

# PMI TECHNICAL GUIDANCE

## FY 2022



**This document contains technical guidance for PMI teams and can also serve as a resource for implementing partners. It is updated at least annually to reflect the most recent global policies and the state-of-the-art of malaria control.**

**PMI** | U.S. PRESIDENT'S  
MALARIA INITIATIVE

LED BY



# Table of Contents

VECTOR MONITORING AND CONTROL .....	10
Vector Control Coverage Goals .....	11
Evidence-Based Selection of Vector Control Interventions .....	11
Entomological Monitoring.....	12
New ITN and IRS Products.....	12
Larval Source Management (LSM) .....	13
Frequently Asked Questions for Vector Monitoring and Control .....	14
ENTOMOLOGICAL MONITORING.....	16
Introduction .....	16
Insecticide Resistance Monitoring .....	17
<i>Site selection and sampling frequency</i> .....	17
<i>Prioritization of insecticides for testing</i> .....	18
<i>Testing methods</i> .....	19
<i>Interpreting results of insecticide susceptibility testing</i> .....	20
<i>Molecular markers of insecticide resistance</i> .....	21
Vector Bionomics Monitoring .....	22
<i>Site selection and sampling frequency</i> .....	22
<i>Entomological indicators</i> .....	23
<i>Mosquito identification</i> .....	26
Quality Assurance and Residual Efficacy Monitoring of IRS.....	27
<i>Test methods</i> .....	27
Bioefficacy Monitoring and Chemical Analysis of ITNs .....	28
<i>Monitoring PBO synergist and dual insecticide ITNs</i> .....	29
Maintenance and Characterization of Mosquito Colonies.....	29
Entomological Monitoring in Elimination Settings.....	30
Entomological Monitoring Supplies .....	30
Data Collection and Reporting .....	30
INSECTICIDE-TREATED NETS .....	32
Introduction .....	32
PMI ITN Procurement Policy .....	33
Selection of ITNs in the Context of Pyrethroid Resistance.....	34

PBO Synergist ITNs .....	35
Dual-Insecticide ITNs .....	36
Considerations for Selection and Deployment of New Types of ITNs.....	37
Cost of ITNs .....	38
ITN Ownership: Key Distribution Channels .....	39
<i>Mass distribution campaigns</i> .....	39
<i>Continuous distribution channels</i> .....	40
ITN Indicators .....	42
Care of ITNs .....	43
Environment Risks of ITN Disposal, Misuse, and Repurposing .....	45
<i>Disposal</i> .....	45
<i>Misuse</i> .....	46
<i>Repurposing</i> .....	47
Durability Monitoring.....	48
<i>Introduction</i> .....	48
<i>Should ITN durability monitoring be carried out?</i> .....	48
<i>Standard Durability Monitoring (“Tier 1”)</i> .....	49
<i>Streamlined Durability Monitoring (“Tier 2”)</i> .....	49
<i>Interpretation and use of the results of ITN monitoring</i> .....	50
Frequently Asked Questions for ITNs.....	51
INDOOR RESIDUAL SPRAYING.....	53
Introduction .....	53
Insecticide Selection.....	54
<i>Rationale for introducing an insecticide rotation</i> .....	56
<i>New IRS Insecticide Procurement Policy</i> .....	57
Key Issues .....	57
Frequently Asked Questions for IRS.....	62
MALARIA IN PREGNANCY .....	65
Introduction .....	65
Intermittent Preventive Treatment in Pregnancy.....	66
WHO ANC Guidelines .....	67
Opportunities for Community-Based Programming .....	70
Insecticide-Treated Mosquito Nets in Pregnancy .....	70

Case Management of Malaria in Pregnancy .....	71
HIV-Infected Women.....	72
Prevention of Anemia in Pregnancy.....	72
Improving Program Implementation for IPTp.....	73
Additional Resources.....	74
Frequently Asked Questions for MIP .....	74
SEASONAL MALARIA CHEMOPREVENTION .....	76
Introduction .....	76
Considerations.....	77
<i>Implementation issues</i> .....	78
<i>Resistance monitoring vs. pharmacovigilance</i> .....	79
<i>Commodities</i> .....	79
<i>Surveillance, monitoring, and evaluation</i> .....	80
Additional Resources.....	81
VACCINES AND OTHER PREVENTIVE APPROACHES .....	82
Introduction .....	82
Intermittent Preventive Treatment in Infants (IPTi) .....	83
Malaria Vaccine.....	83
Mass Drug Administration.....	84
Mass Screen and Treat .....	87
Pro-active Community Case Management.....	87
CASE MANAGEMENT .....	89
PMI Priority Areas Supporting Comprehensive Malaria Case Management .....	90
Key Technical and Programmatic Guidance.....	90
<i>Recognition and management of febrile illness</i> .....	90
Diagnostic Testing .....	91
<i>Universal testing of all patients with suspected malaria</i> .....	91
<i>PMI priority areas for diagnostics in general</i> .....	92
<i>Diagnostic testing: rapid diagnostic tests (RDTs)</i> .....	92
<i>PMI priority areas of support for RDTs</i> .....	95
<i>Diagnostic testing: light microscopy</i> .....	97
<i>PMI priority areas of support for microscopy</i> .....	97
<i>Diagnostic testing: methods not recommended for clinical management</i> .....	98

Case Management .....	99
<i>Treatment of uncomplicated malaria</i> .....	99
<i>PMI priority areas of support for treatment of uncomplicated P. falciparum</i> .....	103
<i>Management of severe malaria</i> .....	104
<i>PMI Priority Areas of support for treatment of severe malaria</i> .....	105
<i>Treatment of uncomplicated malaria in special populations</i> .....	106
<i>Case management of infections caused by non-P. falciparum species</i> .....	106
Integrated Community Case Management .....	108
<i>PMI Priority Areas of support for iCCM</i> .....	108
Diagnosis and Treatment in the Private Sector .....	109
<i>PMI Priority Areas of support for Private Sector interventions</i> .....	110
Case Management Surveillance, and Monitoring and Evaluation .....	111
<i>Case recording and reporting</i> .....	111
<i>Quality of Case Management Services</i> .....	111
<i>Monitoring the efficacy of antimalarial drugs</i> .....	112
<i>PMI Priority Areas of support for monitoring the efficacy of antimalarial drugs</i> .....	112
Behavior Change and Case Management .....	114
Health Systems Strengthening and Case Management .....	114
HEALTH SYSTEMS STRENGTHENING.....	116
Introduction .....	116
Integration with Other Health Programs .....	117
Promotion of Partnerships to Advance Malaria Control.....	118
Peace Corps.....	119
<i>Background</i> .....	119
<i>Additional information – PC Malaria Volunteers</i> .....	120
<i>Training/country orientation</i> .....	121
<i>Supervision, communication, and assessment</i> .....	122
<i>Pre-service and in-service training</i> .....	122
Training and Capacity Strengthening of NMCPs and Other Local Government Entities.....	122
Field Epidemiology Training Program .....	123
DIGITAL COMMUNITY HEALTH .....	127
Background .....	127
Digital Community Health Initiative Vision .....	128

Key Investment Guidance .....	129
<i>Examples of Appropriate Investments</i> .....	129
<i>Principles</i> .....	130
Incorporation of Digital Health Investments In Table 2 .....	131
SOCIAL AND BEHAVIOR CHANGE.....	132
Introduction .....	133
Key Areas of PMI Support for SBC.....	133
<i>Capacity Strengthening</i> .....	133
<i>Design and Implementation</i> .....	135
<i>SBC in Service Delivery</i> .....	142
<i>Monitoring and Evaluation</i> .....	144
Special Considerations .....	150
<i>IRS and SMC</i> .....	150
<i>Larval Source Management</i> .....	150
<i>Changes in Transmission Settings</i> .....	150
<i>Malaria SBC During Public Health Emergencies</i> .....	151
<i>Zero Malaria Starts With Me</i> .....	152
<i>Operational Research / Program Evaluation</i> .....	152
<i>Peace Corps</i> .....	152
<i>Management and Budget</i> .....	153
SBC Appendix 1 - Additional Resources .....	155
ELIMINATION .....	158
Introduction .....	159
Shrinking the Malaria Map.....	163
Integrated Approaches to Malaria Elimination and Response.....	163
<i>Malaria Stratification and Tailoring of Intervention Packages</i> .....	163
<i>High-risk Populations</i> .....	165
<i>Foci Investigation and Response</i> .....	166
Entomological Monitoring and Vector Control .....	167
<i>Role of vector control in elimination settings</i> .....	167
<i>Role of entomological monitoring in support of vector control</i> .....	168
<i>Site selection for entomological monitoring</i> .....	168
Malaria in Pregnancy.....	169

<i>Prevention</i> .....	169
<i>Case management of pregnant women</i> .....	170
<i>Other interventions: ISTp and MDA</i> .....	170
Case Management .....	171
<i>Diagnosis</i> .....	171
<i>Treatment</i> .....	173
Surveillance, Monitoring, and Evaluation .....	175
<i>Household surveys</i> .....	175
<i>Disease surveillance</i> .....	176
<i>Disease surveillance tools</i> .....	177
<i>Draft PMI Elimination Indicators</i> .....	180
Social and Behavior Change (SBC).....	181
<i>Vector control</i> .....	181
<i>Case management</i> .....	182
<i>Malaria in pregnancy</i> .....	182
<i>Surveillance, monitoring, and evaluation</i> .....	182
Prevention of Reintroduction and Elimination Certification.....	183
<i>Prevention of Reintroduction</i> .....	183
<i>Certification of malaria elimination</i> .....	184
SURVEILLANCE, MONITORING, AND EVALUATION.....	185
Introduction .....	185
PMI Surveillance, Monitoring, and Evaluation Principles.....	186
<i>Coordination and partnership</i> .....	186
<i>Cost-effective, sustainable solutions</i> .....	186
SM&E Framework .....	187
Measuring PMI Objectives .....	187
Five Areas of Strategic Focus.....	189
SM&E for the PMI Strategy, 2015-2020 .....	189
Guidance on SM&E Approaches and Tools .....	189
<i>Malaria disease surveillance</i> .....	189
<i>Parallel malaria-specific efforts</i> .....	195
<i>ANC-based Surveillance</i> .....	197
<i>Malaria stratification mapping</i> .....	197

<i>Population-based surveys</i> .....	198
<i>Special cross-sectional surveys</i> .....	201
<i>Health facility-based surveys</i> .....	201
Evaluation.....	205
<i>Program evaluation</i> .....	205
<i>Impact evaluation</i> .....	206
Activities No Longer Supported By PMI .....	206
<i>Demographic surveillance system sites</i> .....	206
<i>Verbal autopsies</i> .....	206
SM&E Appendix 1: Minimum System Requirements at Various Health System Levels During Control and Elimination Phases .....	207
SM&E Appendix 2: Key Reference Manuals .....	207
DATA INTEGRATION.....	208
Introduction .....	208
Background .....	209
Goal and Vision for Data Integration.....	210
M-DIVE Platform .....	210
Data-Specific Staffing Requirements on PMI Country Teams .....	210
Access to Data Created or Obtained with PMI Funding.....	211
Quarterly Report Process - Frequently Asked Questions.....	213
OPERATIONAL RESEARCH AND PROGRAM EVALUATION.....	216
Introduction .....	216
PMI OR and PE Objectives.....	217
PMI OR Priority Setting Process .....	217
<i>Annual OR Prioritization</i> .....	217
<i>Guidelines for Proposing OR/PE Activities for PMI Funding</i> .....	218
Funding Sources and Channels for PMI Operational Research and Program Evaluation .....	219
Co-funding of OR Activities .....	221
Study Development, Review, and Approval Process.....	221
<i>MOP-funded PE/OR inclusion in the MOP and concept note development</i> .....	222
<i>Protocol review of MOP-funded OR studies</i> .....	223
Core-Funded OR/PE .....	223
<i>Core-funded concept note development process</i> .....	223
Distinguishing Operational Research and Program Evaluation.....	224

Research Determination Process .....	226
Facility Surveys and Blood Collection in the Context of OR/PE.....	227
What is Considered Under PMI Support for OR/PE? .....	228
Commodities for OR.....	228
Study Budget.....	228
Responsibilities of the OR Management Team and OR Committee .....	229
Dissemination.....	230
<i>Reporting Requirements for Ongoing OR/PE Activities.....</i>	<i>230</i>
<i>Authorship of Publications Resulting from OR Activities.....</i>	<i>230</i>
<i>Guidelines for Listing PMI and Agency Affiliations for Publication .....</i>	<i>231</i>
OR Appendix 1: Concept Note Template for PMI Operational Research and Program Evaluation (for both MOP or core-funded OR/PE) .....	232
OR Appendix 2: PMI OR/PE Study Update Form .....	232
OR Appendix 3: Completed OR/PE Study Questionnaire .....	232
COMMODITY PROCUREMENT AND SUPPLY CHAIN MANAGEMENT .....	233
COMMODITY PROCUREMENT .....	234
Introduction .....	234
Types of Commodities.....	234
<i>Insecticide-treated nets.....</i>	<i>235</i>
<i>ACTs, other antimalarial medicines, and essential medicines .....</i>	<i>237</i>
<i>Sulfadoxine-pyrimethamine .....</i>	<i>238</i>
<i>AQ+SP for seasonal malaria chemoprevention.....</i>	<i>239</i>
<i>Severe malaria medicines .....</i>	<i>240</i>
<i>Rapid diagnostic tests .....</i>	<i>240</i>
<i>Lab supplies.....</i>	<i>241</i>
Lot Quality Assurance/Quality Control.....	241
Emergency Commodity and Financial Accounts .....	242
Commodity Theft, Diversion, and Expiry.....	243
Central Commodity Mechanisms.....	244
Government-to-Government Funding for Commodities .....	245
Global Standards through GS1 Implementation .....	245
SUPPLY CHAIN MANAGEMENT .....	247
Introduction .....	247
PMI’s Stockout Reduction Initiative .....	247

Logistics Management Information Systems .....	248
Product Selection .....	249
Quantification .....	249
Warehousing, Storage, and Distribution.....	250
Quality Monitoring.....	252
Monitoring and Supervision.....	253
Supply Chain Assessments .....	254
Capacity Building.....	254
Commodity Procurement and Supply Chain Management Appendix 1: Commodities Costing Table.....	255
Commodity Procurement and Supply Chain Management Appendix 2: Average Lead Time Table .....	255
Commodity Procurement and Supply Chain Management Appendix 3: Assumptions for Quantification of Parenteral Severe Malaria Drugs .....	255
PRIVATE SECTOR ENGAGEMENT .....	257
Background .....	257
MALARIA PROGRAMMING IN HUMANITARIAN CONTEXTS.....	260

---

# VECTOR MONITORING AND CONTROL

---

## **\*New/Key Messages\***

Resistance threatens the effectiveness of insecticide-based interventions and should be a primary consideration in developing an **integrated vector management strategy** in which vector control tools are selected and implemented to ensure maximum impact and cost effectiveness.

