

**PRESIDENT'S MALARIA INITIATIVE
MONITORING AND EVALUATION STRATEGY 2005-2010**

PMI M&E Team

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BACKGROUND

The President’s Malaria Initiative (PMI) represents a five-year expansion of U.S. Government (USG) resources to fight malaria in 15 of the highest-burden countries in sub-Saharan Africa. The Initiative commits an additional \$1.2 billion in malaria funding for the 15 PMI focus countries and sets two ambitious goals for those countries:

- reduce the estimated number of deaths in children under five years of age caused by malaria by 50%; and
- reach 85% of those most vulnerable to malaria – children under five years of age and pregnant women – with a package of four proven and highly effective prevention and treatment measures:
 - prompt effective treatment with artemisinin-based combination therapies (ACTs);
 - indoor residual spraying (IRS);
 - the use of insecticide-treated mosquito nets (ITNs); and
 - intermittent preventive treatment for pregnant women (IPTp).

The PMI focus countries were selected based on the following criteria:

- a significant burden of malaria;
- national policies and practices for the prevention and treatment of malaria consistent with those recommended by the World Health Organization (WHO), and in-country capacity to implement those policies;
- demonstrated political will by national leadership for control of malaria – and willingness on the part of the country leadership to partner with the USG;
- USG on-the-ground capacity;
- potential for impact;
- Global Fund for AIDS, Tuberculosis, and Malaria (GFATM) grant for malaria, and grant performance; and
- other donor involvement.

The 15 focus countries and the year they joined the PMI are shown in the table below:

Year 1 (FY2006)	Year 2 (FY2007)	Year 3 (FY2008)
Angola	Malawi	Benin
Tanzania	Mozambique	Ethiopia (Oromia Region only)
Uganda	Rwanda	Ghana
	Senegal	Kenya
		Liberia
		Madagascar
		Mali
		Zambia

This document is written to provide an overview of PMI’s monitoring and evaluation strategy. The intended audiences for this document include key USG decision makers, USG PMI team, in-country PMI advisors, PMI partners and NMCPs.

GENERAL PRINCIPLES

The PMI is a member of the global Roll Back Malaria Partnership (RBM) and, as such, supports efforts to standardize approaches to monitoring and evaluation (M&E) of malaria prevention and treatment measures across National Malaria Control Programs (NMCPs) and other major partners, including the Global Fund, the World Bank, WHO, and UNICEF. The Monitoring and Evaluation Reference Group (MERG) is the RBM working group that has responsibility for providing guidance and standardizing approaches around the monitoring and evaluation of malaria prevention and treatment interventions at the global level. PMI M&E Team members attend the biannual MERG meetings and participate in several MERG taskforces where most of the discussions and decision making around specific M&E issues occurs.

The PMI M&E Team supports the PMI goal of reducing malaria by 50% and reaching 85% coverage of those most vulnerable to malaria by 2011 by providing the information necessary to monitor and evaluate USG investments in malaria prevention and control in each of the 15 focus countries. In designing and carrying out its M&E activities, the PMI M&E Team adheres to globally accepted standards and the following general M&E principles in each of the 15 focus countries:

- Work closely with the NMCP and within existing NMCP strategies and plans, in line with the principle of “The Three Ones” – one national malaria control coordinating body, one national malaria control strategy, and one national M&E plan;
- Work with the Ministry of Health (MOH) to ensure that the NMCP M&E plan is coordinated with the overall MOH M&E plan;
- Strengthen capacity of the NMCP and other national institutions and staff to address the challenges related to M&E of malaria control efforts;
- Coordinate closely with the NMCP and other national and international partners, and others including nongovernmental organizations and the private sector, to ensure that the national malaria M&E plan is adequately funded and that investments are complementary;
- Support M&E related to all national malaria prevention and control measures and efforts, not just those attributable to PMI funding, to help NMCPs meet requirements and needs of other donors and partners; and
- Coordinate PMI-supported M&E activities with those of other USG programs and initiatives, such as the President’s Emergency Program for AIDS Relief (PEPFAR), whenever possible.

The PMI M&E team will work with following key partners.

1. NMCP – for developing M&E strategies and work plans, monitoring control program efforts, assessing overall impact of PMI
2. Global Fund– for funding malaria control activities, ensuring that NMCPs have costed M&E plans, and conducting data quality assessments
3. RBM/MERG – for harmonizing M&E strategies, sharing best practices, identification of new approaches and methodologies for monitoring and evaluating malaria control.

