breman JG et al, eds. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006. p 415.

⁵ 18% of under-5 deaths in Rowe AK et al. The burden of malaria mortality among African children in the year 2000. *International Journal of Epidemiology*, 2006, 35:691-704.

⁶ White NJ. Antimalarial drug resistance. *Journal of Clinical Investigation*, 2004. 113.

⁷ *World Malaria Report 2005*, Geneva, World Health Organization, 2005; Roll Back Malaria; WHO; UNICEF.

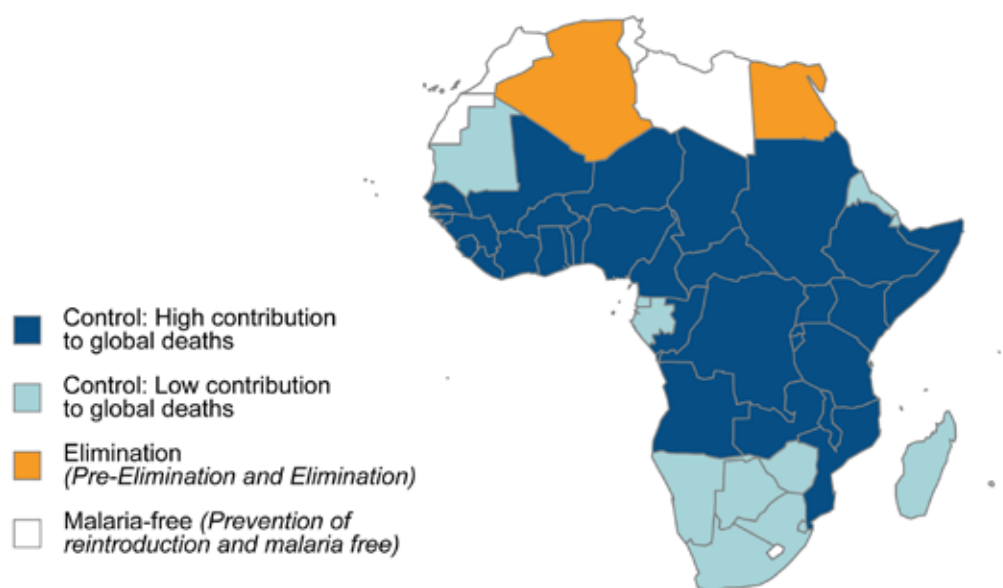
Adapted Approaches and Current Levels of Coverage

Forty-six countries or territories with malarious areas in sub-Saharan Africa (the 47 malarious countries in sub-Saharan Africa except Mauritius)⁸ are currently in the control stage and need to scale-up preventive and case management interventions to all populations at risk and to sustain this level of control. Some countries with effective control programs in place have seen their burden reduced substantially and some others (e.g. Ethiopia, Rwanda, Eritrea, etc.) recently achieved tremendous progress in increasing coverage levels of select interventions. Therefore, these countries need to sustain the interventions which are deployed, and continue the scale-up of all other interventions. In North Africa, Egypt⁹ and Algeria are currently in elimination. Morocco and Mauritius have interrupted local transmission and are classified by WHO as in the prevention of reintroduction stage. Figure III.3 shows country categorization in the region by both burden and stage.

All countries in the control stage use LLINs and prompt case management as part of their national malaria control strategy. Twenty-five sub-Saharan African countries use IRS¹⁰ and the 35 high-burden sub-Saharan African countries where IPTp is recommended have adopted it. As of 2006, half of sub-Saharan African countries report using RDTs.¹¹

The strategies used in the pre-elimination or elimination stage vary widely from one country to another. Successful components of elimination programs can be found in *Part II - Chapter 3: Elimination and Eradication*.

Figure III.3: Country categorization in Africa



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

Locally adapted approaches to malaria control and elimination. Selecting the appropriate tools for malaria control requires a deep understanding of local epidemiology, geography and socioeconomic conditions.

⁸ Mauritius has interrupted local transmission and is currently in the prevention of reintroduction stage.

⁹ While Egypt is officially categorized in the Elimination stage according to the WHO *World Malaria Report 2008*, its last reported case was recorded in 1998, and the country is awaiting verification of malaria-free status to be classified within the prevention of reintroduction stage.

¹⁰ *Africa Malaria Report*. Geneva, World Health Organization, 2006; *The President's Malaria Initiative Progress through Partnerships: saving lives in Africa Second Annual Report*. Washington, D.C., PMI, 2008.

¹¹ *Africa Malaria Report*, Geneva, World Health Organization, 2006.

High transmission settings of P. falciparum. High transmission settings require universal vector control with either LLINs and/or IRS with full coverage for community protection. IPTp is recommended for all pregnant women. According to WHO recommendations,¹² the use of parasitological diagnosis should cover all populations at risk (with the exception of children under 5 who should be diagnosed clinically and promptly treated according to WHO guidelines). ACTs are the first line recommended treatment against *P. falciparum*.

Low transmission settings of P. falciparum. In areas of unstable or seasonal transmission, IRS might be preferred over LLINs, and IPTp is not recommended. The use of parasitological diagnosis should be universal (even for children under 5). ACTs are still the first line treatment of choice.

Current intervention coverage. Many types of interventions have been used in the region with varying degrees of success. These are described below.

LLINs / ITNs. In the past two years, significant progress has been achieved in the delivery of LLINs through large-scale distribution campaigns as well as routine health system delivery mechanisms such as ANC and child health clinics. Based on country data from the UNICEF 2007 Malaria and Children report, an average of 12% of households in sub-Saharan African countries have at least one insecticide-treated net.¹³ All sub-Saharan African countries with available trend data have shown a major expansion in net use: 16 out of 20 sub-Saharan African countries with trend data have at least tripled use since 2000.¹⁴ However, national figures often hide important in-country disparities: across sub-Saharan Africa, children living in urban areas are around 1.5 times more likely to be sleeping under an ITN than those living in rural areas, and children in the wealthiest areas are three times more likely to be sleeping under a bednet than the children in the poorest areas.¹⁵ Estimates show that at the end of 2006, ~72 million effective LLINs / ITNs were in circulation in Africa.¹⁶

IRS. IRS is used either as the main vector control method in certain areas or is used in conjunction with insecticide-treated nets. Twenty-five countries in sub-Saharan Africa are using IRS,¹⁷ although only 17 of them use it routinely, not just for the control of epidemics. Two countries are planning pilot implementation programs with a view to scaling up further as they gain experience and skill.¹⁸ In 2007 and early 2008, about 18 million people were protected with IRS in 10 countries through President's Malaria Initiative (PMI)-supported projects.¹⁹ In total in Africa, ~6 million households have been sprayed with IRS in 2006.²⁰

Other vector control measures. While LLINs and IRS are the primary vector control measures recommended for Africa, there are examples of countries using environmental management successfully. In Sudan, for example, students are involved with the National Malaria Control Program in filling in vector breeding sites. However, in much of Africa, the breeding habits of the mosquito vector *Anopheles gambiae* makes environmental management challenging.

¹² *Guidelines for the Treatment of Malaria.* Geneva, World Health Organization, 2006.

¹³ Households that have at least one ITN, *Malaria and children: Progress in intervention coverage.* New York, UNICEF, 2007.

¹⁴ *Malaria and children: Progress in intervention coverage.* New York, UNICEF, 2007.

¹⁵ *Malaria and children: Progress in intervention coverage.* New York, UNICEF, 2007.

¹⁶ GMAP estimates based on data from WHO World Malaria Report 2008 and the Roll Back Malaria Commodity database, 2008. See Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.

¹⁷ *Africa Malaria Report.* Geneva, World Health Organization, 2006; *President's Malaria Initiative Progress through Partnerships: saving lives in Africa Second Annual Report.* Washington, D.C., PMI, 2008.

¹⁸ *Implementation of Indoor Residual Spraying of Insecticides for Malaria Control in the WHO African Region,* WHO-AFRO, 2007.

¹⁹ *The President's Malaria Initiative Progress through Partnerships: saving lives in Africa Second Annual Report.* Washington, D.C., PMI, 2008.

²⁰ GMAP estimates based on data from WHO World Malaria Report 2008. See Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.

IPTp. IPTp has been adopted as policy in all 35 sub-Saharan African countries²¹ with stable malaria transmission where it is recommended.²² IPTp is part of national malaria control strategies around the region. By the end of 2007, implementation had been initiated in all countries. However, as of 2007, only 20 countries had gone to scale and deployed it at the national level. In sixteen national household surveys conducted between 2006 and 2007, use of IPTp varied from 0.3% of pregnant women who received at least 2 doses of SP in Niger to 61% in Zambia.²³ These estimates are in line with reports from WHO-AFRO²⁴ that show coverage with the first dose (IPT1) ranging from 23-93%, and the second dose (IPT2) from 5-68%. Important challenges remain to scale-up IPT coverage²⁵ and to engage communities in understanding the need for skilled care during pregnancy and promoting early antenatal care attendance to ensure good pregnancy outcomes and survival of the mother and child.

Diagnostics (Microscopy and RDTs). In 2006, ~12.5 million suspected malaria cases were parasitologically diagnosed by microscopy or RDTs. Although use of microscopy is often not tracked in surveys, ~11 million of these cases were confirmed through microscopy, underscoring the importance of this technology. The remaining 1.4 million diagnoses were conducted using RDTs.²⁶ In addition, 24 countries report the use of RDTs in health facilities and 4 countries use them at community level.²⁷ This number is expected to grow substantially if RDT quality issues are resolved, providers are persuaded to follow test results, and if quality assurance systems in countries are improved.

Anti-malarial treatment (i.e. ACTs). There has been a remarkable adoption of ACTs in sub-Saharan African countries: in 2003, only two sub-Saharan African countries had adopted ACTs; as of September 2007, all sub-Saharan African countries except Swaziland and Cape Verde have adopted ACT policy. Approximately 69 million ACTs were distributed in 2006 by sub-Saharan African countries, about one third of the 217 million ACTs needed, provided all ACTs go to malaria cases, not fever cases.²⁸ However, as outlined in the WHO World Malaria Report 2008, effective use of ACTs in sub-Saharan Africa is still extremely low. In household surveys carried out in 18 sub-Saharan African countries in 2006 and 2007, only 3% of children under 5 received ACTs at any time.²⁹

Community Health Workers. Community Health Workers (CHW) networks are key to helping countries to reach all populations at risk, even the most remote populations. Estimates of CHW needs for African countries have been estimated by WHO-Global Malaria Program to amount to 500,000 community health agents and 25,000 supervisors. Scaling up CHWs will require additional work in financing, sustaining intervention supplies and quality assurance.

²¹ *Africa Malaria Report 2006*. Geneva, World Health Organization, 2006.

²² *A strategic framework for malaria prevention and control during pregnancy in the African Region*. Brazzaville, Congo, WHO-AFRO, Regional Office for Africa, AFR/MAL/04/01, 2004.

²³ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

²⁴ Presented at the Roll Back Malaria MIP meeting by WHO-AFRO, April 2008.

²⁵ A number of key challenges / requirements are: 1) Strong collaboration between malaria and reproductive health programs to provide a supportive health systems environment and address constraints for the prevention and control of malaria during pregnancy; 2) need to avoid missed opportunities for reaching the high proportion of pregnant women attending ANC clinics in high malaria transmission areas; 3) need to ensure adequate stocks of the necessary drugs and logistics; 4) strengthening other aspects of the health systems including the availability and capacity building of human resources; and 5) laboratory diagnostic capacities, supportive supervision and monitoring and evaluation capacities.

²⁶ GMAP estimates based on data from WHO World Malaria Report 2008. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates*.

²⁷ *Africa Malaria Report*, Geneva, World Health Organization, 2006.

²⁸ GMAP estimates based on data from WHO World Malaria Report 2008 and the RBM Commodities database, 2008. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates*.

²⁹ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

Recommended Regional Approach to Control and Eliminate Malaria

Targets, approaches, and strategic priorities must be tailored to the region as described in this section.

Targets. The target for 2010 in sub-Saharan Africa is to reduce malaria mortality and morbidity by 50%, meaning Africa will reduce its burden to approximately 158 million cases and 480 thousand deaths, based on the 2000 incidence and mortality numbers. By 2015, the objective is to reduce the morbidity to 79 million cases and reach near zero mortality for all preventable deaths.³⁰ Beyond 2015, the objective is to maintain near zero mortality for all preventable deaths.

While this target is challenging, it is possible and will go a long way to achieving the global targets since Africa bears 71% of global malaria cases. An analysis of 20 high-burden African countries³¹ shows that if 2010 coverage goals are met and sustained, over 4.2 million total lives will be saved by 2015. This equates to over 600,000 lives saved per year in these 20 countries alone.

As outlined in *Part II: The Global Strategy*, this goal will be achieved through universal coverage with appropriate malaria control interventions for all populations at risk in all countries in the control stage and with elimination programs conducted in all countries that are ready.

To reach universal coverage for all populations at risk with appropriate interventions by the end of 2010, significant gaps must be eliminated in sub-Saharan Africa (Figure III.4):

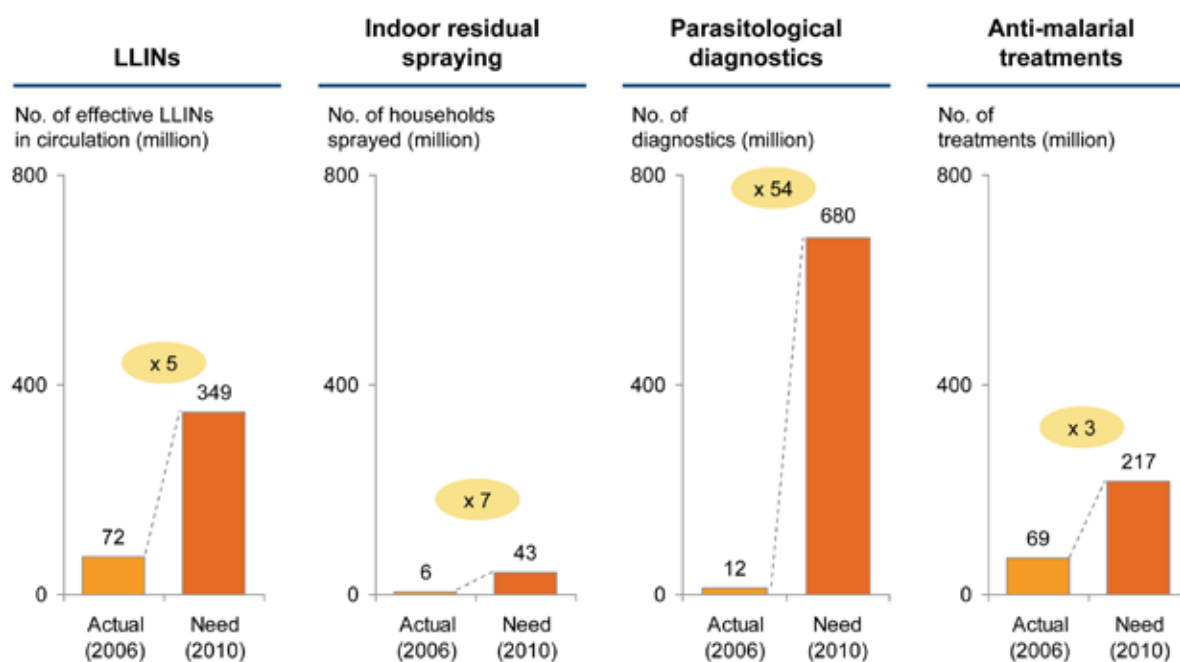
- ~350 million nets need to be in place to reach universal protection with LLINs in sub-Saharan Africa. Assuming that 50-100 million LLINs in circulation today will remain effective over the next two years, 250-300 million new LLINs are needed to reach the 2010 targets, or approximately 125-150 million LLINs per year in 2009 and 2010.
- ~43 million households need to be sprayed with insecticides;
- ~680 million parasitological diagnostics are needed to confirm suspected malaria fever cases; and
- ~217 million ACTs are needed to treat confirmed malaria cases.

Achieving this scale-up will require rapid and concerted action from all RBM partners to accelerate the manufacturing, funding, disbursement and delivery of interventions and support countries in their scale-up efforts. Countries will need a quarterly plan detailing how all commodities will be delivered, by whom and where, based on a full assessment of needs currently being developed with support from the RBM Harmonization Working Group.

³⁰ Preventable death is defined as deaths from malaria that can be prevented with rapid treatment with effective medication. Non-preventable deaths represent an extremely low mortality rate for the most severe malaria cases and occur even with the best available and most rapid treatment.

³¹ Analysis based on the IMPACT model developed by a consortium of organizations led by the Institute of International Programs at Johns Hopkins Bloomberg School of Public Health. This model measures child survival based on work by the Child Health Epidemiology Reference Group (CHERG) and using software developed by the Futures Institute. Countries evaluated represent ~82% of global malaria mortality: Angola, Burkina Faso, Cameroon, Chad, the Democratic Republic of Congo, Cote d'Ivoire, Ethiopia, Ghana, Guinea, Kenya, Madagascar, Mali, Mozambique, Niger, Nigeria, Senegal, Sudan, Tanzania, Uganda, Zambia. The model only looks at the impact on deaths due to *P. falciparum*.

Figure III.4: Scale-up in interventions from 2006 to 2010 in Africa



a) Because of 3-year life span, each year approximately 1/3 of the old nets will need to be replaced.

b) Actual use is likely not all directed to confirmed malaria cases today.

Source: Need based on GMAP costing model; actual based on analysis of World Malaria Report 2008. Geneva, World Health Organization, 2008 and Roll Back Malaria Commodities database.

Approaches to main challenges in the region. Several approaches are recommended for the region.

Build human resource and managerial capacity. Capacity building is required at the national, regional and local level. In many countries, malaria control programs lack sufficient human resources to successfully run their programs. This is due to a variety of factors: high attrition rates of skilled staff, difficulty filling positions, competing demands with other programs and the unwillingness of health providers to be stationed in remote areas. Scaling up human resources will require a threefold approach: reducing attrition, expanding the workforce and strengthening skills. As this approach is not malaria specific, NMCPs will need to work closely with the rest of the health sector to develop better national human resources policies. For example, better career management and incentives need to be in place to retain professionals, especially technical experts such as entomologists or M&E specialists.

Given the size of the human resource gap in Africa, countries need to plan for the scale-up of staff into their national plans. Creative approaches to expanding the workforce should be considered, such as using community health workers, volunteer networks or professionals in the private sector. To support the scale up, there is a strong need for better training programs for staff, through pre-service training for new staff and training programs to develop project management expertise.

Improve monitoring and evaluation systems. Few countries in Africa have adequate monitoring and evaluation systems in place, for malaria or any other disease. Well-developed information systems encourage sound planning and help NMCPs monitor progress in the delivery and utilization of interventions, all essential for scale-up. In addition, monitoring and evaluation systems are critical when countries move from scaling up to sustaining control and elimination. As countries move towards sustaining control, surveillance systems for resistance monitoring, pharmacovigilance and quality assurance will also be needed. NMCPs need to ensure that adequate financial and human resources are dedicated to monitoring and evaluation activities.

Expand R&D and operational and implementation research. R&D for new tools and operational and implementation research for new approaches are needed to help African countries to move from sustained control to elimination. Developing new technologies such as vaccines, increasing the quality and field effectiveness of existing interventions and identifying approaches to deliver interventions to vulnerable and hard-to-reach groups is crucial in achieving the goal of eradication. R&D and operational research priorities are described in *Part II - Chapter 4: The Malaria Research Agenda*.

Optimize procurement and supply chain management (PSM) systems. Effective and timely PSM systems are critical in delivering interventions and providing real-time feedback to NMCPs and district health centers on the flow of interventions. PSM systems need to be optimized to avoid forecasting errors, treatment expiries and intervention stock-outs. Furthermore, effective PSM systems can aid quality assurance and quality control. Currently, the RBM Harmonization Working Group (HWG) is working with many sub-Saharan African countries to assess country needs. These needs assessments will provide a comprehensive forecast of the interventions needed to achieve universal coverage by 2010. Routine forecasting needs to be strengthened and matched with appropriate procurement and delivery strategies, perhaps through links with M&E systems. Using specific PSM systems such as pooled procurement mechanisms or direct payment can play a critical role in shortening the intervention delivery process. See *Part IV - Chapter 7: Procurement and Supply Chain Management*.

Streamline burdensome financing and reporting processes. Country officials indicate that they spend much of their time responding to financing and reporting requirements of donors and other international partners. The funding and M&E reporting processes of different donors are poorly harmonized and often quite demanding (perhaps appropriately so), leading to heavy workloads for government staff members. Harmonization of donor requirements at the international level is necessary, with common sets of reporting indicators or of funding applications requirements. For countries, developing strong business plans that can be presented to the donor community is a first step in this direction. See *Part IV - Chapter 5: In-Country Planning*.

Improve emergency response mechanisms. Many countries are in states of humanitarian crises. Up to 30% of malaria deaths in Africa occur in the wake of war, local violence or other emergencies. Malaria deaths often far exceed those caused by the humanitarian crisis itself.³² Civil unrest can lead to resurgences in malaria, as happened in Burundi.³³ Countries dealing with chronic humanitarian crises over long periods of time, such as Sudan, Somalia, Chad and the Democratic Republic of Congo, require special attention to limit the risk of malaria outbreaks. In these countries, epidemic preparedness systems and rapid response mechanisms are essential. See *Part IV - Chapter 10: Humanitarian Crises*.

*Address Malaria and HIV/AIDS co-morbidities.*³⁴ Malaria and HIV/AIDS together cause more than 4 million deaths a year in some of the most poverty-stricken areas of the world, particularly sub-Saharan Africa. The resulting co-infection and interaction between the two diseases have major public health implications. HIV/AIDS may increase the risk of malarial illness due to advanced immunosuppression. Those infected with HIV/AIDS who get malaria are more likely to develop severe malaria. Furthermore HIV-infected adults with low CD4 counts may experience a higher rate of malaria treatment failures than non-infected adults. Lastly, acute malaria episodes can temporarily increase viral replication and hence the HIV/AIDS viral load.

Considering the interactions between these diseases and their co-existence in some of the highest burden areas, special consideration needs to be made to address both issues simultaneously. Those infected with HIV/AIDS must be considered highly susceptible to malaria, and more attention should be given when diagnosing febrile patients in areas with high HIV/AIDS infection. Additionally, appropriate antenatal care must be in place to address both diseases in pregnant women and infants. Finally, in a multi-disease scenario, integrated health systems approaches described elsewhere in this plan become even more important.

³² *Guiding principles for malaria control in acute and chronic phase emergencies in Africa, Conclusions of WHO / Roll Back Malaria Consultation*, Geneva, World Health Organization, 15 November 2004.

³³ Fatoumata NT and Nabarro D. Breaking the cycle of malaria and death in emergencies: the way forward. Humanitarian Practice Network, 2008.

³⁴ *Malaria and HIV/AIDS interactions and implications: Conclusions of a Technical Consultation Convened by WHO*. Geneva, World Health Organization, 23-25 June, 2004.

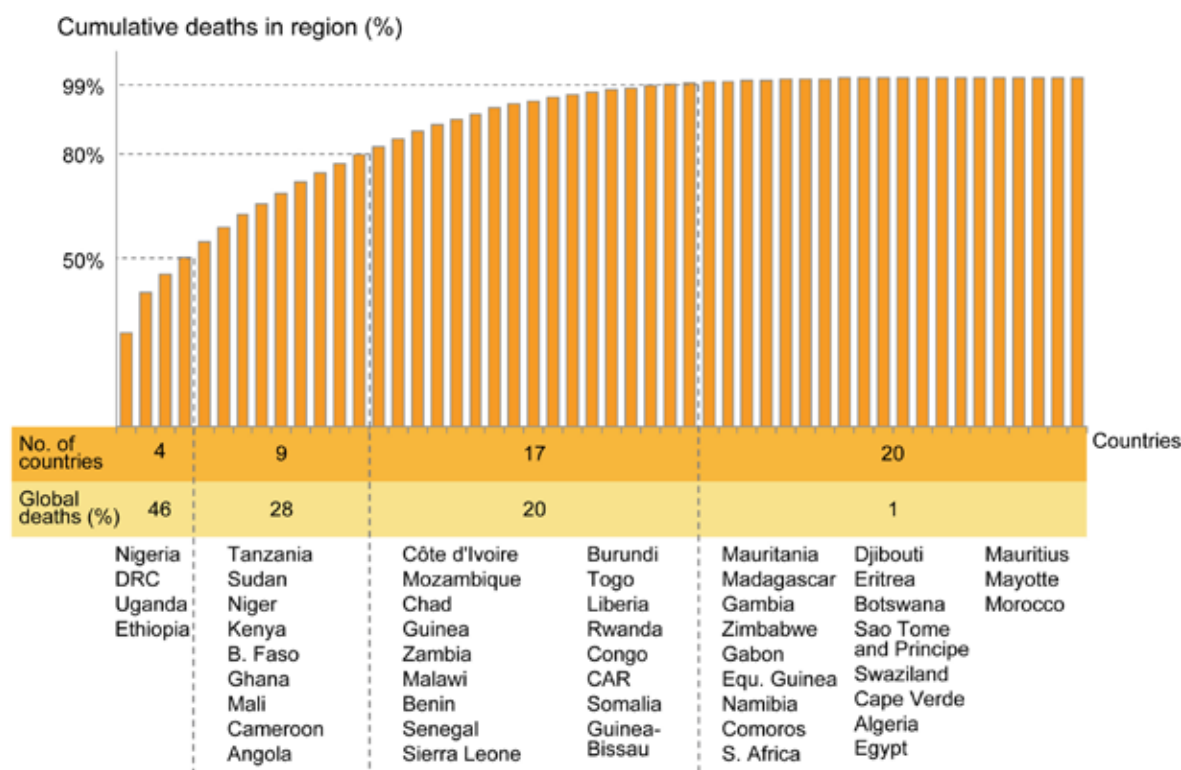
Strategic priorities. Success in malaria control and elimination is essential in all countries. However, some countries are especially important to achieving the RBM targets, both in the short- and medium- to long-term, because of the distribution of malaria deaths. See Figure III.5.

To reach the 2010 targets, countries with the following characteristics are a priority:

- *High contribution to global deaths.* Of the 35 countries that account globally for ~98% of malaria deaths, 30 are located in sub-Saharan Africa. Therefore, a strong focus on countries in sub-Saharan Africa will have significant impact on the achievement of global targets against malaria. These 30 countries account for 98.5% of the deaths in Africa, with four countries alone accounting for ~50% of deaths on the continent (Nigeria, Democratic Republic of Congo, Uganda and Ethiopia). These countries have very large populations at risk of malaria and share borders with numerous other countries, making control in them an important regional priority as well.
- *High burden relative to population size.* Some countries such as Gambia, Gabon and Equatorial Guinea account for few deaths because of their small size but experience high mortality rates relative to the total population.
- *Countries in states of humanitarian crisis.* Countries impacted by chronic humanitarian crisis are of strategic importance in malaria control. The massive population displacement that usually accompanies humanitarian crises is likely to lead to malaria epidemics and increased mortality due to the difficulty in providing affected populations with vector control and case management interventions (difficult access, poor housing conditions, security risks, etc.).
- Successful malaria control in these countries is essential to achieve the regional and global targets of burden reduction. Therefore, in addition to the general support provided to all countries in the control stage, the RBM Partnership will coordinate targeted technical assistance to these high priority countries to increase the speed with which they can achieve universal coverage to meet the 2010 targets.

Beyond 2010, countries need to be supported to sustain universal coverage to avoid a resurgence of malaria and an upsurge in malaria mortality and morbidity. Countries in the elimination stage, primarily in Northern Africa, are encouraged to continue their efforts to bring local transmission down to zero and to move to the prevention of reintroduction stage.

Figure III.5: Distribution of malaria deaths in Africa



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

International cooperation. The RBM Partnership has set up 4 Sub-Regional Networks - Central African Regional Network (CARN), Eastern African Regional Network (EARN), Southern African Regional Network (SARN) and Western African Regional Network (WARN). Each network is coordinated by a regional node which actively works with local partners across and within countries to share best practices and to create strong ties with international organizations. The RBM Partnership will continue to strengthen these networks so that they can identify and resolve implementation bottlenecks for all Africa, but especially for the high-priority countries.

Targeted assistance to high priority countries. Beyond the support provided by the SRNs to all countries, high priority countries will need targeted technical assistance to build their capacity to meet the 2010 targets. In particular, technical assistance from RBM partners is needed for:

- Planning and developing funding proposals
- Responding to technical review panels (TRPs) and accelerating disbursements from major donors
- Identifying and rapidly resolving procurement and supply chain bottlenecks
- Improving national and district level forecasts of commodities
- Designing and implementing communication and behavior change programs
- Strengthening monitoring and evaluation systems
- Strengthening advocacy efforts
- Building long term capacity across the health system, as it relates to malaria control
- Harmonizing donor requests at the global level
- Initializing global partnerships

To ensure the sustainability of successful control programs, technical assistance should be complemented by increased capacity at the country level and targeted training programs. In particular, in-country experts are required for a number of key activities, such as program and financial management, procurement and supply

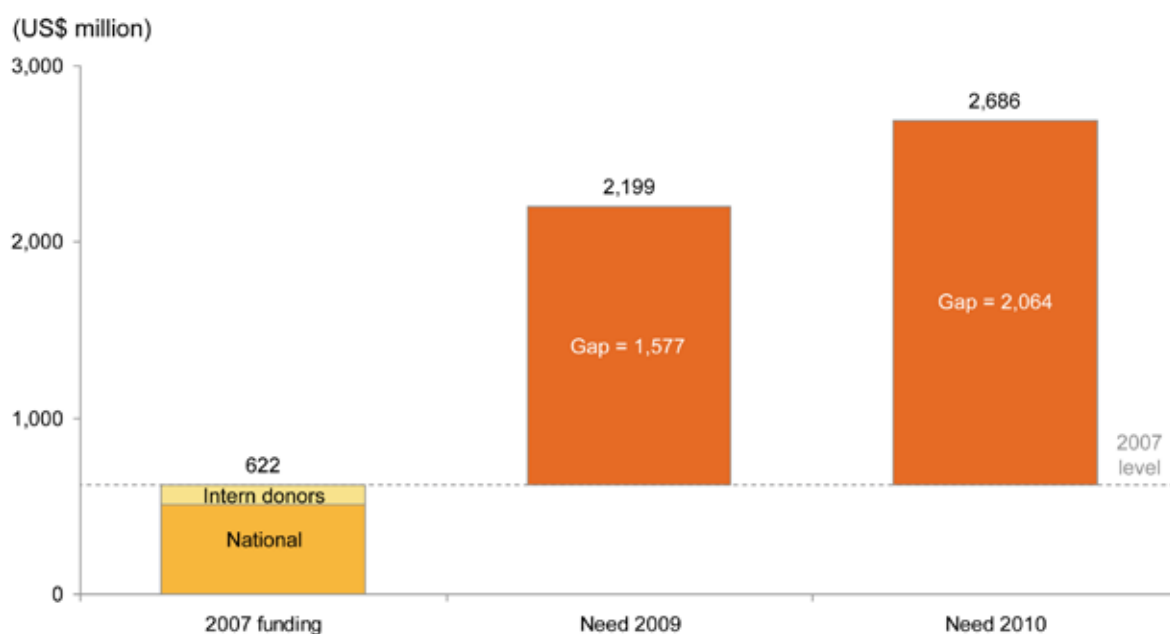
chain management, in country communication and monitoring and evaluation. Providing these experts to the highest burden countries will increase their chances of success in malaria control over the next years. These technical experts in country would work in a network with coordinators at the sub-regional and global level.

Funding Requirements: US\$ 2 billion gap for 2010

In 2003 in Maputo, African leaders affirmed their commitment to increase financial support for the health sector to 15% of total government expenditures. Today, however, 90% of African countries remain below the 15% threshold³⁵ (averaging 10%).³⁶ Even if countries spent 15% on health, national funding would still be too little to cover the scale-up efforts needed to reach universal coverage by 2010.

Estimates for 2007 from the WHO *World Malaria Report 2008* show that resources from endemic country governments in Africa account for only 18% of the US\$ 622 million disbursed, the lowest rate among all regions. The remaining disbursements in 2007 came from international donors (The Global Fund 42%, President's Malaria Initiative 20%, World Bank Booster Program ~8%). (See Figure III.6.)

Figure III.6: Gap in malaria funding in Africa



Note: See appendices on methodologies to estimate costing needs and current funding

Source: GMAP costing model, WHO, the Global Fund, the World Bank and the President's Malaria Initiative (PMI)

Africa, especially sub-Saharan Africa, has attracted significant support from major international donors. In rounds 1 to 7, the Global Fund committed ~US\$ 2 billion for malaria in sub-Saharan African countries (76% of all malaria grants). The World Bank Booster program has committed US\$ 470 million in its Phase I and contemplates a lending target of US\$ 1.2 billion for Phase II in the coming years, depending on country demand. The President's Malaria Initiative has pledged US\$ 1.2 billion over 5 years.

In Africa, US\$ 2.2 billion is needed in 2009 and US\$ 2.7 billion in 2010 to scale-up preventive and curative interventions to reach universal coverage (see Table III.2). Preventive costs comprise approximately two thirds of these costs in 2010, case management costs are approximately 20% of the costs, and the remainder is for malaria control program costs. Declining costs through 2015 are due to lower treatment costs needed due to preventive efforts, and the slight increase in 2020 represents increases in populations at risk which need continued preventive coverage.

³⁵ *Malaria Landscape Report 2007*. Geneva, Roll Back Malaria, 2007.

³⁶ *World Health Statistics 2008*. Geneva, World Health Organization, 2008.

Table III.2: Summary of annual costs in Africa

Cost category (US\$ millions)	2009	2010	2015	2020	2025
LLINs/ITNs	959	959	825	912	1,009
IRS	443	599	657	711	783
IPTp	5	7	8	9	10
<i>Prevention cost</i>	<i>1,407</i>	<i>1,566</i>	<i>1,490</i>	<i>1,631</i>	<i>1,802</i>
RDTs	220	323	152	101	38
ACTs	244	338	158	106	40
Chloroquine and primaquine	1	1	1	0	0
Severe case management	23	20	14	9	3
<i>Case management cost</i>	<i>489</i>	<i>682</i>	<i>325</i>	<i>217</i>	<i>81</i>
Community health workers	42	44	54	54	59
Training	35	31	31	33	36
M&E and OR	91	103	105	112	121
Infrastructure / inst. strengthening	134	260	192	211	233
<i>Program cost</i>	<i>303</i>	<i>438</i>	<i>382</i>	<i>409</i>	<i>449</i>
Total control & elimination cost	2,199	2,686	2,196	2,258	2,333

Note: Diagnostic costs are covered both by RDTs in case management and by microscopy in infrastructure / institutional strengthening.

Source: GMAP costing model; Johns B. and Kiszewski A. et al.

3. The Americas

There are 22 malarious countries in the Americas, located in Central America, around the Amazon Rainforest, in the Caribbean and in southern South America.

Amazon rainforest (9): Bolivia, Brazil, Colombia, Ecuador, French Guiana, Guyana, Peru, Suriname and Venezuela

Central America (8): Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama and Mexico

Caribbean (3): Haiti, Dominican Republic and Jamaica

Southern South America (2): Argentina and Paraguay

Population at risk. Approximately 137 million people live in areas at risk of malaria in the Americas, which represents ~4% of the world population at risk.³⁷

Malaria transmission. Approximately 77 million people at risk live in areas of low transmission, with the remainder living in areas where cases exceed 1 per 1000 people. *P. vivax* is the leading cause of malaria, accounting for 75% of all cases. In the Guyana Shield (French Guiana, Guyana and Suriname), 40-60% of cases are due to *P. falciparum*. In Mexico and Central America, *P. vivax* accounts for 94% of the cases. In the Dominican Republic and Haiti, almost 100% of the cases are due to *P. falciparum*.

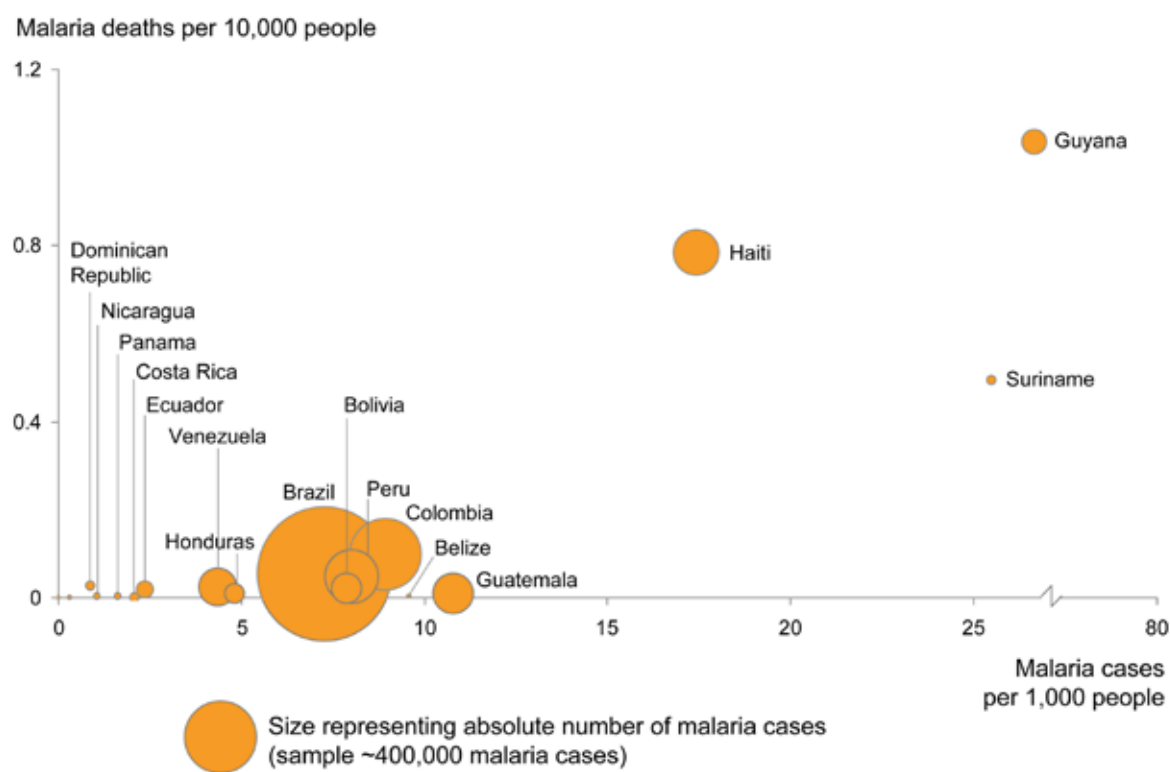
Malaria burden. The Americas had an estimated 4 million malaria cases in 2002 (approximately 1% of global incidence), and approximately 1,000 malaria deaths (or less than 0.1% of worldwide deaths).³⁸ During the period from 2000 to 2006, WHO-PAHO estimates that malaria mortality declined by 20%.³⁹ The countries of the Amazon basin bear the brunt of the problem with ~40% of deaths in the Americas occurring in Brazil alone (Figure III.7).

³⁷ *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

³⁸ Breman JG et al. Conquering Malaria. In: Jamison DT, Breman JG et al, eds. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006. p 415.

³⁹ Based on deaths in the region reported by WHO-PAHO (<http://www.paho.org/english/hcp/hct/mal/malaria.htm>).

Figure III.7: Malaria cases and deaths in the Americas



Note: Countries with negligible burden are not shown (Argentina, French Guiana, Jamaica, Paraguay, Mexico).

Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

Adapted Approaches and Current Levels of Coverage

Malarious countries in the Americas vary greatly in terms of population size, population at risk, burden, impact of geography on transmission (such as islands and rivers) and success of control programs so far. Within the same country, some areas can be malaria free, while others can be in the control or elimination stage, requiring strong stratification efforts and targeted approaches. In the remainder of this chapter, countries will be classified in the control stage unless an elimination program is being conducted nationwide.

According to WHO, Mexico is in the pre-elimination stage, while Argentina, El Salvador, and Paraguay, are in the elimination stage. Jamaica is in the prevention of reintroduction stage. The remaining 17 countries in the region are currently in the control stage and need to scale-up appropriate preventive and case management interventions to all populations at risk and sustain this level of control. Some countries, such as Ecuador or Nicaragua, have robust control programs. These countries need to maintain the deployment of interventions and scale-up other interventions where coverage is not universal. Figure III.8 presents the country categorization in the region.

The 17 countries currently controlling malaria are using integrated vector management, with a combination of LLINs, IRS and targeted larviciding, as well as case management with diagnosis and timely, appropriate treatment. IPTp is not recommended for pregnant women in this region.

The four countries in pre-elimination or elimination (Mexico, Argentina, El Salvador and Paraguay) rely mainly on active case detection and management of active foci.

Figure III.8: Country categorization in the Americas



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

Locally adapted approaches to malaria control and elimination. Choosing the appropriate malaria control tools requires a deep understanding of local epidemiology, geography and socioeconomic conditions. In the Americas, the unique features of the region are that it has many areas of low transmission, a high proportion of cases caused by *P. vivax*, and a number of countries already in elimination. Below is a high level summary of appropriate malaria interventions for these settings. Also see Box III.1 for examples of strong control programs in the region.

Low transmission settings. In several countries of the Americas, levels of transmission are moderate or low. In places where transmission is seasonal or localized in select areas, the use of targeted vector control measures such as IRS or other vector population reduction methods (environmental management, larviciding, etc.) can be very appropriate. As the proportion of fevers due to malaria is low, the use of parasitological diagnosis is essential. Strong capacity to detect and manage epidemics early is required, especially since there is little acquired immunity to protect the populations at risk from developing severe symptoms of malaria.

*Dominant *P. vivax* or mixed settings.* Malaria in the Americas is dominated by, *P. vivax* transmission, which requires adapted tools. Parasitological diagnosis (by microscopy or where not possible RDTs) is essential in areas where both *P. vivax* and *P. falciparum* occur. To treat both the blood stage and the liver stage infections of *P. vivax*, chloroquine combined with 14-days of primaquine is given in places where there is no proven resistance to chloroquine;⁴⁰ however, compliance to the 14-day regimen is sometimes poor. Vector control interventions do not depend on parasite type; however, *P. vivax* transmission is often associated with lower malaria transmission levels where IRS can be appropriate. The use of LLINs should be encouraged as well, both for personal protection and as a community protection tool.

⁴⁰ *Guidelines for the Treatment of Malaria*. Geneva, World Health Organization, 2006.

Countries in elimination. Proposed approaches for the 5 countries in pre-elimination, elimination and prevention of reintroduction (Mexico, Argentina, El Salvador, Paraguay and Jamaica) are detailed in *Part II - Chapter 3: Elimination and Eradication: Achieving Zero Transmission*. These approaches mainly focus on the use of targeted vector control interventions (such as IRS) against residual foci as well as active case detection to track and treat remaining cases. These countries have principally *P. vivax* transmission. Methods for targeting asymptomatic reservoirs are also an important priority.

Current intervention coverage. Many types of interventions have been used in the region with varying degrees of success. These are described below.

LLINs / ITNs. Twelve countries are implementing LLINs as part of their national malaria control strategy, although only 6 of them⁴¹ are targeting the whole population at risk. Estimates based on data from the WHO World Malaria Report 2008 show that ~585 thousand LLINs / ITNs were in circulation in 2006.⁴²

IRS. All countries in the region report use of IRS in targeted areas, but the scale of use is low due to high cost of insecticides. Countries in the region used DDT in the 1960s through the 1980s but are now trying alternative insecticides, such as pyrethroids. Today, none of the countries in the region use DDT. In 2006, approximately 268 thousand households (or ~1.3 million people) were covered by IRS.⁴³

Other vector control measures. Other vector control measures have been used in several countries, such as environmental management, larvivorous fishes or mosquito proofing of houses. In particular, a regional program⁴⁴ in Mexico and Central America is coordinating the development of alternative approaches to DDT for vector control with increased community participation in breeding site reduction.

Diagnostics (Microscopy and RDTs). Microscopy is the most widely used method in the region for parasitological confirmation (approximately 7 million diagnoses with microscopy were performed in 2006).⁴⁵ Rapid diagnostic tests (RDTs) are available but there is limited data so far on their use.

Anti-malarial treatment. Chloroquine (CQ) and primaquine (PQ) are used as first line treatments against *P. vivax* infections in all countries in the region. Due to high levels of resistance of *P. falciparum* to CQ and SP in the Amazon region, ACTs are now first line treatment against *P. falciparum* in all countries of the Amazon basin apart from French Guiana. There is no evidence of *P. falciparum* resistance to CQ in Haiti or the Dominican Republic, so CQ is still first-line treatment there. Mexico and Central America continue to use CQ because of very low reported levels of *P. falciparum* resistance. Approximately 1.1 million treatments for both *P. falciparum* and *P. vivax* infections were delivered in 2006.⁴⁶

⁴¹ Bolivia, Guyana, Haiti, Honduras, Nicaragua, Suriname.

⁴² GMAP estimates based on data from WHO World Malaria Report 2008 and the Roll Back Malaria Commodity database, 2008. See Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.

⁴³ GMAP estimates based on data from WHO World Malaria Report 2008. See Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.

