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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

Contributors from endemic countries or regions

Francisco Bungo	Angola, Military Health Services (MHS)
Gabriel Elsa Fortes	Angola, Military Health Services (MHS)
Nilton Saraiva	Angola, National Malaria Control Program
Moazzem Hossain	Bangladesh, Institute of Allergy and Clinical Immunology of Bangladesh
Nouratou do Rego	Benin, Réseau d’Afrique de l’Ouest contre le Paludisme pendant la Grossesse, Benin
José Lázaro de Brito Ladislau	Brazil, Coordenador Geral do Programa Nacional de Controle de Malaria
Albert Mbonerane	Burundi, Action de Lutte contre la Malaria
Top Samphor Narann	Cambodia, National Malaria Control Program
Boris Boniface Mbah	Cameroon, Fédération Nationale des Syndicats du Commerce & Services
Marlyse Ndi Peyou	Cameroon, Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale
Prosper Thimossat	Central African Republic, National Malaria Control Program
Salomon Garba Chang	Chad, Expanded Program on Immunization
Benjamin Atua	Democratic Republic of Congo, National Malaria Control Program
Tadesse Zerihun	Ethiopia, Ministry of Health
Sardick Kyei-Faried	Ghana, Ghana Health Service
Ramachandran Murali	India, Chettinad Hospital and Research Institute
Vinod Prakash Sharma	India, Indian Institute of Technology
Deepak Gupta	India, Ministry of Health
G P S Dhillon	India, National Anti-Malaria Program
Rita Kusriastuti	Indonesia, Ministry of Health
William Hawley	Indonesia, UNICEF
Mphu Ramatlapeng	Lesotho, Minister of Health and Social Welfare
Samuel Ikwue	Nigeria, Malaria Consortium
Henry Akpan	Nigeria, National Malaria Control Program
Tolulope Sofola	Nigeria, National Malaria Control Program
Majed S. Al-Zedjali	Oman, Ministry of Health
Leo Sora Makita	Papua New Guinea, Department of Health
Rajendra Maharaj	South Africa, Medical Research Council of South Africa
R.R Abeyasinghe	Sri Lanka, Anti-Malaria Campaign
Tarig Mohamad	Sudan, Federal Ministry of Health
Simon Kunene	Swaziland, Southern African Development Community (SADC)
Mufungo Wanjara Marero	Tanzania, Ministry of Health and Welfare, Malaria in Pregnancy Eastern and Southern Africa Coalition
Wichai Satimai	Thailand, Department of Disease Control, Ministry of Public Health
Charles Akora	Uganda, Malaria and Childhood Illness NGO Secretariat
Enid Wamani	Uganda, Malaria and Childhood Illness NGO Secretariat AMREF Country Office

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.

² Many individuals and organizations have been involved in the development of the plan. Undoubtedly, we have not thanked everyone who has been personally involved. Every contribution has been valuable to this process and we apologize for any oversight that has been made.

Owen Munachilemba	Zambia, Kazungula Health Office
Rose Banda	Zambia, Livingstone DMHT
Panganani Njobvu	Zambia, MHS
Pascalina Chanda	Zambia, National Malaria Control Program
Chilandu Mukuka	Zambia, National Malaria Control Program
Kaka Mudambo	Zimbabwe, Military Health Services (MHS)
Alexio Tafirenyika	Zimbabwe, Military Health Services (MHS)
Susan Mutambu	Zimbabwe, National Institute of Health Research
Portia Manangazira	Zimbabwe, National Malaria Control Program
Martha Mpisaunga	Zimbabwe, Syngenta
Keith Carter	WHO - Pan-American Health Organization (PAHO)
Rainer Escalada	WHO - Pan-American Health Organization (PAHO)
Guintran Jean Oiliver	WHO - Inter-country Support Team, Burkina Faso
Jackson Sillah	WHO - Inter-country Support Team, Burkina Faso
Stephane Tohon	WHO - Inter-country Support Team, Burkina Faso
Nathan Bakyaia	WHO - Regional Office for Africa (AFRO), Congo
Rufaro Chatora	WHO - Regional Office for Africa (AFRO), Congo
Tiéman Diarra	WHO - Regional Office for Africa (AFRO), Congo
Georges Alfred Ki-Zerbo	WHO - Regional Office for Africa (AFRO), Congo
Etienne Minkoulou	WHO - Regional Office for Africa (AFRO), Congo
Triphonie Nkurunziza	WHO - Regional Office for Africa (AFRO), Congo
Ibrahima Socé Fall	WHO - Regional Office for Africa (AFRO), Congo
Walter Kazadi	WHO - Inter-country Support Team, Gabon
Antoine Serufillra	WHO - Inter-country Support Team, Gabon
Felicia Owusu Antwi	WHO - Country Office, Ghana
Leonard Ortega	WHO - Country Office, Myanmar
Bayo Fatunmbi	WHO - Country Office, Nigeria
Bakary Sambou	WHO - Country Office, Senegal
Charles Katureebe	WHO - Country Office, Uganda
Charles Paluku Kalenga-Mbudi	WHO - Inter-country Support Team, Zimbabwe
Josephine Namboze	WHO - Inter-country Support Team, Zimbabwe
Mikhail Ejov	WHO - Regional Office for Europe (EURO), Denmark
Krongthong Thimasarn	WHO - Regional Office for South-East Asia (SEARO), India
Hoda Atta	WHO - Regional Office for the Eastern Mediterranean (EMRO), Egypt
Gasem Zamani	WHO - Regional Office for the Eastern Mediterranean (EMRO), Egypt
David Bell	WHO - Regional Office for the Western Pacific (WPRO), Philippines
Eva Maria Christophel	WHO - Regional Office for the Western Pacific (WPRO), Philippines
Raman Velayudhan	WHO - Regional Office for the Western Pacific (WPRO), Philippines