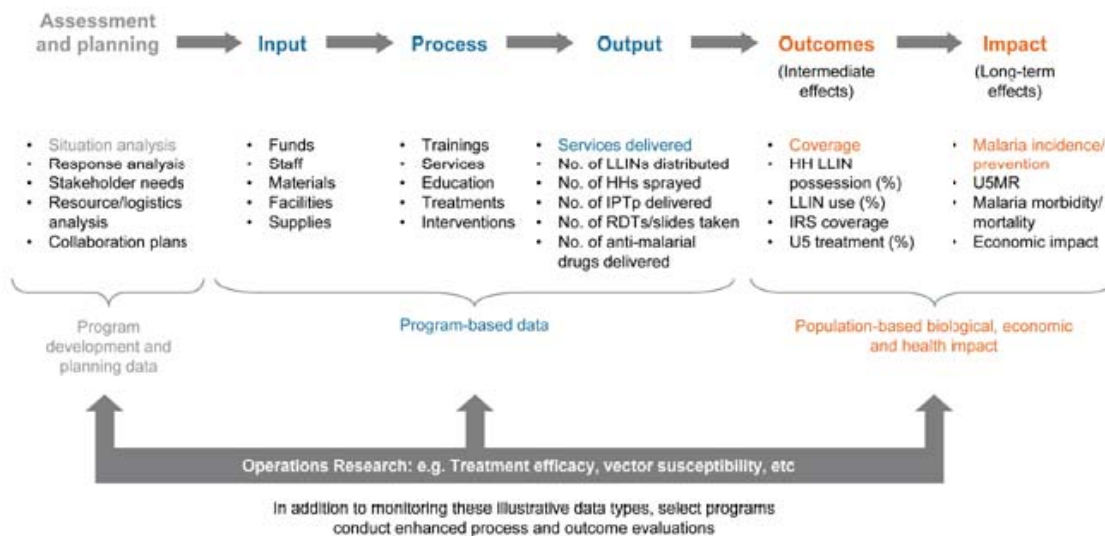
4. WHO – as a partner in MERG-led activities developing national routine health information system-based M&E strategies, capacity building at the district and health facility level for M&E, and use of data for decision making
5. USG contractors and academic partners – for carrying out USG PMI visions and plans
6. Other USG programs, such as PEPFAR – for coordinated USG M&E investment and priorities

MONITORING AND EVALUATION FRAMEWORK

Monitoring and evaluation (M&E) is needed to measure the progress and effectiveness of health programs at all levels. **Monitoring** is an on-going or continuous process used to track, understand, and correct activities as they are being implemented. The results of monitoring are used to adjust work plans to improve effectiveness and efficiency, and the information is usually obtained through routine systems, progress reports or rapid assessments. **Evaluation** is a periodic activity used to assess whether or not a program or activity has reached its intended goal and resulted in the desired outcome and impact. Outcome evaluation aims to assess whether the stated goals in terms of intervention coverage have been met, whereas impact evaluation attempts to attribute changes in population level indicators of health impact to a specific project or intervention. PMI will conduct both outcome and impact evaluations. However, PMI will not attempt to parse out the proportion of change due to PMI-specific funding or interventions. Rather, as per MERG recommendations, PMI will help evaluate the impact of entire country programs, which might include support from multiple donors.

The figure below outlines this M&E framework for disease control, and the different levels of data needed by program managers to assess program performance and to make mid-course corrections, if necessary, to reach intended goals. Importantly, M&E for malaria requires both a stable system that can be utilized to track malaria control programs over time, and a flexible system that can be adjusted as new needs arise (e.g. monitoring for sustained control and elimination).

Figure 1: Malaria Monitoring and Evaluation Framework



Source: *Global Malaria Action Plan, Roll Back Malaria Partnership*

As with other public health programs, malaria control programs may be thought of as consisting of a set of components. Throughout this document, the discussion of M&E indicators is organized around the components of the commonly used input-process-output-outcome-impact framework, depicted in the figure above. For a program to achieve its goals, **inputs** such as funding and staff time must result in **outputs** such as new and improved services, trained staff, and access to services. These outputs are the result of specific **processes**, such as training of staff, which should be included as key activities aimed at achieving the outputs. If these outputs are well designed and reach the populations for which they were intended, the program is likely to have positive short-term effects or **outcomes**, such as increased use of ITNs or more frequent treatment with ACTs. These positive short-term outcomes should lead to changes in longer-term **impact** of programs, measured in terms of fewer cases of malaria and a reduction in malaria-related deaths.

General Overview of the PMI Monitoring & Evaluation Plan

PMI countries represent a wide range of epidemiologic profiles in terms of the levels and patterns of malaria transmission, prevalence of infection and illness, under-five mortality rate, and NMCP capacity and resources. As malaria prevention and treatment measures are scaled up, changes in the local epidemiology of the disease can be expected and are already being seen in several countries. PMI intervention strategies have always been tailored to the local situation; with the changing epidemiologic picture in several of the focus countries, PMI M&E strategies must also be similarly adjusted. As malaria transmission is reduced, the ability for health facilities to report cases of malaria as they are diagnosed and for the NMCP to rapidly respond to outbreaks becomes critical. This strategy has been successfully demonstrated in Zanzibar. PMI

teams should ensure that real-time surveillance is included in the national M&E plan as appropriate.