⁴⁴ Regional Program of Action and Demonstration of Sustainable Alternatives to DDT for Malaria Vector Control in Mexico and Central America (DDT-GEF).

⁴⁵ GMAP estimates based on data from WHO World Malaria Report 2008. See Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.

⁴⁶ GMAP estimates based on data from WHO World Malaria Report 2008 and the Roll Back Malaria Commodity database, 2008. See Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.

Box III.1: Examples of strong control programs

- Nicaragua has focused its efforts on strengthening diagnosis and treatment capabilities at the local level with the support of the Global Fund to fight AIDS, Tuberculosis and Malaria (which benefits other diseases as well) and on developing vector control without DDT, for instance with breeding sites reduction through community participation, as part of the project of the Global Environment Facility, supported by the United Nations Environment Programme (UNEP).
- Ecuador has been successfully implementing the 5 key points of the regional strategy developed by WHO - PAHO⁴⁷
- Countries in the Amazon basin have significantly reduced their malaria burden by analyzing *P. falciparum* resistance patterns and revising their treatment guidelines through the Amazon Network for the Surveillance of Anti-malarial Drug Resistance / Amazon Malaria Initiative which is supported by USAID. See also *Box II.5: Scaling Up and Sustaining Control in Brazil in Part II - Chapter 2: Control.*

Recommended Regional Approach to Control and Eliminate Malaria

Targets, approaches and priorities must be tailored to the region.

Targets. The Americas have experienced some successes with their control programs: incidence declined 20% between 2000 and 2006, while mortality decreased 70% over the same period.⁴⁸ However, opportunities exist to further reduce burden.

To reach universal coverage with appropriate interventions by 2010 in the Americas (See Figure III.9):

- ~17 million LLINs need to be in place in 2010;
- ~5 million of households need to be sprayed with insecticides;
- ~40 million parasitological diagnostics are needed to confirm suspected malaria fever cases; and
- ~2.7 million first-line treatments with chloroquine / primaquine and ACTs are needed.

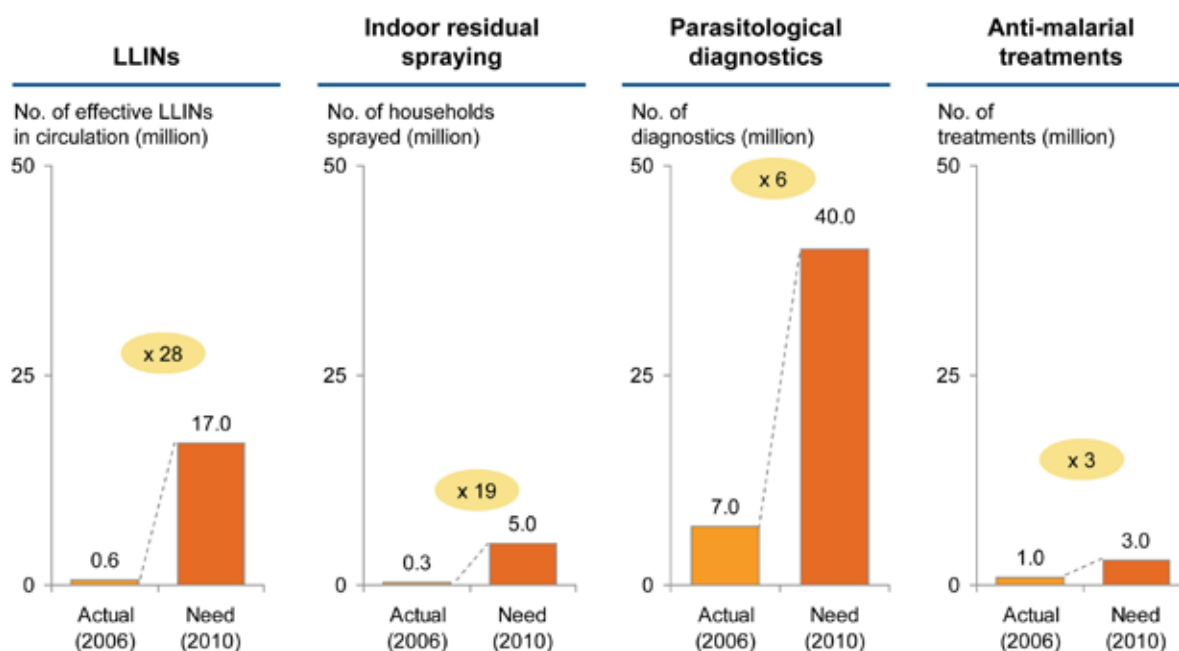
The Americas contribute little to global deaths and cases, and include a number of countries with advanced malaria control programs. While the RBM targets for 2010 and 2015 are likely not as relevant to the Americas situation, they are still considered the primary targets. In addition, with one country in the pre-elimination stage and three countries in the elimination stage, the Americas will contribute substantially to the RBM elimination targets.

As outlined in *Part II: The Global Strategy*, an important aspect of achieving targets is through universal coverage with appropriate malaria control interventions for all populations at risk in countries in the control stage, while elimination programs are conducted in countries where feasible.

⁴⁷ The 5 point regional strategy is 1) prevention, surveillance, early detection and containment of epidemics; 2) integrated vector management; 3) diagnosis and treatment; 4) enabling environment; and 5) health systems strengthening. See *Regional Strategic Plan for Malaria in the Americas 2006-2010*, WHO-PAHO, June 2007.

⁴⁸ *Annual malaria cases and deaths in the Americas, 1998-2006*. World Health Organization, WHO-PAHO, November 2007. These estimates are based on reported cases.

Figure III.9: Scale-up in interventions from 2006 to 2010 in the Americas



- a) Because of 3-year life span, each year approximately 1/3 of the old nets will need to be replaced.
 b) Actual use is likely not all directed to confirmed malaria cases today.

Source: Need based on GMAP costing model; actual based on analysis of World Malaria Report 2008. Geneva, World Health Organization, 2008 and Roll Back Malaria Commodities database.

Approaches to main challenges in the region. Challenges faced by countries in their malaria control efforts are varied. However, some common trends can be found that are unique to malaria in the Americas.

Increase access to health services in isolated populations. There are a number of populations with limited access to health services in the Americas. Populations living in remote areas of the Amazon basin have limited access to health services, especially to reliable diagnosis and treatment for malaria. The high travel cost to access health facilities is usually prohibitive for these populations. Access is also limited for mining populations in countries such as Brazil, French Guiana, Guyana and Suriname, and in many areas of Haiti and the Dominican Republic. The most successful and cost-effective way of reaching these populations is to integrate malaria control with other health services. For instance, malaria control can be effectively delivered with the integrated management of childhood illness (IMCI), or the expanded program on immunization (EPI) programs. Most countries in the region offer free LLINs and anti-malarial drugs including ACTs. In addition, the development of community health workers networks to deliver interventions as well as healthcare trainings at the community level can play a powerful role in achieving universal coverage. Brazil, for example, is working to improve access through the deployment of about 40,000 community health workers.

Improve adherence to treatment and proper use of interventions. The proper use of treatment and preventive interventions (such as LLINs) is a barrier to control. One of several causes is that the instructions are not in local dialects or the people are illiterate. To increase adherence, the use of visual tools or messages appropriately adapted to the local culture is required for communication and behavior change programs. Use of community health workers, as is the case in Brazil, can assist with education on proper intervention use.

Monitor drug and insecticide resistance. Drug resistance is a concern in the Amazon region, where *P. falciparum* is highly resistant to chloroquine and sulphadoxine-pyrimethamine. Chloroquine overall remains effective against *P. vivax* in the Americas, although some resistance has been reported in Brazil, Colombia, Guatemala, Guyana and Peru.⁴⁹ All countries have changed their policies to ACTs as the first-line treatment against *P. falciparum*. As part of the Amazon Malaria Initiative supported by USAID, a network for monitoring drug resistance has been established in 8 countries of the Amazon basin.⁵⁰ Resistance to insecticides (particularly DDT) is also a major concern in the region, especially since insecticides are being used in agriculture. Today, all countries have switched away from DDT to pyrethroids. Also several countries are trying to develop alternatives for vector control (e.g. environmental management or breeding site reduction) to the use of DDT. Countries should ensure sufficient monitoring and surveillance is in place so that potential drug and / or insecticide resistance can be identified early, and control strategies can be revised accordingly.

Build managerial capacity. In a major shift over the past decade, countries in the Americas have moved from vertical programs (such as IRS programs) to more decentralized malaria control programs. Effective decentralized programs can often be more responsive to local situations (e.g. increases in incidence due to epidemics, adapting communication and education to local needs, etc.) Unfortunately, this shift has not been accompanied with increased managerial capacity at the local level. In order to run decentralized and locally adapted control programs, skilled staff is needed. Training can play a vital role in developing critical skills such as program management and financing. Parallel to training is the empowerment of program managers through provision of information, knowledge and decision-making authority. These are key characteristics of the effective decentralized program that has been implemented in Brazil. To effectively implement similar programs, countries and districts should focus on skill development training combined with increased responsibility, authority and information given to local-level managers.

Foster cross-country coordination. Significant information exchange and various forms of innovative partnerships are in effect between and among countries in the region. However, strengthening of these relations becomes all the more crucial as countries move towards malaria elimination. The strength of current malaria sub-regional networks in the Amazon and in Mexico and Central America must be sustained and needs to inherently evolve according to emerging/re-emerging issues that confront them. Bi- and multi-lateral coordination among countries that share common borders with malarious areas (e.g. Brazil, French Guiana and Suriname) should be fostered.

Expand research. More operational research needs to be conducted to validate appropriateness of tools for different settings, and to validate country strategies and policies. In addition, development of effective interventions suitable for outdoor-biting vectors would be highly beneficial to countries in the Americas, where many of these mosquitoes exist.

Strengthen M&E and information systems. M&E and information systems are crucial for malaria control program success, and become even more important as country programs evolve from sustained control to and through elimination. Many countries in the Americas have a system in place; however the quality and relevance of data collected requires improvement. Countries would benefit from guidelines and instructions: one option is for countries to collaborate closely with WHO - PAHO and MERG to optimize M&E programs for their countries until further guidelines and indicators are developed.

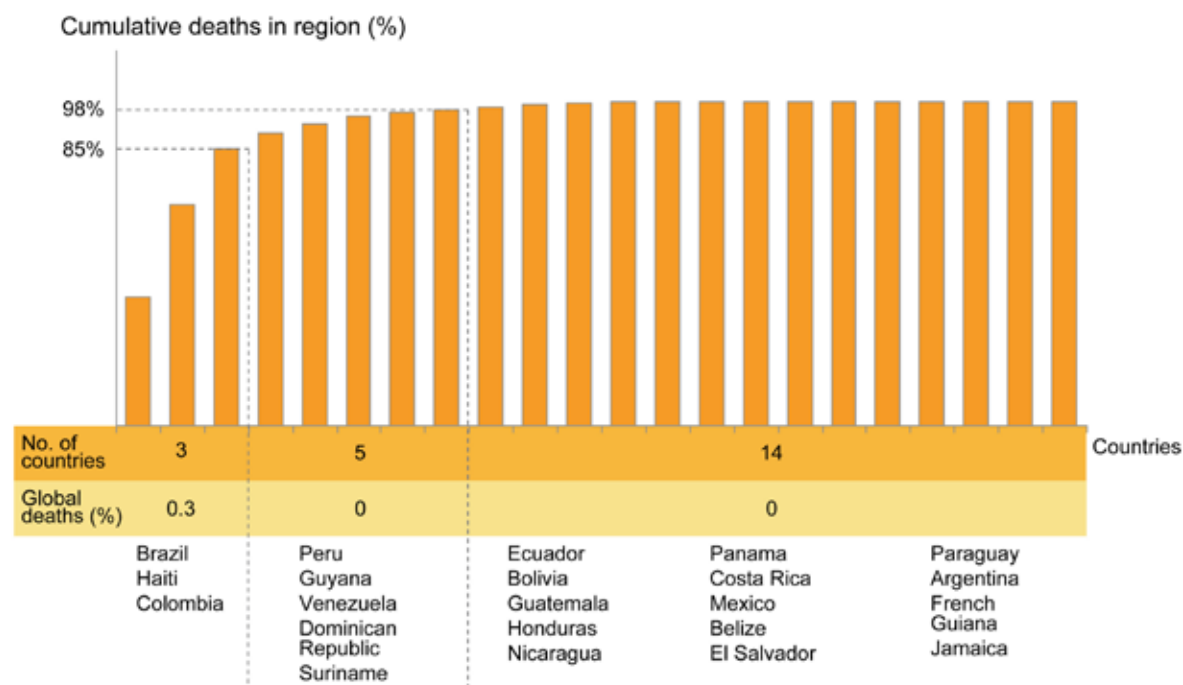
⁴⁹ *World Malaria Report 2005*. Geneva, World Health Organization, 2005.

⁵⁰ Amazon Network for the Surveillance of Antimalarial Drug Resistance/Amazon Malaria Initiative (RAVREDA/AMI).

Strategic priorities. Due to the relatively moderate or low malaria burden in countries within this region, none of the highest burden countries that account for most of the malaria deaths are located in the Americas.

Within the region, the burden is highly concentrated within eight countries (Brazil, Colombia, Haiti, Peru, Guyana, Venezuela, Dominican Republic and Suriname), which account for ~98% of estimated malaria deaths in the Americas (see Figure III.10). However, cases and deaths alone do not provide the complete story: comparing deaths to population at risk over time shows a different picture for Brazil, which has experienced significant declines in death rates due to successful control programs. Still, it is important to provide assistance to all malarious countries in the Americas, even if burden varies. Countries with extremely high burden need attention and assistance, as do countries which have achieved levels of control but need help sustaining it, and countries which are pursuing elimination and which would benefit from technical assistance and other support.

Figure III.10: Distribution of malaria deaths in the Americas



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

To reach the 2010 targets, several factors must be taken into account.

- *High contribution to regional deaths.* Brazil, Colombia and Haiti comprise ~85% of the malaria deaths in the Americas. Haiti in particular has a high burden relative to its small population at risk.
- *Supporting ongoing control and elimination programs.* While efforts are made to lower burden in the highest mortality countries, continued support should be provided to countries which have achieved significant burden reductions, as well as countries embarking on elimination campaigns.

As for priorities beyond 2010, with many countries in the Americas having made significant progress in their control programs, the key priorities will be to sustain the reductions in morbidity and mortality. For countries in sustained control, this will include continued financing of malaria control programs from both country budgets and external donors. Improved M&E to identify epidemics early, as well as potential emergence of resistance, should also be an important part of these countries' strategies. Strengthening management capacity through training and empowerment of decentralized program managers will ensure these countries have the systems in place to eventually embark on an elimination program.

Countries in the pre-elimination and the elimination stage are encouraged to push towards bringing local transmission to zero, and to undertake operational research and share best practices with countries in- and outside the region. These countries will likely need to increase emphasis on cross-border collaboration and on minimizing transmission from transient populations.

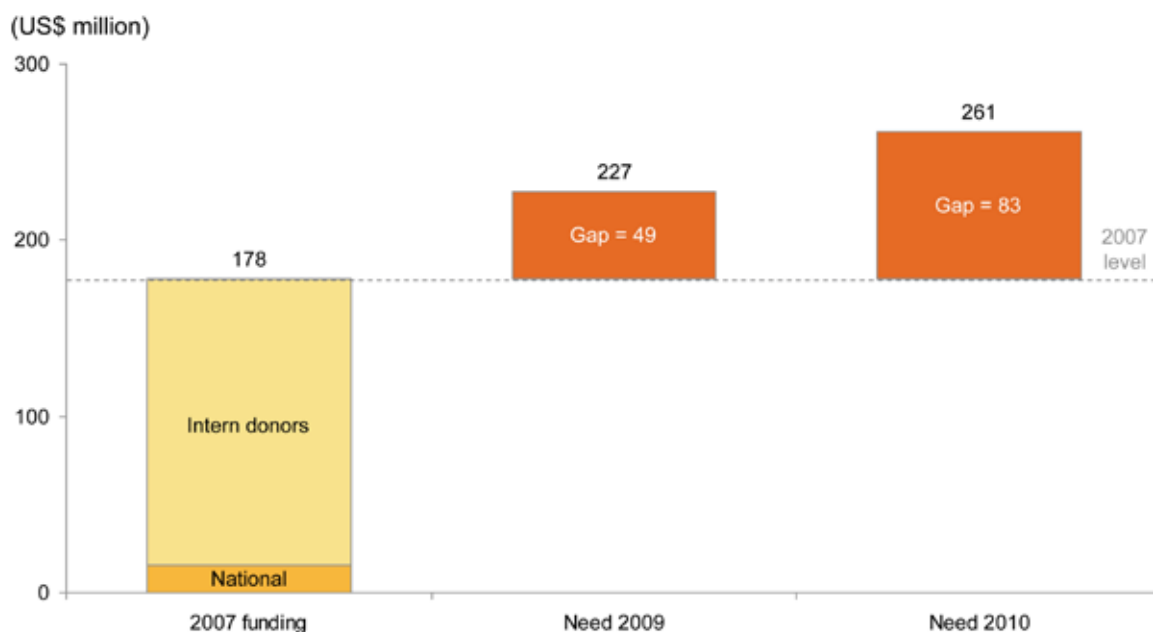
To date, the RBM Partnership not been actively engaged in supporting countries or partners in the Americas. The RBM Partnership may want to establish a focal point to act as a formal interface with the region. The Partnership could play a valuable role by providing opportunities to share and learn best practices from other regions. The active cooperation networks that started in the region (such as the network on drug resistance monitoring) need to be maintained and strengthened.

RBM partners will provide to all countries in the control or elimination stage the general support detailed in *Part II: The Global Strategy* of the plan. Specifically, Brazil, Columbia and Haiti, the countries with the greatest malaria mortality, could be supported by additional technical assistance (e.g. for planning, development of fund proposals, resolving implementation bottlenecks, strengthening M&E systems) to achieve targets. Countries that are more focused on sustaining control programs, such as Brazil, must be assisted in maintaining milestones achieved and in moving towards possible malaria elimination through improved health management information systems (HMIS), management capacity, and access.

Funding Requirements: US\$ 83 million gap for 2010

As illustrated in Figure III.11, an estimated US\$ 178 million was disbursed for malaria programs in 2007 in the Americas. Approximately 91% of this funding came from national budgets, the highest rate for all four regions. The remaining disbursements came from international donors, above all the Global Fund (~9%). The Global Fund has awarded grants worth ~US\$ 90 million to 11 countries in the region, including a multi-country proposal for four Andean countries. The Andean countries (US\$ 25 million), Haiti (US\$ 14 million) and Guatemala (US\$ 14 million) received the largest grants. Other main donors include USAID (US\$ 8.8 million) and the United Nations Environmental Program (US\$ 13 million).

Figure III.11: Gap in malaria funding in the Americas



Note: See appendices on methodologies to estimate costing needs and current funding.

Source: GMAP costing model, WHO, the Global Fund, the World Bank and the President’s Malaria Initiative (PMI).

The Americas comprise approximately 4% of the world’s population at risk and 4% of the total global costs to scale-up. This relatively lower level is due to the large proportion of the population living at low risk, as well as the significant progress made so far in many countries’ control efforts. Approximately US\$ 227 million is needed in 2009 and US\$ 261 million is needed in 2010 to scale-up preventive and curative interventions in the Americas to reach target coverage levels (see Table III.3). Compared to current investment levels, there is an estimated funding shortfall of US\$ 83 million to reach 2010 funding needs, which is the smallest funding gap of all regions.

Table III.3: Summary of annual costs in the Americas

Cost category (US\$ millions)	2009	2010	2015	2020	2025
LLINs/ITNs	66	66	46	49	1
IRS	43	62	66	65	55
IPTp	0	0	0	0	0
<i>Prevention cost</i>	<i>109</i>	<i>128</i>	<i>113</i>	<i>114</i>	<i>56</i>
RDTs	23	28	8	0	0
ACTs	1	1	0	0	0
Chloroquine and primaquine	1	1	0	0	0
Severe case management	0	0	0	0	0
<i>Case management cost</i>	<i>24</i>	<i>30</i>	<i>9</i>	<i>0</i>	<i>0</i>
Community health workers	4	4	5	4	2
Training	28	27	26	26	10
M&E and OR	23	27	27	27	36
Infrastructure / inst. strengthening	39	45	46	47	17
<i>Program cost</i>	<i>94</i>	<i>103</i>	<i>104</i>	<i>104</i>	<i>64</i>
Total control & elimination cost	227	261	226	219	120

Note: Diagnostic costs are covered both by RDTs in case management and by microscopy in infrastructure / institutional strengthening.

Source: GMAP costing model; Johns B. and Kiszewski A. et al.

4. Asia-Pacific

Malaria is present in 20 countries or territories in South Asia, Eastern Asia, Southeast Asia and in the Western Pacific.

South Asia (5): Bangladesh, Bhutan, India, Nepal and Sri Lanka

Eastern Asia (3): China, DPR Korea and Republic of Korea

Southeast Asia (9): Cambodia, Democratic Republic of Timor-Leste, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, the Philippines, Thailand and Vietnam

Pacific (3): Papua New Guinea, Solomon Islands and Vanuatu

Population at risk. More than ~2.2 billion people are at risk of malaria in Asia-Pacific, which represents ~67% of the world population at risk of malaria. Six of the 10 countries worldwide with the largest populations at risk are located in the Asia-Pacific region (India, China, Indonesia, Bangladesh, Viet Nam and the Philippines).⁵¹

Malaria transmission. Of the total population at risk, ~77% live in areas of low transmission⁵² while the remaining ~23% live in areas of moderate to high transmission. In India, Indonesia, Myanmar, Viet Nam and Bangladesh, ~91% of the population at risk lives in areas of high transmission of both *P. vivax* and *P. falciparum*. Frequent epidemics occur in these countries and are often caused by large seasonal weather events. DPR Korea, Indonesia, Myanmar, Nepal, Viet Nam, the Philippines, Papua New Guinea and India (in Rajasthan and Gujarat) have all experienced epidemics in recent years.

P. vivax is endemic in all 20 countries. *P. falciparum* is found in all countries except DPR Korea and Republic of Korea. The proportion of *P. falciparum* malaria has decreased steadily since the late 1970s in Southeast Asia. Myanmar, parts of Papua New Guinea, Indonesia, Vanuatu, Democratic Republic of Timor-Leste, the Solomon Islands, Cambodia, Lao People's Democratic Republic, and some states of India continue to suffer from high transmission of *P. falciparum* malaria.

There are at least six different species of mosquito vectors that contribute to malaria transmission. The mosquitoes can be both indoor- and outdoor-biting, depending on the time of day. Different types of vector control interventions must be employed simultaneously in the region.

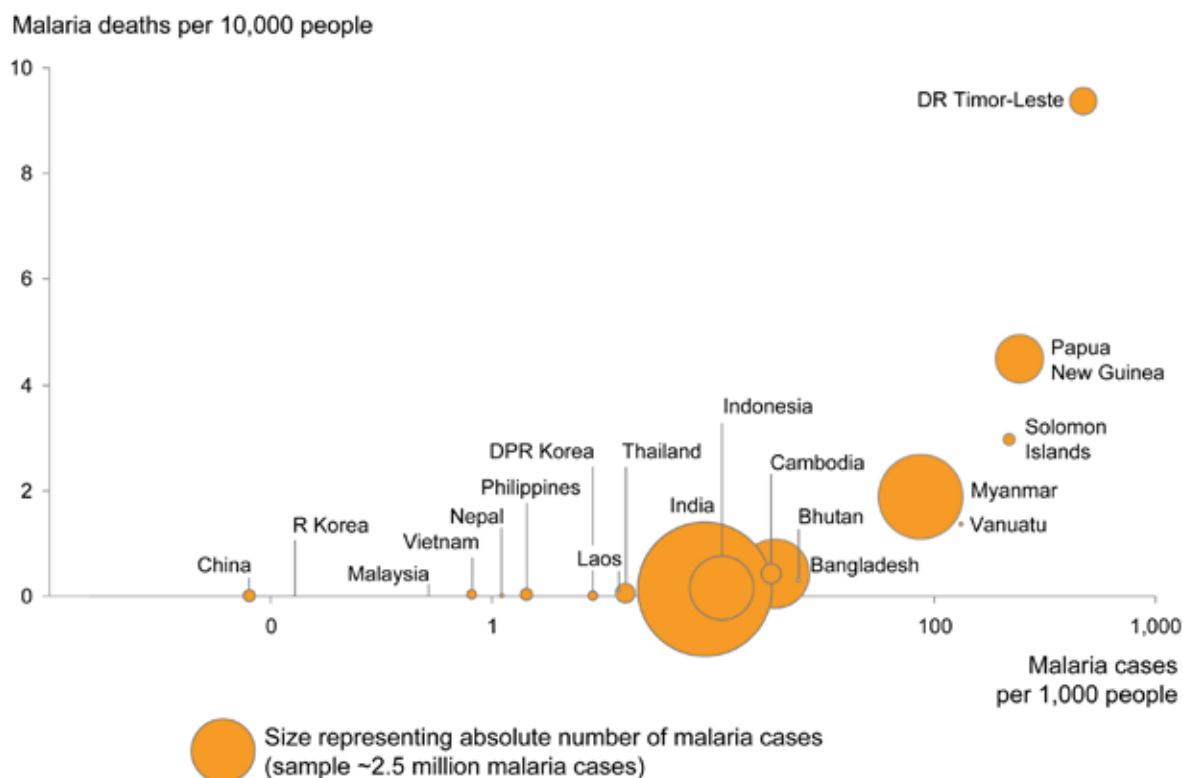
Malaria burden. Asia-Pacific had an estimated 134 million cases in 2002 (26% of worldwide cases) and 105,000 deaths in 2000 (9.4% of worldwide deaths).⁵³ India bears the highest share of cases with ~45% of estimated cases in the region. Five countries (India, Myanmar, Bangladesh, Indonesia and Papua New Guinea) account for approximately ~93% of the death toll in the region (see Figure III.12).

⁵¹ World Malaria Report 2008. Geneva, World Health Organization, 2008.

⁵² Where reported case incidence is <1 per 1000 population per year.

⁵³ Breman JG et al. Conquering Malaria. In: Jamison DT, Breman JG et al, eds. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006. p 415.

Figure III.12: Malaria cases and deaths in Asia-Pacific



Note: Countries with negligible burden are not shown (Sri Lanka).

Source: World Malaria Report 2008. Geneva, World Health Organization, 2008.

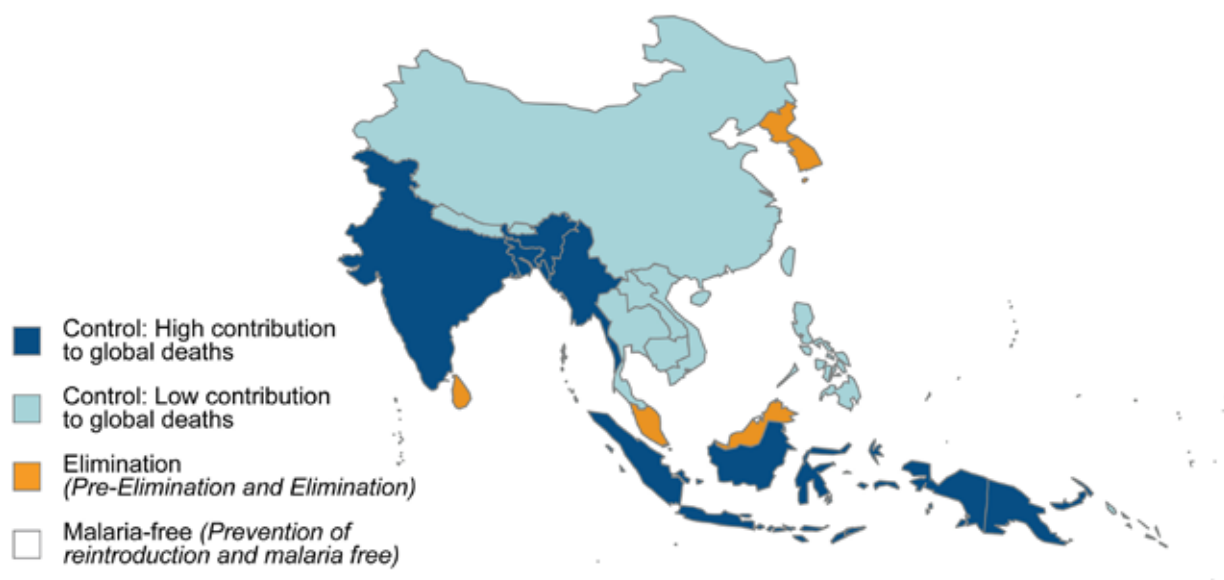
Adapted Approaches and Current Levels of Coverage

Malarious countries in Asia-Pacific are very large with sizeable populations at risk, which hide extreme variations within each country in terms of transmission settings, strengths of health systems and levels of burden (e.g. Indonesia has its highest burden area in the easternmost provinces; Thailand has a large proportion of its burden concentrated in border areas). Within the same country, some areas can be malaria free, while others are in the control stage or the elimination stage, requiring a stratified and targeted approach for each country (see section on *Challenges*). In the remainder of this chapter, countries will be classified in the control stage unless an elimination program is being conducted nationwide.

Sri Lanka, Malaysia and DPR Korea are in the pre-elimination stage, and the Republic of Korea is in the elimination stage.⁵⁴ All 16 other countries are currently in the control stage according to WHO. Some of these countries, such as the Philippines, Indonesia, Vanuatu, China, Viet Nam and the Solomon Islands have “malaria-free” projects in some areas but are classified in the control stage overall. Figure III.13 presents the country categorization in the region.

⁵⁴ Country elimination status is based on the WHO *World Malaria Report 2008*. The country classification is not fixed, and countries' status can change depending on the effectiveness of malaria programs and resulting incidence. Please check with a country's Malaria Control Program for the most up-to-date classification.

Figure III.13: Country categorization in Asia-Pacific



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

Almost all of the 16 countries in the region in the control stage are implementing the two main vector control measures (LLINs / ITNs and IRS) depending on the setting and case management with microscopic diagnosis and appropriate treatment. The role of IPTp in high-burden areas of Asia-Pacific needs to be clarified (See section on *High transmission of P. falciparum* below).

Approaches for the 4 countries in pre-elimination or elimination (Malaysia, DPR Korea, Republic of Korea, and Sri Lanka) are detailed in *Part II - Chapter 3: Elimination and Eradication: Achieving Zero Transmission* and rely mainly on active case detection and management of active foci. DPR Korea, Republic of Korea and Sri Lanka have almost solely *P. vivax* transmission. Due to the liver stage infection, interruption of *P. vivax* transmission is difficult to achieve and requires strong adherence to a program of radical cure (14-days of primaquine). Some countries are using innovative malaria treatments: since 2002 DPR Korea has employed mass prophylaxis of primaquine against *P. vivax* in targeted populations.

Locally adapted approaches to malaria control and elimination. Choosing the appropriate tools requires a deep understanding of local epidemiology, geography and socioeconomic conditions. This section summarizes the appropriate interventions for various settings in Asia-Pacific.

Vector control strategies. The use of at least one of the two core vector control interventions (IRS, LLINs / ITNs) is recommended. The appropriateness of one or the other depends on the epidemiological profile, acceptance by the population, adapted structures to deliver the intervention and other factors outlined in WHO recommendations.⁵⁵ The choice needs to be determined by countries. Additionally, larval control and environmental management measures (e.g. management of salinity in aquaculture and coastal lagoons, rice field draining) can work well in Asia-Pacific as has been illustrated by Indonesia and the Solomon Islands.

⁵⁵ *Malaria vector control and personal protection*. Geneva, World Health Organization, 2006.

P. vivax and mixed transmissions settings. Parasitological confirmation is essential in areas where both *P. vivax* and *P. falciparum* occur. Microscopy is recommended as RDTs currently available for non-*falciparum* infections have low sensitivity and high cost.⁵⁶ To treat both the blood stage and the liver stage infections, chloroquine combined with 14-days treatment with primaquine is recommended against *P. vivax* malaria⁵⁷ in places where there is no proven resistance to chloroquine. Radical cure with primaquine is contraindicated for pregnant women. In regions where both parasite species coexist, mixed infections are common⁵⁸ and require ACTs completed by primaquine.⁵⁹

High transmission of P. falciparum. Some countries in Asia-Pacific have high transmission of *P. falciparum* malaria (e.g. Papua New Guinea, Myanmar, parts of Indonesia, Bangladesh, Solomon Islands, Democratic Republic of Timor-Leste, and some states of India). The use of parasitological diagnosis is recommended for all populations at risk⁶⁰ and ACTs are the recommended first-line treatment against *P. falciparum* malaria. Further research needs to clarify the management of malaria in pregnancy in high transmission settings in this region and especially the appropriateness of IPTp. Trials are underway in Papua New Guinea and the Solomon Islands.

Current intervention coverage. Many interventions have been used in the region with varying degrees of success. These are described below.

LLINs / ITNs. Coverage with LLINs has been historically low in the region since countries used them only for small scale projects. However, tremendous efforts are underway to scale-up their use.⁶¹ Countries such as Bangladesh, Bhutan, Viet Nam, Cambodia, the Solomon Islands, Vanuatu and Papua New Guinea have used insecticide-treated nets for several years. Today all 16 countries in the control stage count LLINs / ITNs as part of their national malaria control strategy. The high up-front cost of LLINs (which are effective for 3-5 years) relative to ITNs (which are effective for approximately 1 year per treatment) is still a barrier to scale-up efforts in Asia-Pacific. In 2006, ~8.6 million LLINs / ITNs were in circulation.⁶² However, these figures likely understate the number of effective nets because they do not count ITNs that have been retreated. For example, in Viet Nam alone, more than 5 million nets are treated annually.

IRS. IRS has historically been the main tool used for vector control, especially in high transmission settings and for the management of epidemics.⁶³ In the mid-1990s, China, Malaysia, the Philippines and Viet Nam replaced DDT and organo-phosphates with other insecticides. Today, IRS is performed without DDT in all control countries except India. Successful IRS programs have been conducted routinely in India, Thailand, Malaysia and Sri Lanka. In Indonesia, Solomon Islands, Viet Nam, Papua New Guinea and the Philippines, IRS is principally used to contain epidemics. Approximately 16 million households (or ~81 million people) in Asia-Pacific are covered by IRS.⁶⁴

⁵⁶ *Guidelines for the treatment of malaria.* Geneva, World Health Organization, 2006.

⁵⁷ *Guidelines for the treatment of malaria.* Geneva, World Health Organization, 2006.

⁵⁸ Price et al. Vivax Malaria: neglected and not benign. *American Journal of Tropical Medicine and Hygiene*, 2007, 77.

⁵⁹ Treatment of mixed infections in *Guidelines for the treatment of malaria.* Geneva, World Health Organization, 2006.

⁶⁰ With the exceptions mentioned in *Guidelines for the treatment of malaria.* Geneva, World Health Organization, 2006.

⁶¹ In 2005, a *Regional Framework for Scaling-Up the use of Insecticide-treated nets* was published by WHO-SEARO office and LLINs are one of the main priorities of the SEARO Revised Malaria Control Strategy 2006-2010.

⁶² GMAP estimates based on data from WHO World Malaria Report 2008 and the Roll Back Malaria Commodity database, 2008. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.*

⁶³ Currently the Western Pacific Region policy on spraying is: that a) IRS is the best method for interrupting malaria transmission, but should only be considered where good quality spraying can be done and where high levels of coverage can be attained; b) DDT remains the best choice for IRS, but due to problems with acceptance and other issues like agricultural exports, alternatives like lambda-cyhalothrin, alpha-cypermethrin or delta-methrin are available which are equally effective; and c) generally two or more cycles of spraying per year are recommended but where two properly timed rounds with high coverage are not possible because of logistics or other problems, then every effort should be made to carry out one complete round with high levels of coverage just prior to the beginning of the main transmission season, using a long-lasting residual insecticide. Source: WHO-WPRO, internal communication, 2008.

⁶⁴ GMAP estimates based on data from WHO World Malaria Report 2008. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.*

Other vector control measures. Countries in Asia-Pacific have a strong history of environmental management. It was used in the early 20th century for vector control. Although IRS became the main vector control intervention in the region after the 1950s, environmental management (such as draining of rice fields, modification in water salinity, blocked river mouths and coastal lagoons) continued to be used in several countries such as Indonesia, India and the Solomon Islands, where the participation of local communities is a key to success in reducing vector breeding sites.⁶⁵ Though larvivorous fish are often used, the evidence base for their effectiveness is weak.⁶⁶ In forest malaria settings, such as the Greater Mekong sub-region, personal protection is required for temporary exposure (e.g. for forest workers, loggers, miners, rubber plantation workers and swidden field cultivation). Personal protection measures include insecticide/long-lasting insecticidal hammock nets, long-lasting insecticidal hammocks, insecticide-treated clothing or veils, insecticide-treated blankets and repellents.

Diagnostics (Microscopy and RDTs). Parasitological diagnosis is essential in Asia-Pacific countries to confirm parasitaemia as transmission is rarely high and malaria constitutes a minority of fevers, and to distinguish between treatment for *P. falciparum* and *P. vivax*. All countries have functional microscopy capabilities but overall coverage is limited. Some countries such as Thailand, Bhutan or Sri Lanka have good microscopy and in the Philippines, Solomon Islands or Viet Nam, microscopy is available down to the community level. RDTs have been integrated into routine practice in several countries (e.g. Cambodia, Indonesia, Sri Lanka and Thailand)⁶⁷ but their use is still limited. Approximately 122 million parasitological diagnoses were reported in 2006, ~88% from India alone. Only ~407 thousand RDTs were used in 2006.⁶⁸

Anti-malarial treatment. *P. vivax* cases are treated with chloroquine and primaquine in most countries. The exception are Vanuatu and Solomon Islands, where cases are treated with ACTs and primaquine and Cambodia and Papua New Guinea where currently primaquine is not widely used due to G6PD deficiency. Currently, treatment of confirmed, uncomplicated *P. falciparum* cases are treated with ACTs in most countries. Countries have different policies for treating unconfirmed cases. An estimated 10 million treatment courses were distributed in 2006.⁶⁹

Recommended Regional Approach to Control and Eliminate Malaria

Targets, approaches and priorities must be tailored to the region.

Targets. The target for 2010 is to reduce malaria mortality and morbidity by 50%, which means Asia-Pacific will have less than 67 million cases and 52,500 deaths in 2010. By 2015, the objective is to have less than 33 million cases and to reach near zero mortality for all preventable deaths.⁷⁰ Beyond 2015, the objective is to maintain near zero mortality for all preventable deaths and further reduce morbidity.

To reach universal coverage with appropriate interventions by 2010 in Asia-Pacific (see Figure III.14):

- ~349 million LLINs need to be in circulation in 2010;
- ~120 million households need to be sprayed with insecticides;
- ~780 million diagnostics are needed to confirm suspected malaria fever cases, either by microscopy or RDTs; and
- ~24 million first-line treatments are needed for both *P. falciparum* and *P. vivax* infections.

⁶⁵ Lindsay et al. Environmental Management for Malaria Control in the East Asia and Pacific (EAP) Region. *HNP discussion paper*, Washington, D.C., World Bank, 2004.

⁶⁶ W Hawley, UNICEF, personal communication, 2008.

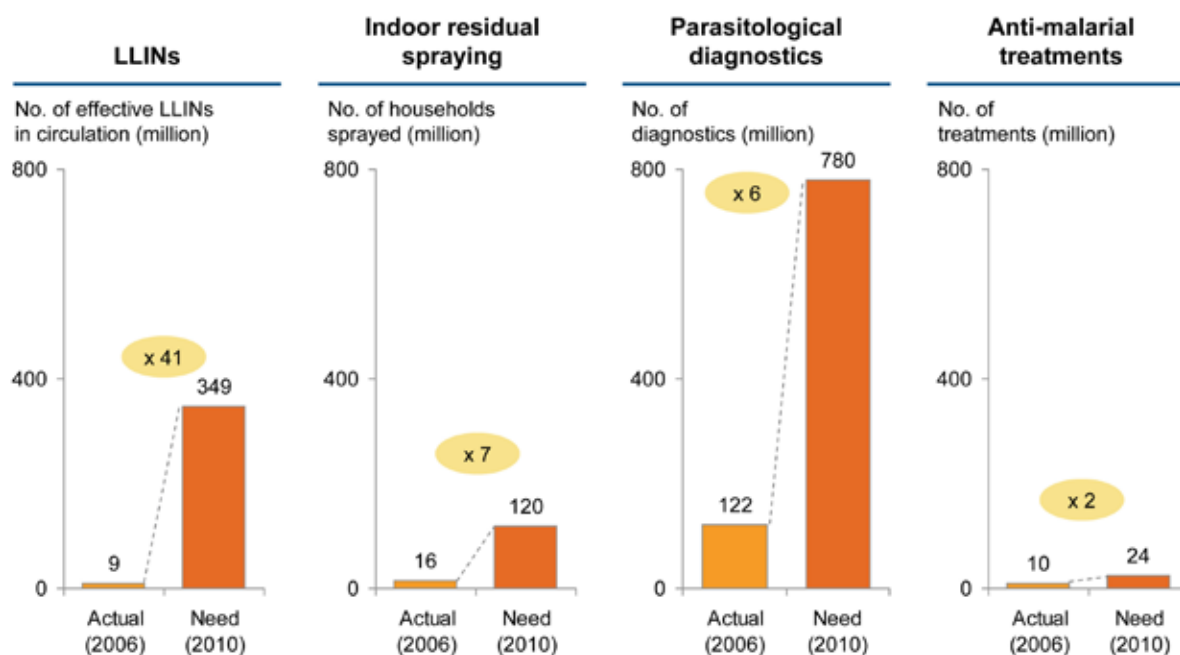
⁶⁷ *Malaria Rapid Diagnosis, Making it work*. WHO - Western Pacific Regional Office, 2003.

⁶⁸ GMAP estimates based on data from WHO World Malaria Report 2008. See Appendix 3. *Assumptions behind Current Burden, Coverage and Funding Estimates*.

⁶⁹ GMAP estimates based on data from WHO World Malaria Report 2008 and the Roll Back Malaria Commodity database, 2008. See Appendix 3. *Assumptions behind Current Burden, Coverage and Funding Estimates*.

⁷⁰ Preventable death is defined as deaths from malaria that can be prevented with rapid treatment with effective medication. Non-preventable deaths represent an extremely low mortality rate for the most severe malaria cases and occur even with the best available and most rapid treatment.

Figure III.14: Scale-up in interventions from 2006 to 2010 in Asia-Pacific



a) Because of 3-year life span, each year approximately 1/3 of the old nets will need to be replaced.

b) Actual use is likely not all directed to confirmed malaria cases today.

Source: Need based on GMAP costing model; actual based on analysis of World Malaria Report 2008. Geneva, World Health Organization, 2008 and Roll Back Malaria Commodities database.

Approaches to main challenges in the region. Challenges faced by countries in their malaria control efforts are varied. However, some common trends unique to malaria in Asia-Pacific are described below.

Respect in-country variations. There are large variations in epidemiology and malaria burden within Asia-Pacific countries. Large countries such as China, Indonesia, or India have regions in very different situations, some bearing most of the malaria burden, others almost or totally malaria free. Stratified approaches are required to adapt the strategy to local needs. In the Philippines, for example, programs are highly decentralized and the establishment of Provincial Investment Plans for Health (PIHP) has enabled the development of detailed workplans at the local level.

Build managerial capacity. Capacity building is required at the national, regional and local level. In many countries, malaria control programs lack sufficient human resources to successfully run their programs. This is due to a variety of factors: high attrition rates of skilled staff, difficulty filling positions, competing demands with other programs and the unwillingness of health providers to be stationed in remote areas. In particular, countries report a dearth of technical experts (e.g. entomologists and M&E specialists), staff for the delivery of interventions (e.g. nurses and skilled IRS teams) and laboratory workers in health facilities to conduct microscopy. There is a strong need to increase trainings for new staff, especially in areas where there is a high demand (e.g. Bhutan, Nepal, Democratic Republic of Timor-Leste). The training network *ACTMalaria* (Asian Collaborative Training Network for Malaria) has been established in 11 countries in the region to provide collaborative training and improve communications on malaria affecting common borders. In addition, the rapid decentralization of malaria control in some countries has led to a greater need for skills (especially program management) at the regional and local level.

Monitor, prevent, and contain anti-malarial drug resistance. Asia-Pacific countries report the highest rates of anti-malarial drug resistance in the world. Chloroquine and sulphadoxin-pyrimethamine resistance by *P. falciparum* are reported from almost all countries (averaging ~40% for CQ and between 20% and 40% for

SP).⁷¹ Chloroquine-resistant *P. vivax* is found in Indonesia, Papua New Guinea and India. Multi-drug resistant *P. falciparum*, which includes decreased sensitivity to artemisinin (called artemisinin-tolerant), is found at the Cambodia-Thailand border, and in northeastern Myanmar bordering Thailand. A major effort is underway to contain artemisinin-tolerant malaria in this area. The potential expansion of artemisinin-tolerant *P. falciparum* to other parts of Asia and Africa is a global threat. The rapid strengthening of monitoring systems for drug resistance is therefore critical in the Asia-Pacific region. To avoid resistance to ACTs, the rational use of anti-malarial drugs should be enforced and the quality ensured. Sub-regional surveillance networks exist in the Greater Mekong sub-region and the Pacific that foster collaboration between countries in monitoring malaria drug resistance.

