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President's Malaria Initiative Strategy

2015–2020

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Brant Stewart, RTI

I. Executive Summary

The fight against malaria has yielded dramatic progress over the last 10–15 years. The World Health Organization (WHO) estimates that the scale-up of malaria control interventions between 2001 and 2013 resulted in an estimated 4.3 million fewer malaria deaths. These impressive results – particularly in sub-Saharan Africa – are due to a massive scale-up of malaria prevention and case management measures resulting from the combined efforts of national malaria control programs (NMCPs), a broad range of partners, and the launch of three major initiatives: the Global Fund to Fight AIDS, Tuberculosis and Malaria in 2002, The World Bank Malaria Booster Program in 2004, and the U.S. President’s Malaria Initiative (PMI) in 2005. In December 2010, the UK Department for International Development committed to increase its support for malaria control by up to £500 million. While the increased level of donor funding for malaria control during the past decade was unprecedented, it is still significantly below the estimated US\$5.1 billion that is required annually to achieve global targets for malaria control and elimination.

The scale-up of malaria control measures and the resulting decline in malaria illnesses and deaths since 2000 has not been uniform throughout Africa. In some countries, further efforts to attain high coverage with malaria control interventions are needed before substantial reductions in malaria burden can be expected. In contrast, other countries have progressed to a point where malaria is no longer a leading public health problem. These successes have prompted shifts in the goals and targets of many partners in the global malaria community, including the Bill & Melinda Gates Foundation, the Roll Back Malaria (RBM) Partnership, and WHO. While the progress to date is historic, the continued control and ultimate elimination of malaria remains fraught with serious challenges, including resistance to the artemisinin family of drugs, wide availability of substandard and counterfeit malaria treatments, resistance to key insecticides, inadequate disease surveillance systems, and waning country and donor attention as malaria burden drops.

When it was launched in 2005, the goal of PMI was to reduce malaria-related mortality by 50 percent across 15 high-burden countries in sub-Saharan Africa through a rapid scale-up of four proven and highly effective malaria prevention and treatment measures: insecticide-treated mosquito nets (ITNs); indoor residual spraying (IRS); accurate diagnosis and prompt treatment with artemisinin-based combination therapies (ACTs); and intermittent preventive treatment of pregnant women (IPTp). With the passage of the Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act in 2008, PMI developed a U.S. Government Malaria Strategy for 2009–2014. This strategy included a long-term vision for malaria control in which sustained high coverage with malaria prevention and treatment interventions would progressively lead to malaria-free zones in Africa, with the ultimate goal of worldwide malaria eradication by 2040–2050. Consistent with this strategy and the increase in annual appropriations supporting PMI, four new sub-Saharan African countries and one regional program in the Greater Mekong Subregion of Southeast Asia were added in 2011. The contributions of PMI, together with those of other partners, have led to dramatic improvements in the coverage of malaria control interventions in PMI-supported countries, and all 15 original countries have documented substantial declines in all-cause mortality rates among children less than five years of age.

This updated President's Malaria Initiative Strategy (2015–2020) takes into account the progress over the past decade and the new challenges that have arisen, setting forth a vision, goal, objectives, and strategic approach for PMI through 2020, while reaffirming the longer-term goal of worldwide malaria eradication. Malaria prevention and control remains a major U.S. foreign assistance objective, and this strategy fully aligns with the U.S. Government's vision of ending preventable child and maternal deaths and ending extreme poverty. It is also in line with the goals articulated in the draft RBM Partnership's second Global Malaria Action Plan and WHO's draft Global Technical Strategy.

The U.S. Government shares the long-term vision of affected countries and global partners of a world without malaria. This vision will require sustained, long-term efforts to

drive down malaria transmission and reduce malaria deaths and illnesses, leading to country-by-country elimination and eventual eradication by 2040–2050. The U.S. Government's goal is to work with PMI-supported countries and partners to further reduce malaria deaths and substantially decrease malaria morbidity, toward the long-term goal of elimination. Building upon the progress to date in PMI-supported countries, PMI will work with NMCPs and partners to accomplish the following objectives by 2020:

1. Reduce malaria mortality by one-third from 2015 levels in PMI-supported countries, achieving a greater than 80 percent reduction from PMI's original 2000 baseline levels.
2. Reduce malaria morbidity in PMI-supported countries by 40 percent from 2015 levels.
3. Assist at least five PMI-supported countries to meet the WHO criteria for national or sub-national pre-elimination.

To achieve these objectives, PMI will take a strategic approach which emphasizes the following five areas:

1. Achieving and sustaining scale of proven interventions
2. Adapting to changing epidemiology and incorporating new tools
3. Improving countries' capacity to collect and use information
4. Mitigating risk against the current malaria control gains
5. Building capacity and health systems.

These areas of focus are informed by PMI's experiences to date, which include building on the successes that countries have achieved with the support of PMI and other partners, incorporating the lessons learned from implementation thus far, and addressing directly the ongoing and new challenges that could prevent further progress toward malaria control and elimination.



II. Background

Progress in Malaria Control, 2000 to Present

The last 10–15 years have seen dramatic progress in the fight against malaria, especially in sub-Saharan Africa. According to its 2014 report, the World Health Organization estimated that malaria was responsible for as many as 198 million illnesses (range 124–238 million) and 584,000 deaths (range 367,000–755,000) worldwide in 2013. More than 90 percent of all malaria deaths occur in sub-Saharan Africa, where *Plasmodium falciparum*, the most lethal species of malaria parasite, predominates.

Scale-up of malaria control interventions between 2001 and 2013 has resulted in an estimated 4.3 million fewer malaria deaths. Of these, 3.9 million (92 percent) were in children less than five years of age in sub-Saharan Africa. The ten countries with the highest estimated malaria burden in 2000 accounted for 57 percent of malaria cases and 68 percent of malaria deaths averted between 2001 and 2013. During the same time period, estimated malaria mortality decreased by 54 percent in the WHO African Region overall and by 58 percent in children under the age of five.¹ In Asia, the Americas, and the Pacific Islands, declining levels of transmission and the lower baseline prevalence of *P. falciparum* infections has moved a number of countries toward eliminating malaria transmission.

These impressive results – particularly in sub-Saharan Africa where conditions are so favorable to intense, sustained malaria transmission – are due, in large part, to a massive scale-up of malaria prevention and treatment measures resulting from the combined efforts of NMCPs and a broad range of partners. During the first half of the past decade, three major initiatives were launched to help control malaria: the Global Fund to Fight AIDS, Tuberculosis and Malaria in 2002, The World Bank Malaria Booster Program in 2004, and PMI in 2005. In December 2010, the U.K. Department for International Development committed to increase its support for malaria control by up to £500 million. These initiatives have been supported by other multilateral agencies, bilateral donors, foundations, and the private sector and countless non-governmental organizations.