PMI supports evidence-based deployment of traditional and new vector control tools (e.g., new insecticides for IRS and new types of ITNs) to ensure effective vector control, as well as OR/PE for new tools and/or approaches (e.g. LSM, topical repellents).

**Vector Control Coverage Goals:** In line with a global guidance pivot away from universal coverage with ITNs and a focus on universal coverage with the right vector control interventions in the right place, PMI recommends appropriate coverage with at least one effective vector control tool (ITNs and/or IRS).

**ITN Procurement:** PMI focus countries should transition to new types of ITNs (e.g., PBO synergist or dual insecticide ITNs) where supported by insecticide resistance monitoring data and as funding allows and in coordination with other donors and national programs.

**IRS Insecticide Procurement and Rotations:** In areas where IRS is implemented, the insecticide used should be preemptively rotated between classes about every two years to mitigate resistance. Of note, SumiShield 50 WG and Fludora Fusion both belong to the neonicotinoid class of insecticides, and thus switching between these two products does not constitute an insecticide rotation. When deploying a neonicotinoid for IRS in a given year, both products should be used to promote competition and a balanced market per PMI's updated IRS Insecticide Procurement Policy.

**ITN Durability Monitoring:** PMI has supported development of streamlined durability monitoring tools (e.g., protocols, questionnaires, etc.), with an emphasis on new types of nets, for use in countries that already have considerable durability monitoring data.

**Larval Source Management (LSM) implementation in low transmission settings:** PMI funding may be used to support LSM as a supplemental intervention in the context of elimination.

**LSM OR/PE in higher transmission settings:** To support focus countries that are moving forward with large-scale or even nationwide implementation of LSM in accordance with specific national directives, PMI funding may be used to support Operational Research (OR) or Program Evaluation (PE) to assess the effectiveness of LSM in combination with other interventions, and to generate the evidence needed to develop more comprehensive guidance on LSM.

Two of PMI's main interventions – insecticide-treated mosquito nets (ITNs) and indoor residual spraying (IRS) – aim to reduce adult mosquito longevity and limit biting, thereby markedly reducing malaria transmission by mosquitoes that at least occasionally seek blood meals indoors. These two interventions rely on a limited number of insecticides, many of which have been compromised by resistance. PMI supports deployment of traditional and new vector control tools (e.g., new insecticides for IRS and new types of ITNs) through integrated vector management (IVM) strategies to provide effective vector control in the face of emerging insecticide resistance. In some circumstances, supplemental interventions that reduce adult mosquito abundance via destruction of larval habitat or application of larvicides (collectively termed Larval Source Management, or LSM) may be indicated. Please see below for further guidance on **LSM**. Entomological surveillance, including monitoring of insecticide resistance, vector bionomics, IRS quality, and ITN durability, is critical to the selection, implementation, and assessment of vector control interventions. It is important that National Malaria Control Programs (NMCPs) develop IVM strategies that articulate how and where ITNs and IRS, and potentially LSM, will be strategically deployed and monitored to provide the highest quality and greatest programmatic impact and mitigate the threat of insecticide resistance. In some limited situations, deployment of additional interventions such as topical repellents may be supported through OR or PE (Please see the **Elimination chapter** for further guidance).

## Vector Control Coverage Goals

As per the October 2019 WHO Malaria Policy Advisory Committee (MPAC) meeting report,<sup>1</sup> “Universal coverage for malaria vector control is defined as universal access to and use of appropriate interventions by populations at risk of malaria,” thus moving away from universal coverage with nets and focusing on universal coverage with the right interventions in the right place. PMI fully embraces this global guidance pivot and recommends appropriate coverage with at least one effective vector control tool (ITNs and/or IRS). Further information about co-deployment of IRS and new types of nets (e.g., PBO synergist and dual active ingredient ITNs) is available in the IRS chapter.

## Evidence-Based Selection of Vector Control Interventions

Countries should ensure that high coverage and quality with one vector control intervention (e.g., ITNs or IRS) is achieved in an area before deploying supplementary interventions. Selection of the primary vector control intervention should be based on insecticide resistance and vector bionomics data as well as other factors including community acceptance, cost, and national strategy/policies. This is in line with the revised [World Health Organization \(WHO\) Guidelines for Malaria Vector Control](#) (2019).

Insecticide resistance poses a major threat to gains made with core vector control interventions. Standard pyrethroid ITNs may continue to provide personal protection as a physical barrier in areas with pyrethroid resistance. In the context of intense pyrethroid resistance, PMI focus countries should

---

<sup>1</sup> WHO, Statement by the Malaria Policy Advisory Committee on reconsidering the formulation of malaria policy guidance, November 2019.

transition to new types of ITNs (e.g., PBO synergist or dual insecticide ITNs) where supported by insecticide resistance monitoring data, or consider the addition of IRS in these areas. ITN type and insecticides for IRS should be selected according to entomological monitoring data and rotated as outlined in the [ITN](#) and [IRS](#) chapters. Co-deployment of IRS with pirimiphos-methyl and PBO synergist ITNs is not currently recommended, as further investigations are needed to determine if there is an antagonistic effect between the two chemicals.<sup>2</sup> There is currently limited data on the impact of co-deployment of IRS and dual insecticide ITNs (e.g., PBO nets, Interceptor G2s), and OR/PE in this area can be supported.

## Entomological Monitoring

Entomological monitoring is critical to inform and assess vector control interventions, and should be supported in PMI countries to achieve the following:

- Monitoring vector bionomics to identify key vector mosquito species, seasonality (periods of peak abundance), biting location (indoors vs. outdoors) and time to guide when and where to deploy vector control interventions.
- Generating insecticide resistance profiles of relevant vector mosquito species to guide selection and rotation of insecticides for IRS and/or ITNs.
- Monitoring entomological indicators to assess the quality and performance of IRS and ITNs (e.g., spray quality, residual efficacy, durability), and to guide selection and timing of vector control interventions.
- Monitoring entomological indicators to evaluate the impact of vector control interventions (e.g., resting densities, biting rates, entomological inoculation rates).

Please see the [Entomological Monitoring](#) chapter for more information.

## New ITN and IRS Products

The WHO Pre-Qualification Team (WHO PQ) leads evaluation of vector control products.<sup>3</sup> In 2018, two new products with new classes of insecticide have received WHO PQ recommendation: Fludora Fusion for IRS, and the Royal Guard ITN. With the addition of these new products, PMI now supports deployment of three longer lasting products for IRS - Actellic. (organophosphate), SumiShield 50 WG (neonicotinoid), and Fludora Fusion (neonicotinoid + pyrethroid) - and two new types of ITNs - PBO synergist and dual insecticide (i.e., Interceptor G2 and Royal Guard) ITNs. Please see below and the [IRS](#) and [ITN](#) chapters for further guidance on where and how to deploy these tools.

---

<sup>2</sup> WHO 2017. Conditions for deployment of mosquito nets treated with a pyrethroid and piperonyl butoxide. <https://www.who.int/malaria/publications/atoz/use-of-pbo-treated-llins/en/>

<sup>3</sup> <http://www.who.int/pq-vector-control/en/>

## Larval Source Management (LSM)

LSM, which involves the destruction of larval habitats via draining or filling or through the application of larvicides has been successful historically in Europe, Brazil, Africa, and Southeast Asia. Modern randomized controlled trials are few, but those that exist indicate that LSM as a standalone intervention, unless conducted with a high degree of rigor, is inadequate. Thus LSM is recommended by WHO as a supplemental intervention to either ITNs or IRS in those settings where larval habitats are “few, fixed, and findable”<sup>4</sup>. LSM is only indicated when coverage and quality of ITNs or IRS is high, but malaria transmission remains<sup>5</sup>.

In low transmission areas, PMI historically has not prioritized resources to support LSM. However, PMI funding may be used to support LSM in the context of elimination in areas where larval habitats can be efficiently located and accessed, where good coverage and quality of either ITNs or IRS is in place, and it is coupled with high quality case management and case investigation in transmission foci. For more information see the [Elimination chapter, ‘Entomological Monitoring and Vector Control’ section](#).

In areas with higher malaria transmission, including most areas of PMI focus countries, current evidence is insufficient to support malaria vector control interventions other than by ITNs or IRS. However, PMI recognizes that many PMI focus countries are moving forward with large-scale or even nationwide implementation of LSM in accordance with specific national directives, even though this approach is not in alignment with current WHO guidance. In these cases, PMI funding may be used to support OR or PE to assess the effectiveness of LSM in combination with other interventions, and to generate the evidence needed to develop more comprehensive guidance on LSM. Any OR/PE that includes a larviciding component should include both a quality and effectiveness assessment of the larvicides utilized if they are not WHO PQ listed products and should also consider an evaluation of SBC activities and promoted behaviors when deploying LSM in the context of other interventions.

In summary, PMI support for LSM may be considered under the following two conditions:

- (1) **LSM implementation in low transmission settings:** PMI funding may be used to support LSM in the context of elimination in areas where larval habitats can be efficiently located, where high coverage and quality of either ITNs or IRS (at least 85% coverage) is in place, and it is coupled with high quality case management and case investigation in transmission foci.
- (2) **LSM OR/PE in higher transmission settings:** To support focus countries that are moving forward with non-PMI funded large-scale or even nationwide implementation of LSM in accordance with specific national directives, PMI funding may be used to support HQ reviewed

---

<sup>4</sup>[https://www.who.int/malaria/publications/atoz/interim\\_position\\_statement\\_larviciding\\_sub\\_saharan\\_africa.pdf](https://www.who.int/malaria/publications/atoz/interim_position_statement_larviciding_sub_saharan_africa.pdf)

<sup>5</sup> <https://www.who.int/malaria/publications/atoz/9789241550499/en/>

and approved Operational Research (OR) or Program Evaluation (PE) to assess the additive effectiveness of LSM in combination with high quality coverage of ITNs or IRS, and/or other malaria interventions ( not necessarily limited to vector control interventions; e.g., SMC), in order to generate the evidence needed to develop more comprehensive guidance on LSM.

- (3) **LSM OR/PE in areas where *Anopheles stephensi* is present.** As *Anopheles stephensi* uses larval sites such as water storage containers or other containers, these may be efficiently targeted by LSM. PMI funding may be used to assess the impact of LSM programs in urban or dual areas.

Please consult with your PMI HQ Operational and Entomology Leads for guidance on implementation of LSM in elimination context or development of any LSM-related OR or PE in higher transmission settings. See the [SBC Section](#) for guidance on OR/PE related to LSM messaging to communities.

## Frequently Asked Questions for Vector Monitoring and Control

### Q1. Are there any other vector control-based technologies on the horizon?

A. Other vector control technologies under development, but not yet deployed, include treated clothing and shelter materials, attractive targeted sugar baits (ATSBs), eave tubes and ribbons, housing improvements, population-wide deployment of ivermectin drug treatment, topical and spatial repellents, and genetically modified mosquitoes.

Topical repellents may reduce mosquito biting and provide some level of personal protection, therefore their deployment in elimination settings with difficult to reach populations exposed to outdoor biting may be indicated. However, at this time, PMI support for topical repellents is limited to OR/PE. These potential tools are being developed by a number of commercial groups as well as the U.S. Departments of Agriculture and Defense: [http://www.ars.usda.gov/research/projects\\_programs.htm?modecode=60-36-05-15](http://www.ars.usda.gov/research/projects_programs.htm?modecode=60-36-05-15).