Monitor insecticide resistance. Insecticide resistance is also a major issue in several countries in Asia-Pacific. In India, resistance to almost all types of insecticides has been reported. In the Greater Mekong sub-region, insecticide resistance was reported from several countries.⁷² Resistance that occurs even in non-endemic areas needs to be monitored because of the risk of vector migration to endemic regions. Sri Lanka has adopted the rotational use of insecticides for indoor residual spraying to delay the emergence of resistance to insecticides. Insecticide resistance monitoring, quality assurance of products, resistance management strategies, and overarching Integrated Vector Management approach are needed to manage insecticide resistance.

Improve quality of anti-malarial treatments and other commodities. Due to the high cost of effective anti-malarial drugs such as ACTs and the strong manufacturing capabilities of companies in the region, fake and substandard drugs are prevalent, especially in the Greater Mekong sub-region. In 2001, studies showed that more than 30% of artesunate collected from international borders of Mekong countries was fake.⁷³ The issue of poor quality drugs is even more complicated in countries where most of the drugs are obtained from the private sector or from drug peddlers. Therefore, national programs (in Cambodia, Lao People's Democratic Republic and Myanmar) are cooperating with the formal and informal private sector (Public-Private Mix for Malaria Control). Similarly, concerns have been raised on the quality of LLINs and insecticides used for IRS and RDTs, particularly when districts have their own procurement mechanisms. Greater quality control and regional cooperation should be encouraged on this issue for all interventions.

Strengthen control and elimination efforts against P. vivax. The transmission of *P. vivax* is widespread in the Asia-Pacific region. *P. vivax* has a unique biology (generation of hypnozoites in the liver stage) that leads to a large prevalence of asymptomatic cases among semi-immune populations. It also responds differently to anti-malarial treatments than *P. falciparum*. The cure for liver stage infection, 14-days of primaquine, poses challenges as patients often do not adhere to treatment for the entire period. To date, *P. vivax* research has been poorly funded, resulting in few new tools and approaches for controlling *P. vivax*. Basic and operational research on *P. vivax* needs to be expanded and strong behavioral change communication (BCC) programs are required to ensure adherence to primaquine treatments. In addition, regional cooperation networks could be created to share practices on the control of *P. vivax* malaria. An Asian Vivax Network was founded in 2005 to conduct research on *P. vivax* but still lacks funding to become operational.

Focus on forest malaria and migrant populations. In parts of Asia-Pacific (e.g. in the Greater Mekong sub-region) forest malaria is common. Some mosquito vectors (e.g. Anopheles dirus) bite and rest outdoors. These forested areas may contain difficult-to-access trans-border areas. Hence, a significant part of the malaria burden is borne by isolated ethnic groups or new settlers who reside close to the forest and mobile/migrant forest workers (e.g. for logging, mining, plantation work and swidden field cultivation). It is challenging to provide interventions to the resident populations in these areas because they are hard to reach and because traditional vector control interventions (LLINs / ITNs, IRS) are not always effective in these settings. Innovations in personal protection (e.g. insecticide-treated blankets, hammocks or hammock nets) are being tested but the continued development and availability of new tools is crucial.

In Pacific island countries, migration and inter-island travel creates a transient reservoir of infective and infectious carriers (mostly asymptomatic) who serve as a constant source of transmission. In the Solomon Islands, active case detection through periodic mass screening, treatment and follow-up of all positive cases

⁷¹ World Malaria Report 2005. Geneva, World Health Organization, 2005.

⁷² Van Bortel et al. The insecticide resistance status of malaria vectors in the Mekong region. *Malaria Journal*, June 2008.

⁷³ Newton P et al. *The Lancet*, 2001. Regular monitoring of the quality of anti-malarial medicines in the Mekong Region since then has led to a successful cooperation with INTERPOL to stop the production and the distribution of counterfeit artesunate.

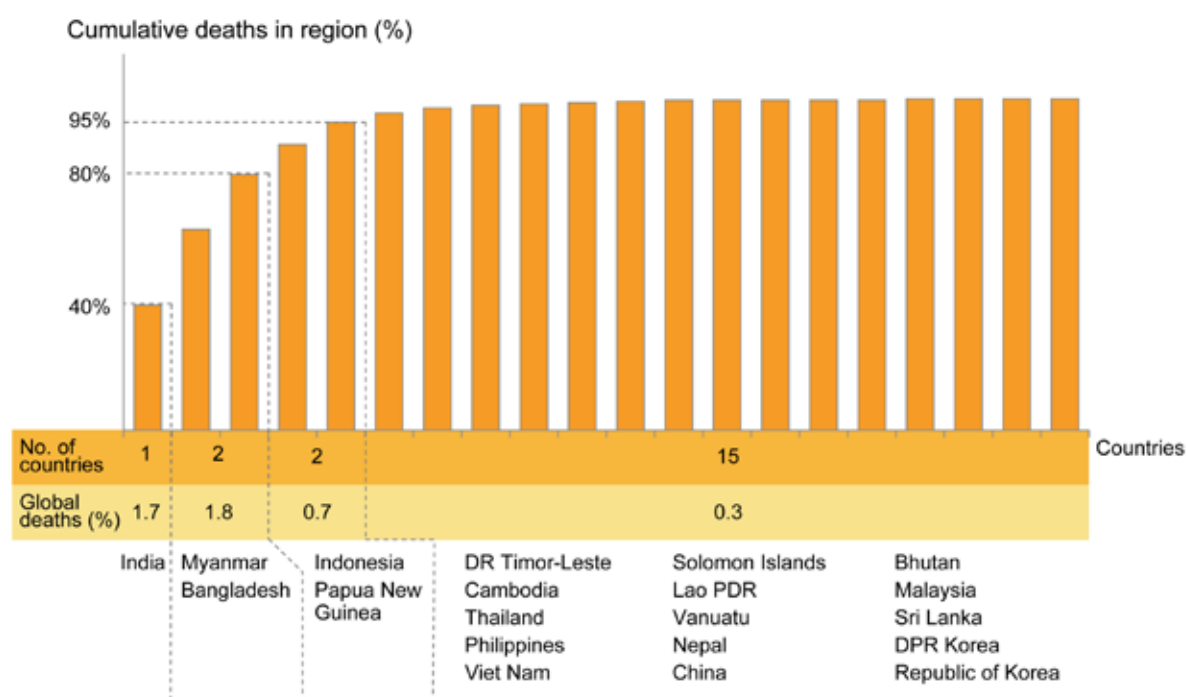
has been a major factor in reducing transmission between the capital city and smaller townships over the past 10 years. This approach will be introduced as part of the malaria elimination strategy in island groups of the Solomon Islands and Vanuatu.

Operational research and regional collaborations with other initiatives (e.g. labor, migration, HIV/AIDS) focused on these populations may be successful in developing comprehensive approaches that include malaria. In order to reach these isolated populations, integration with other health services (such as immunization) and cooperation with other sectors and agencies (such as rural development, military and border police) needs to be strengthened. In addition, community health management could be promoted, with the establishment of networks of community health workers.

Maintain long term malaria funding and political support. Maintaining funding and political support for malaria control efforts, especially in areas where successful control has lowered the burden and led countries in the pre-elimination stage, is critical. Increased national funding will hedge countries from drops in donor support. In-country and international advocacy efforts are required to maintain political and financial support.

Strategic priorities. Success in malaria control and elimination is essential in all countries. However, some countries are especially important to achieving the RBM targets, both in the short and the medium / long term. (Figure III.15)

Figure III.15: Distribution of malaria deaths in Asia-Pacific



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

To reach the 2010 targets, several types of countries must receive focused attention:

- *High contribution to global deaths.* Of the 35 countries that account globally for ~98% of malaria deaths, 5 are located in the Asia-Pacific region. These 5 countries (India, Myanmar, Bangladesh, Indonesia and Papua New Guinea) account for approximately ~93% of the death toll in the region. India alone accounts for ~38% of regional mortality. It is critically important to support these countries to achieve the 2010 targets in the region.
- *High burden relative to population size.* Countries such as Democratic Republic of Timor-Leste or the Solomon Islands have few deaths due to smaller populations but are high burden countries when the number of deaths is considered relative to their populations.
- *Emergence of artemisinin resistance.* The Greater Mekong sub-region is of global importance because emerging artemisinin tolerance has the potential to spread around the world. WHO is coordinating and technically supporting research and containment efforts in affected countries, particularly through its sub-regional WHO Mekong Malaria Program.⁷⁴

Success in malaria control in these countries will be critical to achieving regional targets in Asia-Pacific as well as the global targets of burden reduction. Therefore, in addition to the general support provided to all countries in the control stage, the RBM Partnership will coordinate targeted technical assistance to these countries to increase the speed with which they can achieve universal coverage to meet the 2010 targets.

In terms of priorities beyond 2010, all countries which will have reached universal coverage need to be encouraged in maintaining these efforts while entering the sustained control stage. It is essential that control measures are sustainable in all countries to avoid resurgence of malaria transmission and subsequent upsurge in malaria mortality and morbidity. The 4 countries in the elimination stage need to be encouraged to bring local transmission to zero and then prevent the reintroduction of malaria.

International coordination. Support provided by RBM partners should address the challenges faced by the countries in Asia-Pacific as outlined above. To complement existing sub-regional networks such as the WHO Mekong Malaria Programme, the Pacific Malaria Initiative and the Asian Vivax Network, the RBM Partnership could play a valuable role by encouraging increased coordination between countries and partners in the region and by providing opportunities to share best practices. The RBM Partnership may want to establish two Sub-Regional Network nodes (e.g. linked to the WHO Regional Offices for South-East Asia - SEARO and the Western Pacific - WPRO) in Asia-Pacific to strengthen ties within the region. In addition, technical networks could be created and/or strengthened, such as networks on the management of *P. vivax* malaria and on monitoring the quality of insecticides, LLINs and RDTs.

Capacity building. Most malarious countries in Asia-Pacific require capacity building at the national, regional and local level. Trainings need to be designed and disseminated to increase management skills (program or financial management) as well as technical knowledge of experts (entomologists, M&E specialists etc.). In addition, a certification program for intervention providers (e.g. spraying teams for IRS) could be established to ensure the quality in the delivery of interventions. The Asian Collaborative Training Network on Malaria (ACTMalaria) has over 10 years of experience in addressing these needs and is an exemplary training network for other regions.

Targeted assistance to high priority countries. In addition to the general support provided to countries in the control stage (See *Part II: Chapters 2 and 3*), the high priority countries need targeted technical assistance and increased capacity to successfully scale-up interventions by 2010 and achieve universal coverage.

⁷⁴ For more information, see the WHO website (<http://www.whothailand.org/EN/Section3/Section113.htm>).

In particular, technical assistance from RBM partners is needed for:

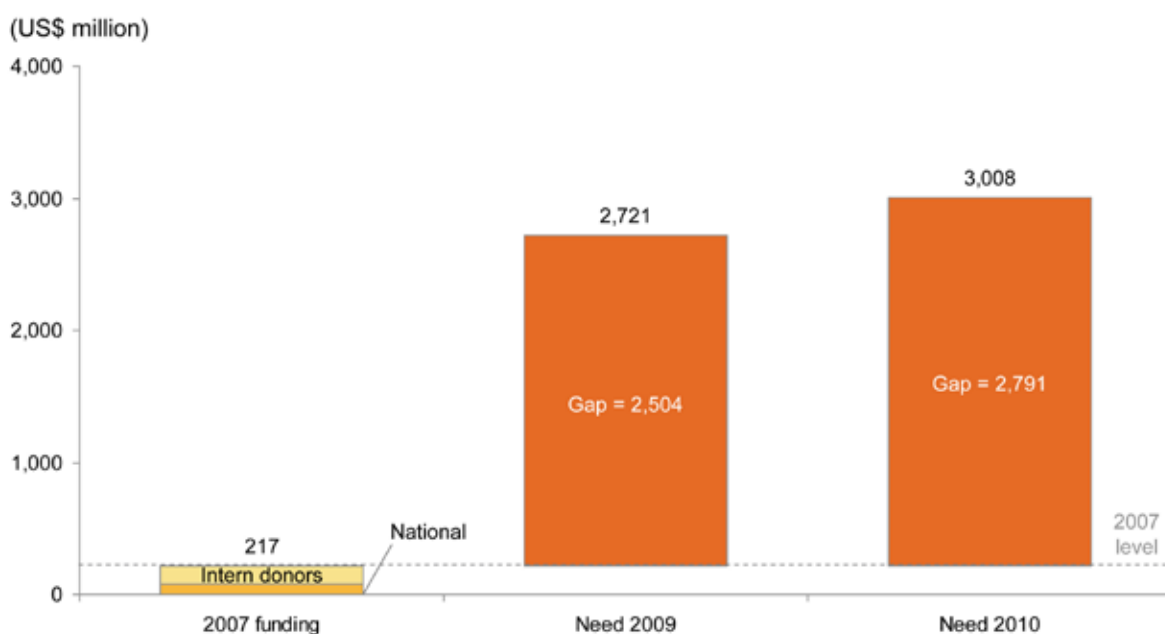
- Planning and developing funding proposals
- Accelerating disbursements from major donors
- Identifying and rapidly resolving procurement and supply chain bottlenecks
- Improving national forecasts of commodities
- Designing and implementing communication and behavior change programs
- Strengthening monitoring and evaluation systems

To ensure sustainability of successful control programs, technical assistance should be complemented by increased capacity at the country level and targeted training programs. In particular, in-country experts are required in a number of key activities, such as program and financial management, procurement and supply chain management, in-country communication and monitoring and evaluation. Providing these experts to the highest burden countries will increase their chances of success. These country-based technical experts would work in a network with coordinators at the sub-regional and global level.

Funding Requirements: US\$ 2.8 billion gap for 2010

In 2007, approximately US\$ 217 million was disbursed against malaria in Asia-Pacific, out of which 66% came from national budgets. (See Figure III.16) After national disbursements, the Global Fund is the main donor in the region (31% of regional disbursements in 2007). The remaining disbursements in 2007 came from other international donors. The Global Fund has awarded grants to 15 countries in the region and a multi-country grant in the Western Pacific for Vanuatu and the Solomon Islands, with a total commitment of US\$ 479 million in the first 7 rounds. In addition, the World Bank approved in July 2008 over US\$ 500 million, approximately US\$ 200 million of which may go to malaria, for a project to support India's efforts against malaria and other diseases.⁷⁵ Other donors include USAID, AusAID and The Asian Development Bank.

Figure III.16: Gap in malaria funding in Asia-Pacific



Note: See appendices on methodologies to estimate costing needs and current funding.

Source: GMAP costing model, WHO, the Global Fund, the World Bank and the President's Malaria Initiative (PMI).

⁷⁵ US\$ 121 million for malaria specific activities, US\$ 52 million for management and policy strengthening (including significant inputs for malaria), and US\$ 37 million not yet allocated which could also be used for malaria.

Compared to 2007 investment levels, there is a funding shortfall of US\$ 2.8 billion to reach the 2010 targets. Approximately US\$ 2.7 billion is needed in 2009 and US\$ 3 billion in 2010 to scale-up preventive and curative interventions in Asia-Pacific to reach universal coverage targets (see Table III.4). Preventive costs are approximately two thirds of these costs in 2010, case management costs are approximately 20% of the costs, and the remaining costs are malaria control program costs. Declines through 2015 are due to lower treatment costs due to preventive efforts and countries shifting from control to elimination.

Table III.4: Summary of annual costs in Asia-Pacific

Cost category (US\$ millions)	2009	2010	2015	2020	2025
LLINs/ITNs	1,016	1,016	782	818	25
IRS	1,121	1,187	1,255	1,247	629
IPTp	0	0	0	0	0
<i>Prevention cost</i>	<i>2,137</i>	<i>2,203</i>	<i>2,038</i>	<i>2,064</i>	<i>654</i>
RDTs	384	556	190	7	5
ACTs	11	16	6	1	1
Chloroquine and primaquine	3	3	1	0	0
Severe case management	3	3	1	0	0
<i>Case management cost</i>	<i>400</i>	<i>577</i>	<i>198</i>	<i>9</i>	<i>5</i>
Community health workers	28	29	34	35	13
Training	32	32	31	31	11
M&E and OR	73	91	91	91	129
Infrastructure / inst. strengthening	51	76	68	71	27
<i>Program cost</i>	<i>184</i>	<i>227</i>	<i>223</i>	<i>228</i>	<i>180</i>
Total control & elimination cost	2,721	3,008	2,459	2,301	839

Note: Diagnostic costs are covered both by RDTs in case management and by microscopy in infrastructure / institutional strengthening.

Source: GMAP costing model; Johns B. and Kiszewski A. et al.

5. Middle East and Eurasia

There are 17 countries or territories with malarious areas in the region, located in Central Asia, Transcaucasia, in the Middle East and on the European-Asian border.

Central Asia (7): Afghanistan, Iran, Kyrgyzstan, Pakistan, Tajikistan, Turkmenistan and Uzbekistan

Transcaucasia (3): Armenia, Azerbaijan and Georgia

Middle-East (5): Iraq, Oman, Saudi Arabia, Syrian Arab Republic and Yemen

Others (2): Russian Federation and Turkey

Population at risk. ~270 million people are at risk of malaria, which represents 8% of the world population at risk. Only ~21% of the population at risk is located in areas of high transmission,⁷⁶ the remaining 79% in areas of low transmission.

Malaria transmission. Since the early 1990s, malaria transmission in the region has increased due to political and socioeconomic problems, mass population migration, extensive development projects, and weakened malaria prevention and control programs. Overall, the countries in the region can be classified in the following groups:

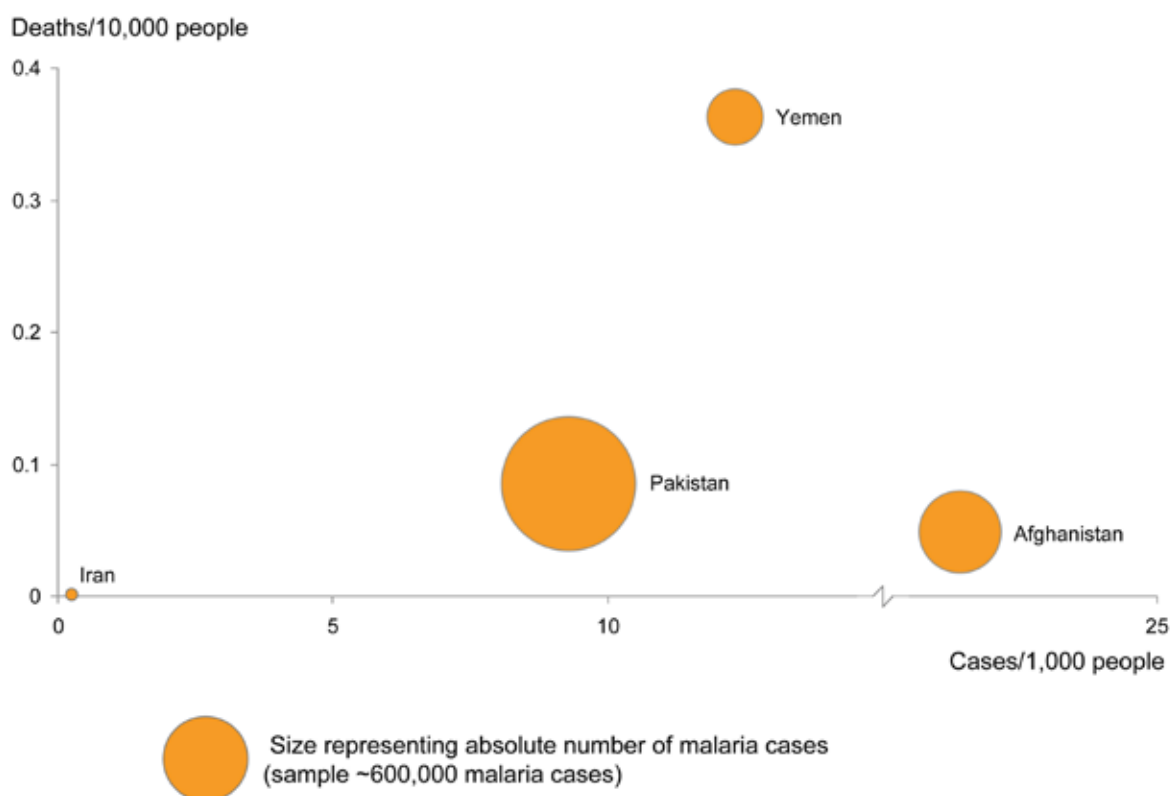
- Afghanistan, Pakistan and Yemen have a moderate to high malaria burden
- Iran, Iraq and Saudi Arabia have a low malaria burden limited to certain areas
- Azerbaijan, Georgia, Kyrgyzstan, Tajikistan, Turkey, Uzbekistan, and the Russian Federation have very limited malaria transmission in residual foci
- No locally acquired cases have been reported in Syrian Arab Republic since 2005 and in Armenia and Turkmenistan since 2006. Oman reported its last locally-transmitted cases in 2003, and was free from malaria until it experienced one outbreak in 2007 from imported cases.

P. vivax is the most prevalent species of malaria and occurs in all malarious countries. The prevalence of *P. falciparum* varies greatly among countries: it is dominant in Yemen (98% of cases) and Saudi Arabia (77%), common in Pakistan (30-40%) and still occurs in a low and decreasing share of cases in Iran, Afghanistan and the southern part of Tajikistan.

Malaria burden. The Middle East and Eurasia had approximately 13 million cases in 2002 and ~56,000 deaths in 2000, comprising less than 3% of worldwide cases and approximately 5% of worldwide deaths.⁷⁷ Among the 17 countries, 3 of them (Pakistan, Afghanistan and Yemen) account for more than 99% of regional deaths (Figure III.17).

⁷⁶ Where reported malaria case incidence is above 1 per 1000 population per year.

⁷⁷ Breman JG et al. Conquering Malaria. In: Jamison DT, Breman JG et al, eds. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006. p 415.

Figure III.17: Malaria cases and deaths in the Middle East and Eurasia

Note: Countries with negligible burden are not shown (Armenia, Azerbaijan, Kyrgyzstan, Uzbekistan, Georgia, Iraq, Turkmenistan, Russian Federation, Oman, Syrian Arab Republic, Tajikistan, Saudi Arabia, Turkey).

Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

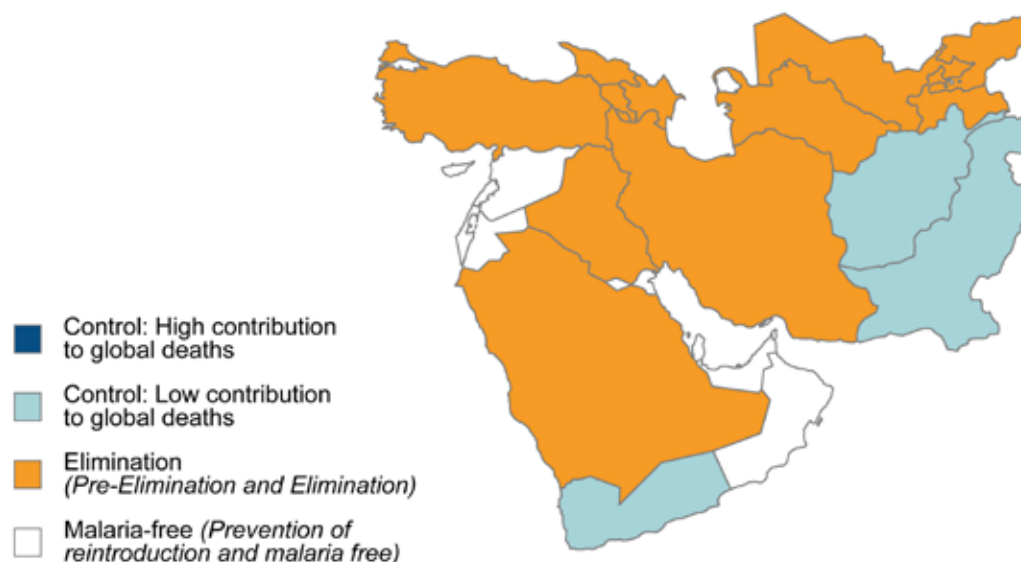
Adapted Approaches and Current Levels of Coverage

Afghanistan, Pakistan and Yemen are classified by WHO in the control stage. All three use LLINs as the main vector control intervention complemented with targeted IRS. IPTp is not recommended in these countries due to the low level of transmission.

Fourteen countries are in various stages of elimination: pre-elimination, elimination or the prevention of reintroduction. Seven are in pre-elimination (Azerbaijan, Iran, Tajikistan, Turkey, Uzbekistan, Georgia and Kyrgyzstan), and four are in elimination (Iraq, Saudi Arabia, Armenia and Turkmenistan). Oman, the Syrian Arab Republic and the Russian Federation are classified by WHO as in the prevention of reintroduction stage. In Oman and the Syrian Arab Republic, targeted IRS with pyrethroids is used as the main vector control intervention. LLINs are part of the national strategy in 8 countries.⁷⁸ The use of larvivorous fish - mostly in rice fields - is being promoted along with impregnated mosquito nets against outdoor-resting *Anopheles* species in most countries. All suspected cases are confirmed by microscopy, almost exclusively through public sector facilities. Treatment policies are in line with WHO recommendations. Figure III.18 presents the country categorization in the region.

⁷⁸ Armenia, Azerbaijan, Kyrgyzstan, Iran, Iraq, Saudi Arabia, Tajikistan and Uzbekistan.

Figure III.18: Country categorization in the Middle East and Eurasia



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

Locally adapted approaches to malaria control. Choosing the appropriate tools for implementation requires a deep understanding of local epidemiology, geography and socioeconomic conditions. This section provides a summary of the appropriate malaria interventions for the three countries in control.

*Control with *P. falciparum* transmission only.* Malaria in Yemen is caused primarily by *P. falciparum* transmission. Populations at risk need to be covered by either IRS or LLINs where appropriate. IPTp is currently not recommended. Case management includes timely diagnosis and timely and efficient treatment with ACTs.

Control with mixed transmission. Afghanistan and Pakistan have both *P. vivax* and *P. falciparum* transmission. LLINs or IRS should cover populations at risk where appropriate. The use of parasitological diagnosis to confirm parasite species is required by microscopy and where not possible, by RDTs. First-line treatment against *P. falciparum* is ACTs and against *P. vivax* is chloroquine and 14-days of primaquine. For mixed cases, ACTs and primaquine is recommended.

Current intervention coverage. The section below provides a summary of coverage with malaria interventions in the region.

LLINs / ITNs. LLINs are distributed free of charge in Pakistan and Yemen. In Yemen, all populations at risk are targeted while in Pakistan and Afghanistan, children under five and pregnant women are targeted. In these 3 countries, ~762 thousand LLINs / ITNs were in circulation in 2006. This represents a significant increase from previous years. In total, 1.2 million effective LLINs / ITNs were in circulation in the region in 2006.⁷⁹

⁷⁹ GMAP estimates based on data from WHO World Malaria Report 2008 and the Roll Back Malaria Commodity database, 2008. See Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.

IRS. Countries in the region are using IRS with pyrethroids as a complementary strategy to LLINs, but the scale of operations is very limited and quality of spraying is low. Pakistan is using IRS only for the containment of epidemics. An estimated ~2.9 million people in the three countries are covered by IRS, which represents ~29% of population at risk.⁸⁰ In all countries in the Middle East and Eurasia, 1.1 million households (or 5.6 million people) are covered by IRS in 2006.⁸¹

Diagnostics (Microscopy and RDTs). Even though parasitological diagnosis is essential in Afghanistan and Pakistan due to presence of both *P. falciparum* and *P. vivax*, the use of microscopy is weak and RDTs are not widely available. In Pakistan, Afghanistan and Yemen, ~5.8 million cases were examined by microscopy. Reported data suggests no use of RDTs. In the entire region, ~11 million cases were examined by microscopy.⁸²

Anti-malarial treatment. Treatment policies against *P. vivax* infections are chloroquine and primaquine in all countries except Afghanistan (where chloroquine only is being used). ACTs are first-line treatment against *P. falciparum* (in Afghanistan, only for confirmed cases due to the low proportion of *P. falciparum* cases). The presence of resistance to chloroquine and sulphadoxin-pyrimethamine from *P. falciparum* has led all countries with *P. falciparum* transmission to change their first-line treatment policies to ACTs. In Pakistan, Afghanistan and Yemen, approximately 512 thousand treatment courses were delivered in 2006. For the region, 1.7 million treatments were delivered in the same year.⁸³

Recommended Regional Approach to Control and Eliminate Malaria

Targets, approaches and priorities must be tailored to the region.

Targets. The target for 2010 is to reduce malaria mortality and morbidity by 50%, which means that the Middle East and Eurasia will have less than 6 million cases and 25,000 deaths. By 2015, the objective is to have less than 3 million cases and to reach near zero mortality for all preventable deaths.⁸⁴ Beyond 2015, the objective is to maintain near zero mortality for all preventable deaths.

As outlined in *Part II: The Global Strategy*, this will be achieved through universal coverage with appropriate malaria control interventions for all populations at risk in all countries in the control stage (Afghanistan, Pakistan and Yemen) and with elimination programs being conducted in all countries that are ready (all other 14 countries).

To reach universal coverage with appropriate interventions by 2010 in the region (see Figure III.19):

- ~15 million LLINs / ITNs are required in 2010;
- ~3.3 million households need to be sprayed with insecticides;
- ~2.4 million first-line treatments are needed; and
- ~96 million parasitological diagnoses are needed to confirm suspected malaria fever cases.

⁸⁰ Dr. Hoda Atta, WHO-EMRO, personal communication, September 2008.

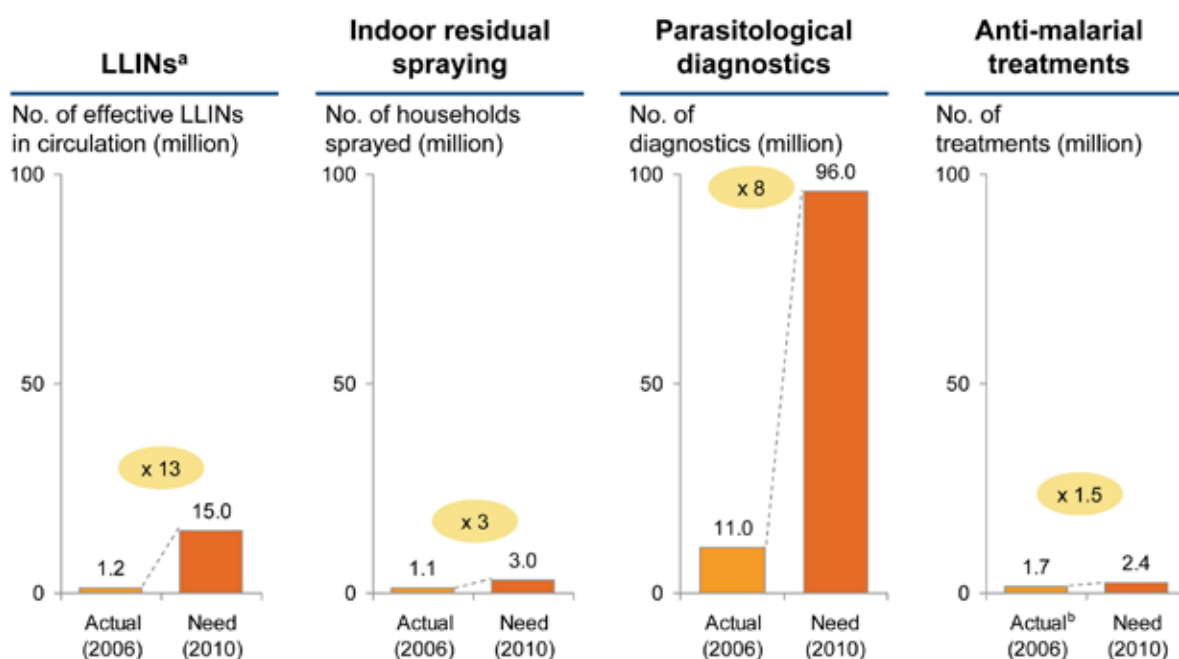
⁸¹ GMAP estimates based on data from WHO World Malaria Report 2008. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.*

⁸² GMAP estimates based on data from WHO World Malaria Report 2008. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.*

⁸³ GMAP estimates based on data from WHO World Malaria Report 2008 and the Roll Back Malaria Commodity database, 2008. See *Appendix 3. Assumptions behind Current Burden, Coverage and Funding Estimates.*

⁸⁴ Preventable death is defined as deaths from malaria that can be prevented with rapid treatment with effective medication. Non-preventable deaths represent an extremely low mortality rate for the most severe malaria cases and occur even with the best available and most rapid treatment.

Figure III.19: Scale-up in interventions from 2006 to 2010 in the Middle East and Eurasia



a) Because of 3-year life span, each year approximately 1/3 of the old nets will need to be replaced.

b) Actual use is likely not all directed to confirmed malaria cases today.

Source: Need based on GMAP costing model; actual based on analysis of World Malaria Report 2008. Geneva, World Health Organization, 2008 and Roll Back Malaria Commodities database.

Approaches to main challenges faced by countries in control stage. Challenges faced by Pakistan, Afghanistan and Yemen differ from those of elimination countries in the Middle-East and Eurasia. The main challenges are outlined below.

Improve quality of laboratory services for diagnosis. In Afghanistan and Pakistan parasitological diagnosis is essential to distinguish between cases of *P. vivax* and *P. falciparum*. However, coverage and quality of microscopy services need to be improved. Afghanistan launched a pilot project to increase the use of RDTs and plans to expand coverage with microscopy facilities as part of its health system strengthening program in its Global Fund Round 8 proposal.

Strengthen monitoring and evaluation systems. In Afghanistan, routine monitoring systems are weak. In Pakistan and Yemen, the quality of M&E systems needs to be improved. There is little standardization and often duplication in the information collected. Robust systems are needed to provide reliable data to the national control program. The number of M&E specialists needs to be increased. M&E specialists need better pay, more training and special career paths and incentives to keep them in the job.

Strengthen leadership and management skills at all levels. Several countries have decentralized national malaria control programs to regional or local levels. However, at the sub-national level, there is little capacity to manage the human and financial resources. Increased training for planning and for program management at the regional and local levels is needed.

Increase compliance in the private sector. In several countries, most anti-malarial drugs are provided through the private sector (e.g. 80% in Pakistan).⁸⁵ Private sector providers often do not comply with the national policies. Quality monitoring systems of anti-malaria interventions (especially drugs) need to be in place.

Continue control during political turmoil. Wars and political turmoil especially in Afghanistan are impacting anti-malarial programs negatively. Indoor-residual spraying activities have been interrupted in Afghanistan as a result of the ongoing conflict. Innovative approaches need to be in place to maintain the activities of the malaria control program where security is a concern, as was done in Iraq with the stock-piling of key malaria interventions ahead of time.

Approaches to main challenges faced by countries in elimination. Countries in elimination in the Middle East and Eurasia face a unique set of challenges.

Preventing large scale epidemics. Recently, large-scale outbreaks of *P. vivax* malaria have occurred in transcaucasian and Central Asian countries. These countries are situated in epidemic-prone areas where malaria transmission could resume, following a weakening or discontinuation of malaria control measures. Processes to detect epidemics and rapid response mechanisms need to be strengthened.

Migrant populations and cross-border coordination. The number of imported malaria cases is on the rise, due to an increase in labor mobility in neighboring countries and displaced populations. Countries such as Turkmenistan, Kyrgyzstan and Uzbekistan are especially at risk from immigration and vector migration from neighboring Tajikistan and Afghanistan. Surveillance at border areas and cross-country collaboration efforts are essential to prevent resurgence in malaria transmission.

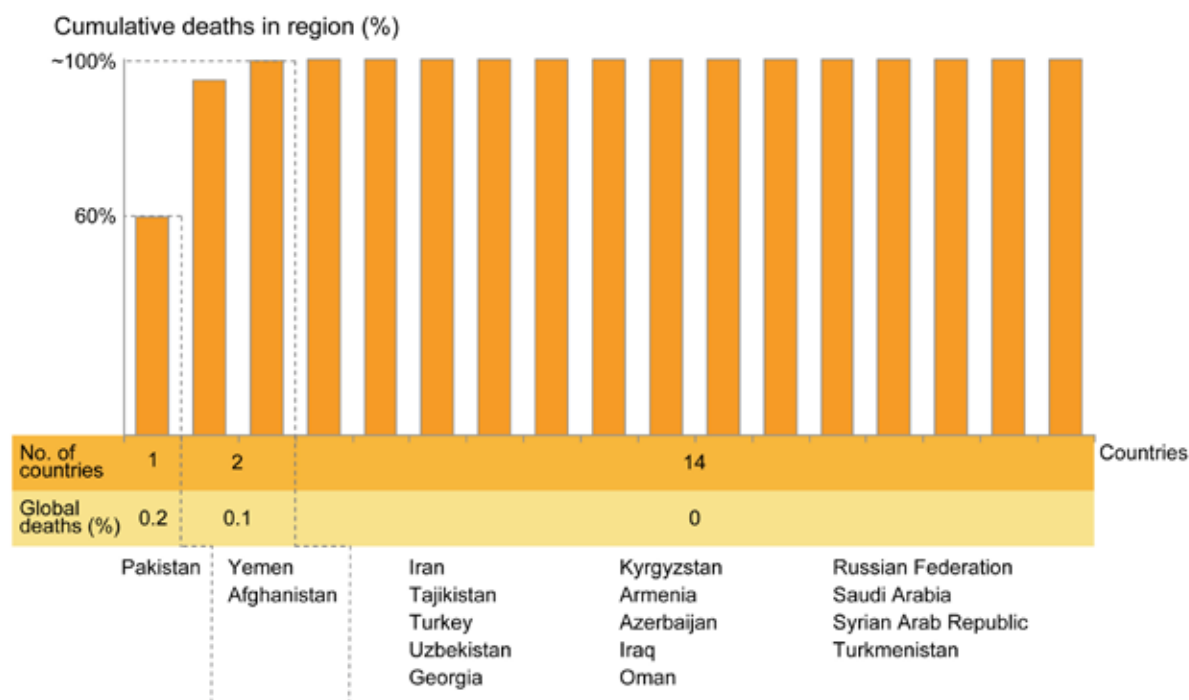
Adapting to changing agricultural behaviors. The often uncontrolled extension of agriculturally-used land (e.g. rice fields) towards population centers brings populations closer to potential malaria breeding sites and can lead to increased malaria transmission. Surveillance and increased use of interventions (such as targeted vector control measures) is key to success.

Sustain political and financial commitment. In countries with very low levels of burden, political commitment and national financial support can decline if malaria is not perceived as a public health priority. It is essential that high level support from political leaders is maintained through continuous advocacy efforts that clearly outline the risks of reemergence.

Strategic priorities. Success in malaria control and elimination is essential in all countries. However, some countries are especially important to achieving the RBM targets. (See Figure III.20.)

⁸⁵ Dr. Hoda Atta, WHO-EMRO, personal communication, September 2008.

Figure III.20: Distribution of malaria deaths in the Middle East and Eurasia



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

Priorities to reach the 2010 targets. None of the 35 countries that account for 98% of estimated malaria deaths worldwide are located in the Middle East and Eurasia. However, within the region, the burden is highly concentrated: almost 100% of deaths and 97% of cases are concentrated three countries - Pakistan, Yemen and Afghanistan (See Figure III.20). Therefore, to successfully meet the targets within the region, these countries should receive focused attention and tailored assistance from partners.

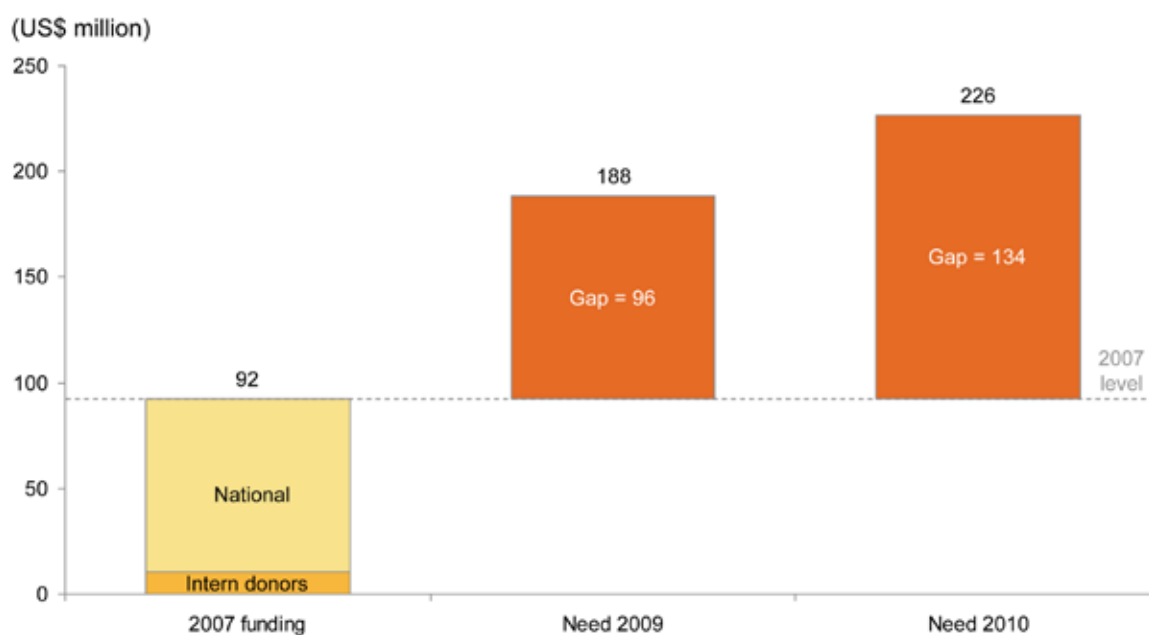
Priorities beyond 2010. When the countries in the control stage have reached universal coverage, they need to be encouraged in sustaining universal coverage to avoid a resurgence of malaria and an upsurge in malaria mortality and morbidity until the move to elimination is possible. Countries in the elimination stage are encouraged to continue their efforts to bring local transmission down to zero and when this is achieved, to move to the prevention of reintroduction stage.

International support required. International support for the control countries is important both to reduce the burden in these countries, but also to ensure that malaria is not reintroduced into the 14 countries currently on the path to elimination or preventing reintroduction. The RBM Partnership does not currently have a Sub-Regional Network (SRN) in this region. Given the lower overall burden in the region, a small SRN focused on coordinating partners and countries could be valuable to ensure regional cooperation. Technical assistance and country capacity building are probably better provided directly by countries or partners in the region than by the RBM Partnership.

Funding Requirements: US\$ 134 million gap for 2010

Estimates show that a large proportion of disbursements against malaria in the region come from national spending. Among the US\$ 92 million disbursed in 2007, 89% came from national health budgets, the rest from international donors. (See Figure III.21) Resource-rich countries such as Iraq or Saudi Arabia fund their national anti-malarial programs to a large extent. So far, grants from the Global Fund have been awarded to 9 countries in Rounds 2 to 7, for a total amount of US\$ 76 million, the three largest recipients being Yemen (US\$20 million), Pakistan (US\$ 18 million) and Afghanistan (US\$ 15 million).⁸⁶ Other major donors include USAID, which funded a project from 2003 to 2006 in Tajikistan, Kyrgyzstan and Uzbekistan.

Figure III.21: Gap in malaria funding in the Middle East and Eurasia



Source: GMAP costing model, WHO, the Global Fund, the World Bank and the President’s Malaria Initiative (PMI).

The Middle East and Eurasia lack US\$ 134 million based on 2007 spend to fully implement its control and elimination programs in 2010. Most of these costs are for the control countries: Pakistan, Yemen and Afghanistan. (See Table III.5) Unlike other regions, the Middle East and Eurasia will experience a significant drop in resources needed as many countries in the region eliminate malaria and limit their malaria spending to prevention of reintroduction activities.

⁸⁶ These are malaria-only grants from the Global Fund against AIDS, Tuberculosis and Malaria. An additional “integrated” grant of ~US \$3 million was awarded to Afghanistan to build the country capacity against all three diseases (AIDS, Tuberculosis, and Malaria).

Table III.5: Summary of annual costs in the Middle East and Eurasia

Cost category (US\$ millions)	2009	2010	2015	2020	2025
LLINs/ITNs	50	50	36	29	0
IRS	25	35	48	25	65
IPTp	0	0	0	0	0
<i>Prevention cost</i>	<i>75</i>	<i>85</i>	<i>84</i>	<i>54</i>	<i>65</i>
RDTs	54	68	18	0	0
ACTs	1	1	0	0	0
Chloroquine and primaquine	0	0	0	0	0
Severe case management	0	0	0	0	0
<i>Case management cost</i>	<i>55</i>	<i>70</i>	<i>18</i>	<i>0</i>	<i>0</i>
Community health workers	5	5	5	4	1
Training	8	6	4	3	1
M&E and OR	21	22	23	21	13
Infrastructure / inst. strengthening	23	38	24	18	6
<i>Program cost</i>	<i>58</i>	<i>71</i>	<i>55</i>	<i>46</i>	<i>21</i>
Total control & elimination cost	188	226	157	101	86

Note: Diagnostic costs are covered both by RDTs in case management and by microscopy in infrastructure / institutional strengthening.