The Roll Back Malaria Partnership, created in 1998 and hosted by the WHO in Geneva, has provided leadership in coordinating and harmonizing partners' efforts and has successfully advocated for increased public and private sector

contributions to malaria control. The Millennium Development Goals, promulgated in 2000, helped focus the international development community's attention on improving maternal and child health and combatting major infectious diseases, including malaria.

These efforts have led multilateral and bilateral donors to sharply increase funding for global malaria control and elimination from less than \$100 million in 2000 to an estimated \$2.7 billion in 2013. The bulk of this support has been directed to sub-Saharan Africa, which accounts for the vast majority of malaria cases and deaths. While this represents an unprecedented level of support, the 2008–2015 RBM Global Malaria Action Plan estimated that the global resource requirements to attain international targets for malaria control and elimination exceed \$5.1 billion annually.¹

The President's Malaria Initiative from 2005 to 2014

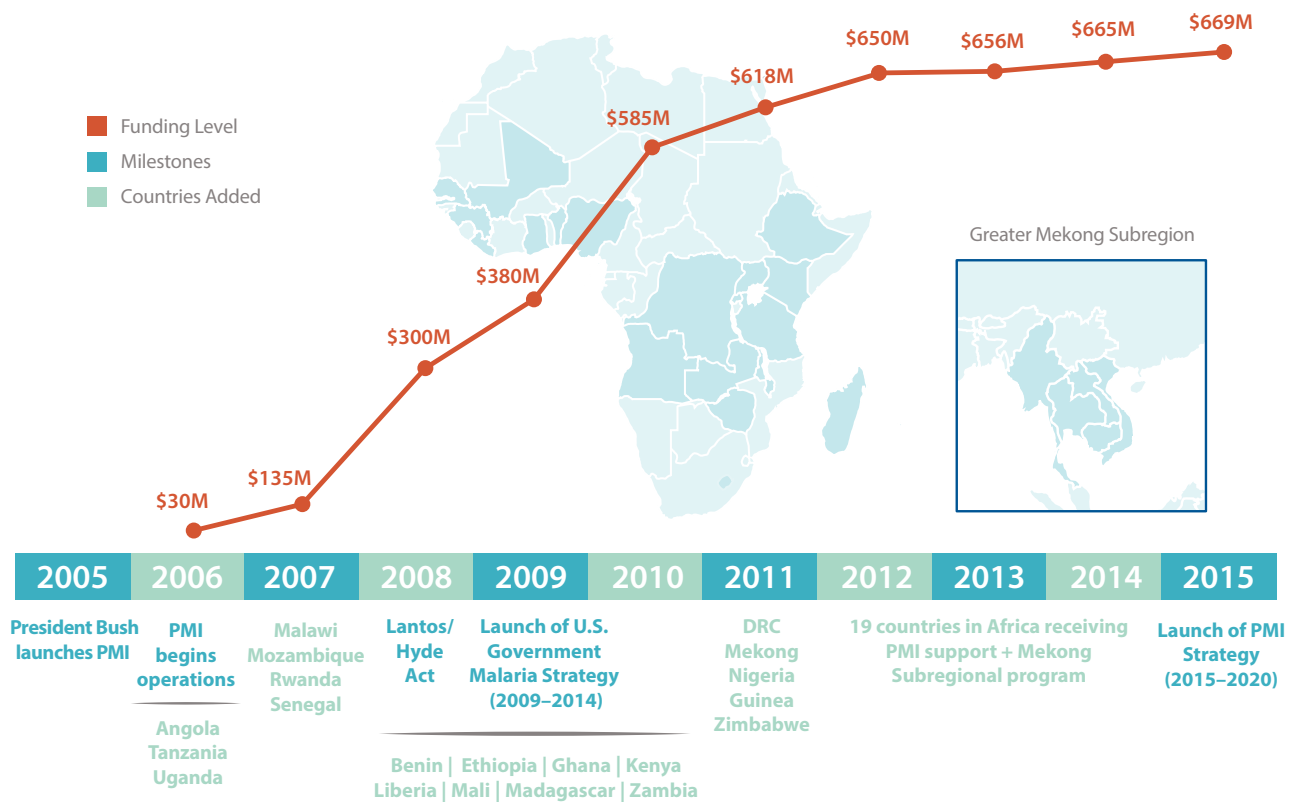
In June 2005, President George W. Bush launched PMI, a major 5-year, \$1.2 billion initiative to support a rapid scale-up of malaria prevention and treatment interventions in 15 high-burden countries in sub-Saharan Africa. The Initiative is led by the U.S. Agency for International Development (USAID) and implemented together with the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC). When it was launched, the goal of PMI was to reduce malaria-related mortality by 50 percent across the 15 PMI-supported countries through a

rapid scale-up of four proven and highly effective malaria prevention and treatment measures: ITNs; IRS; accurate diagnosis and prompt treatment with ACTs; and IPTp.

In 2008, the Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act authorized up to \$5 billion in continued U.S. Government funding for malaria prevention and control through PMI. The Act provided for continued support to the 15 original PMI-supported countries, together with an expansion to up to seven additional countries, including Nigeria and the Democratic Republic of the Congo (DRC), the two largest malaria-endemic countries in Africa.

PMI, which began operations in 2006, was initially expected to cover 15 countries in sub-Saharan Africa, but consistent with the U.S. Government Malaria Strategy (2009–2014) and the increase in annual appropriations supporting PMI, four new sub-Saharan African countries² were added in 2011. In addition, a regional focus involving five countries³ in the Greater Mekong Subregion of Southeast Asia was added in 2011, as evidence began to emerge that resistance to ACTs was intensifying and spreading from its original focus on the Thai-Cambodian border to other parts of the region.


1. World Malaria Report 2014. World Health Organization, Geneva, 2014. http://www.who.int/malaria/publications/world_malaria_report_2014/report/en/
 2. Democratic Republic of Congo, Guinea, Nigeria, and Zimbabwe
 3. Burma, Cambodia, Laos, Thailand, and Vietnam



Progress in PMI-Supported Countries

PMI's contributions, together with those of other partners, have led to dramatic improvements in the coverage of malaria control interventions in PMI-supported countries. As a result of PMI's support for ITNs, IRS, IPTp, and appropriate diagnosis and treatment, a large proportion of at-risk populations in PMI-supported countries are now benefiting from highly effective malaria control measures.