The goal of PMI is to achieve a 50% reduction in malaria-related mortality in the 15 focus countries. To achieve this goal, PMI supports the scale up of interventions that have been proven to be highly effective – ITNs, IRS, and IPTp to prevent malaria infections, and ACTs to treat malaria infections – to 85% coverage of pregnant women and children under five.

Program monitoring

The routine monitoring of PMI-supported activities related to the four main intervention areas - ITNs, IRS, IPTp, and case management with ACTs – will be carried out primarily by PMI implementing partners as a part of their responsibilities in a grant, cooperative agreement, or contract. This routine monitoring will include the various functions at the input, process, and output levels. The information collected for program monitoring will come from various routine sources, including the health management information system (HMIS) data, sentinel surveillance, and quarterly reports prepared by implementing partners. This information will be shared with the PMI teams on a quarterly basis to allow timely review of progress and fine-tuning of program activities.

Outcome Evaluation

The primary focus of outcome evaluation is to assess whether PMI has met its stated goals in terms of scale up and coverage of its key interventions. Assessment of coverage of program interventions will be carried out primarily through regularly scheduled, nationally-representative household surveys, such as the Demographic and Health Surveys (DHS) and the Multi-indicator Cluster Surveys (MICS). A description of the various household survey programs is included in Appendix A. Additional information to evaluate PMI programs may come from the analysis of data from pre-existing demographic surveillance sites, sentinel surveillance sites, and other in-country NMCP-led M&E activities. Data collection and reporting will be designed to support and complement national M&E plans and efforts.

Impact Evaluation

Since valid, nationally representative data sources on malaria morbidity and mortality are not available, PMI will follow the MERG recommendations to examine trends in all-cause <5 mortality. Using other data such as trends in intervention coverage, anemia, parasitemia, and confounders such as rainfall, a plausibility argument will be constructed. To further strengthen the plausibility argument, other reasonably valid data sources such as sentinel sites, demographic surveillance sites, and verbal autopsy studies will also be used. As with the outcome assessment, a key source of data for the impact evaluation will be national household surveys which measure all-cause <5 mortality rates, and can be used to determine prevalence of parasitemia and anemia as well. In general, PMI will not attempt to attribute changes in morbidity and mortality to its specific interventions, but will instead measure the national-level improvements that result from a variety of interventions and financing mechanisms.

Capacity Building

As an integral part of its M&E efforts, the PMI will support capacity building related to M&E within NMCPs. In most countries, the first step in this process will be through a workshop to complete the Monitoring and Evaluation System Strengthening Tool (MESST), a checklist developed by the Global Fund and Roll Back Malaria partners to assess the content and quality of the existing national malaria M&E plan. Completion of the MESST was a requirement for disbursement of funds in Round 6 and later rounds of the Global Fund. However, since several countries did not have written M&E plans when their MESST workshop was held, PMI will begin by working with the NMCP and other partners to develop a written national M&E strategy and costed plan. Once that is done, PMI should coordinate with the NMCP and partners to reach agreement on what parts of the plan they will support during each year of the Initiative.

PROGRAM MONITORING

Program monitoring is an essential function of any public health intervention. The data collected for routine program monitoring are used for program maintenance – to ensure that supplies are ordered, commodities are in stock, and personnel have the appropriate training. The data are also used as an ‘early warning system’ for potential problems in the program so that the program managers can make the necessary adjustments in a timely fashion.

The types of activities that are routinely monitored are **inputs**, **processes** and **outputs**, such as the procurement, distribution, availability, and use of commodities for the prevention, diagnosis, and treatment of malaria; training of health-care workers; and health education efforts. The table below provides illustrative, but not exhaustive examples of the types of activities and indicators that should be followed through routine monitoring.

Table 1: Monitoring Framework for Key PMI Interventions

Intervention	Input	Process	Output	Outcome
Frequency of data collection	Routine monitoring on a monthly or quarterly basis			Every 2-3 years
ITN/LLIN	Procurement of nets	BCC activities Training for distribution teams	No. of nets distributed	HH net ownership (%) Net use by target populations (%)
Diagnosis and Treatment	Procurement of ACTs Procurement of RDTs Procurement of microscopes and other supplies	Training for providers Training for lab techs Development of data forms and procedures	No. of RDTs/slides examined No. treatments of anti-malarials given	% of <5s with fever tested/treated for malaria with an ACT
IPTp	Procurement of SP	Training of providers Distribution of SP to facilities Sensitization of population	No. of clients seen for IPTp	% of pregnant women receiving IPT in last pregnancy
IRS	Insecticides purchased Equipment purchased Staff hired	Training of spray teams Sensitization in the community	No. households in target areas sprayed	% households targeted that were sprayed

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Data Collection

Monitoring of PMI-supported activities will be carried out by PMI implementing partners as a part of their routine responsibilities in a grant, cooperative agreement, or contract. The frequency of the data collection will be determined by the type of activity and should be spelled out in the implementation plan submitted by the partner. In most cases the data will be collected and reported to PMI on a quarterly basis, though some indicators may only need to be tracked annually. In some PMI countries this information is collected directly by USAID Mission staff from their implementing partners for their regular portfolio reviews. In other countries (e.g., the Uganda Monitoring and Evaluation Management Services, MEMS, Project), the Mission has contracted a group that then takes responsibility for gathering the information from each implementing partner and synthesizing that information into one comprehensive report.