Source: GMAP costing model; Johns B. and Kiszewski A. et al.

“ 35 countries (30 in Sub-Saharan Africa and 5 in Asia-Pacific) account for 98 percent of global malaria deaths. These countries need rapid international support. ”

Since the Roll Back Malaria (RBM) Partnership's founding, coordinated action by RBM partners has significantly increased access to malaria prevention and treatment services and commodities, causing malaria cases to drop by more than 50 percent in countries in which prevention and treatment strategies have been rolled out on a large scale.



PART IV The Role of the RBM Partnership

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1. Introduction to the Role of the RBM Partnership

Part II: The Global Strategy and *Part III: Regional Strategies* describe what the international community and individual countries can do to ensure that countries scale-up control, sustain control and ultimately eliminate malaria.

The purpose of *Part IV: The Role of the RBM Partnership* is to describe what the RBM Partnership, particularly through its core mechanisms of the Secretariat, Working Groups and Sub-Regional Networks, can do to support countries directly. Given the number of partners operating in malaria, the GMAP would quickly become overwhelming if it tried to outline each partner's role in the Global Strategy. Instead, this part of the plan focuses on the RBM structure that will bring together partners working around a specific topic to ensure the work gets done. In particular, this part of the plan:

- Highlights the role that the RBM Partnership can play in coordinating partner activities for the topics outlined in Table IV.1
- Provides a deeper exploration of topic areas where coordinated action is critical to achieve the RBM targets for 2010, 2015 and beyond.

The Role of the RBM Partnership

Today, Working Groups act as the primary coordinators of global RBM partner activities for many of the topic areas. However, as outlined below in Table IV.1, there are several important areas - Resource Mobilization, Communication and Behavior Change Methodologies, and Humanitarian Crises - where the coordinator is not currently agreed upon. In Policy and Regulatory, the role of the RBM Partnership could further be clarified.

Table IV.1: Areas of partnership coordination

Topic	Partnership Coordinator
Advocacy	Malaria Advocacy Working Group (MAWG)
Resource Mobilization	<i>Proposed: Resource Mobilization Task Force</i>
Policy and Regulatory	Various WHO bodies
Planning	Harmonization Working Group (HWG)
Financing	Resources Working Group (RWG)
Procurement and Supply Management	Procurement & Supply Management Working Group (PSM)
Communication and Behavior Change Methodologies	<i>Proposed: Communication Working Group</i>
Monitoring and Evaluation	Monitoring and Evaluation Reference Group (MERG)
Humanitarian Crises	<i>Proposed: Formal liaison</i>

In addition to the Partnership Coordinators listed above, there are three other important groups to mention.

RBM Working Groups focused on delivery. The Scalable Vector Control Working Group (WIN) and the Malaria in Pregnancy Working Group (MIP) both play an essential role in identifying effective approaches to delivery of vector control and MIP interventions. Because *Part II - Chapter 2: Control: Overcoming Malaria* focused heavily on delivery of interventions, separate chapters have not been included on those topics here. However, the role of both Working Groups is critical to defining and testing approaches to scale-up interventions, advocating for increased research and better policies around these topics, and generally providing a focal point for these activities within the RBM Partnership. Of all the interventions, case management interventions are the only ones that currently do not have an associated RBM Working Group. Currently WHO - Global Malaria Program operates as a Working Group in convening partners around case management issues.

Research Groups. The recommendations in *Part II - Chapter 4: The Malaria Research Agenda* suggest the creation of a focal point or other interface for groups involved with R&D for new tools, research to inform policy, and operational and implementation research. Where groups already exist, the focus will be on increased involvement and collaboration with the RBM Partnership. Where groups do not exist or where they do exist but meet or collaborate infrequently, the focus will be on bringing together key stakeholders to begin a dialogue on global research priorities, while liaising with the RBM Partnership.

Sub-Regional Networks (SRNs). At the country level, Sub-Regional Networks provide support to regions in coordinating local partners' activities. Currently, the RBM Partnership has 4 SRNs based in Africa but no SRN elsewhere in the world. In *Part III: Regional Strategies*, it was recommended that an SRN be established in Asia-Pacific and a focal point created for the Americas to link these regions more closely with Africa and RBM partners.

A Deeper Exploration of Topic Areas

In *Part II: The Global Strategy* and *Part III: Regional Strategies*, nine key topic areas were identified as critical to achieving the 2010 and 2015 targets. These nine topics are listed below.

- Advocacy
- Resource Mobilization
- Policy and Regulatory
- In-country planning
- Financing
- Procurement and Supply Chain Management
- Communication and Behavior Change Methodologies
- Monitoring and Evaluation
- Humanitarian Crises

Three of these topics, Advocacy, Resource Mobilization, and Policy and Regulatory, primarily take place among global actors at the international level, although they have implications for in-country action. Progress in these three areas lays the ground work for activities to take place within countries. The six other topics – Planning, Financing, Procurement and Supply Chain Management, Communication and Behavior Change Methodologies, Monitoring and Evaluation, and Humanitarian Crises – are focused more directly on supporting countries to more efficiently carry out the strategy at country level.

In this part of the report, each of the nine topics has its own chapter which includes a short introduction, an overview of the most urgent challenges and the priorities of the RBM Partnership to support the 2010 and 2015 targets. In addition, the cost and organizational implications are discussed. Finally, a table gives an overview of the key activities. The chapters are intended to be a high-level outline of priorities and responsibilities. They will serve as the basis for the RBM Partnership's detailed Harmonized Workplans in years to come.



2. Advocacy

Advocacy is an important tool for the RBM Partnership to promote the key messages with partners, countries and donors, to drive implementation of the Partnership's strategy and to foster collaboration (and harmonization) among partners. The main coordinators for the RBM Partnership are the RBM Secretariat and the Malaria Advocacy Working Group (MAWG).

Advocacy is defined as strategic communication that aims to create the social pressure and political accountability required for attracting resources, shaping policy agendas and removing socio-cultural barriers in both donor and endemic countries, and thus primarily attempts to affect the behavior of decision-makers and politicians¹ for stakeholders at every level of society. Advocacy can set the ground work for related activities like resource mobilization and in-country behavior change communication but requires a different skill set and focuses on a different audience from these activities. This section focuses exclusively on strategic advocacy and shaping policy agendas at the international, regional, national and local governmental level. For this reason, resource mobilization and communication and behavior change methodologies are presented in separate chapters of this plan.

Box IV.1: Advocacy successes over the years

Through the dedicated efforts of RBM partners, malaria advocacy has achieved a number of significant victories in recent years. Though not comprehensive, the examples below highlight what the RBM Partnership can achieve through coordinated efforts.

- **Nov. 1998** – RBM is founded to mobilize action and resources against malaria
- **April 2000** – African heads of states pledge to halve malaria mortality in Africa by 2010
- **Sept. 2000** – The MDGs, agreed by every UN member state, articulate the goal of halting and reversing malaria incidence by 2015
- **Jan. 2002** – The Global Fund - the world's largest donor for disease and poverty is founded. Its mandate includes providing funding for malaria, HIV and tuberculosis
- **June 2005** – The World Bank Booster Program for Malaria Control in Africa is launched. Funding for 2005 to 2008 increases nine-fold from the \$50 million committed by the World Bank from 2000 to 2005
- **June 2005** – The President's Malaria Initiative (PMI) is launched, pledging to increase US funding by more than 1.2 billion over 5 years
- **Nov. 2005** – Yaoundé Declaration - commitment by Partnership to work towards harmonized planning, monitoring and coordination at country level
- **Nov. 2005** – The Gates Foundation pledges \$258.3 million for research and development
- **June 2007** – The G8 pledges \$60 billion to strengthen health systems in Africa and advance the MDGs related to HIV, tuberculosis and malaria
- **April 2008** – UN Secretary General calls for universal coverage by the end of 2010
- **Summer 2008** – The Global Fund opens another round of funding (Round 9) to increase funds available to countries for the 2010 targets

¹ A Global Advocacy Framework to Roll Back Malaria 2006-2015. Geneva, Roll Back Malaria, 2006.

Key Challenges

There are many challenges for the RBM Partnership related to malaria advocacy.

Avoid drop in awareness of and support for malaria. With competing global health and development priorities, malaria must retain a prominent position on the international agenda in order to receive ongoing support. Connecting the benefits of supporting malaria to broader development agendas (e.g. eliminating poverty, strengthening health systems) and demonstrating how malaria will contribute to the Millennium Development Goals will strengthen the overall support for malaria in its own right. This is required at all levels: internationally, regionally, nationally and locally.

Limited information base for advocacy messages. Advocacy based on accurate and timely information is needed to ensure that decision-makers who control the allocation of resources understand the benefits of supporting malaria. They need to receive the appropriate feedback encouraging them to continue to invest in the fight against malaria. Currently, few data are collected either from countries or from partners that are used strategically to strengthen advocacy messages.

Research needs not fully supported. Advocacy for research is required to emphasize the importance of ongoing support to provide new tools and products for the fight against malaria. Advocacy activities also need to ensure that R&D and operational research needs are being adopted by the research community and that there is a vibrant malaria research community ensuring scientific breakthroughs and innovation in malaria research. Furthermore, during the development of new tools/products, advocacy is needed to support the introduction and acceptance of these at both the international and country-level.

Collaboration and coordination among RBM partners. Collaboration and coordination among all RBM partners is important to successfully fight malaria and to achieve consensus around strategy, decisions, resource allocation and implementation approach. For 2010, it will be particularly important to continually reinforce the RBM approach to ensure that partner efforts are coordinated and to support the ongoing harmonization activities.

Commitment to scaling up globally. Achieving the RBM 2010 targets will require significant advocacy at both the international and country-level to drive the rapid scale-up forward. In particular, advocacy is needed to ensure the following:

- Awareness of WHO policies and guidelines for scaling up
- Progress and best practices sharing between countries and partners
- Clear understanding of the strategies involved in scaling up and sustaining control
- Effective monitoring of implementation and feedback of results by countries

Policies to support scaling up within countries. There is the need for countries to introduce policies in a number of areas, such as malaria in pregnancy, home management of malaria and epidemic-preparedness. These policies need to be technically sound and feasible, as well as communicated at the policy level, the health provider level and the community level. Therefore, it will be important to advocate for both policies as well as the communication of policies. This includes reaching out to policy makers and stakeholders within countries.

Commitment to sustained control globally. There will have to be strong advocacy and conversations to frame not only the 2010 target for scale-up, but also the 2015 targets and beyond, including the importance of sustained control and elimination and eradication as a long-term goal. For example, one key message is that it will be critical to keep malaria interventions in place to prevent resurgence and epidemics in areas of naturally high transmission. These advocacy activities need to start today to set expectations and generate long term commitment.

Priorities

Malaria advocacy priorities include general priorities for advocacy as well as priorities targeted towards scaling up control, sustaining control and elimination.

General strategy. A general advocacy strategy is needed to maintain awareness and support from both countries and international organizations. Below are some of the key elements in the strategy.

A) Develop strategies for stakeholders at all levels. Malaria stakeholders exist at every level of society. The RBM Partnership and MAWG advocacy efforts will engage decision- or policymakers at international, regional, national and local levels by working closely with partners that have working relationships with these stakeholders. For example, the RBM Partnership can target political forums where international and regional stakeholders might congregate (e.g. G8, World Economic Forum, African Union, Association of Southeast Asian Nations, Southern African Development Community). Overall, the target audiences for malaria advocacy are:

- International stakeholders: companies involved in malaria research or donating funds, multilaterals, funding bodies, international NGOs and international opinion leaders in malaria (e.g. senior research academics)
- Regional stakeholders: regional bodies like the African Union or the European Union
- National stakeholders: presidents, ministers of finance and parliamentarians in both malaria-endemic countries and donor countries
- Local stakeholders to create social pressure on national leaders: local communities, local officials, local opinion leaders in malaria (e.g. academics and experts within malaria-endemic countries)

B) Develop information-based messages. MAWG and Secretariat will communicate performance results to drive continued interest in global progress towards targets. Success stories from the fight against malaria will be shared with donors to emphasize the social return of their investments. Furthermore, the RBM Partnership will promote international collection of baseline data on burden, coverage and funding. This will promote international awareness of the needs and funding gaps as well as the potential impact on cases prevented and lives saved. Additionally it will publish impact analysis of current and projected malaria efforts to emphasize the return on investment. MAWG will work with different Working Groups and partners to identify potential data that they each collect that could be used in advocacy and agree on how to collect the information regularly.

C) Foster collaboration and coordination among RBM partners. To foster collaboration and coordination, the RBM Secretariat will ensure the systematic flow of communication among partners.

- *Inform partners of ongoing activities.* Ensure that all partners are aware of the ongoing activities within the malaria community and the RBM Partnership.
- *Develop tools to share data within the RBM Partnership.* The RBM Secretariat will enhance the use of existing tools and develop new tools to disseminate information among the community. This could include redesigning the website to encourage partners to share data and populate content and making it a more effective tool for outreach, sharing tools, documents and presentations among RBM partners. It could also incorporate new tools such as online discussion forums, newsletters and web-chats.
- *Maximize use of opportunities within the RBM Partnership.* With systematic communication and the fostering of networks and the exchange of information, RBM will be able to benefit from the opportunities (e.g. financial savings or larger impact within countries from implementation activities) that may arise from collaborations among partners and reducing duplication of effort. To maximize the opportunities around advocacy, the RBM Secretariat and MAWG will consider the idea of having a training program for 'Advocacy skills' within the RBM Partnership to create more coordination around the advocacy activities and messages.

- *Share best practice examples.* It will be important to promote the sharing of best practices between countries, e.g. on planning, implementation, BCC, advocacy, PSM and M&E activities. These best practice examples will be developed together with working groups, regional networks and other experts and made available on the RBM website or in written publications so that all RBM partners can access them. Similarly, the Secretariat will ensure the flow of feedback on implementation progress to partners at all levels.

D) Ensure research needs are adopted by the academic/scientific community. MAWG will work with the research community to advocate for research around topics where there is a strong need. Furthermore, to integrate R&D further into the malaria advocacy platform, the RBM Secretariat will share R&D results and progress within the RBM Partnership, building upon the existing newsletter that lists recent malaria publications. There will be a clear communication of developments of new tools, explaining how they can be implemented and used and what impact or outcome they will have.

MAWG and RBM Secretariat will work with RBM research partners to strongly promote malaria among the research community in order to ensure that new scientists enter the field of malaria research, as well as advocate for strengthening research capabilities within endemic countries and establishing attractive research opportunities to scientists from malaria-endemic countries.

Priorities for scaling up. To meet the 2010 targets, the RBM Partnership advocacy priorities and activities are as follows.

E) Advocate for dedicated and rapid commitment to scaling up globally. To support scale-up, it will be important to continually reinforce and promote the strategy reflected within this plan. At the highest level it will be important to convey the overall approach of the RBM Partnership to achieve the targets, including RBM's aims to achieve the target of universal coverage with preventive and curative interventions for populations at risk from malaria.

This will include advocacy for the country-level activities required for scale-up for impact. One example is the need to conduct rigorous annual planning and identify gaps with the needs assessment process. Another example is the need for an increase in human resources with training and career opportunities (incentives and clear career paths), including in the area of PSM, M&E, vector control and public health entomology.

Besides advocating for the overall approach, it will also be necessary to advocate for the supporting activities that will be required by both international partners and malaria-endemic countries. For this, the specific groups need to work together with the MAWG to feed the technical information required. MAWG can then help with the advocacy strategy, for example, regarding messaging and the appropriate audience to target. Based on the global activities outlined in this plan there will be a need for advocacy surrounding:

- In-Country Planning
- Policy and Regulatory
- Financing
- Procurement and Supply Chain Management
- Communication and Behavior Change Methodologies
- Monitoring and Evaluation
- Humanitarian Crisis

Priorities for sustained control and elimination. The activities listed below have particular relevance in the medium-term future, when most countries are expected to be in sustained control or considering elimination rather than scaling up control efforts for existing commodities. However, advocacy activities by nature have to be continuously adapted to the environment and political situation. Therefore, only a high-level outline is given in the GMAP.

F) Advocate for ongoing commitment to sustained control and elimination globally. It is important to focus the key messages around two main target audiences. For the international community and donors, present why continued funding, investments and support are required throughout sustained control. For malaria-endemic country partners, emphasize the need to maintain interventions and support their in-country communication and behavior change activities around continued use of preventive interventions. Furthermore, adopt advocacy messages that promote the ongoing strengthening of in-country systems.

G) Communicate connection with other diseases and development goals. To promote sustainability beyond scaling up, MAWG will work to link the benefits of investments in malaria to improved outcomes for other diseases and development goals. In particular, MAWG will look for opportunities to partner with advocacy groups working outside malaria to co-develop messages and strategies.

Organizational Implications

As outlined above there are many advocacy needs to support the RBM Partnership approach for 2010 and 2015, which will require mobilizing the available advocacy mechanisms as well as sufficient financial support.

Organizational support. All mechanisms within the RBM Partnership have a role to play in advocacy activities, i.e. the Board members, the Executive Committee, the Executive Director, Partners, the RBM Partnership Secretariat, RBM Ambassadors, Working Groups and Sub-Regional Networks.

- Communication and advocacy is a key role of the RBM Partnership Secretariat as outlined in the RBM Global Strategic Plan 2005-2015,² with a focus on creating alignment within the RBM Partnership around global messages, maximizing opportunities within the RBM Partnership for advocacy and providing a Global Advocacy Framework for the RBM Partnership. The Executive Director is an important representative of the RBM Partnership and a high-level advocate to promote awareness for malaria.
- In addition, many individual partner organizations work on malaria advocacy (e.g. VOICES, Global Health Council, European Alliance Against Malaria, Malaria No More, Malaria Consortium, Coalition Against Malaria, Africa Fighting Malaria, Friends of the Global Fund, Asian Collaborative Training Network for Malaria) for their own organizations as well as for the RBM Partnership.
- Integrating and coordinating the ongoing advocacy activities of the partners is facilitated by the RBM Malaria Advocacy working group (MAWG). MAWG operates at global, regional and national levels as well as within specific sectors and has a defined set of global priorities to guide partner advocacy activities. MAWG may also assist other Working Groups in defining their key messages and advocacy strategies based on technical input.

Recommendations. Coordinating and fulfilling all advocacy needs within the RBM Partnership is not possible with existing levels of financial and human resources. There needs to be a clear definition of roles and responsibilities of all RBM advocacy mechanisms within the RBM Partnership to focus on maximizing the advocacy opportunities. Furthermore, a large proportion of MAWG advocacy work is done by partners 'in kind' and additional financial resources are required for MAWG to be able to commit to more activities.

² *Global Strategic Plan 2005-2015.* Geneva, Roll Back Malaria, 2005.

Table IV.2: Summary of Advocacy Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
C	Devise communication strategy and tools within the RBM partnership to foster collaboration, coordination and the exchange of information and best practices among partners	Ongoing	RBM Secretariat
D	Research: Advocate to the research community to ensure the malaria research agenda is adopted by the academic / scientific community	Ongoing	MAWG , Research and Academia
C, D	Integrate R&D activities, results and progress more closely within the RBM partnership, e.g. by enhancing the RBM partnership newsletter	Ongoing	RBM Secretariat
A, B, F, G, H	Develop advocacy strategy to encourage adoption of key messages from the Global Malaria Action Plan at the international, regional and national level	2009	MAWG , RBM Secretariat
A, B, F	SUFI: Advocate to both international bodies and countries the specific efforts and activities required to support scaling up globally and achieve targets	2010	MAWG , RBM Secretariat
A, B, G, H	Sustained control: Devise a comprehensive advocacy strategy aimed at emphasizing the importance of maintaining support (e.g. financial, TA, etc) for sustained control efforts at international, regional and national levels	2015	MAWG

a) Main coordinating group / body in the RBM partnership indicated in bold. Closely linked contributors within the RBM partnership are also listed. RBM partners are not listed explicitly as their involvement occurs through the Working Group.

“ *The Global Malaria Action Plan makes a strong case for investing in malaria. I urge advocates in countries and at global level to use this plan to mobilize resources for malaria control and help answer the UN Secretary General’s call for universal access to malaria prevention and treatment.* ”

Ray Chambers, UN Special Envoy for Malaria



3. Resource Mobilization

Since 2003, the financial resources disbursed by major international donors for global implementation activities have increased by about 14-fold, from US\$ 51 million in 2003 to US\$ 701 million in 2007, and above US\$ 1.1 billion in 2008.³ Funded activities included global interventions, national monitoring and evaluation and health system strengthening. Financial support for the core Partnership bodies (Secretariat, Working Groups and Sub-Regional Networks) has also increased. Despite this success, a significant increase in financial support and sustained commitment will be required to reach the 2010 and 2015 targets, and the RBM Partnership's longer term vision for eradication.

A strong resource mobilization strategy will ensure that these required financial resources are raised and that global implementation activities go forward. Such a strategy would outline the needs, responsibilities and messages of the RBM Partnership and also define the support required to develop, implement and monitor the resource mobilization activities. Currently, there is no coordinating body for resource mobilization within the RBM Partnership.

Key Challenges

There are many challenges for the RBM Partnership to overcome in resource mobilization.

Resources for global implementation activities. To achieve the 2010 universal coverage targets for all countries, approximately US\$ 5.3 billion in 2009 and US\$ 6.2 billion in 2010 will be required. Furthermore, to reach the 2015 targets, an average of US\$5.1 billion will be needed annually between 2011-2020; significant amounts may need to be sustained beyond 2015 to ensure that the burden of malaria does not re-emerge.

Resources for core Partnership activities. The RBM Partnership bodies must be funded to support implementation in countries. The 2008 Harmonized Work Plan estimates that US\$ 32.8 million per year is needed to fund the RBM Secretariat, Sub-Regional Networks and Working Groups.

Coordination of resource mobilization activities. Raising the resources outlined above will require significant coordination. Although many groups are active in resource mobilization, there is no formal body tasked to ensure the coordination of all activities and a focus on the highest priority areas.

Reporting system. The RBM Partnership must strengthen its international reporting system to obtain the investments necessary to meet the 2010 and 2015 targets. A reporting system will enable more accurate interpretation of investment returns, predictions of long-term aid flow, and measurement of performance against fixed performance indicators.

Priorities

The recommended resource mobilization priorities are to:

- Audit the resource need
- Identify target donors
- Outline the approach for each donor
- Develop targeted messages for advocacy
- Track performance of funds and provide accountability

A) *Audit the resource need.* An audit involves an overview of financial needs and a strategy for filling funding gaps one to two years in advance of when the funds are required. The audit should have a five-year horizon to allow longer-term planning and sustainability. It should also define the channels through which the resources are intended to flow, for example, the RBM Partnership, the Global Fund to fight AIDS, Tuberculosis and Malaria, the President's Malaria Initiative, the World Bank or Malaria No More.

³ See Part I - Chapter 4: Funding for Malaria Today.

B) Identify target donors. The strategy should include an overview of all existing and potential donors, along with a review of past donor activities and areas of interest. For sector-wide activities, it will be important to ensure that funding from existing international donors is maintained, but also that new donors are addressed. For example, the sustained control stage may attract different donors than the rapid scale-up for impact (SUFI) stage. The resource mobilization strategy will also involve targeting the countries which require funds to scale-up or to sustain control. These countries should be encouraged to allocate part of their national budget to malaria control, commensurate with the burden and impact of the disease, and ensure that overall spending on health care is 15% of their national budgets.

C) Outline approach for each donor. The funding gaps should be matched to individual donors, based on the knowledge about the donor. The strategy should also outline how best to approach donors and which body from within the RBM Partnership, such as board members or executive directors, should do so.

D) Develop targeted messages for advocacy. Consistent, accurate messages regarding resources and funding must be communicated within the RBM Partnership. These messages will have to be targeted for specific donors and for clearly articulated resource needs. The Malaria Advocacy Working Group will develop general advocacy messages, such as promoting adherence to the RBM Partnership strategy.

E) Performance tracking of funds. To ensure accountability and a sustained interest, it will be important to track the use of funds, monitor the performance and establish clear reporting mechanisms both within the RBM Partnership and to donors within and outside the RBM Partnership. A good tracking mechanism will enable a detailed prioritization of spending of available funds for Partnership activities.

F) Coordination and collaboration within the RBM Partnership. Tracking the funds will require interactions and collaboration between the performance sub-committee and the Monitoring and Evaluation Reference Group (MERG). Furthermore, a close link with Malaria Advocacy Working Group (MAWG) is essential to develop and implement the advocacy for resource mobilization. Beyond support on different activities within the resource mobilization strategy, there will be ties with all core Partnership structures (Secretariat, Working Groups and Sub-Regional Networks) to ensure that financial needs are captured in the overview and to feed back the results of performance monitoring.

Organizational Implications

Currently a number of bodies within the RBM Partnership provide support to resource mobilization.

- The RBM Board has resource mobilization as a mandate, and also directly contributes financial resources.
- The RBM Partnership Secretariat, especially the Executive Director and the RBM Ambassadors,⁴ may advocate for increased resources and to ensure malaria remains high on the international agenda. Furthermore, the Secretariat coordinates the budget needs for RBM Partnership bodies' costs.
- The Resources Working Group focuses on providing guidance around effective financing such as AMFm, tracking of funds within countries such as malaria sub-accounts, and the economics of malaria control.⁵
- The Malaria Advocacy Working Group is strongly engaged in advocacy for resource mobilization and has a “\$1.5 billion+” task force which focuses on advocacy to a defined set of new donors to raise funds for SUFI.
- Individual partners play a strong role in raising funds for their organizations, which cover sector-wide malaria activities. This function remains important, and should be reflected in a coordinated RBM Partnership resource mobilization strategy.

⁴ The Roll Back Malaria Ambassadors are well-known individuals who agree to advocate for the fight against malaria. Currently RBM has two ambassadors who attend events around the world to increase the visibility of malaria.

⁵ *Terms of Reference for the Resources Working Group*, Geneva, Roll Back Malaria Partnership. Also see RBM webpage on http://www.rbm.who.int/partnership/wg/wg_finance/docs/tor_RWG.pdf.

Due to the urgency and importance of securing resources to achieve the targets, there must be dedicated institutional support for resource mobilization. In-kind support from the partners, though generous, needs to be augmented by dedicated personnel with the capacity to carry-out the day-to-day tasks. This support could be situated within the RBM Partnership Secretariat or within a Partner organization and have the role of providing coordination support to a taskforce / working group, ensuring close links with other Working Groups, such as the performance sub-committee, MERG and the MAWG, and coordinating activities between RBM partner institutions involved in resource mobilization. Developing a strong resource mobilization strategy for the RBM Partnership must be a Partnership priority, and the institutional support needed to facilitate and coordinate these activities should be identified and put in place immediately.

Additionally, the RBM Partnership would gain a strong core team if the resource mobilization staff was supported by a group convened to coordinate the resource mobilization activities. The RBM Partnership recommends establishing a formal body with the institutional mandate of developing and coordinating the resource mobilization strategy within the RBM Partnership. This body could assist with immediate fund-raising activities and later be disbanded or made permanent as needed.

This formal body could be in the form of a taskforce or working group and would coordinate resource mobilization for both the core Partnership activities as well as sector-wide activities. The body could be appointed by the RBM Partnership Board and report to the Executive Committee. Members for the body could be drawn from donors (e.g. President's Malaria Initiative, the Bill and Melinda Gates Foundation) and other groups with a strong mandate for resource mobilization (e.g. the UN Special Envoy for Malaria, the Global Fund to fight AIDS, Tuberculosis and Malaria), as well as the RBM Partnership Secretariat.

Table IV.3: Summary of Resource Mobilization Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
Organizational Priority	Establish formal body with the mandate to develop and coordinate the resource mobilization strategy	2009	RBM partnership Board
A, E, F	Develop and regularly review the resource mobilization strategy for sector-wide activities and RBM partnership bodies	2009	Resource Mobilization Task Force*
B, C, D	Raise funds annually to support country strategies	Ongoing	Resource Mobilization Task Force*
B, C, D	Raise funds annual to support RBM partnership body activities	Ongoing	Resource Mobilization Task Force*

* Assuming a Resource Mobilization Task Force is established.

a) Main coordinating group / body in the RBM partnership indicated in bold. Closely linked contributors within the RBM partnership are also listed. RBM partners are not listed explicitly as their involvement occurs through the Working Group.



4. Policy and Regulatory

Policy and regulatory processes are vital early steps in rolling out safe and effective new products and establishing best practice approaches to malaria prevention and management. Policy and regulatory bodies and processes are essential at both the international and country level.

WHO is responsible for setting many technical standards and policy guidelines. WHO provides international regulatory standards for Good Manufacturing Practice (GMP), as well as systems to evaluate quality of medicines (WHO pre-qualification and efficacy and safety of pesticides: WHOPEs). WHO sets international guidelines for treatment and interventions, such as the inclusion of new products in WHO treatment guidelines and on the WHO Essential Drugs List.

Ideally, national regulatory and policy decisions are in line with such international guidelines. National regulatory bodies register products, ensure quality assurance and enforce mechanisms for quality control of commodities. National policy processes establish and update national treatment guidelines and drug lists. National health authorities ensure that policies are adopted and implemented throughout the country.

Regulatory decisions and policy making rely on having good information on quality, safety and effectiveness of new products and interventions. Therefore, Phase IV clinical trials, drug resistance surveillance, pharmacovigilance and ongoing operational research activities are critical inputs for successful international and national policy and regulatory processes.

Key Challenges

Today, a number of policy and regulatory challenges affect interventions and procedures needed to combat malaria. These can be grouped into two categories:

- The upstream development and generation of regulatory decisions and policies; and
- The downstream use of regulatory recommendations and policies to control the quality of interventions and to adopt and enforce existing policies.

Upstream: regulatory decisions and policy making. There are a number of challenges and issues around the development and generation of regulatory decisions and policies, including:

- *International Regulatory.* Not all products undergo full review by stringent regulatory authorities, e.g. ACTs. This increases the importance of the WHO technical review processes undertaken for drugs (pre-qualification), for RDTs and for insecticides and nets. Both of these processes have been criticized in the past few years for a lack of transparency and for long delays. More transparent and streamlined processes at WHO are currently a high priority.
- *International Policy.* International policy processes can be time-consuming, but are extremely valuable to countries. WHO is the acknowledged source of technical guidelines for countries, and is widely respected for its effectiveness in disseminating technical guidelines to countries for adoption. However in some cases, there is a lack of solid data based on field experience to inform development of such technical guidelines. For example:
 - For RDTs, the international mechanism for pre-qualification and quality assurance is currently being established but batch variations are making the task more difficult.
 - Policies regarding community-based case management/home management of fever are unclear, and best practices for scaling up are urgently needed.
 - Policies on the management of severe malaria with artemisinin derivatives are necessary and pharmacovigilance to document adverse events.
 - Policies regarding the treatment and management of malaria in women in their first trimester of pregnancy should be clarified.
 - Policies to support countries mitigate and manage the risk of drug and insecticide resistance should be created.

- *National Regulatory.* Country regulation processes, for regulatory authorities to approve commodities are often complex, time-consuming and thus costly. In the case of malaria drugs and insecticides, there are often a wide variety of differing requirements for registration, which increases costs for manufacturers/distributors, and reduces incentives to register products in countries with relatively smaller markets.
- *National Policy.* In the absence of clear technical guidelines from WHO, country policy processes lack standardized evidence and research to support the policy-making process. This increases confusion and reduces the ability of National Malaria Control Programs to plan effectively.

Downstream: quality control, adoption and enforcement of policies. A number of challenges and issues exist after regulatory recommendations and policies are made:

- *International Regulatory.* Need for harmonization of quality assurance criteria across organizations and compliance with international regulatory recommendations.
- *International Policy.* Ensure compliance with international policy recommendations by organizations.
- *National Regulatory.* National regulatory bodies have limited capacity and resources for enforcing regulations and quality control.
- *National Policy.* Difficulties with and lack of capacity and resources for the roll-out and implementation of policies within countries.

Priorities

Specific partners within the RBM Partnership, most importantly the World Health Organization at the international level, and national regulatory authorities and governments at the country level, have very clear mandates regarding the regulatory and policy process. However, all partners have a collective responsibility to adopt international or national regulatory and policy decisions, e.g. to support quality assurance and control.

Furthermore, the RBM Partnership should support the international and national bodies that are responsible for regulatory processes and policy-making. The RBM Partnership can provide support to strengthen regulatory and policy processes by a number of means:

1. Advocate for increased attention to urgent regulatory and policy needs at both the international and national level and support activities to expedite the processes.
2. Encourage operational research to create the knowledge base for regulatory decisions and policy-making.
3. Promote and support enforcement, adoption and implementation of regulatory and policy processes.

Priorities for scaling up. For 2010, the immediate focus of the RBM Partnership is on advocating for some of the most critical policy and regulatory needs:

A) *Advocate for enhanced regulatory processes and needed regulatory decisions.* To ensure the 2010 targets of scaling up for control can be achieved there are a number of urgent regulatory needs that the RBM Partnership will strongly advocate for:

- *International regulatory:* The RBM Partnership will advocate for speeding up the global level registration process and improving the transparency of these processes within WHOPES, the WHO pre-qualification process, and the Global Fund purchasing guidelines. The RBM Partnership will advocate for an acceleration of the drug pre-qualification process⁶ with WHO. It will also support WHOPES approval process at the international level. This will involve working with manufacturers on ways that will accelerate the process and ensuring independence in evaluation. Furthermore, RBM will advocate for the importance of these international regulatory bodies and that they receive sufficient support in terms of resources.

⁶ WHO informal consultation with manufacturers of artemisinin based pharmaceutical products in use for the treatment of malaria. Geneva, World Health Organization, August 2007.

Additionally, the RBM Partnership will advocate for interim recommendations for necessary malaria commodities and drugs that are not yet fully pre-qualified or for when there is no Stringent Regulatory Authority (SRA) authorized alternative, such as is recently being proposed for ACTs.⁷

The RBM Partnership will also support the ongoing process for international certification or recommendations regarding RDTs to support countries with quality assurance and quality control when procuring RDTs.

Lastly, the RBM Partnership will advocate for the international regulatory acceptance of Home Based Management of Fevers (HBMF) with ACTs.

- *National regulatory:* To reduce critical time-delays during the scale-up for impact, the RBM Partnership will advocate for and encourage acceptance of international body regulatory recommendations by countries and regions (e.g. WHOPEs recommendations for LLINs and pre-qualification recommendations for ACTs). RBM will also advocate for strengthened enforcement and monitoring capacity of national regulatory agencies.

The RBM Partnership will assess the potential to support the creation of regional regulatory agreements, potentially driven by regional economic groupings. These may be particularly relevant to small countries where the market is of insufficient size for suppliers to be willing to go through individual country regulatory process. Furthermore, regional regulatory bodies are a mechanism to pool expertise regarding the regulatory processes.

B) Advocate for enhanced policy processes / needed policies. To ensure the 2010 targets of scaling up for control can be achieved there are a number of urgent policy needs that the RBM Partnership will strongly advocate for. The SRNs and in-country partnerships will play an important role in these:

- *International policy:*
 - Policies regarding appropriate use of diagnostics as well as RDT quality control at the peripheral level
 - Policies regarding the treatment and management of malaria in women in their first trimester pregnancies
 - Development of policies to minimize the risk of resistance spreading (i.e. policies for resistance monitoring, policies for insecticide rotation where feasible)
- *National policy:*
 - Policies to provide guidance related to the sustained use of control measures, including the elimination of trade barriers, taxes and tariffs on malaria-related commodities
 - Technical assistance to develop country and regional legislative frameworks to support development of country and regional policies

C) Advocate for enforcement and adoption of regulatory decisions and policies. To ensure the 2010 targets of scaling up for control can be achieved, there are a number of urgent policy and regulatory needs that the RBM Partnership will strongly advocate for:

- *International:* Promote adoption of regulatory decisions and policies by partners within the RBM Partnership
- *National regulatory:* Promote and support pharmacovigilance and quality control activities in countries, as well as best practices for enforcing decisions, particularly in resource-constrained environments
- *National policy:* Support the adoption and role out of policies within countries

⁷ *Interim report on progress against outstanding AMFm implementation challenges.* Roll Back Malaria AMFm Taskforce, February 2008.

Priorities for sustained control and elimination. For 2015 the policy and regulatory will continue to advocate for important improvements to the policy and regulatory process as stated in the previous section, as well as encourage operational research to create a strong knowledge base.

D) Advocate for enhanced policy processes / needed policies. Similarly, the RBM Partnership will also support and advocate for enhanced policy processes both at the international and national level:

- *National policy.* The RBM Partnership will support capacity development of governance structures within countries to strengthen and speed-up the national policy-making process as well as advocate for a best practice policy process within countries. The latter point includes, for example, emphasizing the importance of an early involvement of the private sector (i.e. manufacturers, wholesalers, and agencies) and local manufacturers in the national policy implementation.

Organizational Implications

Also, RBM partners need to work with the bodies with the mandate for regulatory and policy-making, to explore and support mechanisms that will accelerate the process. The RBM Partnership can facilitate this process in a couple of ways:

- Working Groups can assemble and write up Best Practices for country guidance on how to implement WHO recommendations.
- The RBM Partnership can convene key partners to discuss collaborative action to ensure effective development of policy guidelines, adoption of the policies, and implementation within countries of the recommendations. (Please see the recommendations in *Part II - Chapter 4: The Malaria Research Agenda*).
- The RBM Partnership can convene representatives of country regulatory agencies, the private sector (global manufacturers and local producers and distributors), donors and WHO technical representatives to discuss issues and allow for collaborative identification and resolution of problems.

This will require increased funding support. Similarly, it will be important to strengthen the bodies that provide regional support to countries with their regulatory and policy issues, such as SRNs and WHO Regional Offices.

Table IV.4: Summary of Policy and Regulatory Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
B	Advocate to international policy-making bodies for policies on RDTs, management of malaria in first trimester of pregnancy, community-based case management	2010	RBM partnership bodies
B	Identify and promote mechanisms to reduce the availability of artemisinin monotherapies	2010	WHO-GMP
B	Advocate to both international policy-makers and national governments for policies for resistance monitoring and containment	2010	WHO-GMP , Regional RBM partners ^b
A	Strongly encourage development and adoption of international regulatory recommendations in SUFI countries to enable scaling up activities and in sustained control countries	2010	HWG , WHO-GMP, PSM WG, MAWG
C	Advocate for resources to countries for strong national government structures for policy-making and regulatory processes within countries	2010	RBM Secretariat, SRNs, WHO-GMP
B	Advocate to international policy-making bodies and funding bodies for enhanced and accelerated preparation of treatment guidelines, inclusion of malaria treatments in Essential Drugs List and pre-qualification for anti-malarials at the international level	2010	To be determined
B	Advocate to international policy-making bodies and funding bodies for enhanced and accelerated preparation of policy guidelines and recommendations by WHOPEs for public health pesticides	2010	MAWG
D	Advocate to SUFI and sustained control countries for enhanced and accelerated policy processes at the national level	2015	MAWG , RBM Secretariat, SRNs, Regional RBM partners ^b

a) Main coordinating group / body in the RBM partnership indicated in bold. Closely linked contributors within the RBM partnership are also listed. RBM partners are not listed explicitly as their involvement occurs through the Working Group

b) Regional RBM partners are country/regional offices of the WHO, UNICEF, World Bank, NGOs and other organizations



5. In-Country Planning

Successful malaria control requires strong planning at the country, regional and district level. Planning is needed to determine the overall strategy, the required actions, the necessary resources and how the implementation should be monitored. As outlined in the OECD Paris Declaration on Aid Effectiveness,⁸ all partners within a country need to be aligned behind a single strategy and actions need to be harmonized and complementary to increase effectiveness. These planning objectives, however, are often not met. In recent years, increased interest from different donors and aid organizations has led to a proliferation of plans and the time spent on planning. There is a need to harmonize and streamline planning activities within each country. The Harmonization Working Group (HWG) and the Sub-Regional Networks (SRNs) are the main coordinating bodies within the RBM Partnership for in-country planning.

Planning for malaria control programs should always be closely integrated with the general public health planning for all diseases. Such integration ensures that the activities are aligned and that synergies, for example in building health systems or delivery of interventions, can have a maximum effect. Although integrated public health planning is more likely to occur during the rapid scale-up of interventions to achieve the 2010 targets, it is equally important for a sustained planning effort when the burden from malaria is lower.

This chapter describes the challenges of planning, the priorities of the RBM Partnership in response to these challenges, and Partnership recommendations for in-country planning processes. The chapter concludes by sharing recommendations for good planning practices compiled after work with countries.

Key Challenges

There are a number of challenges regarding the planning within countries. While harmonization of donor requirements needs planning coordination at the international level, other planning efforts should be addressed within countries.

International Planning Process. Lack of harmonization of donor requirements can lead to burdensome financing and reporting processes imposed by the international community. The funding and monitoring and evaluation processes of different donors are often quite demanding (perhaps appropriately so), leading to heavy workloads for in-country government staff members. Many country officials indicate that they spend a significant portion of their time complying with financing and reporting requirements made by donors and other international partners. Harmonizing donor requirements for proposals and indicators to track performance would remove a high capacity burden on countries.

Country Planning Process.

- *Narrow involvement in planning process.* Often, the planning exercise undertaken in countries does not involve all partners and stakeholders, making it difficult to coordinate and align activities. In some cases, planning does not reach outside the malaria community, which impedes integration with other health programs.
- *Poor coordination between national and district plans.* Another challenge is the limited dialogue among the national, regional and district-levels. This leads to poor coordination and differences in planning targets and approaches.
- *Little prioritization in a resource-limited environment.* There may be a gap between activities described in plans and what is effectively implemented on the ground. This gap occurs when plans set objectives and activities to achieve them with limited consideration of whether resources are available. Prioritization processes in a limited resources environment are often not part of the planning process and therefore cannot be controlled. Although country business plans need to be based on country needs and not on the available resources, the annual implementation plans have to take the budget and funding into account.

⁸ Paris Declaration on Aid Effectiveness: Ownership, harmonization, alignment, results and mutual accountability. Paris, OECD, 2005.

- *Lack of capacity.* In many malarious countries, the lack of program managers or planning skills within malaria departments impedes the ability to develop strong plans without the help of consultants or support of partner organizations such as WHO and UNICEF or Partnership mechanisms such as Harmonization Working Group (HWG) and Sub-Regional Networks (SRNs). There is a strong need to build capacity at the country level for the planning process.
- *Lack of regular review.* Country plans are often revised only at the end of their lives and are not subjected to regular revisions. Good monitoring and evaluation systems are needed to track progress against targets and make necessary changes.
- *Lack of medium-term planning for financing.* Tools or frameworks for medium-term financial planning at the national level, such as Medium Term Expenditure Frameworks (MTEFs), enable countries to coordinate planning and budgeting with a medium-term horizon (~3 years) across several sectors. It is essential for malaria activities to be included in these analyses, in order to be prioritized at the national level and to clarify medium term budget requirements. There are synergies between this effort and the elaboration of country business plans with medium-term perspective.

Priorities

Planning priorities vary according to the stage of malaria control.

Priorities for scaling up.

A) Support the development of needs assessments and country business plans focused on rapid scale-up by 2010. HWG will continue to provide support for overall malaria control planning by providing countries with a needs assessment template and tools. HWG and SRNs will also coordinate assistance to countries as they complete needs assessments, and will assist in writing country business plans based on the needs assessments.

While the above planning process is essential to achieve the 2010 targets, there is also a need to strengthen district planning capabilities. The Tanzania Essential Health Interventions Program Team (TEHIP) experience and learning, discussed in more detail later in this chapter, provides a framework for enhancing district level planning.⁹

B) Tools for planning. Working together with members of HWG, the RBM Secretariat will share available tools and best practices for planning on their website, which is available for those involved in country planning activities.

C) Advocate for the harmonization of partners and donors. Strong country business plans can be the basis for donor support to countries. Coordination and harmonization between donors at the country level will ensure that they are aligned around the strategy and business plans. Harmonization of donors at the international level in terms of requirements for fund proposals and performance tracking indicators is also a key component to lower the burden of planning processes which often impede country implementation capability.

D) Support strengthening of country planning process. HWG and SRNs will support the NMCP in establishing strong structures within the ministry of health to lead the program. This support would include guidance based on the experience of individual partners and continuous improving of the planning process. Support might also include the provision of direct technical assistance to high-burden countries in the form of a full-time employee placed within the NMCP to support planning and financing.

⁹ de Savigny D et al. *Fixing Health Systems*, 2nd Edition, International Development Research Center, 2008.

E) Advocate for a government-led planning process. HWG will encourage strong commitment and support from heads of state and the ministries of finance and health. Such commitment is essential to foster broader support across the country, especially helping to remove the bottlenecks that can impede rapid scale-up.

F) Support translation of needs assessments and business plans into funding proposals and support to dialogue with major donors. A high approval rate of proposals in the Global Fund's Round 8 and other upcoming funding applications such as the World Bank and the U.S. President's Malaria Initiative (PMI) will ensure that countries have the necessary funds to undertake the rapid scale-up of activities planned for 2008, 2009 and 2010. HWG and SRNs will provide support for the writing and submission of funding proposals by setting-up workshops and holding mock technical review panels. This support is designed to build country capabilities and to assist country teams directly with the writing of funding proposals to maximize approval chances. Negotiations and dialogue with international donors also need to be supported.