As new tools become available and receive a WHO policy recommendation for malaria control, PMI will develop policy and technical guidance for use within PMI supported program efforts. An overview of new tools under review by the WHO Vector Control Advisory Group (VCAG) can be found at <https://www.who.int/vector-control/vcag/en/> and those in development through the Innovative Vector Control Consortium can be found here: <http://www.ivcc.com/creating-solutions/our-work/new-vector-control-tools>.

PMI will initiate an OR study in 2020 to investigate the effectiveness and potential to scale-up housing modifications. The study will be conducted in Uganda and will include an evaluation of eave tubes, eaves ribbons, and house screening in combination with PBO ITNs.

**Q2: What vector control strategies are not recommended for support with PMI funding?**

**A.** Some mosquito control strategies are not recommended by PMI for programmatic implementation in Africa, but may be appropriate for OR/PE. These include: (1) environmental manipulation and biocontrol agents (it is the rare context where this can be effectively implemented); (2) attacking the adult stages through aerial or space spraying of insecticides by ultra-low volume or fog applicators (except in the most rare emergency settings, this is never recommended for malaria control); (3) personal protection through topical and spatial repellents and coils, except under limited circumstances in malaria elimination settings and (4) grass cutting (this has not been shown to have an impact on malaria and should not appear in any control strategy).

---

# ENTOMOLOGICAL MONITORING

---

## Introduction

Since 2000, the scale up of interventions for malaria control including vector control and improved case management has led to dramatic reductions in the malaria burden in Africa with prevalence declining by 50% and the incidence of clinical disease by 40%. Much of the decline has been attributed to the scale up of vector control, with insecticide treated nets (ITNs) and indoor residual spraying (IRS) estimated to account for 68% and 10%, respectively, of the cases averted<sup>6</sup>. The contribution of vector control to the reduction in malaria burden is a reflection of both their effectiveness as well as the substantial investment in scaling up ITNs, in particular. Most countries now aim for universal coverage (see **Vector Control Coverage Goals**, above) with at least one vector control tool and vector control accounts for a major share of PMI's budget.

To protect this investment and ensure maximum benefit from vector control efforts, PMI supports entomological monitoring, which is the backbone of an IVM strategy, in all focus countries. As countries scale up vector control interventions, insecticide selection pressure on vector mosquito populations is likely to increase, and changes in vector susceptibility to insecticides, species composition and/or behavior are expected. The large investments in ITNs and IRS made by the Global Fund, PMI, and other donors, and our dependence on a limited number and classes of insecticides make it imperative that national programs monitor and evaluate entomological parameters. As part of an IVM strategy, entomological monitoring should include:

1. **Insecticide susceptibility testing** of relevant vector mosquito species to guide selection and rotation of insecticides for IRS and/or ITNs.
2. **Vector bionomics monitoring** to inform selection and timing of vector control intervention as well as to evaluate their quality and impact.
3. **Quality and performance assessments of IRS and ITNs** to determine insecticide residual efficacy and ITN durability (see [ITN chapter](#) for guidance on durability monitoring).
4. **Maintenance of well characterized mosquito colonies**, including susceptible and possibly also resistant strains, to enable insecticide susceptibility testing and quality/performance assessments of vector control interventions.

The overall aim of entomological monitoring is to answer specific questions to inform programmatic decision making. Longitudinal entomological monitoring is encouraged but it should not be a static process. Each year programs should strive to answer certain questions and raise new ones, and this should be done within a broader context, considering how best to complement collection of other types

---

<sup>6</sup> [Nature](#). 2015 Oct 8;526(7572):207-211.

of malaria data. While it is expected that resistance monitoring will be conducted every year (or at least every other year to ensure adequate geographic coverage), the insecticides used for testing will vary depending on the insecticides currently being used or under consideration for vector control. Similarly, while it is important to understand the biting times of mosquitoes, it could be a waste of resources to continuously report on well-established outcomes with no new information, such as repeatedly demonstrating that *Anopheles gambiae* s.l. primarily bites during the night. Rather, it would be more useful to investigate specific behavioral anomalies (or changes in behaviors) in time, space or by species. Alternatively, any risk between human behavior(s) and peak biting time could also be determined. While this example is an oversimplification, the main point is that entomological monitoring should be purposeful and answer key questions relevant to vector control operations.

## **Insecticide Resistance Monitoring**

A key component of entomological monitoring includes testing wild populations of mosquitoes for susceptibility to insecticides used for ITNs and IRS. The goals of insecticide resistance monitoring are to:

1. Generate data to support the selection of appropriate insecticide for use in ITNs or IRS.
2. Assess the distribution, frequency, and underlying mechanisms, and likely operational impact of any resistance observed.

The concept is simple, though the details can be complex: match insecticides delivered (whether via LLINs or IRS) to measured susceptibility patterns of target mosquito populations. This section provides guidance for monitoring of insecticide resistance in PMI focus countries, including site selection, prioritization of insecticides, testing methods, cut-off criteria and responses, as well as molecular identification of resistance mechanisms.

### ***Site selection and sampling frequency***

At least two sites for insecticide resistance monitoring should be identified in each administrative division where PMI supports monitoring. An administrative division is the smallest unit in which a change in vector control policy can be applied. This is typically a state, province, region, or county for ITNs and a district for IRS. A site may consist of several villages in close proximity. Insecticide resistance testing need not be linked with longitudinal monitoring. While it is recommended that insecticide resistance monitoring be conducted annually at each site, it may be desirable or necessary to rotate between a set of sites each year to maximize geographic coverage and resources, though it will be important to align the timing to ensure that data is available to inform insecticide and/or ITN procurements. In countries with large numbers of such sites, regional sampling could be considered. **Countries should consult with the Entomology and Operational Leads to design a useful and cost-effective sampling scheme** that meets the needs and answers the questions of the national program.

Once monitoring sites are established, baseline insecticide susceptibilities should be determined before interventions are implemented.

### ***Prioritization of insecticides for testing***

Currently, there are seven classes of insecticides that have received WHO prequalification for use in adult malaria vector control: organochlorines, organophosphates, pyrethroids, carbamates, pyrroles, neonicotinoids, and insect growth regulators (IGRs).<sup>7</sup> Pyrethroids were the most widely used class of insecticides until 2017 and these were the only insecticides recommended for use on ITNs. In 2017, the Interceptor G2 was introduced as a long-lasting insecticidal net (LLIN). This product includes both a pyrethroid (alphacypermethrin) and a pyrrole (chlorfenapyr) insecticide. Several products include a pyrethroid and piperonyl butoxide (PBO), a synergist that may mitigate pyrethroid resistance that is due to increased oxidase activity. A study in western Tanzania indicated substantial improvement in effectiveness in context of oxidase based resistance while a more recent study in Uganda indicated a smaller but still significant reduction in prevalence in clusters with PBO ITNs. Further, ITNs incorporating the growth regulator pyriproxyfen (Royal Guard) showed promise in early studies. The range of insecticides that can be delivered via ITNs is thus expanding.

For IRS, there are currently five classes of WHO-recommended insecticides: pyrethroids, organochlorines, carbamates, organophosphates and neonicotinoids. Pyrethroids are less often used due to widespread resistance to this class of insecticide. Organochlorines (DDT) are rarely deployed due to resistance as well as environmental concerns, while carbamates are moderately expensive and have limited residual efficacy on some wall surfaces. Therefore, most IRS programs are implemented with organophosphate insecticides (Actellic) with many now also using clothianidin, a newly recommended neonicotinoid insecticide that is available alone (SumiShield 50 WG) or as a mixture in combination with deltamethrin (Fludora Fusion), as part of a rotational strategy to manage resistance.

Further background information on insecticides used in vector control for public health, including their safety and efficacy, can be found at the [WHO PQ Team website](https://www.who.int/pq-vector-control/prequalified-lists/en/).<sup>8</sup> An excellent resource for learning more about the modes of action is the [Insecticide Resistance Action Committee](http://www.irac-online.org/).<sup>9</sup>

Ideally, susceptibility testing should be done for the full range of insecticides. In practice, limitations on the numbers of mosquitoes for testing preclude this. Therefore, insecticides for testing should be prioritized based on the insecticides in use or under consideration for the vector control intervention(s) being implemented (ITNs, IRS, or both), as this data can provide immediately actionable information, as well as any historical insecticide resistance data. As new insecticides are recommended for IRS or use on

---

<sup>7</sup> <https://www.who.int/pq-vector-control/prequalified-lists/en/>

<sup>8</sup> <https://www.who.int/pq-vector-control/en/>

<sup>9</sup> <http://www.irac-online.org/>

ITNs, it is important to include these for baseline testing and to assess whether products with the new insecticides should be considered for procurement.

PMI currently supports IRS with Actellic, SumiShield 50 WG, and Fludora Fusion, and therefore recommends insecticide susceptibility testing with the active ingredients of these products:

1. Pirimiphos-methyl (organophosphate)
2. Clothianidin (neonicotinoid)
3. Deltamethrin (pyrethroid)

Testing for carbamates (bendiocarb) or DDT are only recommended if these insecticides are currently being used. Resistance intensity testing for IRS insecticides should not be a priority, as an insecticide will most likely not be used if resistance is detected at the diagnostic dose (see section on [Testing Methods](#) for additional guidance). Guidance on how to use these results to inform IRS insecticide procurements and development of rotation strategies is provided in the [IRS chapter](#).

As new types of ITNs are now available, PMI recommends prioritizing insecticide susceptibility testing with the active ingredients of these products, especially in sites with documented pyrethroid resistance, as listed below:

1. Deltamethrin +/- PBO
2. Permethrin +/- PBO
3. Alphacypermethrin +/- PBO
4. Chlorfenapyr

Pyrethroid susceptibility tests and PBO synergist assays should be conducted in parallel where possible to maximize resources. Assays with PBO pre-exposure should be done starting with the lowest insecticide dose as this often restores susceptibility. Resistance intensity testing for pyrethroid insecticides should not be a priority, as PMI recommends transitioning to new types of nets (e.g., PBO synergist of dural insecticide ITNs) if resistance is detected at the diagnostic dose (see section on Insecticide resistance intensity testing for additional guidance). Guidance on how to use these results to inform ITN procurements is provided in the [ITN chapter](#). See the [Supply Chain](#) and [Procurement](#) chapters for information about procurement timelines, which should guide the timing of susceptibility testing for active ingredients.

### ***Testing methods***

Insecticide susceptibility tests should be conducted with 2 to 5 day old, non-blood fed, female mosquitoes reared from larvae of the dominant local vector(s), or on F1 (first) generation mosquitoes raised from the eggs of field-caught females. Larval collections should cover multiple sites, and eggs for an F1 generation should be from a large number of field-caught females to ensure adequate

representation of resistance frequencies in the field populations. Where F1 mosquitoes cannot be obtained and field-caught females themselves have to be used for testing, it is likely that resistance will be underestimated, as metabolic resistance often declines dramatically with age of the mosquito.<sup>10</sup> In contrast, if mosquitoes are collected resting indoors on sprayed surfaces, the F1 generation of these mosquitoes may provide an overestimate of the frequency of resistance. If males are tested due to lack of female samples, the data for each sex should be recorded separately since males are likely to show somewhat more susceptibility in bioassays than females. All mosquitoes used in insecticide susceptibility tests should be sorted by dead or alive following exposure and preserved for subsequent laboratory analyses for confirmation of species identification and detection of molecular markers of resistance.

Sampling mosquitoes along transects may offer an advantage over isolated monitoring sites in order to get a representative sample of mosquitoes for resistance testing. Mosquitoes should be morphologically identified as vectors, to the best of the technician's ability, prior to the resistance assay. For both larval and adult collections, collection sites should be close together (e.g., within the same village) and georeferenced. The nearest health facility should also be georeferenced to allow linkage of epidemiological data (e.g., DHIS-2 data) trends with resistance monitoring.

Both the WHO tube test and the CDC bottle bioassay can be used for determining the frequency and intensity of insecticide resistance.<sup>11</sup> It is recommended that one (not both) methods be used for any given insecticide. As the bottle bioassay is readily available now, PMI encourages use of this method particularly for resistance intensity and synergist testing. Clothianidin, chlorfenapyr, and pyriproxyfen do not yet have WHO recommended susceptibility assays (although these may be available in the near future). To ensure that susceptibility tests are done according to the most recent versions of testing protocols, countries are encouraged to communicate with their Entomology and Operational Leads.

### ***Interpreting results of insecticide susceptibility testing***

According to the WHO guidelines<sup>12</sup>, results from insecticide susceptibility tests conducted using the diagnostic dose should be interpreted as follows:

- Susceptible: 98 - 100% mean mortality
- Possible resistance: 90% - 97% mean mortality
- Resistance: <90% mean mortality

---

<sup>10</sup> Note, however, that if sufficient specimens are available, determining the susceptibility of wild-caught, adult mosquitoes may provide additional supplementary information

<sup>11</sup> Prior to 2017, only the CDC bottle bioassay could be used for determining the intensity of insecticide resistance. However, WHO now produces papers at 1x, 5x, and 10x.