Monitoring of PMI will focus on program outputs reported by NMCPs, local governments, and other implementing partners carrying out specific activities with quality control by the PMI in-country teams. Specific PMI-funded activities are monitored on a regular basis to allow in-country program managers to track progress, make adjustments, and redirect resources as needed. Activities within the four main intervention areas – ITNs, IRS, IPTp, and case management with ACTs – will be tracked through reports from implementers and international and local partners. All PMI country teams will report on a set of similar output indicators with data from multiple sources, depending on which group is responsible for implementation of that activity. The types of activities that are monitored include procurement, distribution, availability and use of commodities for the prevention, diagnosis, and treatment of malaria; training of health-care workers; and health education efforts.

It should be noted that all partners receiving funds from PMI are required to provide access to data that are collected as a part of their scope of work, and are responsible for reporting appropriate information to the NMCP as well as to the USG PMI team.

Data sources

There are a number of sources of data for routine program monitoring. At the health facility level, documentation of commodities and supplies should be maintained in the logistics system, and routine tracking of numbers of patients and drugs prescribed should be available through the HMIS (though national systems may need to be enhanced to collect some pieces of information) and sentinel sites system. Other programmatic activities, such as trainings, community education sessions, will be documented in project reports and other records held by the implementing partner.

The critical point in program monitoring is that each PMI country team should have a documented monitoring plan that details which indicators will be collected by which partners as well as the data sources and timeframe for reporting.

Coverage with Malaria Control Interventions

Evaluation of outcomes will be based on indicators that correspond to the coverage targets for specific interventions.

Eight specific PMI targets focus on achieving high coverage with the four malaria control interventions. Nationally-representative, household surveys, such as the DHS or MICS, are not conducted on an annual basis in every country, and many PMI countries did not have a survey within one year of the start of activities in that country. Consequently, PMI will use methodologically rigorous national surveys conducted the closest in time to the start of the program in each country, and follow serial national household survey data during PMI implementation.

By the end of FY 2010, PMI will assist each country to achieve the following targets in populations at risk of malaria:

ITN

1. Greater than 90% of households with a pregnant woman and/or children under five will own at least one ITN;
2. 85% of children under five will have slept under an ITN the previous night;
3. 85% of pregnant women will have slept under an ITN the previous night (Note: the sample size in MIS and MICS surveys is not large enough to measure this with any degree of accuracy);

IRS

4. 85% of houses in geographic areas targeted for IRS will have been sprayed;
5. 85% of pregnant women and children under five will have slept under an ITN the previous night or in a house that has been sprayed with IRS in the last six months;

IPTp and ACT

6. 85% of women who have completed a pregnancy in the last two years will have received two or more doses of IPTp during that pregnancy;
7. 85% of government health facilities have ACTs available for treatment of uncomplicated malaria; and
8. 85% of children under five with suspected malaria will have received treatment with an ACT within 24 hours of onset of their symptoms.

Seven of these eight PMI targets correspond to outcome indicators of coverage with malaria control interventions. Three of these indicators (numbers 5, 7, and 8 above) have been added in addition to the standard MERG indicators recommended by the Roll Back Malaria Partnership to allow PMI to account for progress toward its specific goals. All of these indicators, as well as the Roll Back Malaria indicators, can be obtained from the standard MICS, DHS or MIS surveys. As with the evaluation of impact on malaria mortality, PMI will make use of serial national household survey data from three to four years leading up to the initiation of PMI activities in each of the 15 focus countries, together with follow-up surveys every two to three years in all countries up to 2011-2012 and then into the second phase of the USG Malaria Program from

2010-2014, to assess progress towards the PMI outcome indicators. Since large-scale household surveys such as the DHS and MIS collect additional information on the major malaria prevention and control measures beyond what is required to calculate the above eight indicators, PMI may conduct analyses of this additional information to assist in the interpretation of outcomes and impact.

MEASURING IMPACT

PMI defines impact in two ways: reductions in parasitemia and anemia in the <5 population; and reductions in both all-cause and malaria-specific mortality in the same <5 population. It is important to measure both morbidity and mortality because: (1) Reductions in malaria morbidity (illness) reflect reduced transmission in the population as a whole as a result of scaled up prevention mechanisms such as bednets and IRS; and (2) Reductions in mortality may also be the result of reduced transmission in the population, but could also reflect improvements in access to treatment and the quality of case management. PMI's target is to reduce malaria-specific deaths in children under 5 by 50% at the end of the 5-year Initiative.