Priorities for sustained control and elimination.

G) Support development of plans aimed at sustaining control and strengthening health systems. HWG will provide support for overall planning at the country level with a strong emphasis on strengthening health systems and integrating malaria with other existing health services. This support for needs assessment and country business plans will include developing template tools tailored for sustained control, holding workshops involving health systems experts and organizing best practice sharing.

H) Support planning for scale-up of new commodities, especially rolling-out of malaria vaccine. There will need to be consideration of how a malaria vaccine will be distributed and supplied within countries, e.g. integrated within the Expanded Program for Immunization (EPI). Furthermore, a malaria vaccine would need adequate procurement and supply chain management (PSM) structures including strong cold chains and increased refrigeration capacity. A group from HWG will be designated to work in coordination with the PSM WG in order to support planning and provide technical assistance on the implementation of new tools, including vaccines.

I) Encourage the development of multi-country regional plans. HWG and SRNs will support the development of multi-country regional plans and funding proposals in order to foster coordination between neighboring countries.

Organizational Implications

Within the RBM Partnership, partners working with the Harmonization Working Group as well as the RBM Sub-Regional Networks are strongly supporting countries with their planning efforts. HWG is focusing on a number of high-burden countries in sub-Saharan Africa. There needs to be an increase in resources to support more countries with the planning process, both for MAWG but also at a more regional level within the SRNs, who also play a very strong role in planning activities. In all regions, WHO regional and country offices, as well as other local partner organizations, play a critical role in supporting country planning activities.

Table IV.5: Summary of Planning Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
A, B	Create tools for needs assessments and templates for country business plans	Q3 2008	HWG
A	Assist countries in rolling out needs assessments and business plan tools with help of consultants	Q4 2008	HWG , SRNs, Regional RBM partners ^b
C	Advocate for the harmonization of donors requirements at the international and national level	2010	HWG , SRNs
D, E	Advocate for strong country planning process and leadership from national authorities	2010	HWG , SRNs, Regional RBM partners ^b
F	Support the development of funding proposals for major donors (GFATM R8 and R9, WB, PMI) to ensure enough funds for scale-up	2010	HWG , SRNs, Regional RBM partners ^b
G,H,I	Assist countries in updating their plans to adapt them to Sustained Control	2011	HWG , SRNs, Regional RBM partners ^b
G,H,I	Support the development of funding proposals for major donors (GFATM, WB, PMI) to ensure enough funds for sustained control	2015	HWG , SRNs, Regional RBM partners ^b

a) Main coordinating group / body in the RBM partnership indicated in bold. Closely linked contributors within the RBM partnership are also listed. RBM partners are not listed explicitly as their involvement occurs through the Working Group.

b) Regional RBM partners are country/regional offices of the WHO, UNICEF, World Bank, NGOs and other organizations.

Partnership Recommendations

As described by MACEPA¹⁰ the strongest plans are:

1. Led by governments
2. Inclusive of all partners' contributions to malaria control
3. Informed by data gathered through monitoring and evaluation
4. Complementary at all levels

Government leadership. High-level country officials (head of state, ministries of health and finance) should announce a commitment to support efforts against malaria. Following these commitments, the planning effort should be led by the National Malaria Control Program.

Inclusive of all partners. The planning process should involve all partners within the country. Depending on the country, this could include members of the National Malaria Control Program, representatives of the public and private health sectors, representatives of NGOs and faith-based organizations active in the country, representatives of donor institutions, and members of the local research community, including operational research. The planning process should also include experts from outside the malaria field for guidance on specific topics, especially representatives of other sectors such as finance, agriculture or education, as well as health experts from other programs such as child and maternal health. The planning activities for the fight against malaria must be coordinated with those for other diseases to obtain synergies, for example, multiple diseases might be able to utilize shared delivery methods.

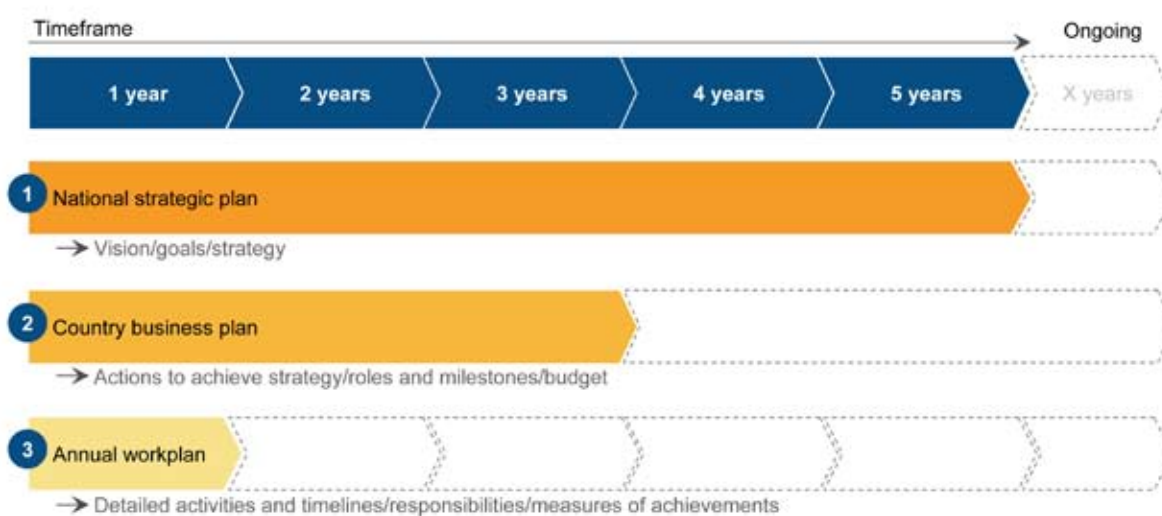
Informed by data. To prioritize activities in a resource-constrained situation, planning must be supported by data gathered through monitoring and evaluation. An example of how data can be used to inform country business plans is the comprehensive needs assessments currently supported by the RBM Harmonization Working Group. The results of the needs assessments are being used to prepare strong country business plans based on the actual needs of countries.

¹⁰ *Planning: Coordinating and Aligning efforts.* MACEPA Learning Community. Available on the MACEPA website (<http://www.macepallearningcommunity.org/planning.php>).

Complementary at all levels. In-country planning requires complementary efforts at the national, regional and district levels. At the national level, the planning effort often includes a number of components - each with a different purpose and focus - which complement each other to form the overall national plan. A recommended structure for this plan has three core components with complementary purposes and different time horizons (see Figure IV.1):

- *The Strategic Plan:* defines the country's vision and high-level strategy for fighting malaria, as well as the program's main goals. The time-frame for this plan may be around 5 years, but in some cases may also be longer, for example covering a timeframe of 10 years.
- *The Business Plan:*¹¹ gets partners aligned by detailing the main activities that need to happen to achieve the goals, with clear milestones, responsible parties, and budgets. The business plan builds on the work of the strategic plan and then uses a needs assessment process (human, financial, interventions) to achieve the targets laid out in the strategic plan. The time-frame for the business plan should be shorter than the strategic plan and is often around 3 years.
- *The Workplan:*¹² is a detailed operational document that sets forth step-by-step all activities that should happen within a planning cycle including timelines, and identifies parties responsible for implementing them. Progress should be monitored throughout the year at regular intervals (quarterly for instance). The time-frame for the workplan typically covers one year, but may also be shorter if required for rapid action.

Figure IV.1: Three types of country plans with different focus and timeframe



It is important that the national strategy and business plan is translated into regional and local plans. Initially this may be led from the national level, but to strengthen the country planning process, the district level should be strongly involved and accountable for their planning process.

An example of the positive impact of more decentralized ownership of planning was demonstrated by the Tanzania Essential Health Interventions Program Team (TEHIP).¹³ In this case, a decentralized planning and funding process using evidence-based planning tools resulted in improved efficiency and effective coverage for key primary health care services and large health gains. These improvements enabled the district health planners to target their budgets toward local health priorities. To enable such programs, funding support should be provided to the district budgets as well as good tools for planning and management, such as the tools developed for TEHIP.

¹¹ May also be referred to by other names such as Implementation Plan.

¹² May also be referred to by other names such as Action Plan.

¹³ de Savigny D et al. *Fixing Health Systems*, 2nd Edition, International Development Research Center, 2008.

Owned by implementers. Ownership of the plan by those who will implement it is a key to success. Ownership by implementers can be increased through decentralization of planning: e.g. national authorities provide detailed guidelines and the planning effort is conducted at the local level. Decentralization is a dynamic accompanying the move from scale-up to sustained control and elimination which redefines roles: the national malaria control program evolves from being an implementer to providing overall guidance and consolidating certain activities that may be more rationally managed at the national level.

Elements of a Good Planning Process

One objective of the plans developed by countries is to organize and coordinate efforts from all local partners in all regions of the country behind common objectives and a common strategy. Therefore, the plans should be oriented towards concrete and measurable actions with clear milestones and identification of roles. Table IV.6 presents an indicative list of topics which could be covered in business plans and workplans.

Table IV.6: Key elements of country plans

"Business plan (timeframe ~3 years)"	"Workplan (timeframe ~1 year)"
<ul style="list-style-type: none"> • Objectives and targets • Situation analysis (baseline, achievements) including needs assessments / gap analysis • Strategic priorities and prioritization principles • Main actions to achieve the strategy with milestones, responsible parties and budget • Overall cost and budget analysis • Details on risk management • Description of review process 	<ul style="list-style-type: none"> • Objectives and targets • Strategic priorities • Resources available • Learnings / challenges from previous year • Detailed activities with milestones, timeframes, costs and roles • Plan for progress tracking

Include human resources plan. All plans should take into account and plan for the human resources required to carry-out the activities, so that these needs are also budgeted and funded accordingly. Human resources issues are a key element of health systems strengthening, currently supported by several global initiatives. Malaria planners at the country level need to participate in these initiatives and ensure that the needs of the national control program are taken into account.

Regular review and updates. In every planning process, there should be a regular review and analysis of strengths and weaknesses of the malaria control program. This requires that health metrics be defined and that monitoring and evaluation be conducted to track the ongoing activities and the impact. Regular review is essential to identify bottlenecks, such as whether commodities were reaching end users, and, if not, why not; to determine whether there were any stock-outs; to assess the impact of behavior change communication programs; and to determine if there are sufficient human resources to support the activities and make any adjustments to the plans. Every activity of the plan should be monitored through specific metrics and indicators as part of the ongoing country M&E system, and regular analysis of the program should take place at least quarterly and could entail revisions of the plans (See *Part IV - Chapter 7: Monitoring and Evaluation*). Updates of plans need to be made regularly, especially to align medium and long-term plans with local annual workplans.

Plans tailored to the stage: scale-up, sustained control, elimination.

Scale-up stage: For countries engaged in rapid scale-up, plans should focus on rapid nationwide roll-out of interventions to achieve the 2010 targets. The Harmonization Working Group and WHO through its regional and country offices has been supporting countries with this planning process by providing tools and technical assistance to carry out comprehensive needs assessments. These are then translated into a detailed 3-year business plan with quarterly timelines for the roll-out and delivery of malaria interventions. These plans are based on the needs identified—for example, the number of interventions and activities needed to achieve the 2010 targets—and incorporate all timing considerations that have to be integrated—for example, rainy seasons, procurement and delivery times, and funding cycles.

Sustained control stage: When countries have achieved their scale-up targets, it will be important that their plans also include how to maintain coverage with malaria interventions through numerous distribution channels, health systems strengthening and maintenance of in-country communication to ensure correct use of interventions. Advocacy will also be needed to ensure there is continued support for the malaria efforts. During sustained control, the process for increasing integration of malaria interventions into the broader health systems should be translated into the plans.

Elimination stage: Plans for the elimination stage would need to be targeted around active case detection, foci and outbreak identification, and achieving and maintaining high levels of surveillance, monitoring and evaluation with strong health management information systems (HMIS) and reporting systems.

Planning in a resource-limited environment. Country business plans based on the needs in the country should ideally provide the basis for proposals submitted to external donors and to ministries of finance for funding. In order to avoid discrepancies between targets and implemented activities, country business plans need to explain clearly the principles and criteria that will be used for prioritization (geographically and in terms of activities implemented) in the event that the funding does not cover the full budget requirements.

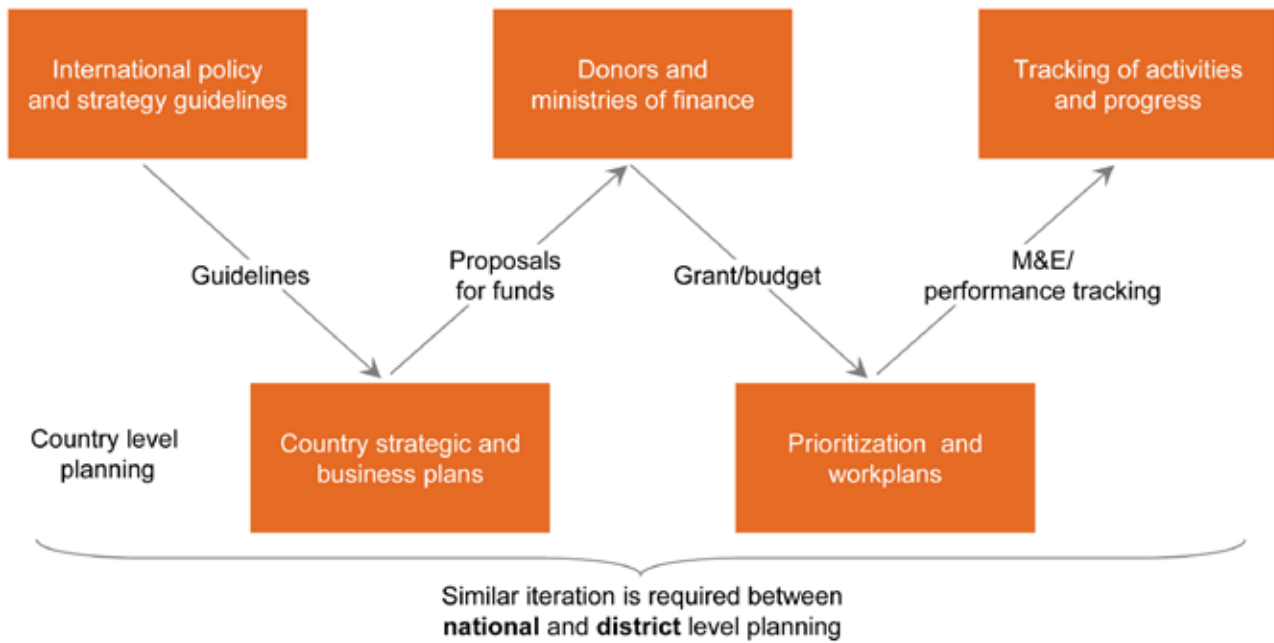
The ‘W’ principle, which has been adapted from an industry best practice example, can be applied to malaria for the two levels of planning and prioritization that need to occur: 1) the national level planning and prioritization based on the allocation of grants, and 2) the district level planning and prioritization based on the budgets set for different districts.

Figure IV.2 shows the planning process for *country level planning*. National strategic and business plans incorporate international guidelines and are based on country needs. The business plans or proposals are then submitted for funding to both the national ministry of finance and international donors. After grant allocation, there may need to be a subsequent prioritization of activities if the requested budget is not fully funded and the activities are detailed in the workplans. Finally, the tracking of the activities and progress has to occur.

At the *national* level, the prioritization will need to consider district budget allocation as well as the highest priority activities. Budget allocation across districts can, for example, take into account population at risk, transmission levels or levels of poverty, whereas criteria for budgeting for different activities could take into account the estimated impact on burden per dollar spent or the estimated feasibility. Annual workplans developed can then take these criteria into account and base planned activities for the coming year on the available or pledged funding.

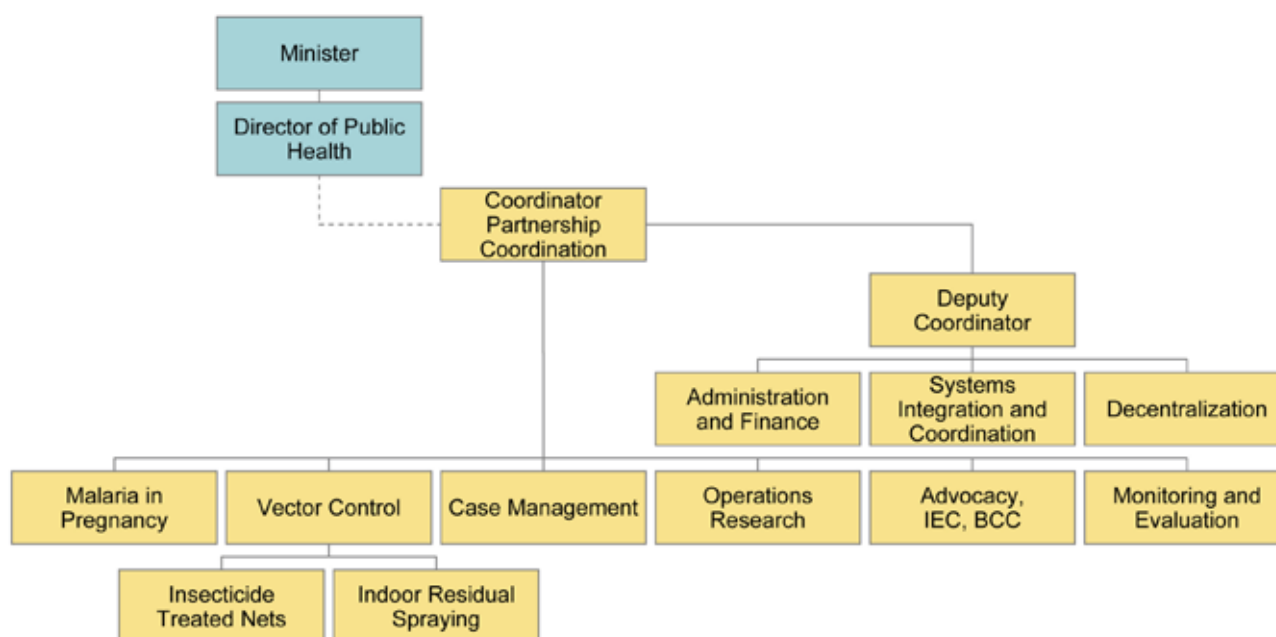
At the *district* level, the ‘W’ principle should be applied and prioritization has to occur. Districts should prepare their business plans based on the national strategy, policies and guidelines. The budget requests are then submitted to the national government for funding. Based on the actual budget allocations across districts, the districts may then have to prioritize within their borders how they should best spend the available resources.

Figure IV.2: Recommended malaria program planning process



National Malaria Control Program structure. For a strong national control program and the associated planning efforts, there needs to be a good NMCP structure. An example for how an NMCP may be organized is provided in Figure IV.3, from work by MACEPA.¹⁴ The example demonstrates the importance of operational relationships within the ministry of health, both vertically and laterally. However, it is important to emphasize that each country may have or need to develop its own variation based on factors including partner roles, degree of decentralization, public / private compositions and management styles. The number of people required can be determined with a rapid assessment of the strategic / organizational needs.

Figure IV.3: Illustrative malaria program organizational structure



Source: MACEPA; interviews.

¹⁴ Paul Libiszowski, MACEPA, personal communication, June 2008.



6. Financing

In many malaria-endemic countries, the growth of external funding for malaria has not been matched by a growth of national resources. For the medium and long term, donor funding must be sustained and national public resources must increase. But perhaps as important, the funds that are available must be used as effectively as possible. Effective financing processes and financial management are critical to meet the 2010 and 2015 global targets.

Effective global and local financing mechanisms can ensure that existing funds, both national and external, have the greatest possible impact. The biggest financing challenges and the recommendations for meeting these challenges are summarized below and detailed in this chapter.

Key Challenges

Numerous challenges linked to financing need to be addressed to make funds available in a timely manner for malaria control and elimination activities.

Time-consuming processes. While unprecedented amounts of money pour into the fight against malaria, little time remains to achieve the 2010 global targets. One critical roadblock is the time-consuming disbursement process of some of the main international donor bodies. When these lengthy processes are followed by long procurement times, the result is an unacceptable time-delay between initial proposal acceptance and the final disbursement and distribution of interventions: approximately between 18-21 months in total. This time-consuming process will make it especially difficult for ACTs and LLINs to be disbursed in sufficiently high numbers to achieve the 2010 targets.¹⁵

Inadequate ability to manage large amounts of funds. Many countries are overwhelmed when large funding donations arrive. Increasingly this will be an issue as countries prepare themselves to scale-up malaria control interventions. National Malaria Control Programs repeatedly pointed out that capacity building for financial management is needed to ensure funds are properly managed.

Difficulty sustaining predictable funding flows. Sustainable and predictable financing for the sustained control and elimination stages are essential to avoid resurgence of malaria due to relaxation of control efforts. To advocate nationally and internationally for sustainable and predictable financing, countries must have the tools to manage current funds and to track how they are used. These tools will support the development of sustainable mid- to long-term financing strategies which can be based on a realistic mix of external and national, public and private, resources.

Priorities

As with most topic areas, priorities for the RBM Partnership differ according to the malaria stage.

Priorities for scaling up. The RBM Partnership recommends the following priorities be taken to meet these financing challenges in the scale-up stage.

A) Support negotiations with major donors. Coordination is needed among all donors within a particular country. For some high-burden and high-need countries, this could take the form of roundtables of negotiations between the major donors and the countries supported by the Harmonization Working Group (HWG), as is the case for Nigeria. (*Support for the translation of country business plans into funding proposals is presented in Part IV - Chapter 4: In-Country Planning.*)

B) Support disbursement processes. Timely disbursement of funds is important to ensure that the scale-up activities take place on time. Disbursement support will be coordinated by MAWG for approved funding proposals by building country capabilities for response to the Technical Review Panels and helping to resolve disbursement bottlenecks.

¹⁵ *Workshop: Tackling the challenge of rapid LLIN scale-up*, Washington, D.C., World Bank, April 2008.

This includes assisting countries in completing high-quality procurement and supply chain management (PSM) and monitoring and evaluation (M&E) plans for Global Fund proposals, under the leadership of the PSM and MERG Working Groups.

C) Use existing tools to accelerate funding flows. To meet the 2010 goals, using the flexibility of the major donors (especially the Global Fund and the World Bank) needs to be encouraged. For example, these donors permit front-loading of disbursements linked to interventions, shortening the periods between disbursement phases, and amending previous projects used in the country's advantage. In addition, options such as direct payment could further accelerate the use of funds: donors could make direct payments to procurement agents, suppliers or fiduciary agents thus shortening the path to commodity procurement. This option could avoid time-consuming, in-country procedures for disbursements to procurement agents or suppliers, as well as reduce transaction costs (bank fees, exchange rate losses).¹⁶

D) Establish innovative financing mechanisms for ACTs and LLINs. To ensure that countries are able to achieve their targets, the RBM Partnership must establish innovative financing and procurement mechanisms for malaria interventions. For ACTs, the RBM Partnership (under the leadership of the AMFm taskforce) is developing a mechanism which would make low cost ACTs widely available through the public and private sectors (See Box IV.2). Furthermore, the RBM Partnership is considering financing and third-party procurement options to ensure that finances are rapidly available to procure LLINs within malaria-endemic countries.

Box IV.2: Affordable Medicines Facility - malaria

The AMFm is an innovative financing intervention that seeks to make affordable ACTs available to patients in the malaria endemic world who use facilities run by the public or NGO sectors or who purchase drugs themselves.

The idea behind the Affordable Medicines Facility for malaria (AMFm) emerged from a 2004 report by Institute of Medicine (IOM) "Saving Lives, Buying Time" that highlighted the risks of resistance emerging to artemisinin due to the widespread availability of artemisinin mono therapies in the private sector and the potential benefit of an ACT subsidy to promote wide-spread use of effective anti-malarial drugs. After the publication of the report, the RBM Partnership decided to examine further the ACT subsidy concept and began work with the World Bank to develop a detailed proposal for the design and operation of such a global ACT subsidy.

The core principles of the AMFm are:

- 1) reducing consumer prices to an affordable level (approximately US\$ 0.20 - 0.50 in the private sector) through price negotiations and a co-payment and
- 2) ensuring the reduced price benefits those suffering from malaria by introducing in-country supporting interventions

The potential benefits of AMFm are considerable. This price reduction is expected to more than triple ACT usage to a projected 360 million treatment courses per year. In turn, this will reduce purchases of less effective treatments and delay the emergence of resistance to artemisinin by the malaria parasite. It is expected to save 175,000 to 300,000 lives per year, mostly children in sub-Saharan Africa.

Continued field research will be required after launch to ensure that the AMFm achieves these goals. For more information, please visit the website for the AMFm taskforce at <http://www.rbm.who.int/globalsubsidytaskforce.html>

¹⁶ The direct payment option has been used in about 14% of the malaria disbursements from the Global Fund from mid-2007 to mid-2008 in 19 countries: Afghanistan, Bangladesh, Cameroon, Ethiopia, Ghana, Guinea-Bissau, India, Kenya, Mali, Nepal, Nigeria, Papua New Guinea, Somalia, Sri Lanka, Tanzania, Uganda, Yemen, Zambia and Zimbabwe. Source: Internal analysis conducted by Vestergaard Frandsen, 2008.

Priorities for sustained control and elimination. To support sustained control and elimination within countries, the RBM Partnership recommends a focus on capacity building and on medium- and long-term financial planning.

E) Continue support with funding disbursements. HWG will continue to support countries with the timely disbursement of funds. This includes advocating that international donors sustain financial commitments throughout the sustained control and elimination stages.

F) Advocate for and support medium- and long-term planning for financing. Malaria activities need to be included in national, medium-term planning efforts to increase clarity regarding future funding requirements, enable better funding predictability, and ensure that malaria is part of national priorities and receives an adequate amount of money. (See also *Part IV - Chapter 4: In-Country Planning.*) NMCPs require technical assistance for the development of medium-term financing plans and capacity building to reinforce their role on financial forecasting and planning.

G) Track expenditures for increased accountability. National Health Accounts (NHA) and malaria sub-accounts track spending on health care (amount and flows) including public, private, household and donor contributions. They are important to assist countries and donors in evaluating the effective expenditure of available funds and to increase transparency. Rather than being stand-alone tools, questionnaires for malaria should be integrated into existing household surveys and malaria indicator instruments, which would greatly reduce the cost of implementing sub-accounts. The RBM Resources Working Group (RWG) will assess these options and the outcomes of the ongoing malaria sub-account activities. As this will take years to institutionalize, NHA malaria sub-account preparations need to begin today to prepare the groundwork.

Organizational Implications

The key coordinating bodies for the RBM Partnership are the Resources Working Group and the Harmonization Working Group. Currently, different partners support countries with financing processes. HWG, other Working Groups, and individual partners provide support to countries with the disbursement of funds. RWG is closely involved with AMFm activities and supports recommendations regarding effective financing and tracking within countries.

Table IV.7: Summary of Financing Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
C	Frontload financing from Global Fund and WG grants for LLIN and provide voluntary 3rd party procurement service to enable global scale-up by 2010	Q1 2009	HWG, RWG
D	Establish AMFm as an innovative financing and procurement mechanism for ACTs to enable global scale-up by 2010 and reduce risk of counterfeits and resistance	Q4 2009	AMFm taskforce
B	Accelerate Global Fund funding disbursements by holding workshops with mock Technical Review Panels to build country capabilities to respond to TRPs	Q3 2008 and beyond	HWG, SRNs
G	Work on integrating malaria sub-accounts within M&E activities to track financial flows	2015	RWG, MERG

a) Main coordinating group / body in the RBM partnership indicated in bold. Closely linked contributors within the RBM partnership are also listed. RBM partners are not listed explicitly as their involvement occurs through the Working Group.



7. Procurement and Supply Chain Management

Procurement and Supply Chain Management (PSM) is crucial to ensuring that high-quality interventions reach the target population of end users. Close to 50% of Global Fund budgets are used to procure interventions.¹⁷ The main procuring bodies for malaria interventions are governments of malaria-endemic countries at the national level and United Nations agencies and international organizations at the global level.¹⁸

International PSM efforts support in-country supply chain management and procurement activities, such as forecasting, availability of interventions, procurement guidelines for quality control/quality assurance, and pooled procurement. An ongoing international dialogue around PSM issues has largely concluded that in-country PSM for malaria should be integrated with PSM for other diseases where appropriate to prevent the creation of multiple parallel structures. Private sector mechanisms, such as those used within countries for distribution, are also important for procurement and supply of malaria interventions.

Key Challenges

PSM is critical to ensure that countries can achieve their 2010 targets of universal coverage with malaria interventions.

International level. At the *international* level, several major issues must be addressed.

- Limited forecasting and intervention tracking
- Limitations to raw materials supply
- Need for updated procurement guidelines
- Different product eligibility criteria across donors
- PSM challenges regarding malaria intervention specifics
- Need for preparation for PSM systems for new malaria tools

Forecasting and intervention tracking. To strengthen PSM internationally and locally, better forecasting capabilities are needed to match capacity to the demand for interventions (anti-malarial drugs, insecticide-treated nets, rapid diagnostic tests (RDTs), insecticides). Tracking consumption of interventions, an activity in close connection with monitoring and evaluation activities, is also important to determine where interventions have been disbursed, to recognize any roadblocks in PSM, and to assess whether the universal coverage targets can be achieved.

Limitations to raw materials supply. Adequate quantities of raw materials are needed to produce and supply sufficient intervention quantities to support scale-up efforts. For example, in view of the long-lead time in producing the plant needed for ACTs, there is a need to address supply of artemisinin raw material to ensure it will be available to support the planned scale-up of treatment.

Updated procurement guidelines. Updated international guidelines for malaria interventions, both in terms of PSM guidelines and technical specifications, will support countries with their procurement and supply management. Taking RDTs as an example, procurement guidelines are needed for quality assurance, quality control and supply management as well as quality tests for use at peripheral levels at time of diagnosis (note: RDT product testing ongoing in 2008).

Different product eligibility criteria across donors. Different requirements among donors in terms of product eligibility complicate the procurement of products by countries; this has been the case for ACTs.

¹⁷ *Mid-year report.* The Global Fund to fight AIDS, Tuberculosis and Malaria, 2006.

¹⁸ *Global Strategic Plan 2005-2015.* Geneva, Roll Back Malaria, 2005.

PSM challenges regarding malaria intervention specifics. One major challenge is the shelf-life of ACTs (approximately 2 years), which combines with the customary delays in procurement and supply management (in optimal cases 6 months) to reduce the remaining shelf-life significantly.¹⁹ Another challenge is the bulkiness of a number of malaria interventions (ACTs and LLINs) which require a significant amount of storage space.

Need for preparation for PSM systems for new malaria tools. Although not yet an issue, the RBM Partnership will likely need to support PSM for a potential malaria vaccine which, according to current planning, will be launched in 2012.

Country level. At the *country* level, there is an urgent need for more international guidance and support to address country-specific PSM challenges.²⁰

- Insufficient emphasis on planning for PSM development
- Challenge of multiple parallel distribution systems
- Challenges with in-country logistics
- Inadequate quality assurance and quality control
- Quality assurance of the supply-chain, particularly for ACTs and RDTs
- Time consuming regulatory issues (see *Part IV - Chapter 3: Policy and Regulatory*)

Insufficient emphasis on planning for PSM development. Insufficient emphasis is placed on establishing comprehensive PSM plans within countries. Comprehensive plans would include recognition of country-specific bottlenecks and excellent coordination of all stakeholders within the country who are involved in PSM. Furthermore, incorrect budgeting of implementation costs, such as warehousing and distribution, may occur at the country level.

Challenge of multiple parallel distribution systems. Malaria intervention disbursement and supply management often occurs in multiple parallel systems, rather than integrated within existing structures. This leads to inefficiencies and makes in-country logistics difficult.

Challenges with in-country logistics. Countries experience challenges with in-country logistics, including areas such as inventory management, distribution, consumption data collection and logistics management information systems (LMIS). These challenges, for example with distribution, can lead to malaria interventions staying in storage warehouses and never reaching the end-user. Another problem is that there are few best practice examples for countries who wish to leverage different distribution systems (such as private, public, and NGO systems) for malaria interventions.

Inadequate quality assurance and quality control. Few countries have adequate country quality assurance and quality control systems. This leaves room for counterfeits or poor quality of products to enter the public and private markets. (See *Part IV - Chapter 3: Policy and Regulatory*).

Priorities

Priorities for scaling up. Given all these challenges, the PSM WG will focus on the most urgent issues to achieve the 2010 and 2015 targets. The PSM WG priorities to achieve the 2010 targets are given below.

A) Continue to support innovative procurement mechanisms for ACTs. (For a description of AMFm, see Box IV.2 in *Part IV - Chapter 6: Financing*). The PSM WG will continue to work with the Global Fund and the AMFm taskforce to design the most effective mechanism for AMFm.

¹⁹ Information from the Procurement and Supply Chain Management Working Group Meeting, Woerden, 29 April 2008.

²⁰ Shretta R. *Summary of lessons learned in the implementation of ACT policies in Ghana, Nigeria and Guinea-Bissau.* The Global Fund to fight against AIDS, Tuberculosis and Malaria, June 2007.

B) Implement direct payment as an option for countries. Direct payment²¹ is a useful option for certain countries wishing to scale-up rapidly. The direct payment option has been used in about 14% of the malaria disbursements from the Global Fund over the last 12 months in 19 countries.²² The principle reason for using this option could be to avoid internal procedures for disbursements of funds to a procurement agent or supplier which for some countries can be quite time-consuming. Direct payment could also reduce transaction costs, such as bank fees and exchange rate losses, which could potentially reduce overall costs and/or time to delivery of goods. The LLIN taskforce established at the RBM Board meeting in May 2008 will evaluate how best to implement direct payment if it is determined to be one of the key strategic PSM priorities. The PSM WG will work closely together with the LLIN taskforce to give input and review analyses.

C) Support countries to use voluntary pooled procurement. Pooled procurement can help countries increase the speed and reliability of the procurement process by minimizing stock outs, decreasing lead times, lowering and stabilizing prices, increasing longer-term supply reliability and generally ensuring availability of high quality products. In line with the Global Fund's decision to support voluntary pooled procurement, the PSM WG will help countries assess when to use pooled procurement services and support them in setting up the appropriate in-country mechanisms and choosing the best procurement option. The LLIN taskforce will look into the mechanism for pooled procurement for LLINs at the global level.

D) Encourage private sector contracting and good practices sharing. The private sector can play an effective role in the procurement and distribution of malaria interventions. Often private sector systems are more adept than the public sector at serving remote populations or in rapidly scaling up distribution systems. The PSM WG will encourage countries and private sector partners to work closely together to contract private sector partners when appropriate. In addition, the PSM WG will work with countries and private sector partners to identify best practices and encourage best practice sharing among countries and companies.

E) Identify and remove delays in PSM processes. To assist countries in rapidly scaling up interventions, the PSM WG will continue its work to identify and remove delays at all levels of the supply chain. The first step identified ways to shorten the delay between Global Fund proposal submission and fund disbursement, thereby shortening the process from two years to 10 months for many countries. The next step will be to monitor delays in other parts of the procurement and supply process to identify solutions to speed up delivery of interventions to the end user. The PSM WG will lead this process and offer technical assistance to countries to speed up overall time to delivery.

F) Prepare and update procurement guidelines and provide overview of tools. To provide guidance to countries for the procurement of products, the PSM WG will support the ongoing process to update existing procurement guidelines for interventions, with an initial focus on ACTs and RDTs, and to assess whether any new guidelines should be added. Furthermore, the PSM WG will collate tools for PSM gap analysis and capacity strengthening.

G) Improve quality of PSM plans. There are two parts to improving the PSM planning process for countries:

- *Harmonize PSM requirements and plans among donors.* Currently the Global Fund, the President's Malaria Initiative (PMI), and other donors have different requirements for PSM. PSM WG will hold round-table discussions with donors and countries to agree on a common framework of requirements supported by donors for country PSM plans.
- *Support countries with PSM Plans.* It is important to provide guidance to countries with PSM plans to help both with the acceleration of funds to countries by shortening the time until grant signature and also by ensuring countries have the PSM structures in place to adsorb and distribute the malaria interventions. The PSM WG will continue to provide support in the form of Workshops and technical assistance by consultants within countries to develop their PSM plans.

²¹ A direct payment as defined by the Global Fund is the disbursement made directly from a trustee fund to others than the principal recipient (PR). The direct payment can be made to a procurement agent (PA), a supplier or a fiduciary agent as opposed to payment directly to the PR, who then subsequently pays the PA, supplier or fiduciary agent. PRs can request the Global Fund to make a direct payment.

²² Afghanistan, Bangladesh, Cameroon, Ethiopia, Ghana, Guinea-Bissau, India, Kenya, Mali, Nepal, Nigeria, Papua New Guinea, Somalia, Sri Lanka, Tanzania, Uganda, Yemen, Zambia and Zimbabwe.

H) Provide technical assistance to countries to resolve local PSM bottlenecks. It is crucial that the RBM Partnership provides technical assistance to countries to assist them in resolving PSM bottlenecks. Technical assistance may be provided by consultants working directly with key stakeholders in countries. PSM WG will keep an up-to-date list of PSM consultants who could support countries. Technical assistance will be required to establish and strengthen integrated PSM systems within countries. These improved PSM systems will help with forecasting and tracking activities to increase monitoring and evaluation. PSM coordination committees may be considered as a country mechanism to coordinate and establish integrated PSM systems. Helping countries use available PSM mechanisms (public sector, private sector or NGOs) and strengthening mechanisms to improve coverage with interventions will be important to ensure universal coverage can be achieved by 2010 in line with the RBM Partnership targets.

A further approach to resolving bottlenecks within countries and helping with the coordination of the key stakeholders and partners is to establish a number of more permanent experts who operate predominantly at the country level and work with all stakeholders, international and national, to resolve key bottlenecks. The benefits would be the expertise regarding the international requirements as well as country/field experience and an ability to have a longer time commitment to support individual countries.²³ While individual partners already provide such support within countries, the support is used mostly to resolve bottlenecks for the partner programs in the respective country.

I) Support capacity building and strengthening for PSM within countries. Besides the technical assistance to resolve critical roadblocks to achieve universal coverage, it will be important to strengthen PSM systems so that there is no need for ongoing technical assistance and there can be a shift to more routine distribution systems rather than campaigns.

J) Strengthen forecasting at the international level and quantification at the national level. A critical component for PSM at both the international and national levels is accurate country-level forecasting of malaria intervention needs. One example is that malaria intervention needs in sub-Saharan Africa from 2008 to 2010 are being provided by the comprehensive needs assessments that are being carried out. Establishing a regular forecasting process will involve identifying the best approach regarding forecasting for ACTs, RDTs, LLINs and insecticides used in IRS for both the public and private sectors; reviewing forecasts with donors and suppliers; and establishing a system to regularly update forecasts. This would include the forecasting of raw materials required for interventions, such as *Artemisia annua* for ACTs. Regular reports with forecast numbers can then be prepared to share with donors, suppliers and countries.

Priorities for sustained control and elimination. Focusing more on capacity building and supporting sustained control within countries, the RBM Partnership priorities are given below.

K) Prevent market failure without distorting the markets. The RBM Partnership will work closely with partners to ensure well-functioning and stable malaria interventions markets. It will investigate and support the development of strict quality-oriented sourcing and procurement guidelines for artemisinin as an active ingredient, as well as for other malaria intervention supplies. The RBM Partnership will also work closely with malaria intervention manufacturers in malaria-endemic countries and producers to help them meet international standards, such as Good Manufacturing Practice standards and pre-qualification by WHO.

L) Support planning for PSM of malaria vaccine. There will need to be consideration of how a malaria vaccine will be distributed and supplied within countries, for example, how it will be integrated within the Expanded Program for Immunization (EPI). Furthermore, a malaria vaccine would need adequate PSM structures such as cold chains distribution systems and increased refrigeration capacity.

²³ Dr. Chavasse, PSI Malaria Control, personal communication, 2008.

M) *Advocacy for PSM*. Together with the advocacy community there will be continued and reinforced advocacy for:

- Improved product presentation (packing / dosages); for example, there have been some difficulties with bulky ACT packages in storage
- Behavior change communication and in-country communication to ensure product acceptance and proper use by patients at the end level
- The removal of taxes and tariffs on malaria interventions, as well as essential supplies for the manufacturing of malaria interventions.

Organizational Implications

Currently, different partners support countries with product procurement (e.g. the RBM Partnership Secretariat Intervention Services, WHO Procurement, UNICEF's supply division, UNOPS) and in-country supply chain issues (e.g. IDA Solutions, Management Sciences for Health - Strengthening Pharmaceutical Systems, John Snow Inc, UNICEF supply division). Furthermore, a number of large manufacturers of malaria interventions are actively engaged within the RBM Partnership (e.g. Novartis, GlaxoSmithKline and Vestergaard Frandsen).

Within the RBM Partnership, the PSM WG has a facilitating role and coordinates responses to key issues around PSM, as well as providing support to countries with the development of PSM plans for Global Fund applications. Currently, the PSM WG focuses on a number of thematic issues/needs including, among others, technical assistance to countries to identify and resolve PSM bottlenecks, forecasting and quantification of malaria interventions and quality assurance and control issues related to product selection and supply management.²⁴ Furthermore, the PSM is closely involved with the AMFm activities particularly regarding buyer eligibility and country preparedness.

²⁴ More information available on the Roll Back Malaria Procurement and Supply Chain Management Working Group webpage (<http://www.rbm.who.int/psmwg.html>).

Table IV.8: Summary of Procurement and Supply Chain Management Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
J	Identify approach and prepare forecast of global demand of LLINs, insecticides for IRS, ACTs, RDTs	Q4 2008	PSM WG Forecasting Task Force
F, H	Prepare LLIN procurement guideline and identify key bottlenecks to support LLIN scale-up activities	Q1 2009	PSM WG, LLIN taskforce, HWG
H	Identify and resolve PSM bottlenecks within SUFI countries with technical assistance	2010	PSM WG, SRNs, Regional RBM partners^b
E, G, H	Offer technical assistance and training to build PSM capacity within control countries	2010	PSM WG, SRNs, Regional RBM partners^b
D	Prepare, update and disseminate international procurement best practices for malaria interventions with an initial focus on ACTs and LLINs	2010	PSM WG
H	Map global supply side of malaria commodities	2010	PSM WG
K	Provide technical assistance to manufacturers of malaria commodities (initial focus on ACTs and LLINs) in malaria-endemic countries to help them meet international standards	2015	PSM WG
L	Establish group to coordinate planning and implementation for PSM process and structures for the roll-out of new tools and technologies (e.g. potential vaccine)	2015	PSM WG
K	Provide guidance and technical assistance to countries in elimination to resolve PSM bottlenecks, such as ensuring stocks of malaria commodities are available for malaria outbreaks despite low number of malaria cases	<i>Beyond 2015</i>	PSM WG, Regional RBM partners^b

a) Main coordinating group / body in the RBM partnership indicated in bold. Closely linked contributors within the RBM partnership are also listed. RBM partners are not listed explicitly as their involvement occurs through the Working Group.

b) Regional RBM partners are country/regional offices of the WHO, UNICEF, World Bank, NGOs and other organizations.



8. Communication and Behavior Change Methodologies

Achieving the RBM 2010 and 2015 targets requires effective communication between service providers and consumers of interventions, whether patients, family members or communities. Communication can be used to increase knowledge of:

- the transmission and prevention of malaria;
- the link between bed net use and malaria control;
- the recognition of signs and symptoms, risk groups, rapid treatment-seeking behavior and full compliance with treatment;
- the consequences of malaria in pregnancy and the need for antenatal care which includes LLINs and, as appropriate, IPTp; and
- the motivation and intention to use tools for malaria prevention and control.

Motivating households to prevent and treat malaria requires sustained communication interventions guided by well-planned and locally appropriate communication strategies. Communication programs embrace basic strategies to increase demand for and acceptance of malaria interventions and services, including information, education and communication (IEC) and behavior change communication (BCC) methodologies.²⁵ IEC is broadly defined as providing knowledge to enable individuals, families, groups, organizations and communities to play active roles in achieving, protecting and sustaining their own health. BCC includes the basic components of IEC, but starts with a focus on the key individual and group behaviors to be changed and employs a wider range of interventions beyond cognitive-based, knowledge transfer. Communication for Social Change is a more participatory approach to engaging communities that focuses more on the client-identified end actions in regard to the health intervention. There is wide agreement that communication programs need to combine both the delivery of messages and other behavioral interventions and opportunities for dialogue, shared learning and consensus-building to produce results.

Regardless of the methodology, any effective communication program aims to affect the health-seeking or care-providing behavior of individuals and communities creating demand and sustaining use of malaria services and products.²⁶ It is important to not only create demand via communication, but also to focus on increasing appropriate utilization of service and products, such as ensuring a household dynamic where pregnant women and children sleep under mosquito nets. The resulting field effectiveness due to appropriate utilization of preventive interventions is a key driver of treatment costs. For example, increasing operational effectiveness of LLINs and IRS from their current field effectiveness of 50-60% up to 98% can theoretically reduce incidence and therefore treatment costs, by almost 50%. Modeling a 98% effectiveness rate showed a potential cumulative savings globally of US\$ 960 million from 2009-15. This makes a powerful argument for investing in communication and behavior change programs. (See *Appendix 4: Assumptions behind Country Implementation Cost Estimates*).