The RBM Working Group Co-Chairs

The RBM Working Groups have played a critical role in providing input and feedback on different aspects of the plan. The Roll Back Malaria Partnership would like to recognize all Working Group members as well as the chairpersons listed below for their commitment to the development of the GMAP.

MAWG	Nicole Bates	Global Health Council
MAWG	Peter McOdida	KeNAAM
HWG	Suprotik Basu	Office of the United Nations Special Envoy for Malaria
HWG	Melanie Renshaw	UNICEF
PSM	Rima Shretta	Management Sciences for Health
PSM	Henk den Besten	IDA Solutions
RWG	Olusoji Adeyi	World Bank
RWG	Yann Derriennic	Abt Associates

WIN	Don de Savigny	Swiss Tropical Institute
WIN	Kabir Cham	WHO - Global Malaria Program
MERG	Tessa Wardlaw	UNICEF
MERG	Richard Steketee	Malaria Control and Evaluation Partnership in Africa (PATH/MACEPA)
MIP	Juliana Yartey	WHO - Making Pregnancy Safer
MIP	Angus Spiers	UNICEF

Contributors from RBM Partner organization

Susna De	Abt Associates
Halima Mwenesi	Academy for Educational Development (AED)
Francois Maartens	Africa Fighting Malaria
Richard Tren	Africa Fighting Malaria
Marc Blanchard	Artemisinin and Farming International
Pedro Alonso	Barcelona Centre for International Health Research (CRESIB)
Carolyn Daher	Barcelona Centre for International Health Research (CRESIB)
Dieter Stuerchler	Basel University and Stuerchler Epidemiologics
Anthony Kiszewski	Bentley College
Kate Altman	Bill & Melinda Gates Foundation
Girindre Beeharry	Bill & Melinda Gates Foundation
David Brandling-Bennett	Bill & Melinda Gates Foundation
Tom Brewer	Bill & Melinda Gates Foundation
Janice Culpepper	Bill & Melinda Gates Foundation
Gabrielle Fitzgerald	Bill & Melinda Gates Foundation
Tom Kanyok	Bill & Melinda Gates Foundation
Carol Medlin	Bill & Melinda Gates Foundation
Jessica Milman	Bill & Melinda Gates Foundation
Andrew Serazin	Bill & Melinda Gates Foundation
Anne-Marie Deans	Boston Consulting Group
Mathieu Lamiaux	Boston Consulting Group
Abigail Moreland	Boston Consulting Group
Francois Rouzaud	Boston Consulting Group
Philippe Soussan	Boston Consulting Group
Lori Spivey	Boston Consulting Group
Wendy Woods	Boston Consulting Group
Paul Emerson	Carter Center
Yoel Margalith	Center for Biological Control, Ben-Gurion University Beer Sheva
Ido Tsurim	Center for Biological Control, Ben-Gurion University Beer Sheva
Patrick Kucher	Centers for Disease Control and Prevention
Larry Slutsker	Centers for Disease Control and Prevention
Kwame Asamoah	Centers for Disease Control and Prevention and US Presidential Malaria Initiative
Amy Ratliffe	Centers for Disease Control and Prevention and US Presidential Malaria Initiative
Justin Cohen	Clinton Foundation
Bruno Moonen	Clinton Foundation
Patrick Moonasar	Clinton Foundation
Oliver Sabot	Clinton Foundation
Jeffrey Sachs	Columbia University
Delna Ghandi	Department for International Development (DFID)
Vel Gnanendran	Department for International Development (DFID)
Dilip Shah	Department for International Development (DFID)
John Worley	Department for International Development (DFID)
Suzanne Wood	Department for International Development (DFID)
Jessica Rockwood	Development Finance International