PMI's approach to impact evaluation is based on the recommendations of the Roll Back Malaria Monitoring and Evaluation Reference Group (MERG) and is the result of a consultative process with a wide range of stakeholders in the Initiative.

Morbidity

Routine tracking of cases of malaria is critical to the day-to-day management of the national control program. In each of the focus countries, the PMI teams will work with the NMCP and other stakeholders to strengthen HMIS systems to track both inpatient and outpatient malaria cases in all relevant health care sites¹. However, most HMIS systems allocate only a minimal set of indicators to any given disease area, so PMI focus countries will need to work with the NMCP to establish malaria-specific sentinel sites to capture the necessary morbidity information on a timely basis. These sentinel sites will track both inpatient and outpatient cases of malaria, including whether the case was confirmed by microscopy or RDT, and the treatment given to each case. The number and location of the sentinel sites will be determined jointly by the NMCP and the PMI in-country team. The goal of the sentinel site system is not national-level prevalence monitoring, but rather a selection of sites that can monitor the trends in malaria burden in high burden zones, or in areas of specific PMI intervention. The specifics of site selection and data collection for the PMI sentinel systems are described elsewhere (see Annex).

One of the interventions supported by PMI is improvements in the diagnostic capacity of the health care sites. To that end, PMI will track both unconfirmed malaria cases at sentinel sites, as well as confirmed cases and will including information on whether confirmation was done by RDT, microscopy, or both.

In addition to the data collected in a routine fashion through the HMIS and the sentinel site system, PMI will also support the periodic tracking of parasitemia and anemia through national household surveys. Ideally these surveys would be conducted at the start of PMI implementation in a country, at a midpoint in the process (2-3 years), and at the project endpoint. Realistically, not every country has been, or will be able, to time the surveys so precisely, so the general recommendation is that a survey with biomarkers be conducted every 2-3 years. These data can

¹ The definition of 'relevant health care site' could include primary, secondary, and tertiary health care facilities, or facilities run by NGOs or the private sector, if they are included in the national strategy.

then be used to track trends in parasitemia and anemia at the national level over the duration of the project.

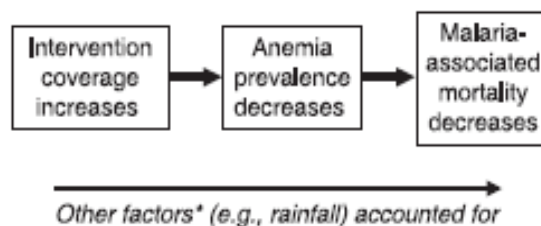
Mortality

Malaria-related mortality is very difficult to measure with any degree of validity. In sub-Saharan Africa, malaria is thought to be responsible for a large percentage of mortality in children under five. However, most deaths occur outside the health system, the deaths are infrequently registered, and specific cause of death is not assigned. Even within the health system, it is often difficult to know whether malaria was a primary cause of death given the constellation of health problems facing young children, and the lack of diagnostic capacity in many countries. Due to these issues, PMI will use a multi-pronged approach (see plausibility argument) to measure change in malaria-specific mortality in its focal countries.

Plausibility Argument

The RBM MERG recommendation for evaluating the impact of malaria control efforts on mortality is to follow trends in the coverage of malaria control interventions, all factors influencing childhood mortality, malaria-associated morbidity such as anemia and parasitemia, and all-cause childhood mortality. With this information, a plausibility argument can be constructed. A plausibility argument is an assumption that mortality reductions can be attributed to programmatic efforts if there are improvements in coverage and morbidity indicators between intervention scale-up and mortality trends. As reductions in mortality and anemia get larger and increases in malaria intervention coverage get larger, the conclusion that malaria control activities reduced malaria-associated mortality becomes more plausible. To strengthen the plausibility argument, other valid data sources can be added such as trends in indicators of malaria transmission, information from demographic surveillance systems and sentinel sites, and verbal autopsies linked to household surveys.

Over a clearly defined time interval....



Conclusion (via a plausibility argument): If intervention coverage increases, anemia prevalence decreases, and malaria-associated mortality decreases, then conclude malaria control efforts reduced malaria-associated mortality.

All-cause <5 mortality

The mortality burden of malaria in sub-Saharan Africa is concentrated among children under five years of age and a large percentage of the <5 deaths are estimated to be due to malaria. In addition, censuses and national household surveys, such as MICS and DHS, provide robust estimates of mortality that can be used to track survival in populations without strong vital registration systems. For these reasons, it continues to be important for NMCPs to track all-cause <5 mortality at periodic intervals as a means of gauging program effect on overall child survival. The estimates provided by these surveys are not point estimates, but rather reflect a period of 3-5 years prior to the survey so the data might not match directly with project intervention dates. However, MICS and DHS both happen at regularly scheduled intervals and provide an important component of the mortality picture that needs to be included in the overall M&E plan.