There are many steps in the process of engaging whole communities to prevent and treat malaria effectively. Such engagement requires a change in normative standards, which is most effectively achieved when local leaders are active in program planning and implementation, along with NGOs and other community organizations.

Communication programs should create opportunities and motivate people to discuss malaria issues, both among themselves and with decision-makers and service-providers. In addition to changing household practices, social norms and mobilizing communities to participate actively in malaria interventions, communication programs can also improve the quality of client-provider interactions by providing health workers with the interpersonal skills and the motivation to communicate more effectively with clients.²⁷ Communication objectives should include increasing knowledge, intention to act, a sense that actions conform to social norms, visible support from community leaders and modification of service delivery to increase opportunities for people to adopt appropriate health seeking behaviors.

²⁵ Also known as Communication for Behavior and Social Change (CBSC) and Communication for Development (C4D).

²⁶ *Global Advocacy Framework*. Roll Back Malaria, 2005.

²⁷ *The Role of Communication in Malaria Control in Africa*. A concept paper for the Roll Back Malaria Communication Working Group, September 2003. See Roll Back Malaria webpage (<http://www.rbm.who.int/cwg.html>).

Formative research, early research which helps to highlight the community context and how best to structure a program for that community, can be the basis on which to build effective communication strategies. Such research can help planners understand the basic social, cultural and political opportunities and challenges the intervention program faces. The communication program planners can then fashion service delivery and messages to address gaps in knowledge, perceived norms or other barriers to accessing and utilizing services. To ensure that the program has not deviated from the intended plan, planners need to monitor process indicators carefully and report on activities and results. An evaluation of the impact of malaria programs will include both intermediate objectives (knowledge, attitude, perceived norms and efficacy) as well as behaviors, such as the appropriate use of bed nets in homes.

Communication activities should be integrated into National Strategic Health Plans, malaria business plans, and education programs from the very beginning. Community involvement and participation during the design and implementation will ensure the activities are successful. Lessons learned in health promotion have demonstrated that neglecting community involvement in all stages of the program design and implementation will decrease the chances of the program succeeding.

Key Challenges

When working in harmony, communication programs at international, national and community levels lead to more successful communications that are likely to increase demand for and utilization of services in communities and simultaneously improve service delivery. Given the importance communication has in achieving the RBM 2010 and 2015 targets, more dedicated funding for communication activities is necessary at international, national and community levels. Gaps in the current malaria communication structure are outlined below.

International level. In recent years, communication has not received the necessary attention at the international level to develop appropriate guidelines and tools to guide country efforts. This has led to a number of issues, including:

- Lack of a global coordinating mechanism such as a Communication Working Group
- Insufficient operational research to identify and evaluate best practices and to document lessons learned for malaria IEC / BCC programs²⁸
- Absence of sufficient evidence regarding the effectiveness of particular channels, specific messages and topics for discussion, or types of integrated approaches for malaria specific programs²⁹
- Lack of consistent use of limited data to determine behavior and attitude patterns in the highest risk populations and monitoring and evaluation indicators to inform planners of the success of malaria communication programs

National level. At the national level there are a number of challenges around communication and behavior change methodologies. Some of the key cross-cutting issues include:³⁰

- Lack of time, capacity and resources for the design and implementation of communication programs due to low prioritization
- Ineffective advocacy to promote malaria control programs as priority interventions in national government agendas
- Failure to evaluate communication contributions to malaria program objectives
- Differing priorities and insufficient resources for communication programs
- Lack of sustained communication with multiple channels (schools, workplace, women's groups, etc.)
- Poor capacity to engage in social research necessary to understand household and community dynamics and guide innovative, locally sensitive (season, venue, product availability) interventions

²⁸ Barker J and Payes R. *Overview of Programmatic Interventions for Communication for IRS, Insecticide-treated nets, Case Management and Malaria in Pregnancy*. Washington, D.C., USAID, 2008.

²⁹ *PMI Communication and Social Mobilization Guidelines*. Washington, D.C., PMI, 2008.

³⁰ *The Role of Communication in Malaria Control in Africa*. A concept paper for the Roll Back Malaria Communication Working Group, September 2003. Also see Roll Back Malaria webpage (<http://www.rbm.who.int/cwg.html>).

- Over-reliance on mass media and promotional items at the expense of participatory and interpersonal communication
- Insufficient partner coordination in creating harmonized approaches, messages and integrated messaging with national health education services

Community level. At the community level, national programs often fail to overcome a number of challenges, including:

- Failure to identify and ensure the participation of local political, religious and traditional leaders to facilitate information dissemination and malaria control within the community
- Insufficient attention paid to participatory methodologies, especially in the development of messages and interventions
- Insufficient communication targeted for home-based care and service providers
- Application of broad, generic strategies, including messages and specified behavioral outcomes, without understanding the unique dimensions of specific communities, especially the most marginalized populations that are often most at risk and will remain that way when other populations benefit from program interventions
- Insufficient insights drawn from community leaders and grass roots efforts
- Lack of integration of malaria communication activities with other health programs (Expanded Program for Immunization (EPI), etc.)

Funding. One of the main challenges for developing successful communication interventions is that they must be adequately funded and developed based upon research and existing evidence. Communication budgets should include the costs of research and evaluation, community mobilization, pre-testing messages and materials, training and supervising clinical and community based providers, developing IEC materials (tools for providers and information for households), and media and coordination costs of all of these budget items. The costs per capita or per household should be determined to communicate with people about malaria, bed nets, IPT and new treatment and to motivate them to use these means to keep their families healthy. In addition, budgets should include costs to reach each household, with multiple messages through multiple channels sustained through the entire project cycle.

Priorities

Communication priorities for the RBM Partnership vary according to the malaria stage as described below.

Priorities for scaling up. Communication interventions must be designed with the active participation of those directly involved at the community level, e.g. service providers and intervention participants. Communication and community mobilization must be recognized as key to increasing the use and coverage of households protected by insecticide-treated nets, home-based management of fever and timely ANC services. Programs need to reflect the regional, community and individual characteristics that present barriers and afford opportunities for meeting malaria program objectives. In addition, there is still a strong need for advocacy with international donors, partners, national, regional and local leaders and the inclusion of basic principles for communication campaigns to guide selection of channels, message content and to evaluate outcomes. The priorities recommended by the RBM Partnership are as follows.

A) Advocate for communication programs. The RBM Partnership will encourage donors and organizations working in country programs to provide funding, capacity building, training or technical assistance for communication programs. A standard formula for calculating the need and cost for communication funding (e.g. cost per household, standard formative and summative³¹ research activities) is required so that future budgets can be properly estimated. The RBM Partnership will also encourage malaria-endemic countries to increase attention and resources to malaria communication programs.

³¹ Summative research is research undertaken to assess a program on its completion.

B) Advocate for operational research for communication programs. There is a need to identify and evaluate best practices and document lessons learned for malaria IEC / BCC programs, especially to address the challenges at the international level. The RBM Partnership will strongly advocate for more operational research for country communication programs.

C) Technical guidance. To support communication and behavior change efforts, the RBM Partnership will develop and provide guidelines for communication interventions based upon best practices:

- *Guidelines for communication programs.* The RBM Partnership will aim to achieve consensus around recommended approaches for IEC / BCC during scale-up for impact and make these guidelines available for country programs. The guidelines should cover the initial research protocols, design, implementation monitoring and evaluation of communication programs. They should also contain specific recommendations of key messages, identify appropriate communication channels and recommended participatory approaches. Furthermore, existing guidelines (e.g. the President's Malaria Initiative (PMI) Communication and Social Mobilization Guidelines), lessons learned from other health communication efforts (e.g. polio eradication, control of diarrhea, measles) and tools for the design and implementation of communication programs will be reviewed and made available on the RBM Partnership website.
- *Best practice sharing.* Best practice examples and experience with malaria IEC /BCC exist in partner organizations (e.g. UNICEF, the President's Malaria Initiative, Population Services International, MACEPA and Malaria Foundation International). Additionally, partners and other development agencies have accrued vast experience in communication programs for other health activities³² that can provide valuable insight on methods and approaches that could be adapted for malaria communication activities, which will be assessed and disseminated through the RBM Partnership.
- *Resources clearing house.* The RBM Partnership should consider establishing an international 'Resource Clearing House' to enable the easy access and sharing of guidelines and best practice examples on communication activities. While realizing that communication programs cannot be standardized and participatory programs are required in addition to messaging, the resource clearing house would be a useful source for malaria communication materials: pamphlets, posters, audiotapes, videos, training materials, job aids, tools, electronic media and other media/materials designed to promote effective prevention, proper treatment and control of malaria. The clearing house should include materials that target different age groups and educational levels, using a variety of locally relevant languages.
- *Direct technical support for national malaria communication interventions.* Besides providing guidelines and best practices, it is imperative that the RBM Partnership assist countries directly with their national malaria communication strategies, including the design, implementation, evaluation and scale-up of activities. One strategy recommended is to directly support the placement of staff at the NMCP to coordinate malaria communication strategies within each high burden country.

Priorities for sustained control and elimination. As the RBM Partnership moves into 2015 and beyond, country communication programs will be as critical as during initial scale-up periods to ensure sustainability of the individual and community behaviors regarding malaria prevention and treatment. The activities mentioned below need to be started today. Service delivery, access issues and positive health related behaviors at the community and individual levels will need to be maintained, while governments and the donor community will face other priorities in the wake of diminished mortality due to malaria. Communication activities under the RBM Partnership will need to adapt to large scale maintenance programs while simultaneously keeping resources and health systems focused on malaria-related objectives. The key areas include:

D) Integration of community-level activities. Malaria communication initiatives that embrace diverse strategies to adapt to community realities will need to be merged into standard health message programs. There is a need to provide training for health workers and supervisors and to give them guidelines to ensure that routine service delivery fully supports malaria control and treatment. Health education around malaria prevention and control will also be incorporated into routine communication protocols and checklists at the community-level.

³² For example: Polio Eradication, StopTB, HIV/AIDS, TOSTAN.

This includes implementing guidelines for merging malaria messages into school packages, community service outlets and other participatory approaches. Guidelines for malaria health promotion at schools already exist³³ and can be developed further to support the multi-dimensional educational and cultural needs of all malaria endemic countries, regions and communities.

E) Strengthen communication and behavior change efforts for sustained control and elimination. Beginning today, activities to promote sustained malaria control will require different messages, channels and frequency of delivery. The RBM Partnership will facilitate consensus building and support operational research to provide guidelines for IEC / BCC programs for sustained control and elimination, as well as continuing to encourage monitoring and evaluation to ensure quality of interventions does not deteriorate and that activities remain adaptable to political, social-economic or epidemiological changes.

F) Additional considerations for elimination. While there is significant overlap in priorities for sustained control and elimination, there are some additional communication activities necessary as a program moves from sustained control to elimination. Specifically, given the length of each stage, varied communication approaches will be necessary as the program approaches elimination to ensure that messages evolve to reflect the changing epidemiology and maintain desired behaviors to achieve and sustain gains. In addition, it will be essential to emphasize the continued need for awareness and proactive intervention to avoid resurgence of the disease.

Organizational Implications

Currently, there is no structure within the RBM Partnership that coordinates partners' country level communication support. Scale-up of activities to achieve the 2010 targets requires a significant increase in the RBM Partnership's efforts in IEC / BCC as an integral part of the RBM package. Following a RBM Board decision in 2007, the MAWG was tasked with seeing where a revitalized focus on country level communication activities could be situated (e.g. as a task team or new WG).

Therefore, the RBM Partnership needs to clarify if a global coordinating mechanism (such as a working group) should be established and who/which group(s) within the RBM Partnership will coordinate the required communication and behavior change interventions. The decision on communication leadership within the RBM Partnership should involve close coordination and integration with partners, including donors and other stakeholders who have expertise in communication and behavior change methodologies with malaria, but must also link to the available expertise in other areas of health communication and health promotion to ensure adequate capacity and best practices are available.

³³ For example: *Malaria Prevention and Control: An Important responsibility of a Health-Promoting School*. Geneva, World Health Organization, April 2008. Also see WHO webpage (http://www.who.int/school_youth_health/resources/information_series/en/); Malaria Foundation International's Student Leaders Against Malaria network (SLAM).

Table IV.9: Summary of Communication and Behavior Change Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
Organizational Priority	Establish a coordinating mechanism such as a working group (Communications Working Group)	2010	RBM Board
C, D	Facilitate consensus building and consolidation of guidelines for communications programs to increase appropriate use of interventions	2010	Communications Working Group*
C, E	Prepare and disseminate best practices on IEC / BCC for the national, regional and community level	2010	Communications Working Group* , RBM Secretariat, SRNs
A, C	Provide technical assistance to countries to develop, review and roll-out their national malaria communication and behavior change strategies	2010	Communications Working Group* , Regional Networks and SRNs, Regional RBM partners ^b
C, D	Provide training guidelines, supervision guidelines and protocols/checklists to strengthen communication programs at the level of community health workers, etc.	2010	Communications Working Group* , SRNs, Regional RBM partners ^b
C, E, F	Establish standardized M&E indicators to monitor communication programs around elimination	2010	Communications Working Group* , MERG
B, C, E	Encourage operational research of communication channels, messages and approaches in further develop impact of communication programs	2010	Communications Working Group* , Group facilitating OR agenda, Research and Academia, TDR

* Assuming a Communications Working Group is established.

a) Main coordinating group / body in the RBM partnership indicated in bold. Closely linked contributors within the RBM partnership are also listed. RBM partners are not listed explicitly as their involvement occurs through the Working Group.

b) Regional RBM partners are country/regional offices of the WHO, UNICEF, World Bank, NGOs and other organizations.

YEAR: 2008

Name	Age		Address	History of Fever	Temperature	Other
	P	M				
MA A	C		CHI-OKOLU	NTL	-	3/12 (R)
			CHI-OKOLU	✓	-	1/12 (R)
			CHI-OKOLU	NTL	-	1/12 (R)
			CHI-OKOLU	NTL	-	1/12 (R)
			CHI-OKOLU	NTL	-	1/12 (R)
			CHI-OKOLU	YES	-	1/12 (R)

CHI-OKOLU
 FERUSOJ
 NERVOS
 AKTOWSO
 AKTOWSO
 AKTOWSO

AKTOWSO
 3/12 (R)
 1/12 (R)
 (R)

CHI-OKOLU YES
 CHI-OKOLU YES
 CHI-OKOLU YES
 CHI-OKOLU YES

9. Monitoring and Evaluation

Monitoring and Evaluation (M&E) has been central to the RBM Partnership's work from the outset—both within countries at national, district and local levels to track and guide the work, and outside of the country to inform the global and donor community on progress and opportunities. Robust and reliable data are critical for monitoring progress toward achieving the global goals, including the RBM targets (2010 and 2015) as well as the malaria-specific target of the Millennium Development Goals.³⁴

Monitoring has been defined as the *routine* tracking of program performance through record keeping, regular reporting, surveillance systems or surveys. In contrast, evaluation refers to the *episodic* assessment of a program's effectiveness, and the extent to which a particular program intervention may be linked to a specific output or result.³⁵ A strong, combined monitoring and evaluation system will help improve the performance of programs by assessing the degree to which a plan is implemented as planned and how successfully it has achieved its intended results.

The Roll Back Malaria Monitoring and Evaluation Reference Group (MERG) was established in 2003 in order to provide expert guidance on monitoring and evaluation for malaria at the global, regional and national levels.³⁶ To date, MERG has provided guidance on technical issues related to monitoring malaria control activities. Notably, this work has resulted in the development of a core set of indicators and standard data collection methods to ensure consistency and harmonization in malaria information reported through major national-level household surveys.³⁷ Since 2000, data on these core set of indicators have been routinely collected through the Multiple Indicator Cluster Survey (MICS), the Demographic and Health Surveys (DHS) and the Malaria Indicator Survey (MIS). The MIS was developed by MERG and its partners. Its development informed the malaria sections of both the MICS and the DHS surveys. All surveys are now being implemented in numerous countries across Africa.³⁸ This data collection has allowed for a more comprehensive assessment of progress of key malaria control interventions.

MERG has also provided guidance on important technical issues, such as monitoring malaria-specific mortality³⁹ and has supported partners in the development of major tools and reports, such as the Global Fund M&E Toolkit⁴⁰ as well as global malaria reports, including the Africa Malaria Report 2003, World Malaria Report 2005 and the Malaria and Children 2007 report.⁴¹ More information on the work of the MERG, as well access to these documents and reports are available at: <http://www.rollbackmalaria.org/merg.html>.

³⁴ The list of Roll Back Malaria goals and targets are available on the RMB webpage (http://www.rollbackmalaria.org/forumV/docs/gsp_en.pdf); MDG 6 focuses on combating HIV/AIDS, malaria and other diseases, and one of its targets is to have halted by 2015 and begun to reverse the incidence of malaria and other major disease. A full list of the Millennium Development Goals, including targets and indicators are available on the UN webpage (<http://www.un.org/millenniumgoals/>).

³⁵ *Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria, Second Edition*. The Global Fund to fight AIDS, Tuberculosis and Malaria, 2006 (http://www.theglobalfund.org/pdf/guidelines/pp_me_toolkit_en.pdf).

³⁶ *Framework for Monitoring Progress and Evaluating Outcomes and Impact*. Geneva, Roll Back Malaria, 2000 (http://rbm.who.int/cmc_upload/0/000/012/168/m_e_en.pdf).

³⁷ *Guidelines for Core Population Coverage Indicators for Roll Back Malaria: To Be Obtained from Household Surveys*. Calverton, Maryland, USA, Roll Back Malaria, MEASURE Evaluation, WHO, UNICEF, 2006.

³⁸ *Malaria Indicator Survey: Basic Documentation for Survey Design and Implementation*. WHO, UNICEF, MEASURE DHS, MEASURE Evaluation, CDC, 2005 (<http://www.rollbackmalaria.org/merg.html#MIS>).

³⁹ *Assessing the Impact of Malaria Control Activities among African Children Under Five Years of Age: Guidance Note*. Roll Back Malaria MERG, 2006 (<http://www.rollbackmalaria.org/merg.html#MIS>).

⁴⁰ *Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria, Second Edition*. The Global Fund to fight AIDS, Tuberculosis and Malaria, 2006 (http://www.theglobalfund.org/pdf/guidelines/pp_me_toolkit_en.pdf).

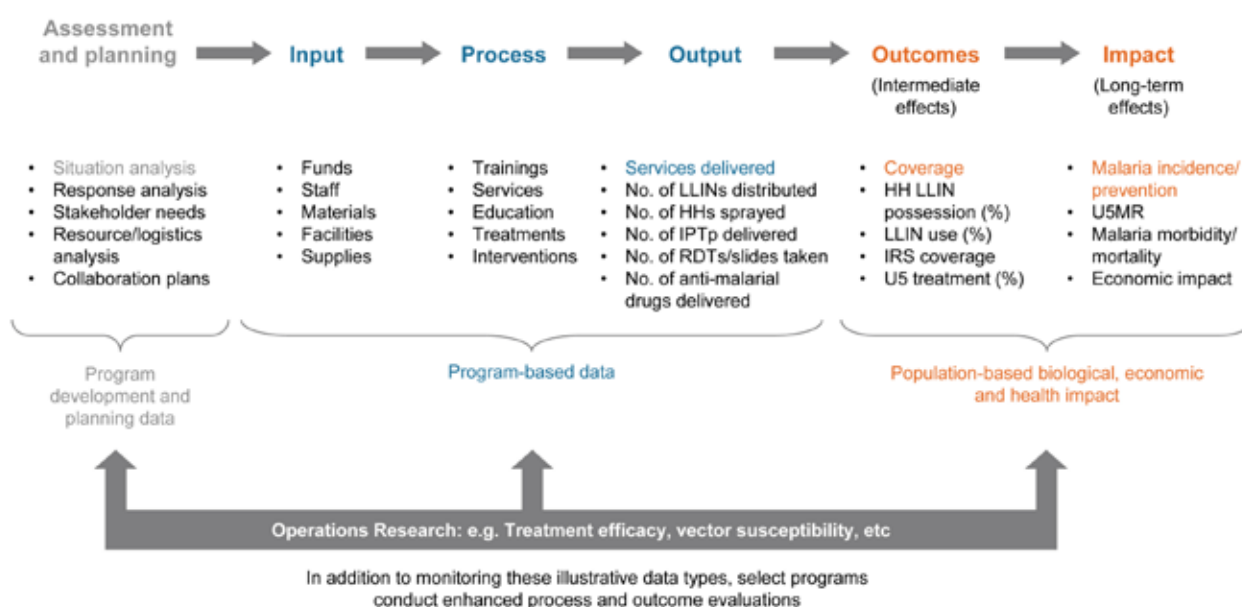
⁴¹ *Africa Malaria Report 2003*. WHO and UNICEF, 2003 (<http://malaria.who.int/>); *World Malaria Report 2005*, Geneva, World Health Organization, 2005 (<http://rbm.who.int/wmr2005/index.html>); *Malaria and children: Progress in intervention coverage*. New York, UNICEF, 2007 (http://www.childinfo.org/files/malaria_and_children.pdf).

As countries improve their control efforts, MERG continually reviews and updates monitoring and evaluation needs (including indicators and systems for information collection) for the evolving spectrum of malaria transmission and disease in existing and changing situations across countries in all regions.

MERG has developed a malaria M&E framework as a guide for “One M&E System for Malaria.” The framework will serve as a solid base for future M&E needs but may require modifications as programs move towards sustained control and elimination.

Figure IV.4 below outlines this M&E framework for disease control, and the different levels of data needed by program managers to assess program performance and to make mid-course corrections, if necessary, to reach intended goals. Importantly, M&E for malaria requires both a stable system that can be utilized to track malaria control programs over time, and a system that can be built on as new needs arise (e.g. monitoring for sustained control and elimination).

Figure IV.4: Malaria Monitoring and Evaluation framework



Key Challenges

Despite efforts, major challenges remain in monitoring the malaria situation in most endemic countries and for reporting on progress toward global goals. The new call for elimination of malaria places even further demands on these systems. This section highlights some notable gaps in malaria M&E in most endemic countries. For example, most endemic countries have weak vital registration and health information systems that greatly underestimate the number of clinical malaria cases and deaths in the general population. This is in large part because most patients with malaria do not seek treatment in formal health facilities, and many malaria-related deaths occur at home. These systems, however, are useful for informing local programs and may be used to help estimate disease incidence. In addition, there is an urgent need to strengthen the number of skilled malaria M&E staff at the national and sub-national levels, in particular, but also at the regional and global levels as well.

Importance of M&E to improve program management. A strong monitoring and evaluation system will help improve the performance of programs by assessing the degree to which an operational plan or design is implemented as planned and how successfully it has achieved its intended results. Thus, information is needed at different levels for different and specific purposes. Data for global or national tracking should augment efforts to strengthen good program monitoring for local action. In this context, malaria programs should be designed to develop sound routine and interval data collection as well as special focused studies to answer specific questions as they arise. The need for some special studies can be anticipated (e.g. ongoing tracking of intervention efficacy, quality, and safety); others will need to be developed as the need arises.

Strengthen M&E and data collection. Substantial work has been undertaken by the RBM MERG, national governments and country partners in order to improve information available on the malaria situation in endemic countries and to strengthen monitoring systems overall. Notably, this work has resulted in a wealth of new malaria data from DHS, MICS and MIS that has allowed for a more comprehensive assessment of progress in expanding coverage with key malaria control interventions. Routine reporting systems and special studies have been improved; however expanded work in additional countries and over time is required to fully track scale-up and sustained malaria control. For example, enhanced efforts are needed to strengthen routine surveillance systems, and skilled staff is needed at national and local levels, as well as at regional and global levels to collect relevant data, analyze data to present useable information and then support programs to actually make data-supported decisions.

Evolve M&E system from scale-up to sustained control to elimination. As programs evolve from initial rapid scale-up to high coverage, the frequency and focus of data collection should also evolve. As further experience is gained, the RBM partners through MERG will continue to provide guidance using the RBM website (see: <http://www.rollbackmalaria.org/merg.html>). Additionally, MERG will increase focus on developing indicators important for low transmission areas.

Determine efficacy and cost effectiveness through M&E. Studies are needed to clarify the efficacy and cost effectiveness of new interventions to establish their role in the package of malaria control interventions. Standard M&E systems can then be used to track coverage, overall benefit to populations at risk, and coverage shortfalls.

Strengthen funding and human resources. An estimated 5-10% of program costs (or a more carefully calculated budget using local information) should be allocated for the substantial work required in M&E. This funding is needed to support the development of the costed M&E plan, core staff, and the costs for national and local surveys, routine monitoring (including local training and supervision), transport, communications, administration and local and national reporting. A supportive human resources policy environment within the health sector will be required to assure that available finances can lead to quality staff to do the work. Linkage with other program M&E efforts (e.g. reproductive health, Expanded Program for Immunization, HIV/AIDS) will allow shared costs.

Monitor for resistance. Emergence of drug and pesticide resistance will have a major impact on the ability to sustain control efforts. Hence, resistance monitoring should be a priority in order to identify quickly where certain interventions will fail to work, so that new intervention strategies can be implemented where possible.

Priorities

While the core framework for malaria M&E is expected to be robust as countries move from scale-up to sustained control to elimination, some components will likely need additional attention and others may move to a different frequency. The following sections provide brief descriptions of priority issues for the stages from scale-up to sustained control and moving to elimination.

Priorities for scaling up. The RBM Partnership has prioritized scale-up for impact as a focus for all countries between now and 2010. Consequently, malaria M&E systems will need to be strengthened dramatically to document rapid scale-up and to track action in the delivery of interventions at local levels in the country and at the national level.

Priorities for endemic countries include:

- A) *Develop and use a costed malaria M&E Plan.* The plan should address national and local needs, specify key information and data collection needs, analysis and reporting responsibilities, and link to decision making. This work may draw on the RBM M&E framework and available tools such as the Check List for M&E Plan Development;⁴² the Global Fund Monitoring and Evaluation System Strengthening Tool,⁴³ the Data Quality Assessment Tool,⁴⁴ and the Attachment A from Global Fund proposals⁴⁵ to summarize program goals, objectives, indicators, targets, and timelines
- B) *Staff and build staff competencies* to complete the M&E work within national and partner organizations (e.g. NGOs and community groups)
- C) *Undertake national population-based surveys* at sufficient frequency to track progress in intervention scale-up, utilization, children under-five mortality, as well as other relevant impact measures
- D) *Strengthen health information and vital registration systems* so that they may provide more robust and timely data to track intervention coverage at sub-national levels, including district and community levels, as well as to monitor changes in the number of malaria case and deaths. Importantly, these systems will need to incorporate data from private and public health providers
- E) *Report on a regular and timely fashion* to all stakeholders and share the information widely for global tracking of progress and advocacy
- F) *Create a culture* of reporting and evaluating relevant data
- G) *Ensure regular monitoring and reporting* of potential drug and pesticide resistance

Priorities for country partners and the RBM Partnership include:

- H) *Support countries* in each of the areas listed above with particular attention to capacity building at national and local levels
- I) *Strengthen international mechanisms* to compile relevant malaria information from endemic countries, including tracking progress and disparities in intervention scale-up and other health and socio-economic indicators. This information should be jointly reported by partners to monitor progress towards global targets
- J) *Report on changes in malaria burden.* While the long-term goal is to strengthen routine reporting systems in endemic countries, there is an immediate and urgent need to report on changes in the malaria burden since such information is critical for improved program management and to monitor global goals. To this end, a model has been developed that estimates malaria-specific mortality based on coverage estimates and their known efficacies. This model is now being developed into a user-friendly software for countries to use. There is an immediate need to implement and train NMCPs in the use of this software
- K) *Support countries in their development of a costed M&E plan.* Track resource allocation, actions and progress from the partners to assure that M&E needs and gaps are addressed as laid out in this plan

Priorities for sustained control and elimination. Following the rapid scale-up to high coverage that is to be achieved by 2010, the RBM Partnership has set priorities to help countries sustain systems for high intervention coverage and move toward elimination by 2015. Support for M&E to track these stages will require continued strengthening of systems noted above, and additional work to support specific sustained control and elimination needs. Several aspects of this “additional work” can be anticipated: it will need to draw increasingly on available technologies of mapping and communication to track and respond to intervention gaps and infections and illness; it will require increasing capacity at local levels (districts and communities) for information and for response.

⁴² *Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria, Second Edition.* The Global Fund to fight AIDS, Tuberculosis and Malaria, 2006 (http://www.theglobalfund.org/pdf/guidelines/pp_me_toolkit_en.pdf).

⁴³ *Monitoring and Evaluation Systems Strengthening Tool.* The Global Fund to fight AIDS, Tuberculosis and Malaria, 2006 (http://www.theglobalfund.org/pdf/guidelines/M+E_Systems_Strengthening_Tool.pdf).

⁴⁴ *Data Quality Assessment Tool.* The Global Fund to fight AIDS, Tuberculosis and Malaria, 2007 (http://theglobalfund.org/en/files/rfp/RFP-HQ-GVA-07-039/DRAFT_DQA_Guidelines_for_Implementation.doc).

⁴⁵ *Proposal Form Round 8, Attachment A.* The Global Fund to fight AIDS, Tuberculosis and Malaria, 2006 (<http://www.theglobalfund.org/en/apply/call8/single/>).

Priorities for endemic countries include:

- L) *Continue to strengthen all systems* described above under the scale-up stage
- M) *Establish or strengthen systems* at district and community levels to optimally track and immediately resolve local gaps and needs in intervention coverage
- N) *Strengthen local systems* to undertake surveillance and active case detection of malaria infection and illness and to connect to immediate response systems to investigate and address local transmission.
- O) *Staff and build staff competencies* to support this enhanced work at local levels
- P) *Report regularly to all stakeholders.* If routine systems provide robust and timely coverage and impact data, then the need for model-based estimates of the malaria burden and frequent national population-based surveys would decline. As the country moves closer toward the goal of elimination, there may also be less need for routine facility-based monitoring systems to track the numbers of cases. However, the need to regularly report to all stakeholders and share the information widely for global tracking of progress and advocacy will continue.

Priorities for country partners and the RBM Partnership include:

- Q) *Continue to strengthen* all systems described above under the scale-up stage
- R) *Support countries* in each of the additional areas listed above with particular attention to capacity building and technology support at national and local levels
- S) *Increasingly move national support systems* to the sub-regions to enhance timely response to national and local needs
- T) *Develop core indicators* for countries with low incidence as value of survey data declines

Organizational Implications

MERG has been responsible for providing M&E guidance to countries and the RBM Partnership. In the context of growing demands for information to track country progress, MERG may need to further expand its mandate to undertake the RBM Partnership's work and to support the country work. This support includes helping countries develop costed national M&E plans, and training qualified workers. These needs will likely increase as countries transition from scale-up to sustained control to elimination, considering the financing, staff and capacity building required at district and community levels.

Table IV.10: Summary of Monitoring and Evaluation Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
A, D, H, K	Support the development of costed M&E plans through regional and country support using MESST, M&E plan checklist, the GF Attachment A and other tools and templates	Ongoing	MERG
B, F, O, R, S	Examine and address M&E human resource needs at national, regional and global levels	tbd	RBM partners (via MERG)
L, M, N, Q, T	Continue to strengthen M&E guidelines for scale-up and expand the scope to address sustained control and elimination	tbd	MERG
C, E, I, J, P	Establish and maintain global and regional tracking of malaria control progress [*]	Ongoing	UNICEF, WHO, MERG

a) Main coordinating group / body in the RBM partnership indicated in bold. Closely linked contributors within the RBM partnership are also listed. RBM partners are not listed explicitly as their involvement occurs through the Working Group.

* The major decision by the RBM Partnership to effect the “Partnership-support for M&E” will be to determine what investment (financing and staff) the Partnership and partners are prepared to make for what specific outcomes. To date, the MERG as an advisory / technical group represents modest partner-donated staff time and travel for a specific set of guidance and oversight actions. The MERG members have worked hard, but they are not dedicated staff that can be assigned a partnership workplan. The partners have a clear thirst for information, often driven by internal requirements, but have not invested in a joint partnership system to support the core and shared information collection systems. Thus the resources (if they exist) are provided by individual grants or donor support or national systems at country level. This process does not easily translate to address the need for a comprehensive data / information system that tracks country and regional progress, intervention coverage, disease burden reduction, economic investment and return on investment, etc.

“ *The Global Malaria Action Plan aims to ensure that no country is left behind in the global fight against malaria - comprehensive, continent-wide coverage is critical to long-term success.* ”

Tedros Adhanom Ghebreyesus, Minister of Health of Ethiopia



10. Humanitarian Crises

Up to 30% of malaria deaths in Africa occur in the wake of war, local violence or natural disasters. Malaria deaths often far exceed those that are directly caused by the emergency.⁴⁶ Furthermore, civil unrest has led to significant malaria resurgences in the past, for example in Afghanistan and Burundi.⁴⁷

To achieve the goals of the RBM Partnership, especially in the scale-up and sustained control stages, special efforts must be made to control malaria in humanitarian crises as these situations may quickly lead to a loss of the benefits achieved previously by the malaria control programs and a deterioration of malaria control in the affected country.

A humanitarian crisis is a situation which is triggered by either manmade disasters or natural disasters or even both. Most emergencies follow disasters of human cause and are described as situations that affect large civilian populations with war or civil strife, food shortages and population displacement, resulting in excess mortality and morbidity.⁴⁸ Humanitarian crises have an acute phase (immediate: 0 to 4 weeks; stabilization: 4 to 10 weeks) and a chronic phase (recovery: several months; settlement or repatriation: months or years). During the acute, immediate phase, the affected people are usually not accessible. Also, shifts between different phases for many years are common.

Today, the evidence suggests that natural disasters are becoming as common as manmade disasters and affect as many if not more people (e.g. tsunami, earthquake, large-scale flooding and famine). Humanitarian crises and other emergencies can undermine pre-existing malaria control measures and lead to a collapse of health services. If malaria was previously not endemic, the populations may have limited coverage with effective treatments and preventive measures. Displaced persons living in makeshift housing are vulnerable to malaria because they are more likely to be bitten by mosquitoes, are often ill with other infections and lack access to health care.

International responses to humanitarian crises follow highly coordinated processes. For example, when faced with a crisis, the Office for the Coordination of Humanitarian Affairs (OCHA) with guidance from the Inter-Agency Standing Committee (ISAC) coordinates the humanitarian activities of UN agencies and international NGOs.⁴⁹ Humanitarian activities are grouped into 11 clusters, of which the 'health cluster' is currently led by WHO. International agencies involved in the health cluster are aware of the risks of malaria and are involved in distributing Interagency Emergency Health Kits. These kits are always supplied with the malaria modules and are designed to meet the initial primary health care needs of a displaced population without medical facilities, or a population with disrupted medical facilities in the immediate aftermath of a natural disaster or during an emergency.⁵⁰ For malaria, the basic malaria module includes artemether-lumefantrine, quinine sulfate and rapid diagnostic kits.

Furthermore, in humanitarian crises, the Communicable Diseases Working Group on Emergencies (CD-WGE) at WHO headquarters provides technical and operational assistance, including risk assessments, technical notes and country specific profiles. Technical notes provide up-to-date guidance on the major communicable disease threats to health professionals in UN agencies, nongovernmental organizations, donor agencies and local authorities working with populations affected by emergencies. The WHO-Global Malaria Program (GMP) contributes malaria-specific information to these technical notes.

⁴⁶ *Guiding principles for malaria control in acute and chronic phase emergencies in Africa, Conclusions of WHO/ Roll Back Malaria Consultation.* Geneva, World Health Organization, 2004.

⁴⁷ Fatoumata NT and Nabarro D. *Breaking the cycle of malaria and death in emergencies: the way forward.* Humanitarian Practice Network, 2008.

⁴⁸ *Malaria in Complex Emergencies: An inter-agency field handbook.* Geneva, World Health Organization, 2005.

⁴⁹ See Health Action in Crisis webpage (<http://www.who.int/hac/en/>).

⁵⁰ *The Interagency Emergency Health Kit 2006, An interagency handbook,* Geneva, World Health Organization 2006.

Priorities

The Malaria in Emergencies Network (MEN) serves as a mechanism to provide effective and efficient response in malarious countries affected by humanitarian crises and other emergencies. Responses include evidence-based, malaria-specific guidelines and technical assistance to partners and agencies implementing humanitarian aid. MEN consists of more than 60 members from numerous organizations such as WHO, UNICEF, Merlin, the MENTOR Initiative, and Médecins Sans Frontières.

Priorities for scaling up. For 2010, the RBM Partnership will enhance the current mechanisms to support high-burden control countries in humanitarian crises. These mechanisms include the support by the Harmonization Working Group and support by the WHO-GMP. The RBM Partnership will also ensure a close link and active participation with the Malaria in Emergencies Network, which is facilitated by WHO.

A) Support countries in humanitarian crises. The Harmonization Working Group, WHO-GMP and the MEN as well as other partners supporting scale-up will provide support where it is possible, for example in countries that are experiencing prolonged humanitarian crises, such as Sudan, Chad and the Democratic Republic of the Congo. For example, the partners will help develop applications for funding from sources such as the Global Fund and will provide technical assistance to strengthen and develop malaria control programs.

B) Ensure a strong Malaria in Emergencies Network. WHO facilitates MEN, which is open to all major partners and implementing agencies. The network hosts regular telephone conferences and has an email *listserv* to share vital information. WHO will continue to support and encourage participation in this network. To strengthen the network, there will be a review of the list of current members and additions will be made as necessary. There should be regular consultations of experts, such as the participants in MEN, perhaps through biannual meetings and other forums. The RBM Partnership should advocate for the importance of these meetings to strengthen the global response and support in humanitarian crises and assist with raising the required resources.

C) Ensure exchange between RBM and MEN. The RBM Partnership will provide a close link and active participation with MEN. This may include recommending that the Harmonization Working Group continues to have a representative participate in MEN and key MEN members participate in select RBM meetings during the year, e.g. the HWG meeting. The RBM Partnership will also promote better visibility of MEN by providing a link on the website and by regularly posting upcoming and recent activities and developments together with the MEN facilitator.

D) Update the handbook on Malaria in Complex Emergencies. In 2005, WHO published a detailed inter-agency handbook: *Malaria in Complex Emergencies*.⁵¹ This handbook provides policy-makers, planners, field program managers and medical coordinators with practical guidance for designing and implementing measures to reduce malaria morbidity and mortality. MEN is currently facilitating the production of an updated handbook. The next edition should provide not just technical advice but solid “delivery strategies” that have been proven to work in emergencies and which are appropriate in different “humanitarian crisis” settings, e.g. developed to focus on both man-made and natural humanitarian crises.

E) Advocate for sufficient supplies for rapid response. The RBM Partnership will advocate that malaria modules continue to be included in international emergency health kits. The RBM Partnership will also advocate for the continued funding and availability of Interagency Emergency Health Kits. The RBM Partnership, with guidance from MEN, will assess the recommendation to have a small stockpile of the kits, or potentially only the malaria modules, available for immediate delivery in a humanitarian crisis. Such a stockpile could be coordinated and logistically organized with the WHO-Health Action in Crises Operations Group and pre-positioned at the hubs in Dubai and Accra.

F) Advocate for resources in humanitarian crises. During the acute phase of humanitarian crises, there is often a need for technical assistance from a malaria expert for a short time period, such as three weeks. The RBM Partnership will advocate for the importance of such support to partner organizations.

⁵¹ *Malaria in Complex Emergencies: An inter-agency field handbook*. Geneva, World Health Organization 2005.

During prolonged humanitarian crises, special funds support the development of malaria interventions to coordinate activities within the country. In addition, the funds help countries support a full-time person to redevelop their malaria control programs. These positions have the role of being international program officers supporting the coordination of the activities of the UN agencies, international and local NGOs. These positions also work closely with implementing partners (international and local NGOs) in ensuring that funds and evidence based tools are available to ensure health staff on the ground adequate technical capacity building and supervision to use tools effectively. Successful examples in the past have been in Afghanistan,⁵² Liberia, the Democratic Republic of Congo and Sudan (Southern Sudan).⁵³ The RBM Partnership will advocate for financial resources to facilitate the recruitment of short term staff.

G) Encourage operational research into best delivery approaches. Operational research for humanitarian crises is important to identify effective delivery mechanisms for all emergency situations. The RBM Partnership will also try to create a better understanding of how to support countries in the shift from the humanitarian crisis situation back to a normal, strong malaria control program.

Priorities for sustained control and elimination. As countries move into sustained control and elimination, the potential risks of re-emergence following humanitarian crises will be substantial, especially in areas with high natural transmission levels. Continued emphasis on country preparedness will be important to guard against failures of malaria control in humanitarian crisis situations of the future.

H) Continue advocacy. The RBM Partnership will advocate maintaining the awareness of malaria in humanitarian crises with international donors and with governments. This is particularly important when malaria control programs are successful and malaria is at low levels. Given the possibility that countries with successful malaria control can also be put at risk if their neighbors are experiencing displacement and migration, the RBM Partnership will advocate for funding and technical assistance on malaria control across entire regions. The goals will be to implement malaria interventions in emergency situations and also to maintain existing malaria control structures.

I) Planning for humanitarian crises. In addition, complimentary to a strong response mechanism once a humanitarian crisis occurs, it is fundamental that countries are prepared and have plans as well as emergency stocks in place to deal with a humanitarian crisis. For example, in anticipation of the humanitarian crisis in Iraq, partners increased malaria commodity stocks within the country to allow for continued malaria control when procurement or delivery of commodities is difficult or impossible. The RBM Partnership will continue to provide support to countries with guidance and best practices for how such preparation should look.

J) Encourage research to modify tools for humanitarian crises. The RBM Partnership will support research to identify innovative tools for prevention and cures that are suitable in humanitarian crisis and poorly prepared malaria epidemic situations. One example would be new formulation ACTs that significantly reduce the daily number of tablets to be taken.

Organizational Implications

The existing mechanisms should be reinforced and strengthened. The RBM Partnership will consider a dedicated liaison with the Malaria in Emergencies Network, to ensure alignment and to provide support where required.

In terms of costs, there is a need for an increase in resources towards mechanisms that are required to help in humanitarian crises. These include strengthening MEN, funding full-time staff in a few high priority countries to coordinate the activities within countries in prolonged humanitarian crises, funding the stock pile of interagency emergency health kits (IEHKs) and funding operational research into new approaches and tools. The RBM Partnership could provide support by advocating for these resource needs.

⁵² Kolaczinski J. Roll Back Malaria in the aftermath of complex emergencies: the example of Afghanistan. *Tropical Medicine and International Health*, 2005, Vol. 10.

⁵³ Dr. José Nkuni, World Health Organization, personal communication, 2008.

Table IV.11: Summary of Humanitarian Crises Activities

Reference to priority	Major actions	Completed by	Coordinator (bold) / Sub-coordinators ^a
A	Coordinate implementation support to high-burden countries in humanitarian crises (e.g. DRC)	Ongoing	HWG, SRNs
D	Update Interagency Handbook on Complex Emergencies with major partners	2010	WHO-GMP (MEN)
E	Advocate for continued inclusion of malaria commodities for treatment and diagnostics in emergency health kits due to risks of malaria in humanitarian crises	2010	WHO-GMP (MEN)
F	Advocate to donors and international community for need of sustained financial support in drawn-out humanitarian crises	2010	MAWG
C	Collate and publish information on humanitarian crises on WHO-GMP website, as well as a link to this site from the RBM Partnership website	2010	WHO-GMP (MEN), RBM Secretariat
A, I, F, H	Provide technical assistance to countries in sustained control and elimination to incorporate detailed plans for malaria control in humanitarian emergency situations into their overall planning process	2015	WHO-GMP (MEN), HWG
G	Encourage operational research into new interventions for the management of malaria in humanitarian crises, e.g. blankets, insecticide-treated sheets, etc	2015	WHO-GMP (MEN)

a) Main coordinating group / body in the RBM Partnership indicated in bold. Closely linked contributors within the RBM Partnership are also listed. RBM Partners are not listed explicitly as their involvement occurs through the Working Group.



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Appendix 1: Contributors

The Global Malaria Action Plan has been developed in consultation with members of the Roll Back Malaria (RBM) Partnership and with experts from a diverse set of fields ranging from economics to malaria control to epidemiology.¹ The work has been coordinated by the RBM Secretariat and the Boston Consulting Group. The RBM Partnership would like to thank the more than 250 individuals and institutions for the invaluable input and advice they have provided to the development of the Global Malaria Action Plan.²

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¹ The GMAP is comprehensive and covers a wide range of topics; all sections of the plan have been reviewed and approved by multiple stakeholders. Individually, contributors may have provided input to and / or approved specific sections, but each contributor has not necessarily reviewed or approved the plan in its entirety.