<sup>12</sup> Test procedures for insecticide resistance monitoring in malaria vector mosquitoes, 2nd ed. Geneva: World Health Organization; 2016

For IRS programs, knockdown or mortality <90% at the diagnostic dose (1×X concentration) in either the CDC bottle bioassay or the WHO assay indicates the need to switch to a different class of insecticide. For ITNs, the relationship between insecticide resistance and reduced efficacy is less clear. While resistance to a single insecticide within a class is often interpreted to indicate resistance to all insecticides within that class, field data from multiple sites indicate variability in the frequency and intensity of resistance among different pyrethroid insecticides. Molecular data also show that mechanisms of resistance may be specific to certain insecticides within the pyrethroid class. Therefore, resistance intensity assays may be conducted for pyrethroid insecticides used for the treatment of ITNs (permethrin, alphacypermethrin, and deltamethrin), if resistance is detected, though resistance intensity assays should not be prioritized over those described in the section above on “Prioritization of insecticides for testing”. In areas where PBO ITNs have been distributed, it is recommended to continue pyrethroid resistance intensity testing to monitor the impact of PBO on pyrethroid resistance profiles over time.

The operational significance of insecticide resistance may be further investigated using cone bioassays conducted with locally collected mosquitoes (on treated walls or ITNs) to ensure that IRS and ITNs are capable of killing local vector populations. Additionally, the concentration of insecticide in ITNs can be tested.

### ***Molecular markers of insecticide resistance***

Current molecular markers of insecticide resistance are limited to target site mutations (e.g., *kdr* for pyrethroids or *ace-1* for organophosphates) and a number of genes related to metabolic resistance and cuticular thickening. Metabolic resistance can be detected by using CDC bottle assays with synergists. Piperonyl butoxide will inhibit mixed function oxidases, *s,s,s*-tributyl phosphorotrithioate will inhibit non-specific esterases, and ethacrynic acid, diethyl maleate, or chlorfenethol will inhibit glutathione transferase activity. By exposing mosquitoes for one hour in synergist-treated bottles prior to exposure in insecticide-treated bottles, resistant mosquitoes will return to apparent susceptibility if the inhibited enzyme is responsible for resistance. Alternatively, biochemical assays can be carried out to measure enhanced levels of detoxification enzymes responsible for resistance. Target site resistance in *An. gambiae* can be detected by polymerase chain reaction (PCR) for knockdown resistance (*kdr*) and acetylcholinesterase (*ace-1*) resistance genes. There are also DNA-based PCR assays for detecting metabolic resistance such as CYP6P9a (cytochrome oxidase P450)<sup>13</sup> and GSTe2 (glutathione-S-transferase)<sup>14</sup> in *An. funestus*, and CYP4J5 (cytochrome oxidase P450) and Coeae1d (carboxylesterase) in *An. gambiae*<sup>15</sup>.

---

<sup>13</sup> Weedall et al. (2019) A cytochrome P450 allele confers pyrethroid resistance on a major African malaria vector, reducing insecticide-treated bednet efficacy. *Sci Transl Med.*11(484):eaat7386. doi: 10.1126/scitranslmed.aat7386.

<sup>14</sup> Riveron et al. (2014) A single mutation in the GSTe2 gene allows tracking of metabolically based insecticide resistance in a major malaria vector. *Genome Biol* 15, R27. <https://doi.org/10.1186/gb-2014-15-2-r27>

<sup>15</sup> Weetman, et al. (2018) Candidate-gene based GWAS identifies reproducible DNA markers for metabolic pyrethroid resistance from standing genetic variation in East African *Anopheles gambiae*. *Sci Rep* 8, 2920. <https://doi.org/10.1038/s41598-018-21265-5>

However, with the increasing implementation of modern genomics, it is likely that additional markers will be identified in the future. It is therefore important to preserve specimens tested for insecticide resistance for further analysis of current known markers and to potentially identify new markers and molecular mechanisms of resistance. The changing frequency of these markers can help to measure the rate of selection under different vector control regimens which may be useful to guide insecticide resistance management strategies. While PMI will support monitoring the frequency of known resistance mechanisms, the identification of new resistance markers requires significant investment in molecular sequencing and bioinformatics and should be done through collaborations established with academic research partners.

[Standard operating procedures](#) (SOPs)<sup>16</sup> for all insecticide resistance monitoring methods are available and can be obtained from the **Entomology and Operational Leads**.

## Vector Bionomics Monitoring

Longitudinal vector bionomics monitoring is a key component of any IVM plan. Routine monitoring at fixed sentinel sites allows for changes in vector bionomics to be detected over time, and is therefore critical to inform selection and timing of vector control interventions and to evaluate their impact. This will be particularly important as new vector control tools (e.g., new types of ITNs) are rolled out.

### *Site selection and sampling frequency*

Selection of fixed, routine longitudinal vector bionomics monitoring sites should be made following stratifications of the country based on 1) malaria transmission intensity, 2) ecology/ mosquito breeding habitat types, and 3) location of vector control interventions. It is recommended that countries establish at least one site per eco-epidemiological zone. Additional sites within each zone may be necessary to monitor multiple vector control interventions (e.g., ITNs only, ITNs plus IRS, multiple types of ITNs). A site may consist of several villages in close proximity. Data should be collected from each site monthly or as close to monthly as possible, and sites should only be changed if there is strong programmatic rationale (e.g., deployment of new types of nets, re-targeting of IRS) or if there are challenges collecting mosquitoes during the peak rainy/transmission season. If mosquito seasonality in a given area is already known, then collections may not need to be conducted during the dry season. Baseline data should be collected prior to implementation of a new vector control intervention and/or collected simultaneously from a comparative non-intervention site (e.g., a control village), in order to enable programs to determine the entomological impact of the intervention.

---

<sup>16</sup> <https://pmivectorlink.org/resources/tools-and-innovations/>

Additional ad hoc sites may be established temporarily to investigate country/context-specific questions. The number and location of sites and the type and frequency of collections would be based on the question(s) being answered.

**The number and location of both fixed and ad hoc sites should be discussed and determined in consultation with the PMI CDC and USAID Entomology backstops, keeping in mind that PMI should coordinate and harmonize efforts with the national program and other partners in-country.**

### ***Entomological indicators***

Malaria mosquito vector species may differ in key characteristics that have important operational or programmatic implications. The following indicators are useful in understanding the entomological attributes of sites, but should be used with specific questions in mind. For example, if seasonality has been monitored in an area for several years and a pattern has been shown, it may not be necessary to continue this activity. On the other hand, if there is a suspicion that mosquito seasonality is changing, or an intervention is being monitored, then this activity would make sense. The indicators that can be used are:

- 1. Species composition, abundance, and seasonality.** Vector species composition, abundance, and seasonality should be monitored to determine which mosquito vectors are present in a given area, their abundance, relative proportions, and distributions over time. The same basic mosquito collection techniques are used to calculate abundance, proportions, and seasonality. These include, where appropriate, human landing collections (HLCs), indoor (pyrethrum spray collections, Prokopak aspirations) and outdoor resting (pit traps, clay pots) collections, and CDC light traps. Larval collections may also be conducted, particularly in cases where there may be significant outdoor feeding.
- 2. Indoor and outdoor human biting rates.** Indoor and outdoor human biting rates, defined as the number of mosquito bites per person per unit time, should be determined nightly and/or hourly to understand where and when transmission is most likely occurring. HLCs are the preferred method, and are typically conducted overnight from 6:00 pm to 6:00 am, but may be extended depending on local vector behavior. If ethical approval cannot be obtained for HLCs, appropriate alternatives should be discussed and identified in consultation with PMI Entomology backstops. Additional information is provided below. CDC light traps hung next to a person sleeping under an ITN may be used to provide some indication of the rates of indoor feeding, but not on the relative importance of outdoor transmission.
- 3. Indoor and outdoor resting densities.** Indoor and outdoor resting densities, defined as the number of mosquitoes collected per house/shelter per day, should be determined to assess the suitability or evaluate the impact of indoor interventions, particularly IRS. Resting collections

should take place early in the morning (prior to 8 am) before mosquitoes exit houses or outdoor resting locations. Indoor resting densities may be determined from pyrethrum spray collections or Prokopak aspirations while outdoor resting densities may be determined using pit traps or clay pots. It should be noted that in homes with complete ITN or IRS coverage, indoor resting densities may be extremely low. In this case, PMI Entomology backstops should be consulted on best actions to take.

4. **Sporozoite rates.** Mosquito infectivity is determined by measuring the sporozoite rate, which is the proportion of mosquitoes in a population harboring infective sporozoites in their salivary glands. The sporozoite rate is necessary to determine the entomological inoculation rate (EIR), which is a measure of transmission intensity. It is also useful in detecting differences in infectivity between insecticide susceptible and resistant vectors, which may be an indication of control failure. In areas where species composition is changing, measuring sporozoite rates may be critical to determine vector status of new or secondary vectors. Sporozoite-positive mosquitoes are identified by enzyme-linked immunosorbent assay (ELISA)<sup>17</sup>, bead assays or polymerase chain reaction (PCR), although it should be noted that PCR does not distinguish sporozoite-stage parasites from other stages, so care should be taken in dissection of mosquitoes. It should also be noted that as mosquito populations are reduced, it can become increasingly difficult to collect sufficient mosquitoes to test and this small sample size may not produce a reliable estimate of the sporozoite rate.
5. **Entomological inoculation rate (EIR).** The EIR is a measure of malaria transmission intensity that describes the number of infectious bites an individual is exposed to in a given time period (typically a year or transmission season). EIR estimates may differ widely depending on sampling methods used and the amount of sampling error, which can be great in areas where mosquitoes are rare and/or rarely infected (as in areas with low parasite prevalence and low transmission). Therefore, EIRs should be interpreted with caution.
6. **Human/animal blood indices.** Analysis of mosquito blood meal sources enables one to determine what portion of mosquito blood meals are taken on humans versus animals. Repeated collections after the introduction of a vector control intervention may be used to identify shifts in feeding behavior. Estimates of host feeding rates are strongly affected by host availability and sampling strategy and should therefore be interpreted with caution. Blood-fed mosquitoes can be collected by indoor or outdoor resting collections or CDC light traps. Blood meal sources can be identified using ELISAs or PCRs.
7. **Parity rates.** Parity rates are monitored to determine the age structure of a vector population. This manner of age grading can be a useful indicator as older vector populations are more likely

---

<sup>17</sup> <http://www.mr4.org/Portals/3/Pdfs/Anopheles/3.3%20Plasmodium%20Sporozoite%20ELISA%20v%201.pdf>

to transmit malaria because they have survived long enough for the parasite to develop and complete the sporogonic cycle within the mosquito. Since IRS and ITNs work by shortening the lifespan of mosquitoes, the average age of the vector population will decrease if the interventions are effective. In special circumstances, and depending on the capacity of the entomological monitoring teams, age grading may be undertaken to monitor mosquito survivorship in the presence of IRS or ITN interventions. The simplest method for age grading involves the dissection of mosquito abdomens and the determination of the parity rate in the mosquito population. By dissecting and microscopically observing mosquito ovaries, skilled technicians can determine if a female mosquito has laid eggs at least one time in her life (i.e., if she is parous). The proportion of parous individuals correlates to the average age of a population. Because the “percent parous” indicator is a relative indicator of age, it is best used as a comparison (e.g., before and after an intervention). However, age grading is fraught with sampling issues and should be interpreted with caution. Technicians conducting parity dissection and determination should undergo routine refresher training and assessment using insectary reared mosquitoes of known parity status, to assure consistency and quality of parity results.

For additional information on mosquito collection techniques, see WHO’s comprehensive *Manual on Practical Entomology for Malaria Control*<sup>18</sup>. Other WHO entomology training materials include, Training module on malaria control: Entomology and vector control<sup>19</sup> and *Training Manual on Malaria Entomology for Entomology and Vector Control Technicians*<sup>20</sup>. Training videos are also available for a number of mosquito collection methods at <https://vimeo.com/ivmproject>.

[Standard operating procedures \(SOPs\)](#)<sup>21</sup> for all vector bionomics monitoring methods are available and can be obtained from the Entomology leads. Please consult with PMI USAID and CDC Entomology backstops to 1) develop a field and laboratory entomological monitoring plan based on the questions being asked and relevant indicators, 2) determine appropriate sample sizes and analysis plans, and 3) if not available in country, identify suggested reference laboratories to which samples may be sent.

### **Alternatives to Human Landing Catches**

In some countries, there are objections to the use of human collectors as is commonly done in Human Landing Catches. These objections are usually based on the idea of increased exposure for collectors to malaria and other vector-borne disease. Research shows that HLC collectors on chemoprophylaxis (as

---

<sup>18</sup> [http://whqlibdoc.who.int/offset/WHO\\_OFFSET\\_13\\_\(part1\).pdf](http://whqlibdoc.who.int/offset/WHO_OFFSET_13_(part1).pdf) and [http://whqlibdoc.who.int/offset/WHO\\_OFFSET\\_13\\_\(part2\).pdf](http://whqlibdoc.who.int/offset/WHO_OFFSET_13_(part2).pdf)

<sup>19</sup> <https://www.who.int/malaria/publications/atoz/9789241505819/en/>

<sup>20</sup> <https://www.paho.org/en/documents/training-manual-malaria-entomology-entomology-and-vector-control-technicians-basic-0>

<sup>21</sup> <https://pmivectorlink.org/resources/tools-and-innovations/>

recommended) were at considerably less risk of malaria than the surrounding population<sup>22</sup>. However, there are other vector-borne diseases that HLC collectors may be exposed to, including lymphatic filariasis, leishmaniasis, o'nyong-nyong, etc. Additionally, if collections extend into the daylight hours, there may be increased risk of *Aedes*-borne viruses (dengue, chikungunya, and yellow fever). Whether there is additional risk for these diseases is not known. At present, guidance from PMI is that HLCs may continue, if supported by national ethics committees and National Malaria Control Programs. Should evidence emerge that collectors are at increased risk compared to non-collectors, this guidance will be revised.