In 19 PMI-Supported Countries:




Household ownership of at least one ITN increased from a median of 29 percent to 55 percent.

Usage of an ITN the night before the survey increased from a median of 20 percent to 43 percent for children less than five years of age.

Usage of an ITN the night before the survey more than doubled from a median of 17 percent to 43 percent for pregnant women.




In 15 countries, PMI's support for IRS protected approximately 21 million people from malaria in FY 2013.



In 17 countries where IPTp is national policy, the proportion of pregnant women who received two or more doses of IPTp for the prevention of malaria increased from a median of 13 percent to 25 percent.



All PMI-supported countries have adopted ACTs as their first-line treatment for malaria and, with PMI support, have procured and distributed more than one-quarter billion ACT treatments since 2006.



Almost all PMI-supported countries have documented an increase in the percentage of malaria cases confirmed by diagnostic testing, including five countries where more than 80 percent of reported cases are confirmed.

Coverage data are from national household surveys; see *The President's Malaria Initiative Eighth Annual Report to Congress* for details.

In large part, this progress can be attributed to both the provision of essential commodities and support of interventions to build capacity of ministries of health (MOHs) and strengthen country health systems. PMI has played a key role in harmonizing planning and coordinating funding so that countries have a single national malaria control plan and budget and a unified monitoring and evaluation system, consistent with the Paris Declaration on Aid Effectiveness. Support to strengthening commodity forecasting and supply chain management systems has significantly reduced stockouts of malaria treatments and diagnostic tests, and dramatically increased the availability of quality-assured ACTs and rapid diagnostic tests (RDTs) at the point of care in PMI-supported countries. Similarly, support for strengthening malaria case surveillance and systems for monitoring drug and insecticide resistance has enabled countries to more effectively select and target appropriate malaria control tools.

As a result, progress toward the Initiative's goals in malaria control in the original 15 PMI-supported countries has been impressive since PMI was launched. All 15 original countries have documented significant declines in all-cause mortality rates among children less than five years of age. These declines have ranged from 16 percent in Malawi to 50 percent in Rwanda (see map on page 8).⁴ Impact evaluations in a subset of these countries strongly suggest that malaria control has made a significant contribution to these reductions in under-five mortality.⁵

Improvement also has been seen in Nigeria and the DRC, which became PMI-supported countries in 2009. Under-five mortality rates have dropped from 156 to 128 per 1,000 live births between 2008 and 2013 in Nigeria and from 148 to 104 per 1,000 live births between 2007 and 2014 in DRC following the significant scale-up of ITN coverage.⁶

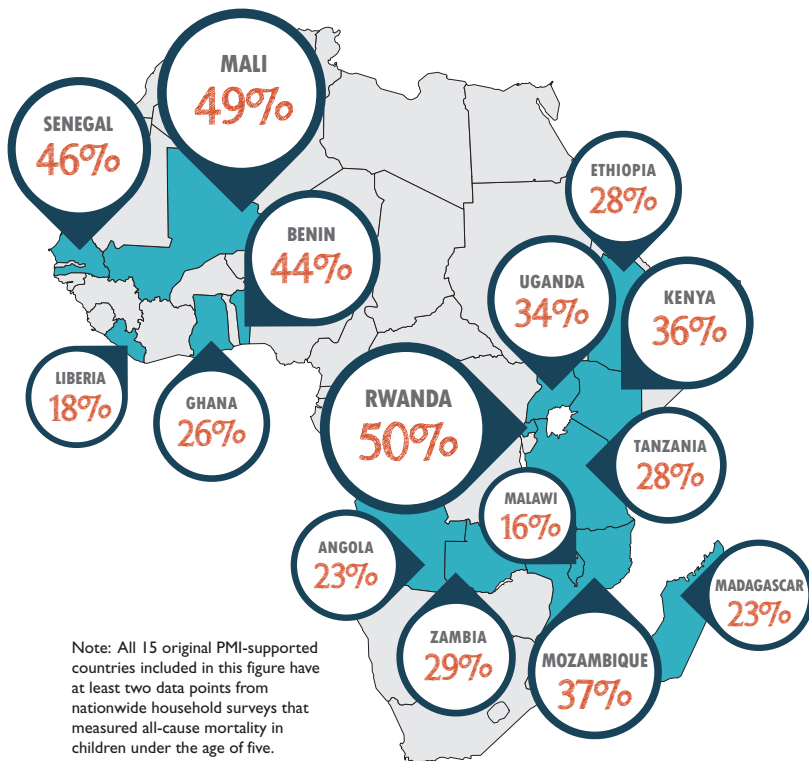
In addition to providing assistance to countries to roll out malaria-specific activities, PMI also helps build national capacity in a variety of crosscutting areas that benefit both malaria and other health programs. This support includes strengthening supply chain management, training for health workers, and support for monitoring and evaluation systems, including disease surveillance systems. PMI also has placed a strong emphasis on building the skills and capacity of MOHs and NMCPs to manage and coordinate malaria control activities in their countries and strengthening the health systems of those countries. This has empowered countries to require all partners to work under a single

4. The President's Malaria Initiative: Eighth Annual Report to Congress, April 2014. http://www.pmi.gov/docs/default-source/default-document-library/pmi-reports/pmireport_final.pdf?sfvrsn=14

5. Progress & Impact Series: Focus on Mainland Tanzania. Roll Back Malaria Partnership, Geneva, 2012. <http://www.rollbackmalaria.org/ProgressImpactSeries/report10.html>

6. The results from DRC and Nigeria are recent. Therefore, it has yet to be determined what interventions, including malaria control, may have contributed to the reductions in all-cause child mortality.

Reductions in All-Cause Mortality Rates of Children Under Five Years of Age



national malaria control plan, rather than a series of uncoordinated donor-driven projects.

The reductions in malaria transmission across Africa have had an important impact on countries' health systems. In most malaria-endemic countries, an average of 25 percent to 35 percent of all outpatient visits and up to a third of admissions are for malaria in children less than five years of age. Where effective malaria control has been achieved in sub-Saharan Africa, it has resulted in many fewer outpatient visits and often a dramatic reduction in hospitalizations. For example, a PMI-funded study from one hospital catchment area in Zambia showed substantial reductions in inpatient admissions and outpatient visits for malaria after the scale-up of malaria control interventions. Hospital spending on malaria admissions also decreased tenfold.⁷ This unburdening of the health system frees up both health worker time and hospital beds, allowing the health system to function more efficiently and making it possible to focus a country's often limited resources on other priority problems.