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Consultations focused on the GMAP

February 2008, 1st Open Discussion Forum (Teleconference)
 March 2008, 2nd Open Discussion Forum (Teleconference)
 April 2008, RBM Working Group Consultation meeting (Washington DC, USA)
 April 2008, RBM EC Consultation meeting (Washington DC, USA)
 April 2008, Endemic Countries Consultation meeting (Addis Ababa, Ethiopia)
 June 2008, 3rd and 4th Open Discussion Forums (Teleconference)
 July 2008, RBM Consultation meeting (Geneva, Switzerland)

Meetings at which information was shared on and/or input gathered for the GMAP

November 2007, RBM 13th Board (Addis Ababa, Ethiopia)
 January 2008, WARN annual meeting (Bamako, Mali)
 January 2008, Trans-Zambezi Initiative meeting (SARN) (Livingstone, Zambia)
 January 2008, Informal Consultation on Global malaria control and elimination: A Technical Review (Geneva, Switzerland)
 January 2008, MIP GMAP teleconference (Teleconference)
 January 2008, MERG annual meeting (Geneva, Switzerland)
 January 2008, MAWG annual meeting (London, UK)
 January 2008, PSM WG GMAP teleconference (Teleconference)
 February 2008, HWG annual meeting (Geneva, Switzerland)
 February 2008, RWG teleconference (Teleconference)
 February 2008, WIN GMAP teleconference (Teleconference)
 February 2008, CARN quarterly meeting (Douala, Cameroon)
 February 2008, MIP Consortium First Meeting (Geneva, Switzerland)
 March 2008, Consultation on Modeling for Malaria Eradication (Seattle, USA)
 March 2008, Malaria Elimination Group First Meeting (Santa-Cruz, USA)
 March 2008, Consultation on R&D for Malaria Eradication (Seattle, USA)
 April 2008, Operational Research in TB, HIV/AIDS and Malaria Control Programs (Geneva, Switzerland)
 April 2008, PSM WG annual meeting (Woerden, Netherlands)
 April 2008, MIP WG annual meeting (Brazzaville, Congo)
 May 2008, RBM 14th Board (Geneva, Switzerland)
 June 2008, MERG annual meeting (Bamako, Mali)

Appendix 2: Glossary

Acquired immunity	People residing in malaria-endemic regions over time acquire immunity to malaria through natural and continued exposure to malaria parasites. Acquired immunity to malaria parasites is not sterile, i.e. it generally protects against severe malaria although low level parasite infections may still occur.
Adjuvant	A substance that helps and enhances the pharmacological effect of a drug or increases the ability of an antigen to stimulate the immune system in a vaccine.
Anopheles	Mosquito genus that transmits the disease.
Antigen	Substance that prompts the generation of antibodies and can cause an immune response; used in vaccines.
Artemisinin-based combination therapy (ACT)	A combination of artemisinin or one of its derivatives with an anti-malarial or anti-malarial drugs of a different class. ^a
Asymptomatic reservoir	Group of individuals carrying <i>Plasmodium</i> infections without any clinical symptoms.
Behavior Change Communication (BCC)	BCC includes the basic components of IEC (please see IEC for definition), but employs a more participatory approach to engaging communities and focuses more on the end actions of the client in regard to the health intervention.
Blood-stage infection	The life-cycle of the malaria parasite in host red blood cells (intraerythrocytic development) from merozoite invasion to schizont rupture (merozoite => ring stage=>trophozoite=>schizont=>merozoites). Duration approximately 48 hr in <i>Plasmodium falciparum</i> , <i>P. ovale</i> and <i>P. vivax</i> ; 72 h in <i>P. malariae</i> . ^b
Burden	The morbidity and mortality impact of malaria. In the document, the text will refer to either the morbidity or mortality burden.
Chloroquine (CQ)	An anti-malarial drug that been used extensively for the treatment and prevention of malaria. Widespread resistance has now rendered it ineffective against <i>P. falciparum</i> infections in most parts of the world, although it still maintains considerable efficacy for the treatment of <i>P. vivax</i> , <i>P. ovale</i> and <i>P. malariae</i> infections. ^c
Control	Reduction of disease incidence, prevalence, morbidity or mortality to a locally acceptable level as a result of deliberate efforts; continued intervention measures are required to maintain the reduction. ^d
Coverage	<p>For each of the following interventions, coverage is defined as:</p> <ul style="list-style-type: none"> • Long-Lasting Insecticidal Nets (LLINs): A household owns one long-lasting insecticidal bed net for every two people living there • Indoor Residual Spraying (IRS): The interior walls of every house are routinely sprayed at appropriate intervals with an effective insecticide • Intermittent Preventive Treatment (IPTp): A pregnant woman living in a high transmission setting receives at least 2 doses of an appropriate anti-malarial drug during her pregnancy • Other vector control measures: Other targeted approaches (e.g. larviciding, environmental management, etc.) are applied wherever appropriate • Diagnosis: A patient receives prompt parasitological confirmation by microscopy or rapid diagnostic tests (RDTs) of malaria diagnosis • Treatment: An infected person receives appropriate anti-malarial drugs for uncomplicated or severe malaria within one day of onset of illness <p>Please note that not all interventions should be used in every setting. See <i>Part II, Chapter 2: Control: Overcoming Malaria</i>.</p>

DDT	Dichloro-Diphenyl-Trichloroethane (DDT) is an insecticide used in indoor residual spraying.
Elimination	Reduction to zero of the incidence of locally transmitted infection caused by <i>Plasmodia</i> in a defined geographical area as a result of deliberate efforts; continued intervention measures are required to prevent reintroduction. ^e
Eradication	Permanent reduction to zero of the global incidence of infection caused by <i>Plasmodia</i> as a result of deliberate efforts; intervention measures are no longer needed. ^f
Gametocytes	Sexual stages of malaria parasites present in the host red blood cells, which are infective to the <i>Anopheles</i> mosquito. ^g
Glucose-6-phosphate dehydrogenase deficiency	Genetic disorder that mainly affects red blood cells and occurs in 10-25% of sub-Saharan African populations. In affected individuals, a defect in an enzyme called glucose-6-phosphate dehydrogenase causes red blood cells to break down prematurely.
Home management of malaria	Coverage with malaria interventions provided at the community level, often to individual households.
Humanitarian Crisis	A humanitarian crisis is a situation which is triggered by either manmade disasters or natural disasters or even both. Crises affect large civilian populations by causing food shortages and population displacement, resulting in excess mortality and morbidity and high risks of malaria. Also known as Complex Emergency.
Hypnozoites	Persistent liver stages of <i>P. vivax</i> and <i>P. ovale</i> malaria that remain dormant in host hepatocytes for a fixed interval before maturing to hepatic schizonts. These then burst and release merozoites, which infect red blood cells. Hypnozoites are the source of relapses. ^h
Indoor Residual Spraying (IRS)	Application of long-lasting chemical insecticides on the walls and roofs of all houses and domestic animal shelters in a given area, in order to kill adult mosquito vectors that land and rest on these surfaces.
Information, Education, Communication (IEC)	IEC is broadly defined as combining communication strategies, approaches and methods that provide knowledge to enable individuals, families, groups, organizations and communities to play active roles in achieving, protecting and sustaining their own health.
Insecticide-Treated Nets (ITNs)	Nets that have been treated with insecticides such as pyrethroids to protect from mosquito bites during the night. Insecticide-treated nets require regular re-treatment. Also see Long-Lasting Insecticidal Nets (LLINs).
Integrated vector management (IVM)	Integrated Vector Management is defined as a rational decision-making process for the optimal use of resources for vector control to make deliberate, evidence-based decisions to target and implement vector control operations including LLINs, and in some situations IRS, larval source management and other measures.
Intermittent preventive treatment (IPT)	The administration of a full course of an anti-malarial treatment to a population at risk at specified time points regardless of whether or not they are known to be infected. IPT in pregnancy (IPTp) is WHO recommended policy in high transmission settings. In IPTp, pregnant women, whether or not they show symptoms of malaria infection, receive at least two doses of an anti-malarial drug, currently sulphadoxine-pyrimethamine (SP), at each scheduled antenatal visit after the first trimester. Research is currently ongoing to assess the benefits of providing IPT for children (IPTc) and infants (IPTi).
Intervention	Products used for malaria prevention or case management. Most common are Long-Lasting Insecticidal nets (LLINs), Indoor Residual Spraying (IRS), drugs (ACTs, CQ), microscopy, and Rapid Diagnostic Tests (RDTs).

Larviciding	Destruction of mosquito larvae by measures such as treating mosquito larvae surfaces, intermittent irrigation, sluicing or biological control.
Long-lasting insecticidal nets (LLINs)	A long-lasting insecticidal net (LLIN) is a factory-treated mosquito net made with netting material that has insecticide incorporated within or bound around the fibers. The net must retain its effective biological activity without re-treatment for at least 20 WHO standard washes under laboratory conditions and three years of recommended use under field conditions.
Monitoring and Evaluation (M&E)	Monitoring is the <i>routine</i> tracking of the key elements of program performance through record keeping, regular reporting, surveillance systems or surveys. Evaluation is the <i>episodic</i> assessment of a program, and the extent to which a particular program intervention may be linked to a specific output or result. ⁱ
Malaria-free certification	Process by which WHO certifies an entire country malaria-free following at least three consecutive years of no local transmission of any of the four human malaria species. Countries can still experience imported cases, as long as no onward transmission occurs due to intense surveillance and effective control.
Monotherapy	Anti-malarial treatment with a single medicine, either a single active compound or a synergistic combination of two compounds with related mechanism of action. ^j
Morbidity	Morbidity refers to the incidence of malaria cases.
Mortality	Mortality refers to the deaths caused by malaria.
Parasitemia	Amount of blood-stage parasites that an individual has within their red blood cells. Often expressed as percentage of infected red blood cells to red blood cells counted.
<i>Plasmodium</i>	A genus of protozoan vertebrate blood parasites that includes the causal agents of malaria. <i>Plasmodium falciparum</i> , <i>P. malariae</i> , <i>P. ovale</i> and <i>P. vivax</i> cause malaria in humans.
Platforms	Viruses, bacteria, virosomes, and nanoparticles used in vaccines to increase breadth, magnitude, and duration of induced immunity.
Population at risk	Human population living in a geographical area where locally acquired malaria cases occur and they are at risk of being infected with the parasite.
Pre-elimination	Malaria control program re-orientation period between the sustained control and elimination stages where emphasis on surveillance, reporting and information systems increases.
Prevention of reintroduction	The period following elimination once surveillance shows a reduction to zero of all locally acquired cases (this does not include imported cases). Countries must be in the stage at least three years before eligible for WHO malaria-free certification.
Primaquine	Effective against intrahepatic forms of all types of malaria parasite. It is used to provide radical cure of <i>P. vivax</i> and <i>P. ovale</i> ^k malaria, in combination with a blood schizontocide for the erythrocytic parasites. Primaquine is also gametocytocidal against <i>P. falciparum</i> and has significant blood stage activity against <i>P. vivax</i> (and some against asexual stages of <i>P. falciparum</i>).
Pyrethroid	Insecticide commonly used in insecticide-treated nets.
Rapid Diagnostic Tests (RDTs)	An antigen-based stick, cassette or card test for malaria in which a colored line indicates that plasmodial antigens have been detected.

RBM Partnership	The RBM Partnership is a mechanism to facilitate and coordinate the planning and implementation of activities of individual partners to avoid duplication and fragmentation and to ensure optimal use of resources. The RBM Partnership's strength lies in its ability to form effective partnerships both globally and nationally. Partners are malaria-endemic countries, bilateral and multilateral development partners, the private sector, local and global nongovernmental organizations, community-based organizations, foundations, and research and academic institutions. Each one maintains its independent function while at the same time contributing to RBM.
RBM Partnership bodies	RBM Partnership bodies are the mechanisms within the RBM Partnership that coordinate and facilitate the activities of the Partnership, i.e. the RBM Board, the RBM Executive Committee, the RBM Partnership Secretariat, the Working Groups and the Sub-Regional Networks.
Reproduction rate	Measure describing how many new infections can occur from one infected case.
Resistance	Reduced susceptibility of the causal agent to a drug. WHO defines resistance to anti-malarials as the ability of a parasite strain to survive and/or multiply despite the administration and absorption of a medicine given in doses equal to - or higher than - those usually recommended but within the tolerance of the subject ^l . Insecticide resistance refers specifically to resistance against insecticides used for vector control of the malaria vector.
RTS,S	The most clinically advanced vaccine candidate scheduled to enter Phase 3 in late 2008 or early 2009. It appears to diminish the capacity of the malaria parasite to infect, survive, and develop in the human liver. ^m
Scale-up for impact (SUFI)	Rapidly reach universal (100%) coverage for all populations at risk with locally appropriate malaria control interventions (i.e. LLINs, IRS, IPTp, drugs and diagnostics), supported by strengthened health systems. This will have a substantial impact on malaria burden.
Slide positivity rate (SPR)	The proportion of slides found positive among the slides examined. ⁿ
Sporozoites	Motile malaria parasites that are infective to humans, inoculated by a feeding female <i>Anopheles</i> mosquito. Sporozoites invade hepatocytes. ^o
Sulphadoxine-Pyremethanine	Combination treatment with sulphadoxine and pyremethanine. It targets the blood-stage infection and is also possibly active against pre-erythrocytic forms of the malaria parasite and inhibits sporozoite development in the mosquito vector. It is effective against all four human malarias, although resistance has emerged and is wide-spread.
Surveillance	Surveillance is the regular collection, monitoring and analysis of information in a given population or subpopulation to detect the presence and any epidemiological changes of malaria.
Sustained control	Once universal coverage with appropriate malaria interventions is achieved, sustained control is the period during which malaria control measures are stabilized and universal coverage is maintained by continued strengthening of health systems, until local field research suggests that coverage can gradually be targeted to high risk areas and seasons only, without risk of a generalized resurgence.
Tafenoquine	An 8-aminoquinoline drug manufactured by GlaxoSmithKline being investigated for both treatment and prevention. The main advantage of tafenoquine is that it has a long half-life and therefore does not need to be taken as frequently as primaquine.

Transmission intensity	<p>Rate at which people in a given area are infected with malaria parasites by mosquitoes (usually expressed by the annual entomological inoculation rate). There is as yet no clear consensus on criteria for determining the thresholds between high, and low to moderate transmission settings. In this report, transmission is defined in line with WHO <i>World Malaria Report 2008</i>^p:</p> <ul style="list-style-type: none"> • Areas of low transmission: the reported malaria case incidence from all species is less than 1 per 1000 population per year but greater than zero. Transmission in these areas is generally highly seasonal with or without epidemic peaks. • Areas of high transmission: the reported malaria case incidence from all species is 1 or more per 1000 population per year • Malaria-free areas: there is no continuing, local mosquito-borne malaria transmission, and all malaria cases are introduced. <p>Guerra et al (2008)^q, uses stable vs. unstable to identify populations at risk. More specifically:</p> <ul style="list-style-type: none"> • Unstable risk was defined as <i>P. falciparum</i> API (Annual Parasite Incidence) < 0.1 per 1000 population per annum • Stable risk was defined as <i>P. falciparum</i> API ≥ 0.1 per 1000 population per annum.
Universal coverage	100% of the populations at risk are covered by appropriate malaria interventions. See definition for coverage above.
Utilization	<p>The appropriate usage of malaria interventions, e.g.</p> <ul style="list-style-type: none"> • All members of a household sleep under LLINs each night • A house is sprayed appropriately each transmission cycle • A pregnant woman takes at least 2 doses of IPTp during pregnancy • Patients take the complete treatment cycle of anti-malarial drugs as recommended.

Glossary footnotes

^a Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

^b Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

^c Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

^d Dowdle W. The principles of disease elimination and eradication from the 1997 Dahlem Workshop. WHO Bulletin, 1998, 76 (supplement 2).

^e Dowdle W. The principles of disease elimination and eradication from the 1997 Dahlem Workshop. WHO Bulletin, 1998, 76 (supplement 2).

^f Dowdle W. The principles of disease elimination and eradication from the 1997 Dahlem Workshop. WHO Bulletin, 1998, 76 (supplement 2).

^g Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

^h Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

ⁱ Monitoring & Evaluation Toolkit - HIV/AIDS, Tuberculosis and Malaria. Geneva, World Health Organization, January 2006.

^j Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

^k Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

^l Malaria Elimination: A field manual for low and moderate endemic countries. Geneva, World Health Organization, 2007.

^m Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

ⁿ Malaria Elimination: A field manual for low and moderate endemic countries. Geneva, World Health Organization, 2007.

^o Guidelines for the Treatment of Malaria. Geneva, World Health Organization, 2006.

^p World Malaria Report 2008. Geneva, World Health Organization, 2008.

^q Guerra CA et al. The limits and intensity of *Plasmodium falciparum* transmission: implications for malaria control and elimination worldwide. PLoS Medicine, 2008, 5(2):e38.

Appendix 3: Assumptions behind Current Burden, Coverage and Funding Estimates

Appendix 3 explains the data sources and methodology used to arrive at the estimates for burden, intervention use and funding for years up to 2008. These estimates for the global level are presented in *Part I: Malaria Today* and for four regions (Africa, The Americas, Asia-Pacific, and Middle East and Eurasia) in *Part III: Regional Strategies*. For a discussion of projected estimates of interventions and costs beyond 2008, please see *Appendix 4*.

Current Burden Estimates

Burden data estimates the number of malaria cases and malaria deaths. These variables provide a starting place to assess the morbidity and mortality of malaria across countries and regions.

Baseline burden estimate. In 2006, the RBM Partnership, led by the Monitoring and Evaluation Reference Group (MERG), developed a consensus estimate of global malaria deaths and cases by region to serve as the 2000 baseline for the RBM targets. This work was published in Jamison DT, Breman JG et al, editors. *Disease Control Priorities in Developing Countries Conquering Malaria*. Oxford University Press and the World Bank; 2006 in the chapter by Breman JG et al. on Conquering Malaria. The global number of malaria cases is estimated for 2002 and global deaths from malaria for 2000. The GMAP uses the Breman 2000 and 2002 baseline data on burden to report burden at a global level and at a regional level.

The specific range of 350 - 500 million cases per year was validated by work by Korenromp E in *Malaria incidence estimates at country level for the year 2004 - Proposed estimates and draft report*. Geneva, Roll Back Malaria, 2005 and is within the inter-quartile range reported by Breman. The 2000 estimate of 1 million deaths globally is closely related to the 804,000 deaths in Africa estimated by Rowe AK et al in The burden of malaria mortality among African children in the year 2000. *International Journal of Epidemiology*, 2006, 35:691-704.

2006 burden estimate from WHO World Malaria Report 2008. In September 2008, the World Health Organization released its latest World Malaria Report (WMR) 2008. The WMR 2008 contains information on burden, policies, coverage and funding for 109 malaria endemic countries as of 2006. In the report, WHO uses an updated and revised methodology to estimate the incidence of malaria outside the African Region. Annex 1 of WMR 2008 describes the methodology.

This new methodology results in fewer malaria cases than previously estimated in the Americas, Eastern Mediterranean, Europe, Southeast Asia and Western Pacific regions. The main reason for the difference is the use of a new estimation method, based on adjusting case reports. The lower figures derived by the new method have been approved by WHO regional and country offices, and they are consistent with the views of some other authors that have found previous estimates to be too high (e.g. in the Western Pacific Region).

WMR estimates of the numbers of cases and deaths in Africa are not significantly different from previous estimates. All recent, published estimates of malaria burden are surrounded by wide uncertainty intervals, and the intervals obtained in various studies overlap. Thus the 212 million cases estimated for the African Region in WMR 2008 are about the same as the 210 million and 230 million previously obtained in separate studies by Snow et al³ and Korenromp.⁴ Likewise the 801,000 deaths lie within the range 700,000 - 1.6 million published by Snow et al.⁵

³ Snow NW et al. The public health burden of *Plasmodium falciparum* malaria in Africa: deriving the numbers. Bethesda, Maryland, USA, Fogarty International Center / National Institutes of Health, 2003 (The Disease Control Priorities Project (DCPP) Working Paper Series No. 11).

⁴ Korenromp E. *Malaria incidence estimates at country level for the year 2004*. Geneva, World Health Organization, 2005 (draft). See webpage (www.malariaconsortium.org/resources.php?action=download&id=177).

⁵ Snow NW et al. The public health burden of *Plasmodium falciparum* malaria in Africa: deriving the numbers. Bethesda, Maryland, USA, Fogarty International Center/National Institutes of Health, 2003 (The Disease Control Priorities Project (DCPP) Working Paper Series No. 11).

Methodology for updating burden estimates. Experts in this field agree that the methods for evaluating malaria burden and trends, and the underlying data, can be improved further. RBM partners, including WHO, are continuing to improve and align estimates of malaria burden worldwide. MERG has two teams tasked with updating and aligning future morbidity and mortality estimates for the RBM Partnership.

Estimates of current interventions

Reviewing the most recent data on number of interventions is essential to identify where countries are today (or as recently as possible) in providing interventions to their populations. It also will show the gaps that need to be filled to achieve universal coverage with all interventions. The methodology for estimating future intervention needs is covered in *Appendix 4*.

Scope of estimates. In the GMAP, global and regional interventions were calculated bottom-up based on data from 109 malaria-endemic countries for the major intervention types (LLINS / ITNs, IRS, diagnostics, treatment). Data reported was for the most recent year available (2006), although not all countries reported data for 2006.

Data sources. The primary data source was the WHO World Malaria Report 2008 (WMR) because the WMR includes both program data reported by countries and survey data from recent household surveys. In the GMAP, program data was used to estimate the number of interventions for two reasons. First, while household surveys are an effective way to assess local usage, the results are less readily aggregated and compared across entire countries and regions. Second, program data has the advantage that it covers all 4 major interventions whereas survey data mostly covers LLINS / ITNs and treatment interventions. When it existed, data from household surveys was reported in the GMAP as well to provide a more wholistic picture of trends in intervention utilization.

The WMR data was supplemented with data from the RBM Commodities Services database when available. The commodities data was compiled by the RBM Partnership. This data includes national procurement figures provided by pharmaceutical companies and international organisations. The procurement figures are considered a good proxy for national coverage figures even if they tend to overestimate coverage. This problem was considered minor as only a small number of coverage figures were derived using procurement figures (5 countries for LLINS / ITNs and 20 countries for treatment).

For countries where both the World Malaria Report and RBM data were not available, the plan assumed zero coverage for these countries. The data sources are summarized in Table A.1.

Table A.1: Availability of country data by intervention

Intervention	Countries with WMR ^a program data	Add. countries with RBM ^b commodities data	Total number of countries with data
LLINs / ITNs	78	5	83
IRS	75	0	75
Diagnostics	71	0	71
Treatment	61	20	81

a) *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

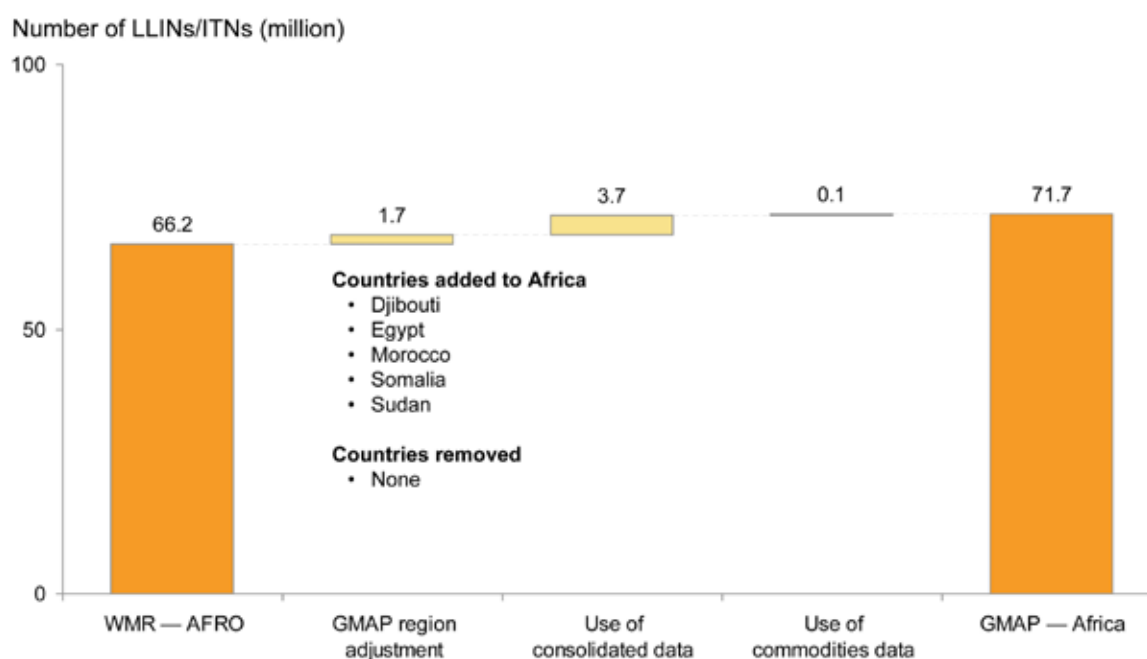
b) Roll Back Malaria Partnership.

Adjustments were made to the WHO WMR data to calculate the number of interventions for the GMAP estimates:

- Countries were reassigned from the six WHO regions (AFRO, AMRO/PAHO, EMRO, EURO, SEARO, and WPRO) to the 4 regions used in the GMAP (Africa, The Americas, Asia-Pacific, and Middle East and Eurasia). See Table A.8 for regional assignments by countries.
- Often multiple variables were available for the same intervention in the WMR (e.g. both detailed and aggregated variables). In countries where a detailed split between variables is not available, the aggregate intervention figure per country was used.
- In countries where program data is not available, commodities data from the RBM Commodities database was used for the closest year.

The above adjustments explain 100% of differences between the coverage data used in the WMR and the GMAP. Figure A.1 provides an example of the differences between the WMR and GMAP estimates for the number of LLINs / ITNs distributed in Africa.

Figure A.1: Reconciliation of WMR and GMAP data for LLINs / ITNs in Africa



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

Description of calculations for each intervention. The GMAP primarily states the level of interventions in terms of absolute numbers of interventions required because this variable is the most relevant for those making purchasing decisions.

LLINs / ITNs. The figures for LLINs / ITNs are calculated as follows:

- *Number of interventions:* each LLIN is effective for 3 years and any other ITN for 1 year. Based on this assumption, the total number of nets was calculated as being equal to the sum of 3 years of LLINs (2004-2006) and 1 year of ITN (2006).
- *People covered:* one LLIN or ITN is needed for every two people at risk. Therefore, the total number of LLINs / ITNs is multiplied by 2 to estimate the total number of people covered.

IRS. The figures for IRS are calculated as follows:

- *Number of interventions:* the number of households sprayed. The figure is derived from the number of people covered by IRS divided by the average household size of each country (or 5 when average household size was not available).
- *People covered:* the number of people covered by IRS was provided by the WMR. If this information was not available, this variable was estimated by multiplying the number of households covered by the average household size of each country (or 5 when average household size was not available).⁶

Diagnostics. The figures for diagnostics are calculated as follows:

- *Number of interventions:* the combined sum of the number of microscopy slides examined and the number of Rapid Diagnostic Tests (RDTs) examined. The reasoning is that although RDTs are increasingly becoming an effective diagnostic tool, microscopy slides are still the most frequent tool used.
- *People covered:* the number of people covered equals the number of diagnostic tests performed.

Anti-malarial treatment. The figures for anti-malarial treatments are calculated as follows:

- *Number of interventions:* For anti-malarial treatments outside of Africa, estimates of the number of drugs are calculated based on the combined number of ACTs and any other first line anti-malarial treatment. In Africa, where ACTs are the recommended treatment for *P. falciparum* malaria, only the number of ACTs were counted.
- *People covered:* the number of people covered equals the number of treatments provided.

Current Funding Estimates

This section presents the scope, data sources and hypothesis used to assess the current malaria funding (up to 2007) and estimated funding for 2008.

Scope of funding estimates. Estimates of current levels of funding for malaria are presented at the global level in *Part I - Chapter 4: Funding for Malaria Today* and at the regional level for the four regions of GMAP (Africa, The Americas, Asia-Pacific, and Middle East and Eurasia) in *Part III: Regional Strategies*.

Global Estimates. *Part I - Chapter 4: Funding for Malaria Today* presents figures aggregated at the global level for:

- Total malaria funding for implementation for 2007 including: funding from major international donors⁷, national government spending by endemic countries and spending by private households.
- Evolution of funding from major international donors between 2004 and 2007 as well as estimates for 2008.
- Evolution of funding for R&D between 2003 and 2007.

As there are significant differences in the amounts and timing between pledges and actual disbursements, figures in GMAP represent annual disbursements (as opposed to commitments) when they were available. This is intended to match the availability of funds as closely as possible to when intervention could be purchased or money used for program costs. When information was not available about disbursements, data on budgets or commitments was used.

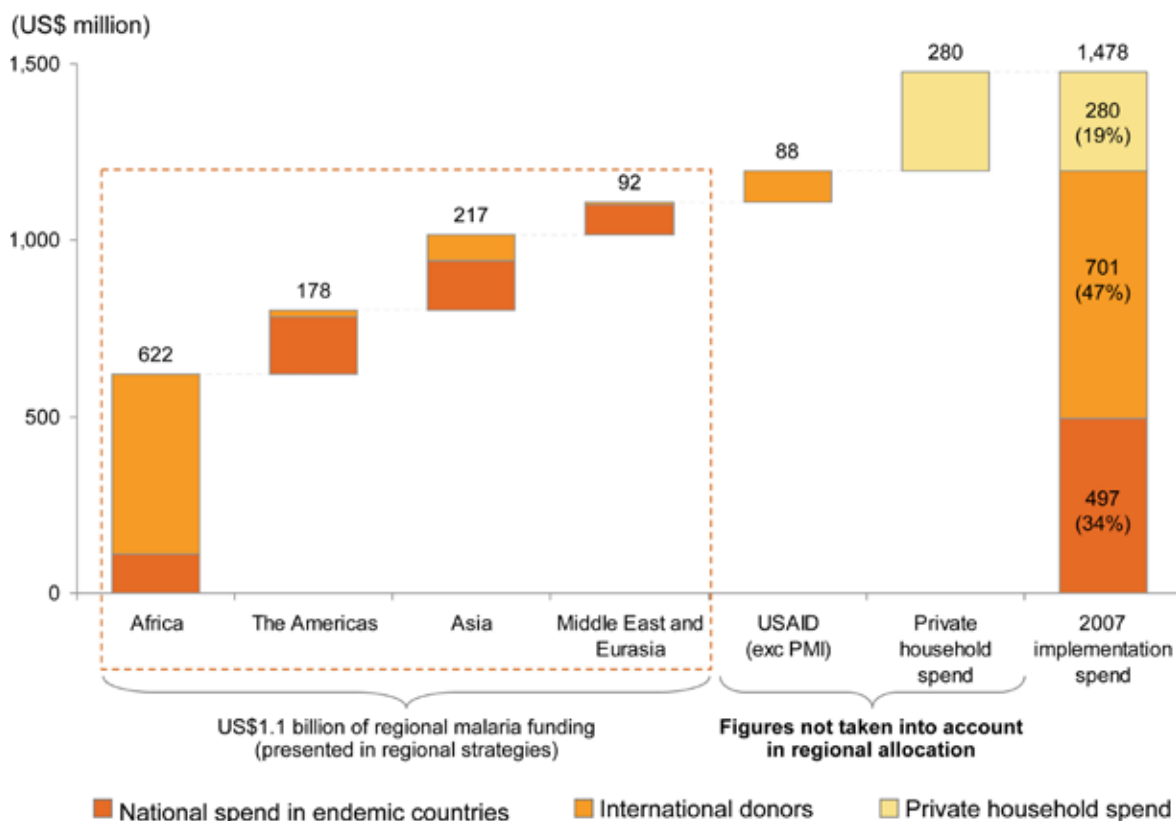
Regional Estimates. *Part III - Regional Strategies* presents a regional allocation of current malaria resources. Figures presented in this chapter represent 2007 regional disbursements including national government spending from endemic countries and funding from major international donors (all listed above except USAID projects other than President's Malaria Initiative (PMI) for which country or regional allocation was not publicly available). As private household spending was estimated at the global level only, this amount is excluded from figures presented in the regional chapters.

⁶ Following consultation with WHO - Global Malaria Program, manual corrections were made to the WHO *World Malaria Report 2008* data for South Africa and Botswana to correct obvious data errors.

⁷ Major international donors include the Global Fund, the World Bank, the President's Malaria Initiative (PMI), USAID, UN Agencies, European Union and other bi-laterals.

Figure A.2 illustrates the link between global figures presented in *Part I: Malaria Today* and regional figures presented in *Part III: Regional Strategies* of the plan.

Figure A.2: Reconciliation of global and regional funding data



Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008 (Government, UN Agencies, Bilaterals, EU), the Global Fund website, PMI operational plans, USAID website, World Bank Booster Program.

Data Sources. No single data source provided a comprehensive assessment of current funding so estimates were built from different sources. The summary below describes the data sources and the methodology for each of the major types of malaria funding: Malaria-endemic country spend, Private household spend, and Funding from international donors.

Malaria-endemic country spend (2007). Information on malaria endemic-country spend are data reported by each country to WHO and gathered in the WHO World Malaria Report 2008. The data represents total government malaria budget reported to WHO. 2007 data was used when available. As only a few countries reported 2007 information, data from previous years was used (mostly 2006 but also 2005 when 2006 was not available). When none of these figures were available, government malaria budgets reported in the Needs Assessments developed with the support from the RBM Harmonization Working Group were also used. The total amount might be underestimated as figures for only 71 countries were available. These 71 countries represent ~84% of global malaria deaths.

Private household spend (2007). Figures for private household spend are based on estimated size of private market for drugs (\$130M) and insecticide-treated nets (\$150M). Private drug spend assumes treatment volume of 10 million ACTs, 396 million monotherapies with fully-loaded cost of US\$ 0.75 pediatric ACT, US\$ 1.50 adult ACT, US\$ 0.3 monotherapy. Private spend for insecticidal nets assumes US\$ 107 million in net sales

with distribution costs of 37.5% of sales.

Funding from international donors (2004-2007 and 2008 estimate). Funding from international donors was calculated for each of the major donors: the Global Fund, the President's Malaria Initiative, the World Bank, bilaterals and other donors.

- *The Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM).* Data from the GFATM for 2004-2007 represent disbursements for malaria grants (Rounds 1 to 7) reported by the fund on its publicly available database⁸ accessed in June 2008. Figures are allocated to each country and region. Estimates for 2008 are based on disbursements that already occurred in 2008 plus an allocation of 2008 grants not yet disbursed (assuming disbursements of remaining round 1-7 approved grant amounts occurs evenly over time until grant end year).
- *President's Malaria Initiative (PMI) and Other USAID.* PMI figures for 2006-2008 are based on actual budgets from country operational plans available on PMI's website⁹ accessed in July 2008. PMI funding is focused only on 15 sub-Saharan African countries. Other USAID data are based on estimated budgets for malaria projects others than PMI available on USAID website¹⁰ accessed in July 2008.
- *World Bank.* World Bank figures are the actual disbursements of the Booster Program Phase I provided by the Bank for 2006 and 2007. Estimates for 2008 are based on actual disbursements until June 2008 to which estimated disbursements provided by the World Bank for the period July-December 2008 were added. Other World Bank general health or development projects include funding for malaria but are not taken into account in this analysis since this funding cannot be easily allocated to malaria. The Bank's malaria project in India has not been included since the first disbursements will start at the end of 2008.
- *UN Agencies, European Union, Other bilaterals.* Data used for these three sources of funding are those reported by countries to WHO for the World Malaria Report 2008. For estimating the 2007 amount, 2007 data was used when available. As only a few countries reported 2007 data, 2006 data was used as a proxy for most countries. Numbers used for 2004-2006 were those reported to WHO without adjustments. For 2008 estimate, it was assumed that the same amount as estimated for 2007 would be provided.
- *Other sources of funding.* Countries also reported to WHO "Other sources of funding" corresponding to external funding support outside the donors mentioned above. As no identification of sources was possible with this data, it has not been used in this analysis, which focused primarily on the major international donors. Other sources of funding (i.e. coming from regional banks or regional institutions etc.) could increase the funds presented in this analysis.

Spending on malaria Research and Development. Figures correspond to disbursements for malaria R&D. Funding from the Bill and Melinda Gates Foundation assumes that grants are evenly disbursed for the calendar year in which they are active. National Institutes of Health (NIH) funding is based on actual spend for 2003-2006 and budget projections for 2007-2008.¹¹ Other funding for R&D by the private sector companies, US Department of Defense, Wellcome Trust, and others is assumed to hold flat at US\$ 165 million based on the Malaria R&D Alliance reported funding estimate for 2004.

⁸ See www.theglobalfund.org/en/files/disbursementsindetail_raw.xls.

⁹ See www.fightingmalaria.gov/countries/mops.html.

¹⁰ See www.usaid.gov/policy/budget/cbj2007/si/malaria.html.

¹¹ See www.nih.gov/news/fundingresearchareas.htm.

Appendix 4: Assumptions behind Country Implementation Cost Estimates

Appendix 4 explains the methodology used to estimate the cost of the country implementation strategies through 2040 recommended by the GMAP. The model estimates the full cost to deliver interventions through scale-up, sustained control, and elimination across 109 malarious countries. It includes country malaria program and systems costs, but does not include global costs such as operational research or monitoring and evaluation (M&E) at an international level. The research and development cost estimates were determined separately and are included in *Appendix 5*.

Scope of model. The estimates were developed using a financial model to aid the planning and budgeting for malaria program implementation and to inform resource mobilization efforts. This analysis is not intended to assess the efficiency, sustainability, or feasibility of implementing programs in certain settings or countries.

The estimates are based on the recommendations laid out in the GMAP. They are aspirational in that they assume coverage targets are met by the end of 2010, that all suspected cases are diagnosed, and that all confirmed malaria cases are treated appropriately.

Baseline estimates are in 2008 US dollars. Future cost estimates do not incorporate individual country inflation rates, because of the difficulty assessing the international prices of many interventions across countries, the variety of funding sources used, and the unavailability of accurate projections for inflation rates for most of the countries evaluated. Below, a section is included on what projected costs would be in the future using an estimated inflation rate.

Process to date. Cost estimates were built from the country level up, using country-specific data and assumptions whenever possible. The major source of data for this model is the WHO *World Malaria Report 2008*. Other major data sources used for the model include the UNICEF's *2007 Malaria and Children: Progress in intervention coverage* report and work authored by Kiszewski A and Johns B, et al. The cost estimates have been formally reviewed in collaboration with the RBM Resources Working Group and Virginia Wiseman of the London School of Tropical Hygiene and Medicine.

This Appendix includes the following information

- Model methodology
- Morbidity and mortality
- Intervention coverage (baseline and targets)
- Intervention costs
- Malaria program costs
- SUFI, sustained control, and elimination

Model Methodology

Prevention. The model uses population at risk (PAR) estimates at low and high transmission levels from the WHO *World Malaria Report 2008* to determine the quantity of preventive interventions needed within each country. The average population growth rate per country from 2005 to 2050 was used.¹² Preventive interventions required are expected to increase by annual population growth rates.

Fevers. For this model, the incidence of fevers was used as a proxy for suspected malaria cases and the number of diagnostics needed. Fever estimates were taken from the WHO *World Malaria Report 2008*, and were estimated based on the inverse of the country's slide positivity rate.

Incidence. Quantity of treatments needed was based on estimated malaria cases per country from the 2008 World Malaria Report. To account for over-treatment due to non- or mis-diagnosis, a multiplier of 1.25 was applied.

¹² Country data based on information collected by the US Census Bureau. See US Census Bureau webpage (<http://www.census.gov/>).

Although populations at risk will increase due to population growth, incidence is assumed to start decreasing in the sustained control stage due to the high intervention coverage rates. Modeling by Richard Cibulskis, WHO, as well as recent country experiences indicate that reaching 80% utilization can reduce incidence by 75% over a 5 year period.¹³ Hence, the first five years of sustained control reflect a linear 75% reduction. This simplifying assumption was used because the complexity needed to adequately model the interlinking dynamics between incidence, populations at risk, intervention use, etc., was beyond the scope of this model. The remaining time in sustained control reflects a linear reduction in incidence to 5 cases per 1000, the point at which a country can consider moving into the elimination stage (according to indicative WHO recommendations).¹⁴ During elimination, incidence decreases linearly from .5% to 0% incidence. (More detail on stages is listed below.)

The breakdown between *P. falciparum* and non *P. falciparum* cases, to determine quantities of ACTs for *P. falciparum* and chloroquine and primaquine for *P. vivax*, was based on percentages listed in the 2008 *World Malaria Report*.

Table A.2: Regional breakdown of *P. falciparum* and non *P. falciparum* cases

Region	<i>P. falciparum</i>	Non <i>P. falciparum</i>
Africa	98%	2%
Americas	29%	71%
Eastern Mediterranean	76%	24%
Europe	2%	98%
Southeast Asia-Pacific	56%	44%
Western Pacific	67%	33%

Source: *World Malaria Report 2008*. Geneva, World Health Organization, 2008.

As the burden of *P. ovale* and *P. malariae* is significantly lower than that of *P. vivax* and *P. falciparum*, these have not been included in the model. The model also assumes that non-*P. falciparum* cases were *P. vivax*.

One percent of total cases are assumed to turn into severe malaria requiring higher cost care.

Intervention Coverage Assumptions

Target coverage and utilization assumptions. The GMAP target is to achieve universal coverage (100%). Therefore, all target coverage levels are for 100% of the populations at risk with appropriate interventions. However, as not all interventions are appropriate to each setting, the percent of the population at risk targeted for a particular intervention could be below 100% based on the best available evidence.

Prevention. Preventive interventions include LLINs, IRS, IPTp, and vaccines.

LLINs. All malarious regions were considered appropriate for LLIN usage unless otherwise stated by the malaria control program manager or indicated in the 2008 *World Malaria Report* as not part of the country's strategy. This includes all of sub-Saharan Africa. Target coverage was assumed to be 100%, unless otherwise indicated in the WMR or by the country program manager.

¹³ Presented by Richard Cibulskis. WHO Informal Consultation on Global malaria control and elimination: A Technical Review. Geneva, World Health Organization, 17-18 January, 2008.

¹⁴ *Malaria Elimination: A Field Manual for Low and Moderate Endemic Countries*. Geneva, World Health Organization, 2007.

The model assumes a three year active life for LLINs, at one net per two people at risk. For the scale-up period, the total number of nets needed was calculated. Then the number of nets recently deployed were subtracted from this amount and the result divided by the number of years in scale-up. In the baseline scenario, scale-up was assumed for two years (2009-2010). After the scale-up period, nets are replaced every three years; however, the replacement cost is averaged over the years as the replacement times will vary. Hence, after scale-up, the annual cost per person at risk covered by an LLIN is 1/6 the cost of the LLIN (see below for specific intervention costs).

IRS. There is much debate on which settings are most appropriate for IRS. Some feel that IRS is most suitable in urban areas where homes are closer together; others believe that IRS is very suitable for some rural settings. Consequently, country-stated strategies and current usage of IRS, based on information in the *World Malaria Report 2008* as well as interviews and other sources, were incorporated into the model to determine the appropriate target coverage and the ongoing annual costs. Based on expert recommendation, the model assumes that countries that are currently using IRS would scale-up further, and that countries not using IRS would continue not using IRS.

IPTp. Eighty percent utilization of IPTp for pregnant women in high transmission settings is recommended. Therefore, IPTp utilization targets for high transmission areas in sub-Saharan Africa were 80%, but 0% for pregnant women in low transmission areas within sub-Saharan Africa and the rest of the world.

Vaccines. It was assumed that a vaccine would be launched in 2013, with scale-up by 2015 to 80% coverage of all infants less than one year old.

Treatment assumptions. Treatment assumptions were made for drugs, diagnostics, and severe case management.

Diagnostics. *P. falciparum* RDTs are modeled for Africa, and combination *P. falciparum* / *P. vivax* RDTs are modeled for the rest of the world. The model optimistically assumes that every fever case suspected of malaria is parasitologically diagnosed, 50% with an RDT and 50% with microscopy. Microscopy costs are included in the malaria control program costs.

Drugs. All malaria cases are assumed to be treated with anti-malarials (but not suspected fever cases as diagnostics have been to confirm cases). *P. falciparum* cases are treated with ACTs and *P. vivax* cases is treated with chloroquine and primaquine. The model takes into account the different cost and dosing regimens across age cohorts. They are split into pediatric dosing (for children under the age of 5), and for those over the age of 5.

Severe case management. The model assumes 1% of cases will turn into severe cases, resulting in treatment costs of US\$ 29.50.¹⁵

Additionally, some coverage levels change over time. It is assumed that severe cases are treated 50% of the time in scale-up, 75% of the time in sustained control and 100% of the time in elimination.

Impact on Morbidity and Mortality

The field effectiveness of preventive interventions was used to determine reduction in cases; however, based on discussions with experts, additive benefits were not applied when multiple interventions were used together. For example, if a region uses both LLINs and IRS, the higher effectiveness level (60%) was applied. ACT effectiveness levels were applied to the resulting number of cases to determine the reduction in mortality.

¹⁵ Kiszewski A, Johns B, et al. Estimated Global resources needed to attain international malaria control goals. *Bulletin of the World Health Organization*, 2007; 85:623-630.