Surveys with verbal autopsy

Because of the difficulty of measuring malaria-specific mortality, PMI is supporting initiatives to add a verbal autopsy component to household surveys in selected countries. The process involves identifying families who have recently lost a child under five, and conducting interviews with the parents to ask about symptoms and duration of the illness that preceded the death. This information is then analyzed by medical experts to classify the death according to standard International Classification of Disease (ICD) codes. The results are used to estimate the number of malaria-specific deaths in children under 5 in the country in which the survey was conducted. The USAID-funded MEASURE DHS and MEASURE Evaluation projects have developed protocols for the verbal autopsies and data analysis and are in the process of using these tools in selected PMI countries. However, there are important statistical caveats to the verbal autopsy procedures and the robustness of this source of data for monitoring impact of PMI interventions has not yet been ascertained. Nevertheless, for those countries which did conduct a verbal autopsy component with a DHS survey, the results will provide complementary data to use in conjunction with statistics on all-cause child mortality to interpret impact.

Demographic and Surveillance Sites

Additional information on malaria-related mortality may come from DSS or from sentinel sites supported by PMI. In the case of DSS, mortality data are collected through periodic censuses of the population in the chosen demographic site followed by verbal autopsies to attempt to assign a probable cause of death (similar to the VA procedure with surveys discussed above). In sentinel sites, information will be abstracted from the health facility records and case registers. While data from these sites may be useful to follow trends over time at that site, it should be recognized that these sites were not necessarily selected to be representative of the country, or even the subnational level, and the results should not be generalized.

Modeling deaths averted

To complement information on all-cause and malaria-related mortality from nationally-representative household surveys, PMI will support efforts to model the effects of various malaria and child-survival interventions on malaria-related mortality. The SPECTRUM model, the current standard tool for modeling deaths averted, is based on earlier work on the effectiveness of interventions by WHO's Child Health Epidemiology Reference Group (CHERG) and RBM's Monitoring and Evaluation Reference Group (MERG). The model predicts the number of lives saved due to different interventions, making assumptions about the cause of death profile in a country and level of under-five mortality and current coverage of child health interventions. The model also builds in assumptions about the effectiveness of the different interventions in reducing cause-specific mortality.

The SPECTRUM model will be used to predict the impact of increased coverage with key malaria interventions, as well as the overall impact of increased interventions on all-cause under-five mortality. Coverage of both malaria-specific and non-malaria interventions will be adjusted based on the most recent data from household surveys. These models will provide predictions of under-five deaths averted as a result of malaria-related interventions.

All the methods mentioned above provide different perspectives on the morbidity and mortality impact attained by PMI programs. Each PMI country team, with assistance of the HQ M&E team, will be responsible for compiling and interpreting the available data for that country and reporting out to PMI senior management. A sample of an impact assessment scheme is provided below:

Example: Morbidity Assessment

- Quarterly: Monitor inpatient and outpatient cases of malaria and treatment, as well as use of diagnostics through specialized sentinel sites.
- Annually: Collect HMIS statistics on cases of malaria and treatment. Examine trends in both surveillance and HMIS data. If the country has DSS sites, data from these sites can also be used to track trends in disease incidence.
- 2-3 years: Use household surveys with biomarkers to track scale up of intervention coverage and national prevalence of parasitemia and anemia.

Example: Mortality Assessment

- Annually: Collect data from HMIS, as well as vital registration and DSS sites (where available) on malaria-specific mortality.
- 2-3 years: Use SPECTRUM model, and most recent coverage figures for key interventions to calculate deaths averted by scaling up programs
- 5 years: Conduct household surveys to estimate all-cause <5 mortality rates. Where appropriate, add verbal autopsy component to estimate malaria-specific of all-cause rates.

REPORTING STRUCTURE FOR PMI

At the country level, project data will be collected quarterly from all implementing partners and reviewed by the PMI country teams for project monitoring purposes. Similarly, the sentinel site HMIS data will also be collected and compiled at a central level each quarter.

On an annual basis, the PMI team will compile all routine data, together with any survey data or data from other non-routine sources (resistance monitoring, special studies, etc.) into an annual report. This report will not only provide a summary of the various data collected during the year, but will also contain an analytic component that examines progress and trends, and points out areas for improvements or enhancements in the coming year. The timeline for the annual reports will be such that the information will be available to inform the development of each year's MOP.

These annual reports from the 15 PMI focus countries should be sent simultaneously to the M&E Coordinators for CDC/Atlanta and USAID/Washington for review and distribution. In addition, PMI senior management may request countries to provide additional data or conduct special analyses to answer country-specific questions that might arise.

In addition to the standard reporting outlined above, any manuscripts, publications, or presentations emanating from those data should be reviewed and cleared by a PMI senior staff member in both agencies prior to submission for publication or presentation.