Steven Phillips	ExxonMobile
Norbert Becker	European Mosquito Control Association
Joel Breman	Fogarty International Center
Evan Lee	Foundation for Innovative New Diagnostics
Mark Perkins	Foundation for Innovative New Diagnostics
Giorgio Roscigno	Foundation for Innovative New Diagnostics
Ian Boulton	GlaxoSmithKline
Kate Taylor	GlaxoSmithKline
Fabienne Jouberton	Global Fund to fight AIDS, Tuberculosis and Malaria
Eline Korenromp	Global Fund to fight AIDS, Tuberculosis and Malaria
Cedric Mahe	Global Fund to fight AIDS, Tuberculosis and Malaria
Mariatou Tala Jallow	Global Fund to fight AIDS, Tuberculosis and Malaria
Elizabeth Brashers	Global Health Group, University of California, San Francisco
Richard Feachem	Global Health Group, University of California, San Francisco
Michelle Hsiang	Global Health Group, University of California, San Francisco
Allison Phillips	Global Health Group, University of California, San Francisco
Rory O'Connor	Globalvision
Barry Bloom	Harvard School of Public Health
Geoff Butcher	Imperial College London
Bob Sinden	Imperial College of Science, Technology and Medicine, London UK
Dariush Akhavan	Independent Consultant
Janet Hemmingway	Innovative Vector Control Consortium
Thomas McLean	Innovative Vector Control Consortium
Marc Coosemans	Institute of Tropical Medicine
Ole Skovmand	Intelligent Insect Control
Elaine Roman	Johns Hopkins University, JHPIEGO, ACCESS Program
Bonnie Gillespie	Johns Hopkins University, Center for Communication Programs - VOICES
Alison Hill	Johns Hopkins University, Center for Communication Programs - VOICES
Djiaba Kane-Diallo	Johns Hopkins University, Center for Communication Programs - VOICES
Hannah Koenker	Johns Hopkins University, Center for Communication Programs - VOICES
Claudia Vondrasek	Johns Hopkins University, Center for Communication Programs - VOICES
William Brieger	Johns Hopkins University, School of Public Health
Benjamin Johns	Johns Hopkins University, School of Public Health
Neff Walker	Johns Hopkins University, School of Public Health
Kara Hanson	London School of Hygiene and Tropical Medicine
Yoell Lubell	London School of Hygiene and Tropical Medicine
Ann Mills	London School of Hygiene and Tropical Medicine
Jayne Webster	London School of Hygiene and Tropical Medicine
Chris Whitty	London School of Hygiene and Tropical Medicine
Virginia Wiseman	London School of Hygiene and Tropical Medicine
Fred Arnold	Macrointernational
Erin Eckert	Macrointernational
Sylvia Meek	Malaria Consortium
Delphine Valette	Malaria Consortium
Kent Campbell	Malaria Control and Evaluation Partnership in Africa (PATH / MACEPA)
Paul Libiszowski	Malaria Control and Evaluation Partnership in Africa (PATH / MACEPA)
Richard Steketee	Malaria Control and Evaluation Partnership in Africa (PATH / MACEPA)
Mary Galinski	Malaria Foundation International
Kate Campana	Malaria No More
Sally Ethelston	Malaria Vaccine Initiative
Christian Loucq	Malaria Vaccine Initiative
Tonya Villafana	Malaria Vaccine Initiative
Gerard Seco	Médecins Sans Frontières
Chris Hentschel	Medicines for Malaria Venture