The Changing Epidemiology of Malaria

The scale-up of malaria control measures and the resulting decline in malarial illnesses and deaths since 2000 have not been uniform throughout Africa. In some countries, including Nigeria and the DRC (which together contribute

approximately one-third of all malaria cases in sub-Saharan Africa), malaria control interventions are still being scaled up. Expanded efforts to scale up to high coverage with malaria prevention and treatment interventions will be needed before substantial reductions in malaria illnesses and deaths can be expected.

In other countries, or areas within countries (e.g., Ethiopia, Rwanda, Senegal, Zambia, and Zanzibar), malaria mortality has been reduced to low levels along with reductions in reported clinical cases. Ethiopia, for example, which was subject to periodic major malaria epidemics every five to seven years, has had no major malaria outbreaks in more than a decade. Dramatic reductions in malaria cases and deaths in Zanzibar have prompted the country's national malaria control program to set its sights on eliminating malaria from its islands. In Senegal, the national malaria control program has set a goal of achieving pre-elimination by 2018. In the Greater Mekong Subregion, elimination of malaria has become the central strategy for prevention of onward spread of artemisinin resistance, particularly in Cambodia and Thailand.

The successes seen in this subset of countries have spurred the global malaria community to recalibrate its goals and targets. For example, the Bill & Melinda Gates Foundation has now adopted malaria eradication as its primary goal. This shift also is reflected in the Roll Back Malaria Partnership's draft second Global Malaria Action Plan 2, 2016–2030 (GMAP 2) and WHO's draft Global Technical Strategy (GTS). The global targets that these plans set forth for 2030 are:

- To reduce malaria mortality rates globally by at least 90 percent compared with 2015
- To reduce malaria clinical case incidence globally by at least 90 percent compared with 2015
- To eliminate malaria from at least 30 countries that had transmission of malaria in 2015 and ensure prevention of re-establishment in countries that are malaria-free

The GTS also sets the following intermediate milestones for 2020:

- To reduce malaria mortality rates globally by at least 40 percent compared with 2015
- To reduce malaria clinical case incidence globally by at least 40 percent compared with 2015

7. Comfort, A.B. et al. (2014). Hospitalizations and Costs Incurred at the Facility Level after Scale-up of Malaria Control: Pre-Post Comparisons from Two Hospitals in Zambia. *American Journal of Tropical Medicine and Hygiene*, 90: 20-32

- To eliminate malaria from at least 10 countries that had transmission of malaria in 2015 and ensure prevention of re-establishment in countries that are malaria free

Going forward, the President's Malaria Initiative Strategy recognizes the need to tailor its support for malaria control activities to the evolving malaria situation in each country. In countries such as DRC and Nigeria, focus must remain on supporting the country to fully scale up current interventions, including ITNs and malaria case management. In countries such as Ethiopia, Rwanda, Senegal, and Zambia, attention will shift to building the needed systems to eliminate malaria from parts or all of these countries, while continuing to sustain core interventions, as appropriate.

New Challenges

In spite of this progress, malaria control and ultimately elimination face serious challenges. One of the most serious threats to progress in malaria control has been the resistance to the artemisinin family of drugs that has been identified in the Greater Mekong Subregion and possibly in South America. Artemisinin-based combination therapy is currently the first-line treatment for *P. falciparum* malaria in most countries worldwide. If artemisinin-resistant strains of *P. falciparum* arose in or were imported to Africa, as is thought to have occurred in the late 1970s with resistance to the antimalarial drug chloroquine, it would be catastrophic for malaria control on the African continent.

Further driving the development and spread of drug resistance is the wide availability of substandard and counterfeit malaria treatments in affected countries. This is particularly true in private sector outlets, where the majority of malaria cases are treated. When such poor-quality treatments are used, they increase the risk of severe disease and death for the patient and select for resistant parasites, which then can be transmitted onward.

Similarly, with the successful scaling up of ITNs and IRS, resistance to key insecticides, including pyrethroids and DDT, is now being identified from a growing number of malaria-affected countries. This has forced many countries to switch to more costly insecticides for IRS and has raised concerns about the possible decrease in effectiveness of ITNs.

Beyond these technical challenges, in many countries the weak health systems and lack of skilled human capacity will continue to slow progress toward malaria control goals and

targets. In particular, lack of well-functioning health information and surveillance systems will hamper evidence-based programming decisions. As countries continue to make progress in scaling up malaria control interventions, it becomes increasingly difficult to get needed commodities and services to those who have not yet been reached, including remote and mobile populations.

New Opportunities

While these developments represent serious threats to malaria control, there is reason to be hopeful that they will not derail continuing progress toward reducing malaria burden. Within the last 10 years, a number of innovations have gone from the laboratory to national scale-up, including long-lasting insecticide-treated nets, a new long-lasting organophosphate insecticide for IRS, and additional ACTs. The availability of high-quality, affordable RDTs for malaria has enabled countries to abandon the practice of presumptively treating every fever for malaria, better ensuring that malaria treatments are reserved only for those infected with malaria and reducing drug pressure, which is a major factor in driving the establishment and spread of antimalarial drug resistance. The scale-up of diagnostic testing also improves the quality of malaria surveillance data, thereby enabling countries to better monitor malaria burden and its response to control interventions. The use of technology, such as mobile phones and internet, can improve the timeliness and the quality of malaria data and improved decision making.

Innovative approaches to deploy existing tools also are being tested, including presumptive insecticide rotation to mitigate the spread and intensification of resistance. Seasonal malaria chemoprevention,⁸ which uses existing malaria treatments, has been shown to be efficacious in reducing morbidity and mortality from malaria in the West African Sahel. Efforts are now underway to take this intervention to scale where it is recommended.

It is anticipated that by 2020, the global malaria community may have entirely new classes of malaria treatments to replace ACTs and possibly more effective insecticide combinations for ITNs. There also is a real possibility of having a vaccine that can reduce severe morbidity and mortality from malaria in the near term. Better diagnostic tools and information technologies to facilitate program management and monitoring also may be within reach.

8. http://www.who.int/malaria/publications/atoz/who_smc_policy_recommendation/en/



Erin Schiavone, Abt Associates

III. The President's Malaria Initiative Strategy, 2015–2020

The 2008 Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act, which authorized funding for PMI through Fiscal Year (FY) 2013, called for the development of a comprehensive multi-year U.S. Government malaria strategy. To align with the six-year timeframe of the Global Health Initiative, a U.S. Government Malaria Strategy for 2009–2014⁹ was prepared. This strategy included a long-term vision for malaria control in which sustained high coverage with malaria prevention and treatment interventions would progressively lead to malaria-free zones in East, West, and southern Africa, with the ultimate goal of worldwide malaria eradication by 2040–2050. This legislation provided for the continuation of support to the original 15 PMI-supported countries and an expansion to other endemic countries.