ANNEX A: MAJOR DATA SOURCES

Information gathered through large-scale, population-based household surveys, such as the Demographic and Health Surveys (DHS) Multiple Indicator Cluster Surveys (MICS) and Malaria Indicator Surveys (MIS) will provide data to evaluate both impact (mortality and morbidity) and outcome (coverage) indicators. These surveys are typically conducted every 2 to 5 years and therefore serve as our long-term approach to evaluate our accomplishments. Each of these surveys is standardized and includes modules which collect all necessary data for the core indicators of intervention coverage. PMI and USAID in-country staff should ensure that questions in the module *are not modified without discussion* with the PMI M&E team, as minor changes in wording or even the order of questions could affect the results of the survey.

Demographic and Health Surveys (DHS): The DHS surveys are nationally-representative, population-based surveys that are routinely undertaken in many countries of sub-Saharan Africa every 4-5 years to collect data on a wide variety of demographic and health indicators. The sample size is driven by all-cause, under-five child mortality and total fertility rates and usually includes at least 6,000 households. These surveys are designed to produce data that are comparable over time and between countries. The DHS survey includes a household register for the ascertainment of the age, sex, and relationship to the head of household for all individuals within the sampled households. The DHS surveys are also typically designed to provide relatively precise population-level estimates by age groups, sex, urban/rural residence, and regions. DHS surveys are a primary source of information on under five all-cause mortality rates, obtained by the direct estimation technique (i.e. from birth histories).

The DHS survey package includes an optional module for malaria that allows the collection of all necessary data for the core indicators of intervention coverage. Interpretation of DHS malaria module data must also take into account the fact that, for logistic reasons, these surveys are typically conducted during the dry season when malaria transmission is lower. Some of the more recent DHS surveys have included measurement of the prevalence of anemia in children under five as an indicator of malaria burden and a proxy for malaria-related mortality. Sample sizes of standard DHS surveys are not sufficiently large to measure anemia in pregnant women. Published reports, questionnaires, and materials related to the DHS surveys can be found online at <http://www.measuredhs.com>.

Multiple Indicator Cluster Surveys (MICS): The MICS surveys are nationally-representative, population-based surveys developed by the United Nations Children's Fund (UNICEF) and its partners. As with the DHS, the sample size of about 6,000 households is driven by all-cause under-five child mortality. Initially designed to collect indicators related to progress toward the World Summit of Children goals, the MICS surveys have continued to be an important component of national data collection in many countries. The MICS surveys are conducted approximately every three years in about 70 countries worldwide. As with the DHS surveys, MICS surveys are designed to produce data that are comparable over time and among countries. They include a household register for the ascertainment of the age, sex, and the relationship to the head of household for all individuals within selected households. The MICS surveys also include a specific malaria module with questions regarding coverage of antimalarial treatment among febrile children and ITN use among all children. A separate section collects information

on antimalarial use in pregnancy; however, MICS surveys do not typically obtain current pregnancy status, so the indicator on ITN use during pregnancy cannot be calculated. As with the DHS, most MICS are conducted outside of the peak malaria season. MICS surveys are not designed to include hemoglobin measurements for anemia prevalence nor malaria parasitemia. Published reports, questionnaires, and materials related to the MICS surveys can be found online at <http://www.childinfo.org>.

Malaria Indicator Surveys (MIS): To supplement standardized data collection from DHS and MICS survey, the Malaria Indicator Survey (MIS) package has been developed for use at the national or sub-national level. The sample size for the MIS (usually about 3,000 households) is driven by national-level malaria prevalence and is smaller than that required for a DHS or MICS, because the primary use of the MIS is to monitor intervention coverage and not child mortality. Consequently, the MIS is less expensive than a DHS or MICS. A MIS can be used in countries where no other malaria surveys are being conducted, or to fill gaps during the intervals between DHS or MICS surveys, for more up-to-date reporting of progress.

The survey includes a core questionnaire and data tabulation plan, as well as related materials for organizing and conducting fieldwork. This stand-alone survey is designed to be implemented in a similar manner to the DHS surveys, producing nationally-representative, population-based data. The MIS survey will also produce a wide range of data for in-depth assessment of the malaria situation within countries. While both DHS and MICS are conducted during the dry season, the MIS can be targeted to the peak malaria transmission season and combined with measurements of hemoglobin and parasite prevalence, in areas where these are considered relevant malaria burden/impact indicators. The MIS survey questionnaire and related materials can be found online at <http://www.rbm.who.int/merg>.

Demographic Surveillance Sites (DSS): Demographic surveillance sites monitor births, deaths, and health in geographically-defined populations continuously over time. They measure mortality due to specific causes, including malaria, using verbal autopsies. Although several of the 15 PMI focus countries have pre-existing DSS sites, most countries have only one or two sites, and thus, their data cannot be considered representative of the entire country. Moreover, most DSS sites serve as study areas for intervention trials and are not pure surveillance sites. Many DSS sites collaborate under the INDEPTH network (International Network of field sites with continuous Demographic Evaluation on Populations and Their Health in developing countries). Further information on the INDEPTH network is available at <http://www.indepth-network.net/>.