Alternative trapping methods that could be used in place of HLCs depend on the aim of the research. If the aim is merely to collect mosquitoes that are attracted to humans, methods that use a human bait that is not exposed to bites can be used, such as a CDC light trap next to a bednet, a Furvela trap, or a miniaturized double-net trap. These methods may also be used to determine the biting times of mosquitoes if mosquitoes are collected hourly throughout the night. If EIRs are to be determined (usually in assessing the impact of an intervention), a calibration may need to be done, but it should be noted that this calibration may vary from place-to-place.

For additional information on alternative collection methods, please contact your respective PMI HQ Operational and Entomology Leads.

### ***Mosquito identification***

Accurate mosquito identification underpins all entomological indicators for malaria. As the major vectors of malaria in Africa are species complexes, whereby different species are morphologically identical (e.g., *Anopheles gambiae*, *An. arabiensis*, and *An. coluzzii*) but genetically distinct, a subsample of specimens identified to the species complex level should be sent to a laboratory for molecular identification of species by PCR. Special care should be taken as most PCR-based assays only distinguish between members of a complex, and may result in spurious results if mosquitoes from outside the complex are tested. If PCRs routinely fail to amplify DNA, this may be a sign of incorrect initial morphological identification. DNA sequencing of cytochrome c oxidase subunit 1 gene from the mitochondrial genome (CO1) or the internal transcribed spacer 2 region from the nuclear ribosomal DNA (ITS2) targets may help resolve the questions surrounding the identity of the species, but it should be noted that there is not yet a complete understanding of how existing species and DNA sequences correspond. The number of specimens in this subsample will be determined by the relative abundance of the sibling species, the capacity of the reference laboratory, and the purpose of the molecular identification tests. It should be noted that as vector control efforts have progressed, formerly minor vectors of malaria may become predominant. Molecular identification is a useful adjunct to morphological identification and should be carried out on a sample of specimens where changes in

---

<sup>22</sup> Gimnig et al. (2013) Incidence of Malaria among Mosquito Collectors Conducting Human Landing Catches in Western Kenya Am. J. Trop. Med. Hyg., 88(2), pp. 301–308

species composition have occurred. Similarly, to parity dissections, programs should maintain a reference collection of different species of mosquitoes, and those identifying mosquitoes should be tested frequently.

## Quality Assurance and Residual Efficacy Monitoring of IRS

Ensuring the quality of IRS is a critical component of IVM. Haphazard, under-dosed spraying is a waste of resources and, like sub-lethal dosing of medications, may select for insecticide resistance in the mosquito population. IRS programs operating under PMI's central mechanism implement clear protocols to ensure the quality of IRS, including robust training of spray operators, supervisors, and all relevant spray personnel and "directly observed spraying" whereby supervisors are required to observe spray operators' technique while spraying houses and to provide on-the-spot correction as needed. Guidelines for IRS management and supervision checklists are available on the PMI website.

Quality assurance and residual efficacy monitoring are conducted using cone bioassays to determine the quality of IRS (e.g., assays conducted shortly after spraying can be used as a proxy to assess spray performance) and the residual efficacy of the intervention (e.g., to determine how long insecticides last in killing or knocking down vectors).

### Test methods

Cone bioassays are currently the only way to measure insecticide decay on sprayed surfaces. Baseline assays should be conducted within a week of spraying to determine initial spray quality. Subsequently, decay rates should be measured monthly to determine the residual efficacy of the insecticide.

To perform cone bioassays, known susceptible laboratory-reared mosquitoes (e.g., *An. gambiae* Kisumu strain) should be used. If these are not available, wild-caught, unfed, female mosquitoes can be used as long as there is no demonstrated resistance in the population. The process for IRS testing is as follows: (1) attach bioassay cones to walls at three different heights (0.5 meter, 1.0 meter and 1.5 meters above the floor) using tape; (2) introduce batches of 10 female mosquitoes into the cones and expose to the wall surface for 30 minutes; and (3) after exposure, transfer the mosquitoes to paper cups, provide them with a sugar solution, and record mortality 24 hours after exposure for pirimiphos-methyl or every 24 hours for up to seven days for clothianidin. Tests should be conducted in enough houses to be representative of different wall surfaces and different groups of spray operators. Control assays should also be conducted – either select houses of similar construction that have not been sprayed or cover sprayed wall with two layers of paper before attaching the cones. Introduce 10 mosquitoes per cone as above. Bioassays should be repeated if mortality is >20% on a given day. However, this requirement may be relaxed for mortality assessments that continue beyond 5 days after exposure, as may be the case for clothianidin assays.

It should be noted that pirimiphos-methyl has an airborne effect when initially sprayed. Therefore, any mosquitoes brought into houses freshly sprayed with pirimiphos-methyl will die, even if they are not placed directly on a sprayed surface. Therefore, results from monitoring at one-month post-IRS should be used as a baseline for residual efficacy monitoring, and alternative methods for determining spray quality may need to be employed (e.g., examining the visual pattern of insecticide residue on walls after spraying).

[Standard operating procedures \(SOPs\)](#)<sup>23</sup> for IRS quality assurance and residual efficacy monitoring methods are available and can be obtained from the **Entomology and Operational Leads**.

Initial spray quality and monthly residual efficacy data should be shared with the NMCP, implementing partners, and PMI as soon as results are available in order to initiate immediate corrective action, if necessary. Monthly decay rate results will be used to determine the residual life of the insecticide under local conditions. For longer-acting formulations, at least the baseline testing and monthly testing beginning in the 4<sup>th</sup> or 5<sup>th</sup> month after spraying should be attempted.

## Bioefficacy Monitoring and Chemical Analysis of ITNs

Monitoring the insecticidal activity and insecticide content of ITNs is a critical component of ITN durability monitoring and may also be important in identifying ITN quality assurance issues. Insecticidal activity of ITNs is measured by exposing susceptible mosquitoes to ITNs in WHO cones. Because the purpose of the activity is to measure insecticidal activity, in general any susceptible species of mosquito may generally be used, though resistant strains are needed to evaluate PBO synergist and dual insecticide ITNs (see following section on Monitoring PBO synergist and dual insecticide ITNs for more information). This activity requires specialized facilities and staff, in particular an insectary with a susceptible colony of mosquitoes and lab staff with the ability to consistently generate large numbers of mosquitoes of uniform quality required for bioassays. If an insectary is not available, net samples may be sent to an outside laboratory for analysis.

Previously, PMI did not routinely support measurement of insecticidal content at all data collection timepoints via durability monitoring, given that ITNs undergo pre-shipment testing. **However, based on recent experience, PMI now recommends bioassay and chemical content testing at all time points, particularly where there are no existing data or where new compounds or new net technologies are in use.** Furthermore, it is recommended to retain 30 nets prior to distribution for confirmation in the event that unexpected results are obtained at any point during durability monitoring.

Measurement of insecticidal content requires highly specialized capacity that is likely limited or absent in nearly all PMI-supported countries. Therefore, this must be done either at CDC or at a WHO

---

<sup>23</sup> <https://pmivectorlink.org/resources/tools-and-innovations/>

collaborating center where the cost of analysis is approximately \$150-\$350 per sample. Furthermore, in some cases, there is a poor correlation between insecticidal content and insecticidal activity, particularly for some ITNs made of polyethylene with insecticide directly incorporated into the fiber.

Further guidance on durability monitoring is available in the [ITN chapter](#).

### ***Monitoring PBO synergist and dual insecticide ITNs***

Some of the vector control tools now available combine multiple active ingredients, including both synergists and insecticides. Some products contain a combination of synergists (i.e., PBO) and insecticides with relatively well-understood properties (i.e., deltamethrin), and/or new insecticides for adult mosquito vector control, which may have different modes of action (i.e., clothianidin, chlorfenapyr, pyriproxyfen). The combination of these active ingredients on the same ITN provides a challenge for evaluation of the efficacy of these products, as one efficacious treatment may “mask” the inefficacy of the other. Ideally, bioassays should be done with both a susceptible strain and a resistant strain derived from local mosquito populations. However, given that most countries do not have access to pyrethroid resistant colonies, bioassays should be conducted with a susceptible colony and wild mosquitoes. If net failures are detected, samples could be outsourced to a lab with a resistant colony for confirmation.

PMI encourages countries to develop colonies of local strains that are resistant to pyrethroids, maintained under selection, and routinely characterized so tests can be performed locally. Strains of resistant mosquitoes must be kept separately from susceptible strains, preferably in separate buildings, but at least in separate rooms, with measures to prevent escape of these strains (e.g., double doors) and clear SOPs and access restricted to those trained on SOPs. Furthermore, PMI encourages countries to build capacity in countries to conduct tunnel tests, recognizing that there may be some initial hurdles around training, animal ethics approval, etc.

For specific guidance on monitoring new types of nets, please contact your respective PMI HQ Operational and Entomology Leads.

### **Maintenance and Characterization of Mosquito Colonies**

Susceptible colonies of mosquitoes are used for the assessment of ITNs, quality control of IRS, and verification of treated papers for WHO susceptibility tests and CDC bottle bioassays. Susceptible colonies should be tested quarterly in order to ensure that these established colonies have not been contaminated by resistant colonies kept in the insectary, or wild mosquitoes entering the insectary. The tests should include a bioassay with the insecticides for which the susceptible strain is used (i.e., if the strain is being used for monitoring Actellic IRS, then the strain should be bioassayed with pirimiphos-methyl; if it is being used for testing standard ITNs, a pyrethroid insecticide should be used). Additional molecular confirmation of the strain can be done by testing the strain for common resistance

mechanisms (i.e., *kdr*, related to DDT and pyrethroid resistance, or *ace1<sup>R</sup>*, related to organophosphate and carbamate resistance). Alternative bioassays may be useful for other strains, such as the *CYP6p9a<sub>R</sub>* mutation in *Anopheles funestus*. However, the key characterization that should be done is a phenotypic resistance test (WHO susceptibility test or CDC bottle bioassay), and these should be done quarterly.

As countries are encouraged to keep pyrethroid-resistant strains of *Anopheles* for testing the efficacy of PBO or bi-treated nets, these must also be regularly selected with a pyrethroid and characterized to ensure they maintain their resistant status. The characterization of these strains should also be done quarterly. As noted elsewhere, it is essential to keep any pyrethroid-resistant strain in a secure insectary, to prevent mosquitoes from entering rooms where susceptible mosquitoes are kept as well as preventing them from escaping into the wild.

While it is less common for a colony to change species, there have been incidences where a colony of *An. gambiae* s.s. has later been found to be a colony of *An. coluzzii*. Verification of the species using PCR should therefore also be done quarterly.

The PMI Vector Monitoring and Control Team (VMCT) advises that testing be conducted quarterly as described above to confirm insecticide susceptibility/resistance status and species identification. For those PMI focus countries with insufficient laboratory capacity to characterize mosquito colonies, teams should work with their entomology backstop to find an alternative.

## Entomological Monitoring in Elimination Settings

As areas approach elimination, vector numbers may decline markedly and be characterized by strong geographic heterogeneity. In these settings, standard entomological monitoring is likely to provide limited information to guide programs and therefore should be adapted to the local epidemiological situation. Specific recommendations for entomological monitoring in elimination areas are provided in the chapter on [Elimination](#).

## Entomological Monitoring Supplies

Supplies for entomological monitoring are to be procured via the current central mechanism or a bilateral implementing partner. No entomological monitoring supplies should be budgeted for using the CDC mechanism in FY 2022 malaria operational plans (MOPs), though certain supplies may be provided by CDC (via CDC country entomologists and funded through PMI core funds to the CDC Interagency Agreement (IAA)). Such supplies may include insecticides for susceptibility testing or reagents for molecular analyses (e.g., ELISA or PCR).

## Data Collection and Reporting

All countries with PMI-supported IRS programs and most countries with PMI-supported entomological monitoring programs will begin using a new centralized database developed on the DHIS-2 platform,

known as VectorLink Collect. The DHIS-2 platform allows for near real-time data reporting and enhanced data visualization and analytic opportunities which were not previously available under the legacy database system. NMCPs and government counterparts will also have access to this system to allow for country ownership of vector control data. Currently, the Entomology instance consists of data collection programs focusing on insecticide resistance, insecticide residual life and vector abundance and behavior data. A laboratory instance is under development and expected to be rolled out over the next 12 months. Pre-programmed analytic objects and dashboards will allow for near-real time analysis and reporting to PMI HQ and country governments of key entomological data as it is directly entered into the system.

All insecticide susceptibility data will be available to NMCPs and district and regional malaria control staff in near real-time in VectorLink Collect, but data collected by other sources should also promptly be made available. At minimum, **current susceptibility data should be submitted to PMI 6 months prior to the next spray campaign to allow for evaluation and timely insecticide procurement, and as soon as possible to inform ITN procurement decisions, given lead times for nets can be more than 12 months.**

To complement the new VectorLink Collect system, the Vector Monitoring and Control Team has completed an analysis of available mobile data collection systems for entomology (e.g., EpiInfo Vector, etc.) and plans to develop and pilot top candidates in 2021 to determine if there is an optimal compatible system that could directly feed into the VectorLink Collect database. If countries are planning on using an already existing system, then **please consult with your Operational and Entomology Leads** to ensure that the system can integrate with the database.