Tim Wells	Medicines for Malaria Venture
Richard Allan	The MENTOR Initiative
Jean Bernard Bouvier	The MENTOR Initiative
Sarah Hoibak	The MENTOR Initiative
Fayaz Ahmad	Merlin
Naeem Durrani	Merlin
Alan Court	Office of the United Nations Special Envoy for Malaria
Minh-Thu Pham	Office of the United Nations Special Envoy for Malaria
Chris Atim	PATH Malaria Vaccine Initiative
Alan Brooks	PATH Malaria Vaccine Initiative
Vicky Cárdenas	PATH Malaria Vaccine Initiative
John Thomas	Phoenix Ordinary LLC
Desmond Chavasse	Population Services International (PSI)
Chris White	Population Services International (PSI)
Chilunga Puta	Regional Center for Quality of Health Care, Makerere University, Uganda
Hellen Gelband	Resources for the Future
Marcos Espinal	Stop TB Partnership
Thomas Smith	Swiss Tropical Institute
Marcel Tanner	Swiss Tropical Institute
Josh Yukich	Swiss Tropical Institute
Don Hopkins	The Carter Center
Peter Burgess	Transparency and Accountability Network
Holly Newby	UNICEF
Angus Spiers	UNICEF
Netsanet Walelign	UNICEF
Francisco Blanco	UNICEF Supply Division
Hanne Bak Pederson	UNICEF Supply Division
Kevin Starace	United Nations Foundation
Elisabetta Molari	United Nations Office for Project Services
Elizabeth Fox	USAID
Kamden Hoffman	USAID / PMI
Michael Macdonald	USAID / PMI
Bernard Nahlen	USAID / PMI
Trent Ruebush	USAID / PMI
Ralph Rack	USAID - Deliver Project
Shamim Qazi	WHO - CAH/FCH
Michelle Gayer	WHO - Communicable Diseases Working Group Emergencies
Tessa Tan-Torres	WHO - Costs, Effectiveness, Expenditure and Priority Setting, Health Systems Financing
Tracey Goodman	WHO - EPI
Erica Wheeler	WHO - GHWA
Maru Aregawi	WHO - Global Malaria Program
Richard Cibulskis	WHO - Global Malaria Program
Pierre Guillet	WHO - Global Malaria Program
Stefan Hoyer	WHO - Global Malaria Program
Ambachew Mehdin	WHO - Global Malaria Program
Kamini Mendis	WHO - Global Malaria Program
Shiva Murugasampilai	WHO - Global Malaria Program
José Nkuni	WHO - Global Malaria Program
Peter Olumese	WHO - Global Malaria Program
Mac Otten	WHO - Global Malaria Program
Aafje Rietveld	WHO - Global Malaria Program
Pascal Ringwald	WHO - Global Malaria Program
Sergio Spinaci	WHO - Global Malaria Program
Ryan Williams	WHO - Global Malaria Program

Andrea Bosman	WHO - Global Malaria Program
David Heymann	WHO - Health Security and Environment
Samb Badara	WHO - Health Systems Strengthening
Chris Dye	WHO - HIV/AIDS, TB, Malaria and Neglected Tropical Diseases
Michael Riggs	WHO - Liaison Office Washington
Viviana Mangiaterra	WHO - Making Pregnancy Safer
Ivane Bochorishvili	WHO - The Special Programme for Research and Training in Tropical Diseases (TDR)
Franco Pagnoni	WHO - The Special Programme for Research and Training in Tropical Diseases (TDR)
Maryse Pierre-Louis	World Bank
John-Paul Clark	World Bank
Melisse Murray	World Bank
Noel Chisaka	World Bank
Jumana Qamruddin	World Bank
Tom Achoki	World Economic Forum
Lakshmi Sundaram	World Economic Forum