Table A.3: Effectiveness level by intervention

Intervention	Effectiveness level
Long-lasting insecticidal nets (LLINs) ^{a,b}	50% reduction in cases
Indoor residual spraying (IRS) ^c	60% reduction in cases
Intermittent preventive treatment in pregnancy (IPTp) ^d	56% reduction in cases

a) Lengeler C. Insecticide-treated bednets and curtains for preventing malaria. In: Cochrane Library, issue 1. Oxford: Update Software, 2001.

b) Morel, CM et al. Cost effectiveness analysis strategies to combat malaria in developing countries. *BMJ*, doi:10/1136/bmj.38639.702384.AE (published 10 November 2005).

c) Curtis CF. Should the use of DDT be revived for malaria vector control? *BioMedica*, 2002. 22 (4): 455-61.

d) Parise M et al. Efficacy of Sulfadoxine-pyrimethamine for prevention of placental malaria in an area of Kenya with a high prevalence of malaria and Human Immunodeficiency Virus infection.

Source: American Journal of Tropical Medicine and Hygiene, 1998. 59 (5): 813-22.

As the model was not intended to estimate impact on morbidity and mortality outside of the impact on the treatment needed, another model was used to determine the impact of the GMAP strategy. A consortium of organizations led by the Institute of International Programs at Johns Hopkins Bloomberg School of Public Health developed an IMPACT model measuring child survival based on work by the Child Health Epidemiology Reference Group (CHERG) and using software developed by the Futures Institute. It determined the impact of preventive interventions, diagnosis and treatment on mortality due to *P. falciparum* in 20 high burden African countries. The model did not evaluate interventions which have not been launched, including vaccines. All future burden estimates in the GMAP are from the IMPACT model.

Intervention Costs

Intervention costs plus costs for distribution, warehousing, etc., were used to determine fully-loaded cost estimates. Most intervention costs were based on UNICEF average cost estimates, which incorporate an additional ~35% to account for distribution costs (based on interviews with experts), except for RDTs¹⁶ and IRS¹⁷.

¹⁶ Yoell Lubell, the London School of Hygiene and Tropical Medicine and Joshua Yukich, Swiss Tropical Institute, personal communication, 2008.

¹⁷ USAID / the President's Malaria Initiative (PMI). Also see PMI webpage (<http://www.fightingmalaria.gov/>).

Table A.4: Cost per intervention

Intervention	Intervention costs (\$)	Fully-loaded costs (\$)
LLINs (3-year)	4.75	6.41
IRS (one round)	n/a	7.50
IPTp	0.20	0.30
Pf RDTs	0.60	0.78
Pf + Pv Combination RDTs	0.90	1.17
ACTs (adult)	1.50	2.025
ACTs (pediatric)	0.80	1.08
Severe case management	n/a	29.50
Chloroquine and Primaquine	0.20	0.30
Vaccine	21	5

Source: UNICEF, USAID/PMI, London School of Hygiene and Tropical Medicine, and the Swiss Tropical Institute.

It is widely recognized that fully-loaded costs to deliver interventions vary significantly by country as well as within countries based on many factors such rural vs. urban settings, routine distribution vs. campaigns, public vs. private sector distribution, infrastructural and seasonal issues, etc. The model has been built so that country-specific information can be incorporated when available. For example, country-specific LLIN delivery costs were used for some countries, although the average cost was applied to most countries.

For the baseline, intervention costs were assumed to stay static over time; this is a simplifying assumption, as costs could increase due to more expensive raw materials, or decline due to improved manufacturing. Specifically there are expectations that ACT prices will come down, and some believe that pesticides prices will increase when current tools are lost due to resistance. Therefore, sensitivity analyses portraying these scenarios are detailed towards the end of this appendix.

Malaria Control Program Costs

Country-specific malaria control program costs developed by Kiszewski, Johns, et. al. were input into the model. For countries they did not evaluate, a uniform percentage based on country-location, population at risk and burden, were used to approximate costs. The approximate percentage of control program costs to overall intervention costs are as follows:

Table A.5: Malaria program costs as percent of overall country costs

Program cost components	Africa	Rest of world
Training / communication	3%	4%
Community health workers	2%	2%
Operational research / M&E	3%	2%
Infrastructure / institutional strengthening	12%	6%
Total	19%	14%

Source: Kiszewski A, Johns B, et al. Estimated Global resources needed to attain international malaria control goals. Bulletin of the World Health Organization, 2007.

The components of the specific categories are as follows:

- Training / communication
 - Training for prevention and treatment
 - Two information, education and communication (IEC) campaigns
 - Advocacy
 - Management training
 - Development of training materials
- Community health workers
 - 1 CHW per 1000 population at risk
 - Honorarium
 - Recruitment costs
- Operational Research / M&E
 - Resistance studies (2-6 per country)
 - M&E surveys based on populations at risk
 - M&E human resources strengthening
 - Central planning / strategic reviews / workshops
- Infrastructure / Institutions Strengthening
 - General health systems
 - Microscopy
 - Management
 - Procurement and storage staff and assessments

Specific annual costs were determined through 2015. Post-2015, program costs were increased by the population growth rate through the end of the sustained control stage.

To account for the extensive surveillance required in the elimination stage, M&E is increased by 50% during the last two years of sustained control. While this may seem high, it reflects the significant costs associated with surveillance during the elimination stage. The other systems costs decline to 80% of their prior levels due to the absorption of malaria control program activities and staff into the general health system.

Scale-up, Sustained Control, and Elimination Stages

The model assigns a baseline starting point for each country based on burden levels. WHO classifications were used to designate countries in the elimination stage.

Duration of time spent in each stage was based primarily on natural-state transmission. Cost estimates are highly sensitive to the length of time a country spends in scale-up, sustained control and elimination. See Exhibit 1 for specific details on countries' current status as well as anticipated duration in each stage.

Scale-up. The model assumes three durations for scale-up: 2 years, 4 years, and 7 years. However, all countries were assumed to achieve scale-up objectives in 2 years (by 2010). In the sensitivity analysis section, a more conservative scenario was also applied in which 15% of countries achieve scale-up in 2 years, 35% achieve it in 4 years, and 50% achieve it in 7 years.

Sustained control. Five potential durations were considered for sustained control. Countries currently in sustained control as well as several low transmission countries are assumed to move through the stage in 5 or 10 years. Most high transmission countries are assumed to move through sustained control in 15 or 20 years, assuming a new tool is developed in 10 or 15 years which will allow elimination in all settings. There is also a 30 year assumption for sustained control, to show the impact on costs if a new tool enabling elimination is not developed in the next 15-20 years.

Elimination. Low transmission countries as well as those currently in elimination are assumed to achieve elimination in 10 years, the minimum time in which a country can reach zero incidence.¹⁸ High transmission countries are assumed to need 20 years to achieve zero incidence levels.

Inflation

As mentioned previously, all cost estimates are in 2008 US dollars. In reality, over time the costs will be impacted by the inflation rates of currencies in the malarious countries as well as those of the countries of international donors and manufacturers which set intervention prices.

However, to understand the potential impact on costs, the projected US inflation rate was applied in order to determine how costs could increase over time.¹⁹ This oversimplifies the impact of inflation, but the lack of accurate projections for most of the countries under consideration necessitated a simplified approach.

Projected impact on cost is detailed in the table below:

Table A.6: Estimated impact of inflation on country implementation costs

Year	Real dollars (US\$ billions)	Nominal dollars (US\$ billions)
2010	5.6	5.8
2020	4.8	6.0
2030	2.4	3.6
2040	1.2	2.1

Source: Bureau of Labor Statistics, Consumer Price Index, Moody's Economy.com

Sensitivity Analyses: What will impact estimated costs?

As indicated above, there are many different factors and uncertainties which can impact the costs. Different factors such as operational effectiveness of interventions, time to scale-up, and duration of stages can cause costs to increase or decrease. To understand the extent of the impact, several sensitivity analyses were completed to quantify the impact of different factors on the required investment.

What could decrease projected costs?

A. Decreasing intervention costs. Recently the Clinton Foundation announced an agreement that will stabilize the market for ACTs and reduce the price of one key product. Additionally, one of the key research priorities

¹⁸ Informal consultation on malaria elimination: setting up the WHO agenda. Tunis, World Health Organization, February 2006.

¹⁹ Estimates of the projected US inflation rate were obtained from Bureau of Labor Statistics' Consumer Price Index (<http://www.bls.gov/CPI/>) and Moody's Economy.com (<http://www.economy.com/default.asp>).

for vector control and drugs is lower intervention costs. Therefore, the impact of a 50% reduction in cost of ACTs was modeled. Unfortunately, as treatment, including diagnostics, drugs, and severe case management costs, is only about 15% of the total malaria control costs, the 50% cost reduction for ACTs translated into a 3% cost reduction overall, or an average US\$ 153 million annually over the 2011-20 period. The change becomes even lower after scale-up, when incidence declines rapidly. Still, while not the largest impact on costs, any amount saved in resource-constrained environments will be beneficial to countries. In fact, costs decreases to preventive interventions are likely to have an even bigger impact on costs. **Implications: Investment in R&D for lower cost tools, as well as increased advocacy for lower intervention prices, can save costs.**

B. Increased effectiveness of preventive interventions. The field effectiveness of preventive interventions is a key driver of treatment costs. This includes the effective application of IRS and/or appropriate utilization of LLINs. Increasing operational effectiveness of LLINs and IRS from 50-60% (their current field effectiveness) up to 98% can theoretically reduce incidence and therefore treatment costs, by almost 50%. Modeling a 98% effectiveness rate showed an average annual savings globally of ~US\$ 109 million every year through 2020. This underscores the value of programs that focus on increasing appropriate use of interventions. **Implications: In the near term, invest in in-country communication programs and operational research that improve field effectiveness of current tools. In the long run, support R&D for more effective tools.**

C. Slower scale-up by 2015, not 2010. Currently, the model estimates that all control countries achieve the scale-up targets by 2010 at a total cost of US\$ 38.4 billion from 2009 to 2015. However, if more conservative assumptions were used²⁰ (approximately 20% of the countries scaling up by 2010, ~50% scaling up by 2012 and 30% scaling up by 2015), the total cumulative costs through 2015 are US\$ 33.8 billion, approximately US\$ 4.6 billion less in total.

²⁰ Assumptions based on discussions with endemic country representatives and anticipated activity if intense scale-up efforts were not undertaken.

Table A.7: Cost comparison of scale-up by 2010 and 2015

Scenario A: Rapid scale-up of all countries by 2010								
Costs (US\$ millions)	2009	2010	2011	2012	2013	2014	2015	TOTAL
Prevention costs	3,687	3,941	3,487	3,543	3,592	3,643	3,693	25,587
Case management costs	968	1,359	1,385	1,186	980	767	550	7,195
Program costs	638	839	810	748	782	792	764	5,373
Total costs	5,335	6,180	5,710	5,506	5,383	5,232	5,038	38,384
Lives saved per year	360,000	626,000	636,000	638,000	644,000	652,000	655,000	4,211,000

Scenario B: Slower scale-up of 20% of countries by 2010, 50% by 2012 and 30% by 2015								
Costs (US\$ millions)	2009	2010	2011	2012	2013	2014	2015	TOTAL
Prevention costs	2,105	2,492	2,832	3,241	3,372	3,504	3,638	21,185
Case management costs	597	803	997	1,186	1,242	1,160	1,075	7,059
Program costs	638	839	810	748	782	792	762	5,372
Total costs	3,353	4,153	4,662	5,202	5,424	5,485	5,505	33,786
Lives saved per year	113,000	224,000	324,000	418,000	506,000	584,000	656,000	2,825,000

Source: GMAP costing model.

This is due to the frontloading of costs in a 2 year ramp-up and the high cost of maintaining preventive measures in the 2010 scenario. While treatment costs are decrease more rapidly due to the impact of preventive measures in the rapid scale-up scenario, they do not offset the high cost of sustaining IRS and LLINs. However, the lives saved, 4.2 million vs. 2.8 million, are a powerful argument in favor of faster scale-up despite the higher cost (discussed in *Section II, Chapter 5: Why invest in malaria: the costs and benefits*). **Implications: Slower scale-up may lower costs, but fewer lives will be saved.**

What could increase projected costs?

D. Decreasing diagnosis and increasing presumptive treatment in Africa. The baseline cost estimate assumes that each fever case suspected of malaria is diagnosed and only confirmed cases are treated with an anti-malarial drug. This is very different from the practice in many African countries. Currently, parasitological diagnosis is under-used, and suspected malaria cases are treated presumptively. Not only does this increase the risk of drug resistance, but overall case management costs increase significantly as well. A sensitivity analysis was conducted for Africa assuming presumptive treatment with fewer diagnostics. When applying a 75% lower usage rate of RDTs than the baseline “aspirational” scenario and subsequent treatment of all fever cases, overall diagnosis and treatment costs are ~40% higher than when all cases are diagnosed and only confirmed malaria cases are treated. **Implications: Appropriate diagnosis and treatment saves significant costs. The scale-up of diagnostics should be a priority, as well as ACT scale-up.**

E. Slow development of new tools. Countries in high transmission settings will likely not be able to move into an elimination program unless new tools are developed. Currently, the model assumes that a new tool will be developed in 10-15 years, allowing the most highly-endemic countries to move into elimination shortly thereafter (for a total of 15 or 20 years in sustained control.) However, if it takes 25 years to develop an elimination-enabling tool (so that sustained control lasts 30 years for high transmission countries), costs will gradually increase to 50% higher than the baseline scenario (as countries must maintain the expensive preventive measures until elimination feasibility can be proved.) **Implications: Support R&D efforts to develop tools which will enable elimination in all transmission settings.**

F. Elimination takes longer than anticipated. Approximately 60 countries are assumed to be able to achieve elimination in 10 years after beginning the phase, and the remaining in 20 years. If all countries not currently in elimination were assumed to need 20 years, the additional costs from today through 2050 would be approximately US\$ 16.3 billion. **Implications: Support operational research to determine optimal elimination approaches in all transmission settings.**

G. Increasing intervention costs. Some experts are concerned that increasing resistance to current pesticide classes will leave the community with no other options than to utilize more expensive pesticides for vector control purposes. Hence a 50% increase in the costs of both IRS and LLINs was modeled. Due to the high percentage of costs comprised by vector control, this change resulted in almost a 40% increase in overall global costs, peaking at US\$ 7.9 billion in 2011. **Implications: Promote R&D for new lower cost tools and active ingredient classes to minimize resistance pressure on current insecticides.**

Current country positioning and duration country spends in each stage.

Table A.8 outlines the assumptions that were used for modeling. These were for modeling only and are not intended to imply country targets. While some members of the malaria community and endemic country representatives reviewed the list, not every country was consulted regarding its current position or expected length of time spent in each stage.

Table A.8: Country positioning

Country	Region	Current framework stage	Length of stage (years)		
			SUFI	SC	On
Afghanistan	Middle East and Eurasia	Control	2	10	10
Algeria	Africa	Elimination	n/a	n/a	10
Angola	Africa	Control	2	20	20
Argentina	The Americas	Elimination	n/a	n/a	10
Armenia	Middle East and Eurasia	Elimination	n/a	n/a	10
Azerbaijan	Middle East and Eurasia	Elimination	n/a	n/a	10
Bangladesh	Asia-Pacific	Control	2	10	10
Belize	The Americas	Control	2	10	10
Benin	Africa	Control	2	20	20
Bhutan	Asia-Pacific	Control	2	15	10
Bolivia	The Americas	Control	2	10	10
Botswana	Africa	Control	2	15	10
Brazil	The Americas	Control	2	10	10
Burkina Faso	Africa	Control	2	15	20
Burundi	Africa	Control	2	15	20
Cambodia	Asia-Pacific	Control	2	10	10
Cameroon	Africa	Control	2	15	20
Cape Verde	Africa	Control	2	5	20
CAR	Africa	Control	2	20	20
Chad	Africa	Control	2	20	20
China	Asia-Pacific	Control	2	10	10
Colombia	The Americas	Control	2	10	10
Comoros	Africa	Control	2	15	20
Congo	Africa	Control	2	20	20
Costa Rica	The Americas	Control	2	10	10
Cote d'Ivoire	Africa	Control	2	20	20
Djibouti	Africa	Control	2	20	20
Dom. Republic	The Americas	Control	2	5	10
DRC	Africa	Control	2	20	20
Ecuador	The Americas	Control	2	10	10
Egypt	Middle East and Eurasia	Elimination	n/a	n/a	10
El Salvador	The Americas	Elimination	n/a	n/a	10
Equatorial Guinea	Africa	Control	2	20	20
Eritrea	Africa	Control	2	15	20
Ethiopia	Africa	Control	2	15	20
French Guiana	The Americas	Control	2	10	10
Gabon	Africa	Control	2	15	10
Gambia	Africa	Control	2	20	20
Georgia	Middle East and Eurasia	Elimination	n/a	n/a	10
Ghana	Africa	Control	2	15	20
Guatemala	The Americas	Control	2	15	10
Guinea	Africa	Control	2	15	20
Guinea-Bissau	Africa	Control	2	15	20
Guyana	The Americas	Control	2	10	10
Haiti	The Americas	Control	2	10	10
Honduras	The Americas	Control	2	10	10
India	Asia-Pacific	Control	2	10	20
Indonesia	Asia-Pacific	Control	2	10	20
Iran	Middle East and Eurasia	Elimination	n/a	n/a	10
Iraq	Middle East and Eurasia	Elimination	n/a	n/a	10
Jamaica	The Americas	Prevention of Reintroduction	n/a	n/a	n/a
Kenya	Africa	Control	2	15	20
Korea DPR	Asia-Pacific	Elimination	n/a	n/a	10
Kyrgyz Republic	Middle East and Eurasia	Elimination	n/a	n/a	10
Lao PDR	Asia-Pacific	Control	2	10	10
Liberia	Africa	Control	2	15	20
Madagascar	Africa	Control	2	15	20
Malawi	Africa	Control	2	15	20
Malaysia	Asia-Pacific	Elimination	n/a	n/a	10
Mali	Africa	Control	2	15	20
Mauritania	Africa	Control	2	20	20
Mauritius	Africa	Prevention of Reintroduction	n/a	n/a	n/a
Mexico	The Americas	Elimination	n/a	n/a	10
Morocco	Africa	Prevention of Reintroduction	n/a	n/a	n/a
Mozambique	Africa	Control	2	15	20

Table A.8: Country positioning (continued)

Country	Region	Current framework stage	Length of stage (years)		
			SUFI	SC	On
Myanmar	Asia-Pacific	Control	2	20	20
Namibia	Africa	Control	2	15	20
Nepal	Asia-Pacific	Control	2	10	10
Nicaragua	The Americas	Control	2	10	10
Niger	Africa	Control	2	20	20
Nigeria	Africa	Control	2	20	20
Oman	Middle East and Eurasia	Prevention of Reintroduction	n/a	n/a	n/a
Pakistan	Middle East and Eurasia	Control	2	10	10
Panama	The Americas	Control	2	10	10
Papua New Guinea	Asia-Pacific	Control	2	10	20
Paraguay	The Americas	Elimination	n/a	n/a	10
Peru	The Americas	Control	2	10	10
Philippines	Asia-Pacific	Control	2	5	10
Republic of Korea	Asia-Pacific	Elimination	n/a	n/a	10
Russian Federation	Middle East and Eurasia	Elimination	n/a	n/a	10
Rwanda	Africa	Control	2	15	20
Sao Tome and Principe	Africa	Control	2	10	10
Saudi Arabia	Middle East and Eurasia	Elimination	n/a	n/a	10
Senegal	Africa	Control	2	20	20
Sierra Leone	Africa	Control	2	20	20
Solomon Islands	Asia-Pacific	Control	2	5	10
Somalia	Africa	Control	2	20	20
South Africa	Africa	Control	2	5	10
Sri Lanka	Asia-Pacific	Elimination	n/a	n/a	10
Sudan	Africa	Control	2	20	20
Suriname	The Americas	Control	2	10	10
Swaziland	Africa	Control	2	5	10
Syrian Arab Republic	Middle East and Eurasia	Prevention of Reintroduction	n/a	n/a	n/a
Tajikistan	Middle East and Eurasia	Elimination	n/a	n/a	10
Tanzania	Africa	Control	2	15	20
Thailand	Asia-Pacific	Control	2	10	10
Timor-Leste	Asia-Pacific	Control	2	10	10
Togo	Africa	Control	2	15	20
Turkey	Middle East and Eurasia	Elimination	n/a	n/a	10
Turkmenistan	Middle East and Eurasia	Elimination	n/a	n/a	10
Uganda	Africa	Control	2	15	20
Uzbekistan	Middle East and Eurasia	Elimination	n/a	n/a	10
Vanuatu	Asia-Pacific	Control	2	5	10
Venezuela	The Americas	Control	2	10	10
Vietnam	Asia-Pacific	Control	2	10	10
Yemen	Middle East and Eurasia	Control	2	5	10
Zambia	Africa	Control	2	15	20
Zimbabwe	Africa	Control	2	15	20

Source: GMAP Costing Model.

Appendix 5: Assumptions behind Research and Development Cost Estimates

Appendix 5 explains the methodology used to estimate the global cost of malaria R&D through 2050. Specifically, the model evaluates the cost for malaria drugs, vaccines, vector control and diagnostics, including the early research, development and information needs after launch. R&D cost estimates were derived from interviews with experts in the malaria community, historical data and industry analysis.

Given the inherent uncertainty in predicting time and costs associated with technology development, this model is based on assumptions that should be continuously updated and cross referenced as new information comes available. A multiplier of 1.2 has been applied to the final cost estimates at this time to account for this uncertainty. As the research agenda for elimination and eradication becomes more defined, the model will need to be further refined.

Model Methodology

Early Research. Preclinical research costs are included in the model estimates. In the 2004 Malaria R&D Alliance Report, basic research was estimated to be 16% of the total malaria R&D costs. For the purpose of this model, the percentage of basic research was assumed to double to 32% of the 2007 R&D costs given the increased efforts necessary to enable malaria eradication. As a result, since the global malaria R&D spend in 2007 was estimated to be -US\$ 422 million, the basic research was estimated to be 32% of this or US\$ 133 million. This basic research cost was assumed to be constant going forward through 2050.

The annual research allocation of US\$ 133 million was divided according to the breakdown outlined in the following table. The basic research need for diagnostics was developed separately and is described in the diagnostic section. The model assumes that basic research on vaccines is 50% of the total basic research costs since the technology is further behind relative to the other interventions. The remaining basic research costs are assumed to be split equally between drugs and vector control.

Table A.9: Allocation of basic research costs by intervention

Intervention	% of basic research	Annual basic research cost (US\$ millions)
Vector control	25%	33
Preventive drugs	13%	17
Therapeutic drugs	13%	17
Vaccine	50%	66
Diagnostics	n/a	See section below

Source: GMAP costing model, 2004 Malaria R&D Alliance Report and expert interviews.

Information Needs R&D Costs. The information needs cost is comprised of post-launch and product integration studies. Specifically, this cost captures implementation research, effectiveness studies, and resistance monitoring. In 2004, these costs were estimated to be 17% of the total R&D cost presented in the 2004 Malaria R&D Alliance Report. For the purpose of this model, these costs were estimated as 20% of the total annual R&D costs. This estimate is based on the assumption that there is a necessity for greater information needs support given the heavy commitment to developing new tools and ensuring they are used effectively in future decades.

Drug R&D Costs. R&D costs for drugs are grouped into preventive and therapeutic.

Preventive Drugs. The priorities for future preventive drugs are aimed at filling gaps in the tool kit by developing IPT-specific drugs. It was assumed that 1 novel combination drug and 1 monotherapy will be launched in the next 10 years. Drug requirements assume non-artemisinin combinations and as a result, 2 active ingredients will be developed for novel preventive drugs in the next 10 years. Furthermore, 1 active ingredient would need to be developed in subsequent decades in order to have enough products to prevent resistance buildup. In addition to developing novel preventive drugs, it is estimated that 4 reformulations will be developed in 10 years and 2 reformulations will be developed each subsequent decade.

The cost of developing a novel active ingredient is estimated to be US\$ 250 million and the development time is assumed to be 10 years. For modeling purposes, the cost was evenly spread out over the 10 year development cycle. The cost of developing a reformulation is estimated to be US\$ 25 million or 10% of the cost of a new active ingredient. The development time is assumed to be 2-6 years. For modeling purposes the cost of 4 reformulations was spread out over 10 years (2008-2018) and the cost of 2 reformulations was linearly spread out over each subsequent decade.

Therapeutic Drugs. Current thinking in the R&D community indicates that the following types of therapeutic drugs are needed:

1. Next generation ACT for *P. falciparum*
2. Therapy targeting the hypnozoite of *P. vivax* in the liver
3. Drugs blocking *P. falciparum* and *P. vivax* transmission (Gametocytocides/sporontocides)
4. Drugs aimed at avoiding resistance

It is assumed that 4 novel combination drugs will be developed in the next 10 years. The first combination drug, a next generation ACT for *P. falciparum*, will require the development of 1 new active ingredient in addition to artemisinin. The second combination drug, a therapy targeting *P. vivax* hypnozoites in the liver, will require at least 1 new active ingredient in addition to a pre-existing active ingredient. It is assumed that 2 new active ingredients are needed for a third combination drug. This drug will block both *P. falciparum* and *P. vivax* transmission through the vector and also simultaneously treat the disease at the red blood cell stage. It may be challenging to design and develop this drug; therefore a more conservative estimate was used in the model. It was assumed that a third combination drug will block *P. falciparum* transmission and a separate, fourth combination drug (also requiring the development of 2 new active ingredients) will block *P. vivax* transmission. These drugs may or may not treat the disease at the red blood cell stage. If they did not treat the disease at the red blood cell stage, a separate, single combination therapy could be developed that accomplishes this for both *P. falciparum* and *P. vivax*. In total, the model assumes 6 new active ingredients will be developed in the next 10 years to yield 4 novel therapeutic combination drugs.

In order to avoid resistance, it is estimated that 2 new active ingredients will be needed to develop new combination therapies every subsequent decade. One active ingredient may be needed for the therapeutic combination targeting *P. vivax* in the liver stage and one active ingredient for the combination used to block *P. falciparum* and/or *P. vivax* transmission.

In addition to developing novel therapeutic drugs, it is estimated that 10 reformulations will be developed in 10 years and 6 reformulations will be developed each subsequent decade. Specifically, given the 4 new combination therapies being developed in 10 years as discussed above, each therapy requires a reformulation for various populations: adults (accounted for), pregnant women (4), children (4), infants (1), and intravenous (IV) formulation for severe cases of malaria (1). As a result, 10 reformulations are needed in 10 years. Given the target of developing 2 therapies in subsequent decades to combat resistance, 6 reformulations will be developed every 10 years starting in 2018: pregnant women (2), children (2), infants (1), and IV reformulation for severe malaria (1).

As with preventive drugs, the cost of developing a novel active ingredient for therapeutic drugs is estimated to be US\$ 250 million and the development time is assumed to be 10 years. For modeling purposes, the cost was evenly spread out over the 10 year development cycle. The cost of developing a reformulation is estimated to be US\$ 25 million or 10% of the cost of a new active ingredient. The development time is assumed to be 2-6 years. For modeling purposes the cost of 8 reformulations was spread out over 10 years (2008-2018) and the cost of 6 reformulations was linearly spread out over each subsequent decade.

Table A.10: Estimated cost of research and development for drugs

Drug R&D	Timeframe	Total cost (US\$ millions)
<i>Preventive</i>		
2 active ingredients	2008-2018	500
4 reformulations		100
2 active ingredients	Subsequent decades	500
4 reformulations		100
<i>Therapeutic</i>		
6 active ingredients	2008-2018	1,500
10 reformulations		250
2 active ingredients	Subsequent decades	500
6 reformulations		150

Source: GMAP costing model, Medicines for Malaria Venture (MMV) and expert interviews.

Vaccine R&D Costs. Many experts consider vaccine development to be a key activity for malaria elimination and eradication. Given the lack of success in moving a malaria vaccine through phase III clinical trials to date, predicting the cost and timing of future vaccine launches is highly uncertain. As a result, assumptions made in generating the vaccine R&D cost numbers will have to continuously be updated as technological progress is made.

Efficacious vaccines are needed for both *P. falciparum* and *P. vivax*. RTS,S, which targets *P. falciparum*, is the most advanced malaria vaccine and is currently in phase III clinical trials. Even if RTS,S launches in 2013-14, a more efficacious *P. falciparum* vaccine is likely necessary for malaria elimination. Based on current vaccine priorities, it is assumed that a next generation *P. falciparum* vaccine would have to exceed 80% efficacy in order to justify the cost of late stage development. In addition to overcoming this hurdle, efficacy comparison studies between both generations of vaccines would have to be conducted. As a result, it is estimated that after the launch of RTS,S 10 years are needed for the deployment of a second generation *P. falciparum* vaccine.

In addition to the vaccines for *P. falciparum*, an efficacious vaccine for *P. vivax* will be necessary for malaria eradication. Several other vaccines would also be tremendous assets for the malaria community: a vaccine that targets both *P. falciparum* and *P. vivax*, a transmission blocking vaccine, and a vaccine for pregnant women. For the purposes of this R&D costing effort, it was assumed that four vaccines could be developed by 2028. Furthermore, one subsequent vaccine would be developed every decade after 2028.

1. 1 RTS,S vaccine for *P. falciparum* (launch 2013-14)
2. 1 next generation vaccine *P. falciparum* (launch 2024)
3. 1 vaccine for *P. vivax* (launch 2024)
4. 1 other vaccine (launch 2028): a vaccine that targets both *P. falciparum* and *P. vivax*, and/or a transmission blocking vaccine, and/or a vaccine for pregnant women

As of 2007, it was assumed the remaining cost to develop RTS,S was US\$ 220 million. For modeling purposes, these costs were linearly spread out through 2013. In general, the baseline cost of the other vaccines was assumed to be US\$ 800 million and the development timeline was assumed to be 13 years. Furthermore, 75% of the cost is spread over 10 years (pre-phase III) and 25% of the cost was spread over 3 years (phase III through launch). However, for the second generation *P. falciparum* vaccine (#2), the development timeline was lengthened to 17 years and the cost increased to -US\$ 1 billion for two reasons. First, the 80% efficacy hurdle makes the probability of success more challenging, thus the pre-phase III timeline was lengthened three years at an annual cost equal to the other pre-phase III years. Second, the Phase III efficacy comparison studies would take considerably longer and are more expensive than the Phase III studies for a first generation vaccine. Thus, one year of additional costs and time was added to the phase III portion of the model for this vaccine.

The US\$ 800 million cost and 13 year vaccine development time estimates were derived from a compilation of historical malaria vaccine performance, comparable vaccine development data, and expert discussions. Specifically, pre-erythrocytic combinations and transmission blocking vaccines or combinations cost on average -US\$ 116 million and take ~13 years. Given an attrition rate that ranges from 0.6-2.4%, the total investment, including cost of failures, ranges from US\$ 550 million - 1.5 billion. Similarly, blood stage vaccines cost on average -US\$ 114 million and take ~13 years. However, the success rate for blood stage vaccines ranges from 2.2-6.8%, therefore the total investment, including cost of failures, ranges from US\$ 350 - 640 million. An average of these vaccine development costs (based on pipeline mix) yields -US\$ 800 million which is the estimate for vaccine cost used in the model. The average development timelines for each type of vaccine is ~13 years.

Table A.11: Estimated cost of research and development for vaccines

Vaccine R&D	Timeframe	Total cost (US\$ millions)
RTS,S for <i>P. falciparum</i>	2008-2013	189
Vaccine for <i>P. falciparum</i>	2008-2024	1,000
Vaccine for <i>P. vivax</i>	2012 -2024	800
Other vaccines	2016-2028	800
Future vaccines	Post-2028	800 / vaccine

Source: GMAP costing model, Malaria Vaccine Initiative (MVI), Bill and Melinda Gates Foundation, expert interviews.

Vector Control R&D Costs. Vector control R&D is aimed at developing new active ingredients, new formulations and new paradigms for killing vectors. Specifically, it was assumed that 3 novel active ingredient classes, 15 reformulations, and 3 new paradigms such as larviciding, consumer products, etc. would need to be developed in the next 10-12 years to achieve control and elimination objectives. The new active ingredients are needed to develop safer, longer lasting, less expensive pesticides and chemicals for new paradigms that emerge. It is estimated that 1 novel active ingredient, 10 reformulations, and 1 new paradigm is needed to prevent resistance in each subsequent decade.

The cost of developing a novel active ingredient for vector control is estimated to be -US\$ 200 million and the development time is assumed to be 12 years. For modeling purposes, the cost was evenly spread over a 12 year development cycle. The cost of developing a reformulation is estimated to be between US\$ 1 - 5 million, so on average -US\$ 3 million. The development time is assumed to be 2-6 years. For modeling purposes, the cost of 15 reformulations was spread evenly over 10 years (2008-2018) and the cost of 10 reformulations was linearly spread over each subsequent decade. The cost of establishing a new paradigm is -US\$ 4 million and there is a 50% failure rate associated with this effort. The development time to validate

the utility of a new paradigm through experimentation is ~5 years. The US\$ 24 million cost associated with developing 3 new paradigms was spread linearly over 10 years as was the US\$ 8 million cost for 1 paradigm each decade thereafter.

Table A.12: Estimated cost of research and development for vector control

Vector control R&D	Timeframe	Total cost (US\$ millions)
3 active ingredients	2008-2020	600
15 reformulations	2008-2018	45
3 paradigms		24
1 active ingredient	Subsequent decades	200
10 reformulations		30
1 paradigm		8

Source: GMAP costing model, Innovative Vector Control Consortium (IVCC) and expert interviews.

Diagnostic R&D Costs. While the current diagnostic methods, microscopy and rapid diagnostic test technologies (RDTs), can confirm clinical diagnoses and provide treatment information, there are still several R&D opportunities in this field. Microscopy can identify which of multiple parasite species are in circulation, and determine the parasite density (quantitation). However, the experience of the technician and the quality of the equipment determines the sensitivity of microscopic diagnosis, and it is therefore limited to larger clinics and inappropriate for most village-based situations. Development of RDTs for malaria offers the potential to extend accurate malaria diagnosis to remote areas without microscopy services.²¹ However, RDTs are not without challenges either: inconsistent quality within and across batches leads to a perception of unreliability in some circumstances. Priorities and assumptions described below were developed with these key issues in mind.

Microscopy. Microscopy has been the reference standard of diagnostic equipment since it enables direct parasite determination. Giemsa microscopy has been the primary microscopy technique used in the past. Newer microscopy techniques are being evaluated which offer greater detection capabilities. Technologies such as incident light fluorescence microscopy are growing rapidly in importance as investigational tools in the fields of medical and biological research, and may have a place in improving accuracy and reliability of malaria microscopy. It is assumed that annual R&D investment in microscopy of at least ~US\$ 2 million will be needed through 2050 in order to continuously improve microscopy technologies.

RDTs. The immediate goal is to improve existing technology to get higher quality RDTs. In the medium- to long- term, one could try to develop new monoclonal antibodies, advanced polymerase chain reaction (PCR) technology, or other broader diagnostic technologies. Due to the uncertainty surrounding the time and cost of realizing each of these R&D options, it was assumed that the 5 R&D strategy scenarios shown below will be conducted in parallel:

1. Current technology is improved thereby enhancing product quality and reproducibility.
2. New monoclonal antibodies are developed to increase diagnostic sensitivity and test stability.
3. PCR technology is developed for mass screening.

²¹ See www.rapiddiagnostics.org.

4. Broader diagnostic technologies are developed: e.g. platform that performs differential diagnoses for a range of infectious diseases (currently in development at Claros Diagnostics), remote diagnosis via telemedicine, etc.
5. Non-invasive tests are developed.

For the purpose of this costing model, it was assumed that improvements to current technology costing US\$ 200,000 per year per research laboratory would be conducted through 2050. Assuming five research laboratories would be conducting R&D on the top diagnostic technologies yields an annual cost of US\$ 1 million. Even if in the next few years significant improvements to current diagnostic technology is seen and higher quality tools were deployed in the field, other types of diagnostic R&D (specifically, scenario #2, #3, and #4 above) would persist.

Research on new monoclonal antibodies and new PCR technology would continue too in an attempt to improve diagnostic sensitivity. This increased sensitivity would enable improved diagnosis of malaria in pregnancy, in asymptomatic patients during population screening, and in other situations where parasite densities are low. Research to develop tests for specific markers of severe disease, such as cerebral malaria, is also expected to proceed. Furthermore, development of new monoclonal antibodies could help improve the thermal stability and shelf life of current diagnostics.

Developing a new monoclonal antibody is estimated to take a lab ~US\$ 750,000 and 4-5 years. Given a 33% probability of success it would cost ~US\$ 2.5 million over 4-5 years to identify a new monoclonal antibody. In addition, multiple field trials would be conducted in various endemic settings, each costing ~US\$ 1 million. For the purpose of this model, the assumption was made that every 5 years through 2025, one new monoclonal antibody would be developed and 3 field studies would be performed resulting in an improved diagnostic at the cost of US\$ 5.5 million. These costs were spread linearly over the 5 year development timeline. After 2025, it is reasonable to assume that countries will be more focused on elimination and thus advances in either PCR technology or broader diagnostic technology will be the dominant technology deployed in the field.

Development of new PCR technology is expected to take ~8-10 years. The model assumes that the development of this technology (scenario #3) or broader technologies (scenario #4) will go on in parallel through 2050 at an annual cost that is double the cost for developing a new monoclonal antibody. As a result, the annual cost to explore both PCR and broader diagnostic technologies is estimated to be ~US\$ 4.4 million.

Development of non-invasive tests, which may use existing technologies to detect markers available from other means of sampling (e.g. saliva, urine), or new technologies such as photoabsorption are estimated to be ~US\$ 1 million and US\$ 2 million per year, respectively.

Overall, the peak diagnostic costs are expected to be US\$ 11.5 million per year. The table below outlines the cost breakdown described above.

Table A.13: Estimated cost of research and development for diagnostics

Vector control R&D	Timeframe	Total cost (US\$ millions)
Microscopy	2008-2050+	2
Improving current technology	2008-2050+	1
New monoclonal technology	2008-2025	1.1
PCR technology	2008-2050+	2.2
Broader diagnostic technology	2008-2050+	2.2
Non-invasive tests	2008-2050+	3

Source: GMAP costing model, Foundation for Innovative Diagnostics (FIND), WHO and expert interviews.

Appendix 6: Compilation of WHO References

Appendix 6 presents the guidelines, position papers, reports of technical reviews and other documents published by the World Health Organization (WHO) which have been used as a basis for the recommendations presented in the Global Strategy of the GMAP. These documents have been used in their version available between January and August 2008. The GMAP uses international recommendations for malaria control and elimination as of August 2008. Some of these recommendations will likely change in the future so please see the WHO websites for updates.

Malaria Control and Elimination

See <http://www.who.int/malaria/>

Global malaria control and elimination: report of a technical review. Geneva, World Health Organization, 2008

ISBN 978 92 4 159675 6

<http://www.who.int/malaria/docs/elimination/MalariaControlEliminationMeeting.pdf>

Strategic orientation paper on prevention and control of malaria, for national and international programme officers involved in malaria control at country level (first edition). Geneva, World Health Organization, 2005

WHO/HTM/MAL/2005.1105

<http://www.who.int/malaria/docs/trainingcourses/NPOreport.pdf>

Malaria control in complex emergencies, an inter-agency field handbook. Geneva, World Health Organization, 2005

WHO/HTM/MAL/2005.1107 - ISBN 92 4 159389 X

http://www.who.int/malaria/docs/ce_interagencyfhbook.pdf

Malaria elimination, A field manual for low and moderate endemic countries. Geneva, World Health Organization, 2007

ISBN 978 92 4 159608 4

http://www.who.int/malaria/docs/elimination/MalariaElimination_BD.pdf

Vector Control

See <http://www.who.int/malaria/vectorcontrol.html>

Malaria vector control and personal protection: report of a WHO study group. Geneva, World Health Organization, 2006

WHO technical report series ; no. 936 - ISBN 92 4 120936 4

<http://www.who.int/malaria/docs/WHO-TRS-936s.pdf>

Global strategic framework for integrated vector management. Geneva, World Health Organization, 2004

WHO/CDS/CPE/PVC/2004.10

http://whqlibdoc.who.int/hq/2004/WHO_CDS_CPE_PVC_2004_10.pdf

Indoor residual spraying - Use of indoor residual spraying for scaling up global malaria control and elimination. Geneva, World Health Organization, 2006

WHO/HTM/MAL/2006.1112

<http://www.who.int/malaria/docs/IRS/IRS-position.pdf>

Insecticide-Treated Mosquito Nets: a WHO Position Statement. Geneva, World Health Organization, 2007

<http://www.who.int/malaria/docs/itn/ITNspospaperfinal.pdf>

Case Management

See <http://www.who.int/malaria/diagnosisandtreatment.html>

Guidelines for the treatment of malaria. Geneva, World Health Organization, 2006
WHO/HTM/MAL/2006.1108 - ISBN 92 4 154694 8

<http://www.who.int/malaria/docs/TreatmentGuidelines2006.pdf>

Framework for Developing, Implementing and Updating National Antimalarial Treatment Policy - A Guide for Country Malaria Control Programmes. Brazzaville, Congo, World Health Organization, Regional Office for Africa, 2003

AFR/MAL/03.02

<http://afrolib.afro.who.int/documents/2003/english/framedrugp.pdf>

The Roll Back Malaria strategy for improving access to treatment through home management of malaria. Geneva, World Health Organization, 2005

WHO/HTM/MAL/2005.1101

http://www.who.int/malaria/docs/RBM_Strategy_HMM_sm.pdf

Scaling up home-based management of malaria: From research to implementation. Geneva, World Health Organization, 2004

WHO/HTM/MAL/2004.1096; TDR/IDE/HMM/04.1

<http://www.who.int/malaria/docs/ScalingupHMMresearchtoimplementation.pdf>

The role of laboratory diagnosis to support malaria disease management: focus on the use of rapid diagnostic test in areas of high transmission. Geneva, Switzerland. World Health Organization, 2006

WHO/HTM/MAL/2006.1111

<http://www.who.int/malaria/docs/ReportLABdiagnosis-web.pdf>

Informal consultation on quality control of malaria microscopy. Geneva, World Health Organization, 2006

WHO/HTM/MAL/2006

<http://www.who.int/malaria/docs/diagnosticsandtreatment/reportQua-mal-m.pdf>

The Use of Malaria Rapid Diagnostic Tests. Geneva, World Health Organization, 2006

ISBN 92 9061 204 5

[http://www.who.int/malaria/docs/RDT/TheUseOfMalariaRDT\(2ndEdition\).pdf](http://www.who.int/malaria/docs/RDT/TheUseOfMalariaRDT(2ndEdition).pdf)

Towards Quality Testing of Malaria Rapid Diagnostic Tests: Evidence and Methods. Geneva, World Health Organization, WHO-WPRO, 2006

ISBN 92 9061 238 X

<http://www.who.int/malaria/pages/rdt/QA-RDTReportTowardsQualityTestingofMalariaRDT.pdf>

Drug resistance

See <http://www.who.int/malaria/resistance.html>

Monitoring antimalarial drug resistance. Report of a WHO Consultation. Geneva. World Health Organization, 2002

WHO/CDS/RBM/2002.39

http://rbm.who.int/cmcc_upload/0/000/015/800/200239.pdf

Assessment and monitoring of antimalarial drug efficacy for the treatment of uncomplicated falciparum malaria. Geneva, World Health Organization, 2003

WHO/HTM/RBM/2003.50

<http://www.who.int/malaria/docs/ProtocolWHO.pdf>

Global malaria control and elimination: report of a meeting on containment of artemisinin tolerance. Geneva, World Health Organization, 2008

ISBN 978 92 4 159681 7

http://www.who.int/malaria/docs/drugresistance/Malaria_Artemisinin.pdf

Basco LK. *Field application of in vitro assays for the sensitivity of human malaria parasites to antimalarial drugs.* Geneva, World Health Organization, 2007

ISBN 978 92 4 159515 5

http://www.who.int/malaria/docs/drugresistance/OMS_FieldApplicationInVitroAssays.pdf

Methods and techniques for clinical trials on antimalarial drug efficacy: genotyping to identify parasite populations. Geneva, World Health Organization, 2008

ISBN 978 92 4 159630 5

<http://www.who.int/malaria/docs/drugresistance/MalariaGenotyping.pdf>

Susceptibility of Plasmodium falciparum to antimalarial drugs. Geneva, World Health Organization, 2005

WHO/HTM/MAL/2005.1103

http://www.who.int/malaria/rbm/Attachment/20041108/SusceptibilityPlasmodium_report.pdf

Malaria in Pregnancy

See <http://www.who.int/malaria/pregnantwomenandinfants.html>

A Strategic Framework for Malaria Prevention and Control during Pregnancy in the African Region. Brazzaville, Congo, World Health Organization, Regional Office for Africa, 2004

AFR/MAL/04/01

http://www.who.int/malaria/rbm/Attachment/20041004/malaria_pregnancy_str_framework.pdf

Technical Expert Group meeting on intermittent preventive treatment in pregnancy (IPTp). Geneva, World Health Organization, 2008

<http://www.who.int/malaria/docs/IPTp/TechnicalExpertMtgIPTpReport.pdf>

Malaria in pregnancy: Guidelines for measuring key monitoring and evaluation indicators. Geneva, World Health Organization, 2007

ISBN:978 92 4 159 563 6

http://www.who.int/malaria/docs/mip/mip_guidelines.pdf

“ Malaria defeated the international community many years ago. We cannot allow this to happen again. A single global action plan for malaria control, that enjoys Partnership-wide support is a strong factor for success. ”

Margaret Chan, Director-General of the World Health Organization

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