Health management and information systems (HMIS): In sub-Saharan Africa, routine health data are often incomplete and reports on malaria cases or deaths are not readily available through routine systems. In most countries, the HMIS functions poorly and the time and resources needed to improve these systems are beyond the scope of PMI. Regardless, the NMCP uses HMIS data to inform programmatic decision making, predict service provision needs, and advocate for malaria control programs. Although PMI does not have resources to address all of the deficiencies of national HMISs, PMI may provide carefully targeted support to HMISs, ensuring that activities will **strengthen** quality of HMIS-based malaria data.

Health Facility-Based Sentinel Sites: Given the limitations of the HMIS and the need to collect additional information on malaria morbidity and mortality that can be used together with the results of nationally-representative household surveys, to better understand the impact of PMI-supported activities, data will be collected on a routine basis from a limited number of health facilities.

Complementary Data: To answer specific questions related to program implementation or in response to specific data needs, such as the PMI Annual Report, PMI may make use of other datasets or fund smaller, stand-alone data collection activities and analyses. Examples of these complementary data are the rapid health facility assessments of trends in malaria morbidity and mortality carried out during 2008 by WHO or Measure Evaluation, surveys of health worker performance, malariometric surveys in urban areas, and knowledge, attitude and practices surveys.

ANNEX B: CRITERIA FOR SENTINEL SITES

Health facilities that receive support from PMI to be part of the sentinel site network should meet the eligibility criteria listed below. Facilities are not expected to become centers of excellence for clinical care or diagnostics but a certain level of care should be met. Facilities may not need to meet all of these criteria when they are selected, but they should be capable of achieving these standards with support from PMI:

- presence of an out-patient pediatric clinic that sees an average of 50 patients/day and an inpatient pediatric ward;
- laboratory capacity to diagnose malaria, preferably through microscopy;
- written guidelines for the diagnosis of malaria;
- provision of ACTs as first-line treatment for uncomplicated malaria; and
- designated personnel responsible for data collection and reporting.

To meet these criteria, selected facilities are very likely to be district hospitals or their equivalent although this will not be an explicit requirement.

Participating health facilities are not expected to be representative of the national set of health facilities or of different types of facilities, nationally. Facilities should be selected to cover the major malaria endemic zones within a country; data from sites in epidemic-prone areas may be difficult to interpret due to fluctuations in malaria incidence from year to year. Many countries may already have a sentinel site surveillance system for malaria or malaria-related activities. Whenever possible, PMI should try to support these existing sites, rather than establishing new sites; however, not all pre-existing surveillance sites will be suitable for facility-based surveillance within PMI.

The number of participating facilities in each country will be dependent on a variety of factors including population density and distribution, catchment area size, malaria transmission, surveillance needs, national program interests and resources available. Between four and eight facilities are probably needed to cover the major endemic zones within a country. It is expected that initially a small number of facilities will be selected; once these sites are functioning well, consideration would be given to expansion. Where sites do not already exist, 4-6 sites should be selected initially.

The following data should be reported by sentinel site facilities to a central level on a monthly basis.

- Number of total outpatients
- Number of unconfirmed outpatient cases of malaria
- Total number of blood slides examined for malaria from outpatients
- Number of slide-confirmed outpatient cases of malaria
- Total number of rapid diagnostic tests (RDTs) examined for malaria from outpatients
- Number of RDT-confirmed outpatient cases of malaria
- Number of total inpatients
- Number of clinical inpatient cases of malaria
- Total number of blood slides examined for malaria from inpatients

- Number of blood smear-confirmed inpatient cases of malaria
- Total number of RDTs examined for malaria from inpatients
- Number of RDT-confirmed inpatient cases of malaria
- Number of anemia cases
- Number of inpatient deaths
- Number of inpatient blood smear-confirmed malaria deaths
- Number of inpatient RDT-confirmed malaria deaths
- Number of antimalarial treatments prescribed by drug
- Number of days out of stock in the last month for each antimalarial drug
- Number of children <5 receiving a blood transfusion

In facilities with an antenatal clinic:

- Number of pregnant women who received IPTp-1 (data related to this and the next indicator may be better captured at ANCs than through household surveys)
- Number of pregnant women who received IPTp-2
- Total number of pregnant women who attended first ANC visit

Importantly, data from sentinel sites will be most useful to compare trends over time within a facility. As such, interpretation of such information may require the collection of at least 1 year's worth of data

ANNEX C: SELECTED REFERENCES

PMI Strategic Plan available at http://www.pmi.gov/resources/reports/strategic_plan.pdf

RBM Goals and Targets available at http://www.rollbackmalaria.org/forumV/docs/gsp_en.pdf;

RBM, 2000, "Framework for Monitoring Progress and Evaluating Outcomes and Impact" available at: http://rbm.who.int/cmc_upload/0/000/012/168/m_e_en.pdf

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