As the current U.S. Government Malaria Strategy comes to an end in 2014, an updated President's Malaria Initiative Strategy is needed that takes into account the progress that has been made in decreasing the burden of malaria over the past decade and new challenges that have arisen, setting forth bold targets and strategic priorities for PMI through 2020, while reaffirming the longer-term goal of malaria eradication.

Vision

The U.S. Government shares the long-term vision of affected countries and our global partners of a world without malaria. This vision, as described in the 2009–2014 Lantos-Hyde U.S. Government Malaria Strategy, will require sustained, long-term efforts to drive down malaria transmission and reduce malaria deaths and illnesses, leading to country-by-country elimination, and eventually eradication by 2040–2050. This vision fully aligns with the long-term goals set forth in WHO's draft Global Technical Strategy and the Roll Back Malaria Partnership's draft second Global Malaria Action Plan 2, 2016–2030.

9. http://www.pmi.gov/docs/default-source/default-document-library/pmi-reports/usg_strategy2009-2014.pdf

Guiding Principles

Malaria prevention and control is a major U.S. foreign assistance objective and an important component of a comprehensive U.S. Government global health strategy to reduce the burden of disease and strengthen communities around the world, contributing to ending extreme poverty. This strategy is fully aligned with the U.S. Government's bold vision of ending preventable child and maternal deaths by 2035, as malaria continues to be a leading cause of child mortality, despite the progress of the last decade.¹⁰ Because malaria also places a heavy financial burden on families and affected countries, this strategy's focus on reducing the burden of malaria in targeted countries further supports the U.S. Government's high-level development goal of ending extreme poverty. The success of U.S. Government efforts to reduce malaria-related disease and deaths going forward is fully dependent on maintenance or possible expansion of current funding levels in the U.S. foreign assistance budget. Assuming stable funding levels are provided during the period of this strategy, PMI will continue its focus on those countries which currently receive PMI support – 19 countries in Africa and two countries (Burma and Cambodia) and a regional program in the Greater Mekong Subregion. Expansion to other countries or regions would only be feasible if current appropriation levels increase.

Building on the progress and experiences of PMI during the past nine years, the President's Malaria Initiative Strategy sets out the following goal and objectives for the period 2015–2020:

Goal

Work with PMI-supported countries and partners to further reduce malaria deaths and substantially decrease malaria morbidity toward the long-term goal of elimination.

Objectives

Building upon the progress made to date in PMI-supported countries, PMI will work with NMCPs and partners to accomplish the following by 2020:

1. Reduce malaria mortality by one-third from 2015 levels in PMI-supported countries, achieving a greater than 80 percent reduction from PMI's original 2000 baseline levels.
2. Reduce malaria morbidity in PMI-supported countries by 40 percent from 2015 levels.¹¹
3. Assist at least five PMI-supported countries to meet the WHO criteria for national or sub-national pre-elimination.¹²

Strategic Approach

The President's Malaria Initiative Strategy for 2015–2020 builds on and reinforces the successful approach that has resulted in significant reductions in malaria burden since 2006 in PMI-supported countries. Even with the demonstrated reductions in child mortality that have been seen in all 15 original PMI-supported countries, further reductions in child mortality can be achieved with PMI's continued support. This is particularly relevant in high burden countries, such as Nigeria and DRC, which became part of PMI in the sixth year of the Initiative and where scale-up to universal coverage of malaria interventions is still underway.

PMI also must adapt to the changing epidemiology of malaria in its focus countries, particularly those that have exceeded original expectations and begun to see significant reductions in malaria morbidity. Countries such as Ethiopia, Madagascar, Rwanda, Senegal, and Zambia have witnessed a sharp reduction in malaria cases as control interventions have achieved scale. Additionally, in higher burden countries – such as Angola and Kenya – malaria burden is increasingly focused in limited geographic areas or in specific high-risk populations that are often the most difficult to reach. In response, these countries, working with PMI and other partners, have recalibrated their goals and targets toward national or sub-national elimination. Where such goals are achievable, PMI must be responsive to these shifting strategies, while ensuring that resources are not diverted from achieving continued reductions in child mortality and morbidity in higher burden areas.

PMI can particularly add value to these efforts to move toward pre-elimination and eventual elimination by supporting countries to develop the information systems that will be essential in reaching those targets. Strengthening surveillance systems and building the capacity to collect, analyze, and use those data to both target interventions and track progress will become central to these programs. In addition, PMI's support can help countries achieve further progress in scaling up and improving the quality of both IPTp and malaria case management.

10. WHO currently estimates that malaria is the seventh leading cause of death in low-income countries.

11. It should be noted that PMI's target for reduction in malaria mortality is lower than those in the GTS and draft GMAP 2 (i.e. a reduction of 33 percent vs. 40 percent). Because most PMI-supported countries already have had great success in sharply reducing all-cause child mortality over the last decade, further mortality reductions will be more limited in those PMI-supported countries when compared to the larger number of countries not supported directly by PMI but which are included in the GTS and GMAP2 mortality reduction calculations.

12. http://whqlibdoc.who.int/publications/2007/9789241596084_eng.pdf

Since it was launched, PMI's approach has been to build capacity within countries to implement and monitor malaria control interventions, rather than bypass country systems. PMI's experience has been that programs are most successful when countries own and lead malaria control efforts. Such country ownership leads to development of strategies and delivery systems that are best tailored to the specific epidemiology and health systems

in which they operate. In some PMI-supported countries, there are already examples of MOHs that have fully mainstreamed activities that were initially piloted with PMI's support. PMI will continue to work with and encourage countries to fully integrate malaria control activities into their health systems and to build their capacity to manage these programs, thus reducing their reliance on external financial and/or technical support.



IV. Core Areas of Strategic Focus, 2015–2020

The President's Malaria Initiative Strategy for the next six years emphasizes the following five areas of strategic focus:

1. Achieving and sustaining scale of proven interventions
2. Adapting to changing epidemiology and incorporating new tools
3. Improving countries' capacity to collect and use information
4. Mitigating risk against the current malaria control gains
5. Building capacity and health systems

These areas of focus are informed by PMI's experiences to date:

- Building on the successes that countries have achieved with the support of PMI and other partners
- Taking on the lessons learned from implementation to date
- Addressing directly the ongoing and new challenges that could prevent further progress toward malaria control/elimination
- Continuing to engage at global and regional level to ensure coordination and adoption of best practices

1. Achieving and Sustaining Scale of Proven Interventions

PMI will continue its strong support to universal coverage of at-risk populations with ITNs, IPTp, and case management, and targeted high-level coverage of IRS. Whether countries are still scaling up core malaria control interventions or have largely achieved scale, sustaining and building on prior achievements must be central to PMI's efforts in the coming years. Well-documented past experiences from Sri Lanka, Zambia, Zanzibar, and Sao Tome e Principe demonstrate that diverting focus from achieving and sustaining scale with effective prevention and control measures will result in resurgence of malaria morbidity and mortality, risking the extraordinary progress achieved to date and the substantial investments made.