The RBM Board Contributors

Regina Rabinovich	Bill & Melinda Gates Foundation
Awash Teklehaimanot	Columbia University
Stewart Tyson	Department for International Development (DFID)
Michel Kazatchkine	Global Fund to fight AIDS, Tuberculosis and Malaria
Erick Rodriguez	Instituto Venezolano de Investigaciones Cientificas (IVIC), Venezuela
Matthew Lynch	Johns Hopkins University, Center for Communication Programs
Sunil Mehra	Malaria Consortium
Anbumani Ramadoss	Minister for Health and Family Welfare, India
Ouk Monna	Ministry of Health, Cambodia
Tedros Andhanom Ghebreyesus	Minister of Health, Ethiopia
Oumar Ibrahime Toure	Minister of Health, Mali
Mohammed Lawal	Minister of Health, Nigeria
Steven Mallinga	Minister of Health, Uganda
Brian Chituwo	Minister of Health, Zambia
André Mama Fouda	Minister of Public Health, Cameroon
Louis-Charles Viossat	Ministère des Affaires Etrangères, France
Awa Marie Coll-Seck	RBM Partnership
René Cazetien	Sanofi-Aventis
Uzo Gilpin	Society for Family Health, Nigeria
Ray Chambers	UN Special Envoy for Malaria
Jeffrey O'Malley	UNDP
Peter Salama	UNICEF
Jorge Bermudez	UNITAID
Timothy Ziemer	USAID / PMI
Mikkel Vestergaard	Vestergaard Frandsen
Hiroki Nakatani	WHO - HIV/AIDS, TB, Malaria and Neglected Tropical Diseases
Olusoji Adeyi	World Bank

The RBM Partnership Secretariat

Patrick Avognon	RBM Partnership Secretariat
James Banda	RBM Partnership Secretariat
Richard Carr	RBM Partnership Secretariat
Alan Esser	RBM Partnership Secretariat
Julian Fleet	RBM Partnership Secretariat
Katie Gates	RBM Partnership Secretariat
Marina Gavrioushkina	RBM Partnership Secretariat
Katya Halil	RBM Partnership Secretariat
Peter Mbabazi Kwehangana	RBM Partnership Secretariat Focal Point EARN
Nadia Lasri	RBM Partnership Secretariat
Caroline Ndiaye	RBM Partnership Secretariat
Leonel Pontes	RBM Partnership Secretariat Focal Point CARN
Claude-Emile Rwagacondo	RBM Partnership Secretariat Focal Point WARN
Boriana Savova	RBM Partnership Secretariat
Michel Smitall	RBM Partnership Secretariat
Pru Smith	RBM Partnership Secretariat
Thomas Teuscher	RBM Partnership Secretariat
Vonai Teveredzi	RBM Partnership Secretariat Focal Point SARN
Boi-Betty Udom	RBM Partnership Secretariat
Jan Van Erps	RBM Partnership Secretariat
Philippe Verstraete	RBM Partnership Secretariat

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.

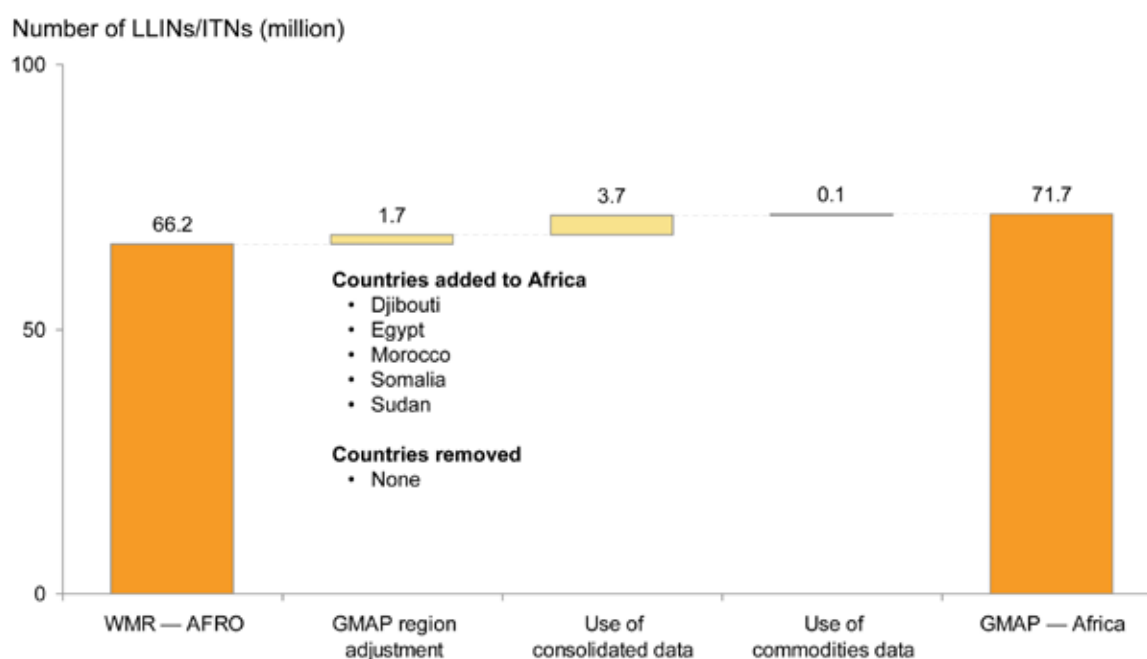
b) Roll Back Malaria Partnership.