The PMI VMCT will work with centrally-managed implementing partners to develop a standard format and recommend frequency of reports, and will publish all final annual entomology reports online for public access once approved by the Mission Activity Manager and PMI HQ COR and made 508 compliant. At minimum, the following should be reported: (1) a report on spray quality, as measured by cone bioassays, within the first few weeks of spraying for quality assurance purposes (i.e., if issues with quality are identified re-spraying may be needed), and (2) semiannual reports highlighting vector bionomics and insecticide susceptibility data to date and results for all basic entomological indicators. Reports should be provided to Missions, PMI headquarters (including Entomology and Operational Leads), and NMCPs. The VMCT recommends that bilateral projects follow similar reporting guidelines PMI country teams should ensure that the PMI Headquarters Entomology and Operational Leads receive all relevant reports from bilateral vector control partners.

Entomological and epidemiological reports (the latter from local health facilities) should be compared and shared by health officials. Some countries have a national Technical Advisory Committee that includes PMI, which can review entomological monitoring data and make recommendations. PMI country teams should ensure that the PMI Headquarters Entomology and Operational Leads receive all relevant entomological information and are involved with these discussions.

---

# INSECTICIDE-TREATED NETS

---

## \*New/Key Messages\*

**Procurement of new types of ITNs:** PMI focus countries should transition to new types of ITNs (e.g., PBO synergist or dual insecticide ITNs) where supported by insecticide resistance monitoring data and as funding allows and in coordination with other donors and national programs.

**Net Transition Initiative (NTI):** The Global Fund’s Net Transition Initiative (NTI) will run from 2021 – 2023 and support transition from the UNITAID-Global Fund New Nets Project (NNP) to Global Fund internal procurement and financing of dual active ingredient nets, spanning the period when WHO policy is expected (mid 2022) and immediately after. The Global Fund will continue to provide some top up funding to some of their grants to support deployment of these more expensive tools, as well as continued evidence building.

**ITN Durability Monitoring:** PMI has supported development of streamlined durability monitoring tools (e.g., protocols, questionnaires, etc.), with an emphasis on new types of nets, for use in countries that already have considerable durability monitoring data. Please contact the PMI Headquarters Vector Monitoring and Control Technical team for details.

## Introduction

Insecticide-treated nets are a core intervention for malaria control and have contributed greatly to the dramatic decline in disease incidence and malaria-related deaths seen since 2000. They are proven to be effective at reducing child mortality, parasite prevalence, and uncomplicated and severe malaria episodes.<sup>24</sup> More than 2 billion ITNs have been delivered since 2004 in malaria endemic countries. The estimated percentage of the at-risk population sleeping under an ITN rose from 30% to 53% between 2010 and 2016. During this time, disease incidence and malaria-related deaths have fallen by 21% and 29%, respectively.<sup>25</sup> Additionally, parasite prevalence in endemic sub-Saharan Africa decreased by 50% between 2001 and 2015, with 68% of this decline attributed to the use of ITNs.<sup>26</sup>

To achieve and maintain ITN coverage, countries should apply a combination of mass net distribution through campaigns and continuous distribution through multiple channels, in particular through antenatal care (ANC) clinics and the expanded programme on immunization (EPI), as well as school-

---

<sup>24</sup> Pryce J, Richardson M, Lengeler C. Insecticide-treated nets for preventing malaria. Cochrane Database of Systematic Reviews 2018, Issue 11. <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000363.pub3/epdf/full>

<sup>25</sup> World Health Organization. Global Technical Strategy for Malaria 2016–2030. Geneva: World Health Organization, 2016.

<sup>26</sup> Bhatt S, Weiss DJ, Cameron E, Bisanzio D, Mappin B, Dalrymple U, et al. The effect of malaria control on *Plasmodium falciparum* in Africa between 2000 and 2015. *Nature* 2015;526(7572):207-11.

based and community distribution. Mass campaigns can rapidly achieve high and equitable coverage. Complementary continuous distribution channels are also required because coverage gaps can start to appear almost immediately post-campaign due to net deterioration, loss of nets, and population growth.<sup>27</sup> See ITN Distribution below.

## PMI ITN Procurement Policy

Current PMI policy requires that ITN products, at minimum, be on the WHO Prequalification (PQ) list of Prequalified Vector Control Products (see full list below) to be eligible for PMI procurements. PMI also reserves the right to apply additional criteria related to label claims, past performance, financial viability and programmatic consistency to qualify ITN products for PMI procurements.

In 2019, WHO released and updated (May 2019) its “Data requirements and protocol for determining non-inferiority of insecticide-treated net and indoor residual spraying products within an established WHO policy class.”<sup>28</sup> The aim of this protocol is to support the generation of entomological data to inform a decision as to whether a candidate insecticide-treated net product should become part of an existing WHO policy class based on equivalency to the innovator net product. These “comparator” products are granted WHO interim or full recommendation status based only on results from WHO chemical laboratory testing. In contrast, to achieve interim recommendation status, an innovator long-lasting ITN must have appropriate lab and field data.

After a technical review, PMI has determined that the equivalency status based only on laboratory studies is insufficient to determine eligibility for PMI procurement because these studies do not determine how the long-lasting ITN product functions in the field where other factors come into play, particularly mosquito behavior around nets. Thus, for those ITN products that have been deemed to be “equivalent” through the PQ conversion process, PMI specifically requires that they have a PQ listing and have demonstrated field effectiveness according to label claims (e.g., against resistant mosquitoes). PMI policy does not currently allow for procurement of the comparator nets unless field testing has been completed. The VMCT will review evidence pertaining to non-inferiority (blood-feeding and mortality indicator) to inform PMI procurement policies.

As of August 2020, WHO has provided a list of current prequalified long-lasting ITN products:<sup>29</sup>

### Pyrethroid Only

- A to Z Textile Mills Limited: Miranet® [*Alpha-cypermethrin*]
- BASF SE: Interceptor® [*Alpha-cypermethrin*]
- Disease Control Technologies: Royal Sentry®, Royal Sentry 2.0® [*Alpha-cypermethrin*]
- Fujian Yamei Industry: Yahe® [*Deltamethrin*]

---

<sup>27</sup> Ibid.

<sup>28</sup> <https://www.who.int/malaria/publications/atoz/non-inferiority-protocol/en/>

<sup>29</sup> WHO Prequalified Products, Vector Control (26 August 2020). <https://www.who.int/pg-vector-control/prequalified-lists/en/>

- Life Ideas Textiles: PandaNet 2.0® [*Deltamethrin*]
- \*Mainpol GmbH: SafeNet® [*Alpha-cypermethrin*]
- Shobikaa Impex Private Limited: Duranet® [*Alpha-cypermethrin*]
- Sumitomo Chemical Co. Ltd.: Olyset® [*Permethrin*]
- \*V.K.A Polymers Pvt. Ltd.: MAGNet [*Alpha-cypermethrin*]
- Vestergaard Frandsen S.A.: PermaNet 2.0® [*Deltamethrin*]
- \*Yorkool: Yorkool® [*Deltamethrin*]
- \*NRS Moon Netting FZE: Tsara® [*Deltamethrin*]
- \*NRS Moon Netting FZE: Tsara Soft®

#### PBO

- Sumitomo Chemical Co. Ltd.: Olyset Plus® [*Permethrin; Piperonyl Butoxide*]
- Vestergaard Frandsen S.A.: PermaNet 3.0® [*Deltamethrin; Piperonyl Butoxide*]
- Shobikaa Impex Private Limited: Duranet Plus® [*Alpha-cypermethrin; Piperonyl Butoxide*]
- \*V.K.A Polymers Pvt. Ltd.: Veeralin® [*Alpha-cypermethrin; Piperonyl butoxide*]
- \*NRS Moon Netting FZE: Tsara Boost® [*Deltamethrin, Piperonyl butoxide*]
- \*NRS Moon Netting FZE: Tsara Plus® [*Deltamethrin, Piperonyl butoxide*]

#### Dual AI

- BASF SE: Interceptor G2® [*Alpha-cypermethrin; chlorfenapyr*]
- Disease Control Technologies: Royal Guard® [*Alpha-cypermethrin; Pyriproxyfen*]

\* Denotes an ITN product not procured by PMI

While these products employ different technical processes for polyester or polyethylene materials, each has been certified by the WHO as being capable of maintaining the full protective effects of an insecticide treated net through a minimum of 20 washes. Furthermore, PMI also supports procurement of long-lasting insecticide-treated hammocks (LLIHNs) for distribution to reach and protect migrant mobile populations (see [Elimination chapter](#) for more information).

## Selection of ITNs in the Context of Pyrethroid Resistance

Emerging insecticide resistance poses a challenge to current malaria vector control methods, as until recently, there were only four classes of insecticide in use for adult malaria vector control (pyrethroids, organochlorines, organophosphates and carbamates). Pyrethroids are the primary insecticides used on ITNs. Resistance to all four classes has been detected in malaria vectors with widespread resistance to pyrethroid insecticides. Based on current entomological data, resistance had been reported in all of the PMI focus countries in sub-Saharan Africa. If the trend of increasing frequency of resistance continues, it may result in a reduction of the effectiveness of pyrethroid-based interventions.<sup>30</sup> Because of this threat, resistance monitoring should be an essential part of every PMI focus country's vector control

<sup>30</sup> Implications of insecticide resistance for malaria vector control with long-lasting insecticidal nets: trends in pyrethroid resistance during a WHO-coordinated multi-country prospective study. *Parasites & Vectors*, 2018. <https://parasitesandvectors.biomedcentral.com/articles/10.1186/s13071-018-3101-4>

strategy. This information will be crucial to better targeting and evaluation of these products in the future. PMI is committed to addressing insecticide resistance by rolling out and rotating new types of nets as they become available. Guidance for entomological and insecticide resistance monitoring are detailed in the [Entomological Monitoring](#) chapter.

In response to increasing pyrethroid resistance, manufacturers have developed new ITNs with additional active ingredients to combat pyrethroid resistance. There are two new types of ITNs that are on the list of WHO Prequalified Vector Control Products: piperonyl butoxide (PBO) synergist nets and dual-insecticide nets. Two trials have demonstrated improved efficacy of pyrethroid-PBO treated ITNs<sup>31,32</sup> and one trial demonstrated improved efficacy of a dual-insecticide (pyriproxyfen and permethrin)<sup>33</sup> ITN. Two dual-insecticide ITNs, the Interceptor G2<sup>34</sup> and Royal Guard<sup>35</sup>, have received WHO PQ approval, though neither has yet received a WHO policy recommendation. The UNITAID New Nets Project (see below) is currently generating additional evidence on the efficacy of these nets to support a WHO policy recommendation. Although WHO has issued interim policy guidance for PBO nets, it has not issued guidance on when to deploy dual-insecticide nets, therefore PMI has separate guidance for each (see below).

## PBO Synergist ITNs

Piperonyl butoxide (PBO) is a synergist that, despite having no insecticidal activity on its own, enhances the potency of certain insecticides. PBO inhibits the natural defense mechanisms of the insect, the most important being the mixed function oxidase system (MFOs), also known as cytochrome P450 mono-oxidases. The MFO system is the primary route of detoxification in insects, causing the oxidative breakdown of insecticides like pyrethroids. Most pyrethroid-resistant populations of mosquitoes have elevated levels of MFOs. There is some evidence to indicate that mosquito populations with high pyrethroid resistance have multiple resistance mechanisms, making PBO less useful against these populations.

---

<sup>31</sup> Protopopoff N, Moshia JF, Lukole E, Charlwood JD, Wright A, Mwalimu CD, et al. Effectiveness of a long-lasting piperonyl butoxide-treated insecticidal net and indoor residual spray interventions, separately and together, against malaria transmitted by pyrethroid-resistant mosquitoes: a cluster, randomised controlled, two-by-two factorial design trial. *Lancet*. 2018;391:1577–88.

<sup>32</sup> Staedke SG, Gonahasa S, Dorsey G, Kanya MR, Maiteki-Sebuguzi C, Lynd A, Katureebe A, Kyohere M, Mutungi P, Kigozi SP, Opigo J, Hemingway J, Donnelly MJ. Effect of long-lasting insecticidal nets with and without piperonyl butoxide on malaria indicators in Uganda (LLINEUP): a pragmatic, cluster-randomised trial embedded in a national LLIN distribution campaign. *Lancet*. 2020: 395:1292-1303.

<sup>33</sup> Tiono AB, Ouedraogo A, Ouattara D, Bougouma EC, Coulibaly S, Diarra A, et al. Efficacy of Olyset Duo, a bednet containing pyriproxyfen and permethrin, versus a permethrin-only net against clinical malaria in an area with highly pyrethroid-resistant vectors in rural Burkina Faso: a cluster-randomised controlled trial. *Lancet*. 2018. [https://doi.org/10.1016/S0140-6736\(18\)31711-2](https://doi.org/10.1016/S0140-6736(18)31711-2)

<sup>34</sup> N'Guessan R, Odjo A, Ngufor C, Malone D, Rowland M. A Chlorfenapyr Mixture Net Interceptor(R) G2 shows high efficacy and wash durability against resistant mosquitoes in West Africa. *PLoS One*. 2016;11:e0165925.