The scale-up of long-lasting ITNs and the implementation of IRS in targeted areas are among PMI's greatest accomplishments to date. This has been largely achieved through support for net distribution campaigns that attain high levels of equitable coverage in a short period of time. Although such campaigns will continue to be an important strategy for reaching and sustaining scale, PMI will support national malaria control plans and partners to explore and implement alternative net delivery strategies to fill gaps missed by campaigns. These alternative approaches could potentially be more cost-effective and sustainable ways to maintain high-level coverage. Use of schools, antenatal and immunization clinics, community health workers, and the private sector to deliver ITNs and community-based applications of IRS are already being piloted and will be scaled up if shown to be effective and to provide equitable coverage.

Although progress in scale-up of malaria case management and IPTp has lagged behind that of ITNs and IRS, rapid advancement has been seen in some areas. A number of PMI-supported countries now confirm more than 80 percent of malaria cases with a diagnostic test, a drastic improvement over just a few years ago when the large majority of malaria cases were diagnosed solely based on clinical findings. In addition, intensified efforts in countries, such as Ghana and Zambia, have relieved some of the policy and health systems bottlenecks to scale up IPTp. Further progress is anticipated in these intervention areas as health systems continue to be strengthened and countries adapt successful approaches to their country context.

This progress has been facilitated by PMI's efforts to address key challenges to scale-up, such as weak commodity forecasting and supply chains and lack of quality assurance systems for monitoring laboratories and clinical services. During the next six years, PMI will continue to identify and develop long-term solutions to remove impediments toward achieving universal coverage of these life-saving interventions. PMI will continue to work across the health sector to strengthen country health systems.

The success of malaria control efforts also has been contingent on PMI's support for effective interventions to educate the public and change their perception and behaviors related to malaria. Through behavior change, communications, and social mobilization interventions, PMI will continue to work to increase the operational effectiveness of our efforts by engaging families and providers in malaria control efforts. We will strive to ensure families seek and use malaria prevention products and services and to promote timely testing and adherence to treatment guidelines.

2. Adapting to Changing Epidemiology and Incorporating New Tools

Continued focus on achieving and maintaining scale of existing interventions, though, does not mean business as usual in U.S. Government malaria assistance efforts. PMI is continually working with countries and the global malaria community to develop, adopt, and implement new proven tools and approaches for malaria control. For example, PMI played a central role in supporting countries to adopt integrated community case management and universal diagnostic testing for malaria as core malaria control strategies. PMI also has promoted the safe and judicious use of insecticides in IRS by supporting countries to develop best management practices that establish a uniform approach for environmental protection. More recently, PMI is providing key support to assess the feasibility of delivering seasonal malaria chemoprevention in targeted countries.

As countries' success in malaria control leads to changes in epidemiology and local strategies and targets evolve in response, PMI will increasingly need to adapt and tailor its approaches and support. This will include testing and scaling up new methods to access the hardest to reach and highest risk populations. Such approaches may include establishing community-based delivery systems; engaging the private sector to reach those who lack access or avoid traditional public health structures; and targeting certain interventions geographically or to hard-to-reach populations (e.g., migrant workers) rather than nationally, for optimal impact with limited resources. Adapting to the changing epidemiology of malaria also means recognizing that the effectiveness of current malaria tools may change. Continuous monitoring of efficacy and effectiveness of implemented interventions will be necessary.

The next six-year phase of PMI will undoubtedly see the development of new tools and implementation approaches with demonstrated effectiveness in controlling malaria. New treatments and vector control tools, and possibly vaccines, are anticipated during this next phase. As it did with the initial introduction of ACTs and RDTs, PMI's commodity procurements, technical assistance, and programmatic support will ensure that countries will have

the assistance needed to implement and evaluate these new tools as they become available.

Through its prioritization and support for operational research, PMI also will continue to play a role in demonstrating the effectiveness, feasibility, and scalability of new proven tools. Operational research support also will continue to focus on identifying best practices and innovative approaches to achieving scale, relieving bottlenecks to implementation for both new and existing tools, and achieving cost efficiencies.

3. Improving Countries' Capacity to Collect and Use Information

As malaria burden drops, control efforts will need to be increasingly targeted to the remaining high-risk areas and populations. Reaching those most at-risk populations can only be achieved if countries have the capacity to identify them. To date, household surveys have been the best method in many countries for monitoring intervention coverage and child mortality. However, these surveys are conducted at most every three years, and thus, their data will not be sufficient for countries with a rapidly changing malaria burden. Countries will increasingly need to adjust their focus and targeting on a yearly, or possibly even monthly, basis to respond to epidemics and real-time gaps in coverage of key interventions. Such surveys also lack the necessary granularity of data that countries will need to differentiate areas in their country with differing levels of malaria burden and intervention coverage.

With PMI support, some countries – including Ethiopia, Rwanda, and Senegal – have already made great strides in strengthening routine malaria surveillance systems and are beginning to use the information gathered from these systems to make decisions on where to target IRS or which communities to prioritize first for ITN campaigns. As malaria burden continues to decrease in countries and these countries move toward pre-elimination, there will be an increasing need to track and follow up individual malaria cases to limit onward transmission that could lead to outbreaks or broader resurgence.

Information gathered through routine disease reporting and health management information systems in PMI-supported countries will become increasingly central to malaria program planning, management, and evaluation. PMI will work with countries and partners to improve the validity, completeness, and timeliness of reporting of relevant information required for malaria program planning and management, tailor them to country requirements, and build capacity to analyze and use those data for decision-making. PMI, when appropriate, will exploit new technologies, such as short message service-based reporting systems, to enable countries to have real-time information on malaria burden for program planning and

response. In addition, PMI will advocate at country and global levels for increased transparency of data required for program planning and monitoring.