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.

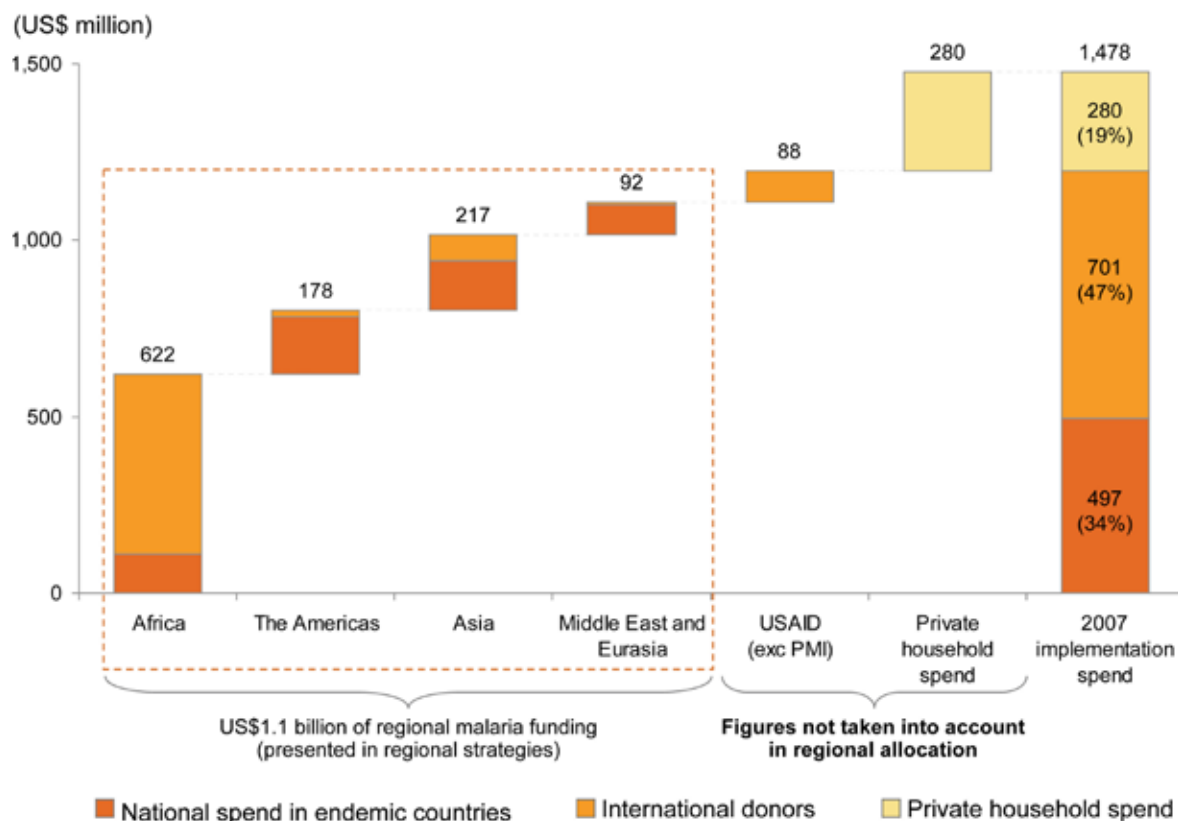
Regional Estimates. *Part III - Regional Strategies* presents a regional allocation of current malaria resources. Figures presented in this chapter represent 2007 regional disbursements including national government spending from endemic countries and funding from major international donors (all listed 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

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<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>

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WHO/HTM/MAL/2006.1108 - ISBN 92 4 154694 8

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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

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Monitoring antimalarial drug resistance. Report of a WHO Consultation. Geneva. World Health Organization, 2002

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http://rbm.who.int/cmcc_upload/0/000/015/800/200239.pdf

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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

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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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design: www.sbgraphic.ch

layout and production: The Boston Consulting Group

The Roll Back Malaria Partnership

RBM Secretariat hosted by the
World Health Organization
20, avenue Appia
1211 Geneva 27
Switzerland
inforbm@who.int
www.rollbackmalaria.org