<sup>35</sup> Efficacy of Three Novel Bi-treated Long Lasting Insecticidal Nets. <https://clinicaltrials.gov/ct2/show/NCT03554616>

In 2015, the WHO Global Malaria Program convened an Evidence Review Group on PBO ITNs to review data from numerous laboratory studies, nine experimental hut trials, and six village-level trials with entomological endpoints. The studies provided mixed results, and the Evidence Review Group concluded that the limited evidence did not justify a switch to PBO nets, but was sufficient to justify limited, pilot “exploratory” implementation of PBO nets accompanied by robust evaluation of impact with both entomological and epidemiological indicators. This evidence was recently supplemented by a cluster-randomized trial in Tanzania with epidemiological endpoints. Based on the positive results of this trial, in September 2017 (and updated December 2017) WHO/Global Malaria Programme provided PBO ITNs an interim endorsement as a new class of vector control products.<sup>36</sup> Data from a recently completed trial in Uganda also demonstrated reductions in parasite prevalence among users of PBO ITNs although WHO has yet to update their recommendations for these products.<sup>37</sup> Meanwhile, as stated by WHO’s policy guidance, “all pyrethroid-PBO nets that have a WHO prequalification listing (Permanet 3.0, Olyset Plus, Dawa 3.0, Dawa 4.0, and Veeralin) will be considered to be at least as effective at preventing malaria infections as pyrethroid-only ITNs, and possibly more effective in areas of low-to-moderate pyrethroid resistance.” WHO’s policy recommendation does not consider PBO ITNs to be a tool to effectively manage insecticide resistance in malaria vectors.

PMI will procure PBO ITNs following the data requirements outlined in the December 2017 WHO policy. The following data should be collected at the district or regional level where PBO ITNs are being considered:

- Current insecticide resistance data (collected within the past two years) confirming moderate to high pyrethroid resistance in the main malaria vector(s).
- Evidence that PBO increases pyrethroid susceptibility by at least 10% by assessing mortality rate differences (i.e., in absolute terms) from susceptibility assays comparing pyrethroid + PBO exposure groups with pyrethroid only exposure groups
- Documented moderate to high malaria prevalence (>20%) in children 2 – 10 years old using existing data sources.

## Dual-Insecticide ITNs

Dual-insecticide nets are ITNs that have two active ingredients. While the only dual-insecticide nets currently available still contain a pyrethroid, it is expected that soon this class will include nets with two different AIs, neither of which is a pyrethroid. Unlike PBO, which is only a synergist, both active ingredients in dual-insecticide nets are insecticides that can individually kill or inhibit reproduction of mosquitoes. The combination of two insecticides can potentially decrease the emergence of resistance,

---

<sup>36</sup> Conditions for deployment of mosquito nets treated with a pyrethroid and piperonyl butoxide, September 2017. Geneva: World Health Organization; 2017. <http://apps.who.int/iris/bitstream/10665/258939/1/WHO-HTM-GMP-2017.17-eng.pdf>

<sup>37</sup> Staedke SG, Gonahasa S, Dorsey G, Kanya MR, Maiteki-Sebuguzi C, Lynd A, Katureebe A, Kyohere M, Mutungi P, Kigozi SP, Opigo J, Hemingway J, Donnelly MJ. Effect of long-lasting insecticidal nets with and without piperonyl butoxide on malaria indicators in Uganda (LLINEUP): a pragmatic, cluster-randomised trial embedded in a national LLIN distribution campaign. *Lancet*. 2020; 395:1292-1303.

as mosquitoes resistant to one insecticide may still be susceptible to the other. There are currently two dual-insecticide ITNs that have received WHO PQ approval, though neither has received a WHO policy recommendation: the Interceptor G2 and Royal Guard. The Interceptor G2 has a combination of alphacypermethrin, a pyrethroid, and chlorfenapyr, a slower-acting insecticide that targets energy production in the mitochondria. The Royal Guard has a combination of alphacypermethrin and pyriproxyfen, an insect growth regulator that reduces fecundity of female mosquitoes and may also reduce their blood feeding and longevity.

The New Nets Project (NNP) was launched in 2018, jointly funded by Unitaid and Global Fund with additional support from the Bill and Melinda Gates Foundation and the President's Malaria Initiative. NNP, which runs through 2022, has the goal of increasing access to newly developed dual-AI ITNs (i.e., Interceptor® G2 and Royal Guard®). IVCC created a consortium of partners to ensure the rapid deployment of new dual-AI nets to a limited number of partner countries where a combination of randomized controlled trials in Benin and Tanzania, and effectiveness pilots in Burkina Faso, Rwanda, Mozambique, Nigeria, and Mali, seek to establish the impact and cost-effectiveness data needed for a World Health Organization (WHO) policy recommendation that would be required for scale-up. In addition, the Bill & Melinda Gates Foundation, in collaboration with MedAccess, entered into a volume guarantee agreement with BASF to offer reduced Interceptor® G2 pricing for the effectiveness, as well as operational pilots. The volume guarantee combined with a co-payment from NNP will enable countries to procure Interceptor® G2 for pilot deployments within their current net budgets through 2022, at which point pricing will drop to levels no longer requiring co-payment. Current operational pilot countries include Cameroon, Côte d'Ivoire, DRC, Ghana, Liberia, Malawi, and Niger. The Global Fund's Net Transition Initiative (NTI) will run from 2021 - 2023 and support transition from the NNP to Global Fund internal procurement and financing of dual active ingredient nets.

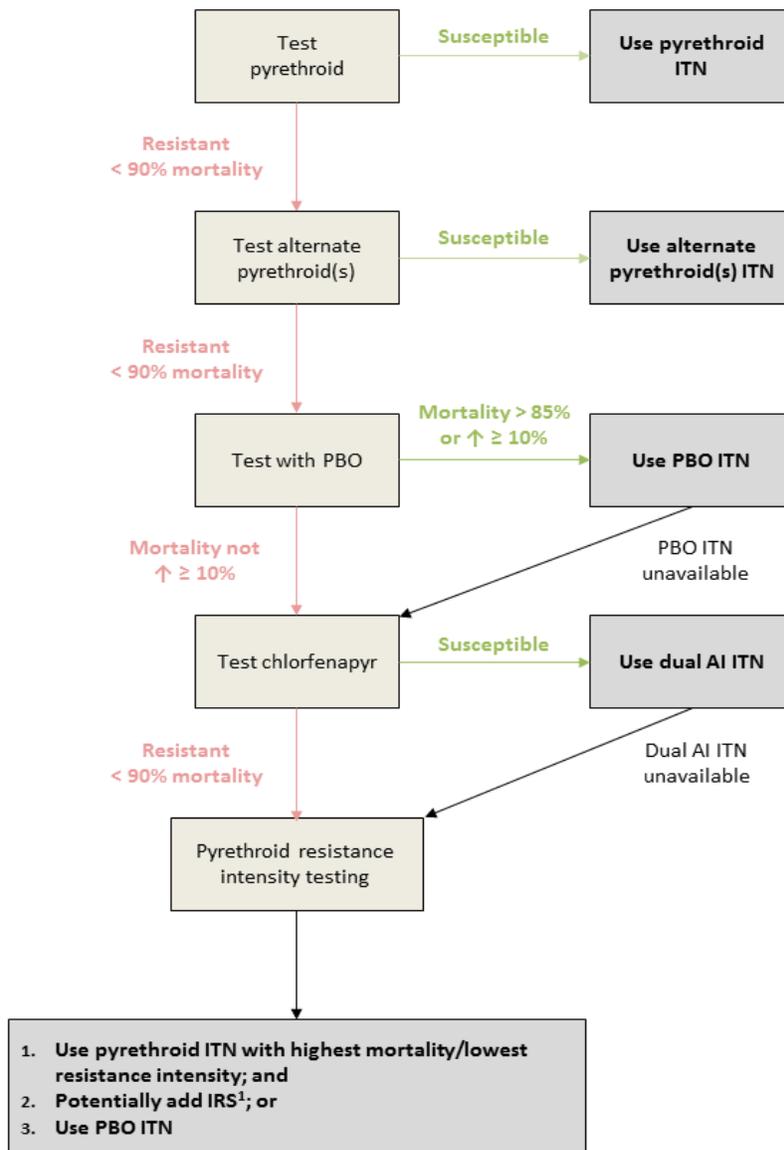
## Considerations for Selection and Deployment of New Types of ITNs

PMI focus countries that are planning to deploy new types of nets should consider the following:

- Ability to collect entomological data and routine health facility data in the geographic areas of deployment.
- Current evidence does not indicate added benefit of co-deployment of new types of ITNs with IRS and is currently not recommended by PMI except in the context of OR/PE.
- As new types of ITNs are currently more expensive than pyrethroid-only ITNs, the benefit of these ITNs must be weighed against a potential decrease of overall ITN coverage.

Insecticide resistance data and these criteria should be discussed with PMI HQ Entomology and Operational Leads in conjunction with country stakeholders (i.e., NMCPs, other donors, implementing partners, entomology institutions) to select the most appropriate type of net using the decision tree below. If NMCPs or malaria partners are procuring PBO or dual-insecticide nets with non-PMI funding, please contact the PMI VMCT team to identify the appropriate partnership role PMI may play.

**Decision Tree for Selection of ITNs Based on Insecticide Resistance Monitoring Data**



<sup>1</sup> See IRS chapter for guidance on IRS insecticide selection

## Cost of ITNs

Cost assumptions for FY 2021 ITN procurements are provided in the [Commodity Procurement](#) chapter. The costs provided there include the purchase price of the net itself, freight (which includes insurance and may include in-country delivery beyond the port of entry from port to destination), and quality assurance. However, the related procurement costs do not include warehousing. There is great variability across countries as to what the government can provide as opposed to what PMI supports via partners (e.g., in some countries warehousing is provided by the government and the partner is only

responsible for distribution costs, whereas in others the partner is responsible for both warehousing and in-country distribution). Therefore, warehousing -- whether temporary for mass campaigns or long-term for routine distribution -- needs to be factored into the “additional costs.”

Furthermore, there are additional costs related to the type of distribution channel used. For mass distribution campaigns, it is also important to budget for specific logistical support to transport the ITNs to the district level and from the district level to the distribution points, post-campaign support activities, targeted SBC efforts, household registrations, etc. The distribution costs for ITN mass campaigns in sub-Saharan African countries ranged from \$0.38 to \$7.91 (median \$2.27) per net, but the lowest costs were for integrated campaigns (e.g. immunization, SMC) where logistics costs were shared with other interventions. Median financial costs for a free-standing ITN distribution (of any kind) of more than 5 million ITNs were about \$2.00.

For continuous distribution efforts, countries should budget adequate funds to support logistics of distributing the nets to the districts and points of service on an ongoing/periodic basis, appropriate communication efforts, and appropriate supervision and monitoring efforts. The costs for delivery of ITNs provided free of charge through continuous distribution through schools, communities, or health facilities ranged from \$0.77 to \$9.94 (median about \$2.72).<sup>38</sup>

## **ITN Ownership: Key Distribution Channels**

### ***Mass distribution campaigns***

To rapidly and equitably achieve coverage with ITNs, PMI and many other donors support free-standing, mass distribution campaigns designed to reach every household in malarious areas.

In line with current Global Fund guidance that a net life-span of three years should be assumed, PMI will only support campaigns more or less frequently if local evidence exists and the country demonstrates commitment to more frequent ITN campaigns through its resource prioritization. While data in some places may demonstrate that ITNs are lasting less than three years, in general, it is likely not feasible from a resource perspective alone to shorten the cadence of mass distribution campaigns. Data should be used to bolster support for increased continuous distribution to complement mass distributions (e.g., bolstered ANC/EPI, introducing or expanding, school-based or community distribution, etc.). Countries interested in piloting new channels of distribution should contact the PMI VMCT.

Consistent with Global Fund’s operational considerations, PMI continues to recommend calculating the total amount of ITNs needed for a mass campaign distribution by dividing the total target population by 1.8. This macro-quantification calculation will estimate the minimum number of ITNs needed to provide an ITN- to-person ratio of 1:2. In places where the most recent population census was conducted more

---

<sup>38</sup> Wisniewski et al. Systematic review and meta-analysis of the cost and cost-effectiveness of distributing insecticide-treated nets for the prevention of malaria. Acta Tropica February 2020. <https://pubmed.ncbi.nlm.nih.gov/31669182/>

than five years prior, countries can consider including a buffer (e.g., adding 10% after the 1.8 ratio has been applied) or using data from previous mass campaigns to justify an alternative total amount.<sup>39</sup>

As per WHO recommendations and in line with Global Fund operational recommendations, PMI generally does not support:

- Storage (more than two weeks) of ITNs in containers<sup>40</sup>
- Mop up campaigns
- Hang up campaigns
- Non-essential data collection (e.g. post-distribution monitoring or “check-ups” sometimes required by other partners)

PMI builds capacity in countries to manage and implement ITN mass distribution campaigns. Thus, in PMI focus countries where in-country capacity exists, teams should look first to local partners to lead implementation of mass campaigns. If technical assistance is not available at the country level for campaigns, PMI works with the RBM Partnership to End Malaria Country/Regional Support Partner Committee (CRSPC) to ensure that external technical assistance can be supported. If an NMCP would like to request external TA for an upcoming mass campaign, they should follow the process outlined on the CRSPC website:

Further information on mass campaigns, including a comprehensive toolkit are available through the Alliance for Malaria Prevention (AMP) website at: <http://allianceformalariaprevention.com/amp-tools/amp-toolkit/>.