4. Mitigating Risk against the Current Malaria Control Gains

History tells us that our current success in malaria control can easily be reversed by failure of our existing tools. Most agree that failure of malaria eradication efforts of the 1960s and 1970s was primarily the result of the development and spread of resistance to chloroquine, the first-line treatment for malaria, and DDT, the primary insecticide used for IRS. Lack of alternative drugs and insecticides and failure to explore approaches to mitigate this resistance resulted in a resurgence of malaria, which ultimately led the international community to abandon its eradication efforts.

PMI and the global malaria community are already faced with the emergence of ACT resistance in the Mekong Subregion and resistance to multiple classes of insecticides in many parts of Africa. Working with our global and country partners, PMI has led global efforts to ensure that all PMI-supported countries routinely monitor the efficacy of current first-line treatment. PMI also has played an important role, working with other partners in efforts to limit the spread of ACT resistance by supporting efforts to reduce and eliminate malaria transmission along the Thai-Cambodian border and other areas of the Mekong where resistance has been identified. Furthermore, PMI is supporting the rapid revision of treatment policies in areas where current first-line treatments are failing. With the recent identification of molecular markers for artemisinin resistance, PMI is already evaluating appropriate uses of this new tool to supplement our existing strategies for monitoring the development and spread of resistance.

The effectiveness of existing vector control interventions, including ITNs and IRS, will depend heavily on whether strategies can be developed to mitigate the spread and intensification of insecticide resistance. PMI already supports countries to monitor insecticide resistance and to use this information to guide the selection and deployment of insecticides. With PMI's support, several countries have used data from entomologic monitoring, which has demonstrated resistance to pyrethroid insecticides and switched to new long-lasting organophosphates for IRS. This approach will not only improve the effectiveness of IRS, but also may limit or possibly reverse the intensification of pyrethroid resistance, which will ensure the continued effectiveness of ITNs.

During the next six years, PMI will continue to support such efforts to monitor and address both drug and insecticide resistance. In addition, identifying, testing, and

implementing new methods to reduce the spread and impact of drug and insecticide resistance must continue to be a priority if we hope to sustain and build upon the successes of PMI.

PMI also has been a global leader in its efforts to assist countries to identify and eliminate poor quality and counterfeit malaria drugs from within their borders. Through PMI requirements that all malaria treatments procured with PMI support pass pre-shipment quality testing, combined with PMI's efforts to monitor the quality of treatments available at service points in both the public and private sector, PMI has had success in removing sub-standard drugs from the marketplace.

In addition, as countries successfully reduce malaria burden they often face a new challenge: waning community participation in malaria control. As the population perceives malaria risk to be declining, they may become increasingly reluctant to use ITNs or may delay seeking care for fever. In some countries, such fatigue has contributed to a resurgence of malaria. Increased emphasis on strategies to maintain appropriate behaviors and raising awareness of the value to the community of eliminating malaria must become priorities.

5. Building Capacity and Health Systems

PMI's experience, to date, has demonstrated that malaria control activities have been most successful when the countries take ownership and lead these efforts. This is only fully possible when country programs possess appropriately-skilled human resources and the necessary infrastructure to plan, implement, and monitor progress of their malaria control activities.

A guiding principle of PMI, from its outset, has been to build capacity to enable countries to implement their own programs rather than building parallel or stand-alone systems. A significant portion of PMI's support to countries is focused on building human capacity, including engaging communities to participate in malaria control, and addressing gaps in country health systems in the key areas of supply chain management, training and supervision of health workers, and monitoring and disease surveillance systems. PMI has provided the necessary resources and technical assistance to strengthen drug management

systems, and for the training and deployment of tens of thousands of community health workers who diagnose and treat malaria, pneumonia, and diarrhea in sick children. In addition, PMI has built skills and provided essential information technology infrastructure for disease surveillance systems, established capacity to conduct entomologic monitoring in almost all countries, and enhanced diagnostic capacity in laboratories to improve case identification, reporting, and tracking.

Increasingly, PMI is exploring how to engage the private sector in malaria control activities. In addition to existing partnerships with major corporate partners, like ExxonMobil and Ashanti Gold, and non-governmental and faith-based organizations, PMI is now working with countries to pilot interventions to improve fever case management at drug shops in targeted countries. These retail outlets are the primary source of malaria treatment in some PMI-supported countries (most notably DRC, Nigeria, and Uganda).¹³ If malaria case management targets are to be achieved, these providers must improve their practices, including adopting the practice of routine diagnostic testing of all suspected malaria cases prior to dispensing treatment.

In the coming years, PMI will continue to work with partner country counterparts to institutionalize and strengthen technical and operational capacity in national malaria control programs and MOHs, as well as key local non-governmental organizations, faith-based organizations, civil society, and academic partners. As partner country malaria programs mature and bring the epidemic under control, PMI will tailor its approach with countries accordingly, taking into consideration the countries' overall economic and health system development. This may entail working with countries to phase out direct program implementation support, while maintaining long-term technical assistance and research partnerships. Governments also may be funded directly (in accordance with USAID policy and other criteria) for specific implementation activities. PMI will use strategic advocacy and diplomatic efforts – from the community to global level – to encourage sustained, long-term country political and financial commitment to malaria control efforts and eliminate bottlenecks to successful implementation.

13. ACTwatch Group, 2013. ACTwatch Baseline and Endline Household Survey Results 2009-2012: Benin, Democratic Republic of Congo, Madagascar, Nigeria, Uganda, Zambia. Washington, DC: Population Services International. Available at: www.actwatch.info



Maggie Halahan

V. Critical Assumptions for Achieving Strategy Goal and Objectives

The goal and objectives set forth in this strategy can only be achieved if sufficient resources are made available to support countries to implement their programs. Consistent with the funding assumptions from the previous 2009–2014 Strategy, if less than full funding of \$5 billion over this six-year period is appropriated, then the expected reductions in malaria burden, including in children, will be reduced. The total numbers of countries of focus and population targeted will be calibrated to the funding allocation to PMI.

The strategy also depends on development of new tools, which could include more sensitive diagnostic tests, novel classes of malaria treatments, vaccines, and new vector control tools. New approaches for delivering these tools – which may include strategies such as mass drug administration, insecticide rotation to mitigate insecticide resistance, and the use of new information technologies to improve information management and to promote appropriate behaviors of providers and affected populations – also will be required.

In addition, the impact of malaria control interventions can be greatly limited if countries suffer from civil unrest, humanitarian or refugee crises, or large-scale public health emergencies (e.g., outbreak of Ebola). In many malaria endemic regions, marginalized populations, such as mobile and migrant workers and ethnic minorities, suffer disproportionately from the burdens of malaria. In contrast, resolution of civil unrest can lead to an acceleration of malaria control activities, resulting in a measurable reduction of malaria burden.



VI. PMI Core Operating Principles

The President's Malaria Initiative Strategy for 2015–2020 is guided by many of the same principles that were established when PMI was launched. These operating principles have played a key role in PMI's success to date and remain valid today. The following principles underpin the approach and success of the strategy:

1. Work within national malaria control strategies and plans and strengthen the capacity of national institutions, host country systems, and professionals to address the challenges of malaria control, building country ownership and sustainability.
2. Promote an integrated and sustainable approach to malaria prevention and control, emphasizing the combined use of proven control measures, coupled with behavior change interventions and system strengthening activities based on appropriate analysis of which mix of interventions provide best value for money.
3. Maintain sufficient flexibility and remain responsive to the ever-changing nature of malaria, tailoring efforts to the local epidemiologic setting.
4. Prioritize high-risk populations – particularly children less than five years of age, pregnant women, and marginalized or mobile/migrant populations – while scaling up key interventions to universal coverage, when appropriate.
5. Adopt and scale up new tools and strategies that have demonstrated effectiveness, have been recommended by WHO, and have been endorsed by the host country government.
6. Ensure that all commodities provided to countries are of high quality and that systems are in place to continually improve the quality of services delivered.

7. Support coordination at global level of key partners – including multilateral and bilateral institutions, affected countries, non-governmental organizations and faith-based organizations, private sector partners, and academia and research institutions – through the RBM Partnership and other working groups and task forces to share lessons learned and best practices and ensure that investments are complementary.
8. Within the parameters of PMI's bilateral country assistance approach, support countries to promote coordinated malaria efforts among neighboring countries and collaborate with established regional initiatives.
9. Whenever feasible and technically indicated, increase the level of integration of malaria activities with maternal and child health, HIV and AIDS, tuberculosis, neglected tropical diseases activities, and the U.S. Government Global Health Security activities.
10. Engage with stakeholders in other sectors – including education, agriculture, and commerce – to enhance our ability to achieve malaria control and elimination objectives.
11. Expand and leverage public-private partnerships to increase support for malaria control.
12. Conduct operational research that helps overcome implementation bottlenecks, tests promising new tools and approaches, contributes to the scale-up of malaria control activities, identifies local solutions to implementation challenges, and identifies the most cost-effective mix of proven interventions under different malaria transmission settings.



VII. Coordinating U.S. Government Malaria Research Efforts

For many years, the U.S. Government has played a leading role in conducting and supporting research to develop and test malaria control interventions, including IRS, ITNs, IPTp, and ACTs, as well as research and development of new tools, such as malaria vaccines and new antimalarial drugs. More recently, the U.S. Government has provided support for development of new insecticides and vector control tools. During the next six years, it will be critical to maintain that strategic leadership role in both basic and applied research.

Per the 2008 Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act, the U.S. Global Malaria Coordinator has primary responsibility for the oversight and coordination of all resources and international activities of the U.S. Government related to efforts to combat malaria. PMI's specific role will be to support operational and implementation research to improve the scale-up and quality of its control activities and support introduction of new malaria control tools. The U.S. Global Malaria Coordinator will ensure that operations and implementation research supported by PMI will closely complement the clinical and program research being undertaken across U.S. Government agencies. Consistent with the Act, CDC will continue to advise the Malaria Coordinator on operational research priorities and be a key implementer of that research.

It is expected that existing National Institutes of Health, CDC, and Department of Defense programs will continue to develop and test new malaria prevention and control tools, as well as train qualified epidemiologists, entomologists, and malaria researchers under those agencies' intra- and extramural research and training programs. USAID will continue its longstanding support for malaria vaccine research and development and for antimalarial drug discovery and development.

With the changing epidemiology of malaria, questions will continue to arise about the use and cost-effectiveness of malaria control measures both individually and in combination, the best mix of interventions in different epidemiologic settings, and how long interventions should be continued as countries approach pre-elimination status. Information from operational research will also help ensure the most efficient allocation of malaria control resources as the epidemiology of the disease changes.

The primary focus of PMI-supported operational research will remain on resolving problems and improving implementation of malaria prevention, treatment, and monitoring and evaluation activities. As new or improved malaria interventions are developed, operational research will be required to see how they can best be incorporated into ongoing malaria control programs. Understanding how well and under what conditions these tools work will be critical to guiding cost-effective and technically sound programmatic decisions. Additionally, PMI-supported operational research activities will provide excellent opportunities for mentoring and building capacity among national public health workers and scientists.



VIII. PMI Governance and Management

The Office of the U.S. Global Malaria Coordinator, which oversees PMI, was established within USAID by the 2008 Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act and remains permanent law. This Office will continue to oversee and coordinate the provision of U.S. Government malaria control assistance, working with relevant executive branch agencies, including the Department of State, the Department of Health and Human Services, and the Department of Defense; as well as multilateral institutions, including the World Health Organization, the United Nations Children's Fund, the Global Fund, U.K. Department for International Development, the World Bank, and the Roll Back Malaria Partnership. Within each PMI-supported country, the USAID Mission Director is responsible for oversight and leadership of PMI activities. An interagency PMI country team composed of U.S.-based and in-country USAID and CDC staff work with the NMCPs and other partners to develop detailed annual implementation plans (Malaria Operational Plans) that describe planned activities, expected results, and budgets, based on the country's NMCP, an analysis of gaps in funding, and lessons learned from previous years' activities.

PMI places a premium on tracking how U.S. Government malaria resources are used; transparency in the way priorities are set and decisions are made; and achieving and documenting results. The PMI management approach stresses:

- Early obligation of congressionally-appropriated funds so that nearly 100 percent of funds are obligated within the same fiscal year
- Close management of financial pipelines and routine tracking and review of all activities
- Minimizing lead times for procurement of critical commodities and services
- Flexibility in working with other donors to fill gaps in core malaria commodities and services

- Maintaining a central emergency procurement fund including a small buffer stock of ACTs to help prevent stock-outs of essential commodities at the country level
- Documenting that procured commodities are reaching beneficiaries
- Ongoing tracking of progress toward PMI goals and objectives

Transparency and accountability are high priorities for PMI. All annual country Malaria Operational Plans, the President's Malaria Initiative Strategy, and malaria programmatic and technical guidance documents are posted on www.pmi.gov, once they have been approved by the U.S. Global Malaria Coordinator. In addition, all large contracts, cooperative agreements, and grants related to PMI-supported malaria activities, together with regular activity reports from implementing partners, are posted on the website. Furthermore, PMI reports annually to Congress on its progress and impact to date.



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