### ***Continuous distribution channels***

Continuous supply of nets is needed to address: (a) those missed by a mass campaign; (b) new entries to the population by birth or immigration; and (c) the physical deterioration of existing nets. A mix of channels may be necessary to maintain a sufficiently high coverage over time. Not all channels are appropriate in all country contexts, and careful planning is needed to identify the optimal combination of continuous channels that will be most effective.

The ITN continuous distribution eToolkit helps planners review delivery options and needs for their setting. It can be accessed at the following website: <https://continuousdistribution.org/>. Along with documents to guide planning and implementation, the website also includes case studies of various delivery models in different settings, and access to many implementation materials used in these case studies.

---

<sup>39</sup> Global Fund, Malaria Information Note, 25 July, 2019.

[https://www.theglobalfund.org/media/4768/core\\_malaria\\_infonote\\_en.pdf?u=637066545970000000](https://www.theglobalfund.org/media/4768/core_malaria_infonote_en.pdf?u=637066545970000000)

<sup>40</sup> See: Alliance for Malaria Prevention. Use of containers to store insecticide-treated nets: operational concerns and considerations. <https://allianceformalariaprevention.com/wp-content/uploads/2020/03/Use-of-containers-to-store-insecticide-treated-nets-operational-concerns-and-considerations.pdf>

Results from an analysis of costs of ANC, EPI, school, community, and mass distributions suggest that continuous distribution strategies can continue to deliver nets at a comparable cost to mass distributions, especially from the perspective of the donor.<sup>41</sup>

### **Routine distribution of ITNs through public-sector antenatal care (ANC) and expanded program on immunization (EPI) vaccination clinics**

Routine distribution of ITNs through public-sector<sup>42</sup> ANC and EPI vaccination clinics targets the most vulnerable groups in the population: pregnant women and children less than five years of age. There is some evidence that these channels also serve as an incentive and thereby increase clinic attendance. In most countries the nets are given free-of-charge, but may also be sold at highly subsidized prices. However, distribution of ITNs through these two channels is not sufficient alone to maintain ownership levels achieved through mass distribution campaigns.

### **School-based distribution channels**

A number of countries now use schools as a channel for delivery of ITNs, as this channel can inject large numbers of ITNs into communities throughout the country on an annual basis. Ghana, Nigeria, Tanzania, and Senegal have carried out school-based ITN deliveries at scale. In Tanzania, the school net program (SNP) has proven to be a feasible and effective strategy for maintaining consistently high coverage.<sup>43</sup> Some smaller school-based distribution pilots have also been conducted (e.g., Guinea, Mozambique). School-based distribution should be considered a viable channel in certain circumstances (including high gross school attendance rate and strong commitment of local health and education officials). A school-based channel requires a large amount of coordination between the ministries of health and education (among others) and may not be appropriate or feasible in some countries or sub-regions. In addition, PMI does not recommend conducting both school and community-based distribution due to potential oversupply (see below).

### **Community-based distribution channels**

Community-based distribution makes ITNs available on a continuous basis to community members who meet certain established criteria. Eligible people may approach community agents who distribute

---

<sup>41</sup> Scates et al. Costs of insecticide-treated bed net distribution systems in sub-Saharan Africa. *Malaria Journal* 2020. <https://malariajournal.biomedcentral.com/articles/10.1186/s12936-020-03164-1>

<sup>42</sup> The range of facilities considered to be part of the public sector will differ by country, but includes government-managed facilities that provide public health services specifically for the general population, as well as public health organizations (typically non-government and faith-based) that provide public health services for the general population on behalf of the government. In some countries, partnerships with private sector facilities may also be considered part of the public health sector, if they provide specific services in accordance with public sector policies (e.g., malaria prevention and curative services for free) and on behalf of the government.

<sup>43</sup> Yukich et al. Sustaining LLIN coverage with continuous distribution: the school net programme in Tanzania. *Malaria Journal*. April 2020. <https://malariajournal.biomedcentral.com/articles/10.1186/s12936-020-03222-8>

coupons that can be redeemed for an ITN at a nearby redemption point (e.g., health facility or other designated storage facility). This channel is most commonly used as a “pull” channel (i.e., a request by a household for a new ITN or additional nets initiates the process). As such, it can help expand the pull component of an overall ITN strategy, which often is largely made up of “push” models (such as ANC clinics) where distribution is driven by attendance of a specific service.

### Other continuous distribution channels

Other potential continuous channels include:

- Social marketing
- Commercial sales
- Child Health Days
- A private-sector E-coupon program.

## ITN Indicators

In 2018, the RBM Monitoring and Evaluation Reference Group updated the guidance on standard indicators from household surveys to measure ITN ownership, access, and use. The following indicators are currently included in all household surveys in endemic countries (MIS, DHS, and MICS).<sup>44</sup>

- Proportion of households with at least one ITN
- Proportion of households with at least one ITN for every two people
- Proportion of population with access to an ITN within their household
- Proportion of individuals who slept under an ITN the previous night
- Proportion of existing ITNs used the previous night

These indicators enable countries to measure household ownership of ITNs, full coverage of ITNs within households, access to ITNs at the population level, and use of ITNs at the population level. The persistent and widespread gap between ownership and use has been a major concern in the malaria community for several years. However, studies as early as 2009<sup>45</sup> demonstrated that the greatest determinant of use of an ITN was ownership. More recent studies supported by PMI have refined that finding and more clearly demonstrated that the persistent and often large gap between ownership and use is frequently due to too few ITNs in the households rather than individual choice to not use an

---

<sup>44</sup> MEASURE Evaluation, MEASURE DHS, President’s Malaria Initiative, RBM Partnership to End Malaria, UNICEF, World Health Organization. Household survey indicators for malaria control. 2018.

[https://www.malariasurveys.org/documents/Household%20Survey%20Indicators%20for%20Malaria%20Control\\_FINAL.pdf](https://www.malariasurveys.org/documents/Household%20Survey%20Indicators%20for%20Malaria%20Control_FINAL.pdf)

<sup>45</sup> Assessment of insecticide-treated bednet use among children and pregnant women across 15 countries using standardized national surveys. Eisele TP, et al., 2009. *Am Journal Trop Med Hyg*, 80:209-214

ITN.<sup>46, 47</sup> The ITN access indicator measures the proportion of the population that could sleep under an ITN if every ITN available in the household were used by two people. (For more information on calculation of this indicator, see the indicator snapshot video at: <https://www.youtube.com/watch?v=YfTXcc13GOI>. Understood together, The population access and use indicators allow data users to distinguish non-use related to access to an ITN from that linked to behavior.

PMI funds secondary analysis of DHS and MIS data from all focus countries to calculate the ratio of use to access, to provide teams with insight into whether there is a behavioral gap for net use that requires shifts in behavioral factors rather than a gap because not enough nets are available. This analysis, which looks at trends in ITN access and use over time and by various sociodemographic characteristics within countries can be found at <https://breakthroughactionandresearch.org/resources/itn-use-and-access-report/>

## Care of ITNs

Social and behavior change (SBC) for increased net usage and good net care is critical. Studies confirm that SBC interventions are effective at increasing use of ITNs among targeted populations. The Malaria SBCC Indicator Reference Guide: Second Edition (2017)<sup>48</sup> is a resource to strengthen the evaluation of the effectiveness of malaria SBC interventions and to measure levels of behavior change for malaria prevention and case management at the country level. Another standardized tool to measure malaria-related behaviors and associated behavioral factors is the [Malaria Behavior Survey \(MBS\)](#)<sup>49</sup>. This is a cross-sectional household survey that provides critical data to inform the design, implementation, and evaluation of SBC interventions and can play a role in guiding decisions about the behaviors and behavioral factors programs should prioritize, such as net care (See [SBC Chapter](#) for additional information).

Net care should continue to be a priority component of SBC activities; having very positive attitudes toward net care has been shown to have a protective effect on ITN durability.<sup>50</sup> Results from durability monitoring studies show that differences in median survival could be attributed at least in part to household environment and net care behaviors, so targeted social and behaviour change activities to encourage net care and retention should be considered.<sup>51</sup>

---

<sup>46</sup> Universal coverage with insecticide-treated nets-applying the revised indicators for ownership and use to the Nigeria 2010 malaria indicator survey data. 2013. Kilian A, et al., *Malaria Jour*, 12:314.

<sup>47</sup> Recalculating the net use gap: a multi-country comparison of ITN use versus ITN access. 2014. Koenker, H and Kilian, A, *PLoS ONE*, 21;9(5):e97496.

<sup>48</sup> <http://www.rollbackmalaria.org/files/files/resources/Malaria-BCC-Indicators-Reference-Guide.pdf>

<sup>49</sup> <http://malariabehaviorsurvey.org/>

<sup>50</sup> Impact of a behaviour change intervention on long-lasting insecticidal net care and repair behaviour and net condition in Nasarawa State, Nigeria and Impact of a behaviour change communication programme on net durability in eastern Uganda

<sup>51</sup> Abilio et al. Monitoring the durability of the long-lasting insecticidal nets MAGNet and Royal Sentry in three ecological zones of Mozambique. *Malaria Journal* 2020. <https://pubmed.ncbi.nlm.nih.gov/32552819/>

PMI continues to promote guidance on net care and use (including reference to misuse and outdoor sleeping); see: Social and Behavior Change for Insecticide-Treated Nets (2019) document. PMI has funded an operational research study in Nigeria and Uganda to understand the knowledge, attitudes, beliefs, and practices that motivate or impede net care and repair behaviors used findings to test the effectiveness of a behavior change communication intervention. Based on these results,<sup>52,53</sup> PMI will not support repair activities (e.g., distribution of ITN repair kits, social mobilization promoting ITN repair efforts, etc.).

SBC activities focused on comprehensive ITN care should emphasize preventive behaviors, such as:

- Tie up the net every day to keep it away from foot traffic and dirt.
- Keep children away from the net.
- Avoid storing food or crops in the same room.
- Fold and store the net safely when not in use.

SBC should promote improving overall care of ITNs at the household level and delaying the development of holes for as long as possible. Incorporating Net Care into Malaria SBCC Strategies: A Step-by-step Guide describes how to integrate activities to promote net care behaviors into existing ITN social and behavior change communication (SBCC) strategies or other platforms.<sup>54</sup>

Reinforcing ITN care behavior should not be a separate activity, as it is easily integrated into existing malaria-related SBC efforts. Messages about ITN care can be included simply by adding a radio spot, updating content within job aids, and including the messages during trainings with community health workers already working on malaria. Messages should be included at the time of ITN distribution and communicated continuously to net users. The cost of integrating care messages into larger malaria SBC efforts is minimal: these are simple, inexpensive, and feasible actions that can be added into existing platforms and do not require new, stand-alone communication efforts. The Nigeria and Uganda studies showed that these simple messages are very likely to result in longer life of nets and better protection of families.

Furthermore, SBC is particularly important for countries that are implementing multi-product campaigns. It should be emphasized that all nets being distributed are effective. Maps or other visual communication materials can facilitate understanding by non-technical audiences. Do not refer to

---

<sup>52</sup> Koenker H, Kilian A, Hunter G. Impact of a Behaviour Change Intervention on Long-Lasting Insecticidal Net Care and Repair Behaviour and Net Condition in Nasarawa State, Nigeria. *Malaria J*, 2015, 14:18. Accessed at: <http://www.malariajournal.com/content/14/1/18>

<sup>53</sup> Helinski M, Namaral G, Koenker H, et al. Impact of a Behaviour Change Communication Programme on Net Durability in Eastern Uganda, *Malaria J*, 2015, 14:366. Accessed at: <http://www.malariajournal.com/content/14/1/366>

<sup>54</sup> Gabrielle C. Hunter, Angela Acosta and Hannah Koenker. Incorporating Net Care into Malaria SBCC Strategies: A Step-by-step Guide. VectorWorks Project, Johns Hopkins Bloomberg School of Public Health Center for Communication Programs. 2016. <https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/incorporating-net-care-into-malaria-social-and-behavior-change-communication-strategies-a-step-by-step-guide.pdf?sfvrsn=7>

certain nets as “better” or “next generation” which infers inferiority of other nets. For more detail, refer to Planning and Operational Recommendations for Multi-Product ITN Campaigns.

## Environment Risks of ITN Disposal, Misuse, and Repurposing

### *Disposal*

Noting the potential environmental impact related to the disposal of nets, in n 2019, WHO released *Guidelines for Malaria Vector Control* which recommends the following:

- Residents should be advised to continue using nets beyond the three-year anticipated lifespan of the net, irrespective of the condition of the net, until a replacement net is available.
- Residents should be advised not to dispose of ITNs in any water body, or use ITNs for fishing.
- In general, retrieval of old nets from households is not recommended. Old ITNs should only be collected where there is assurance that: i) new ITNs are distributed to replace old ones; and ii) there is a suitable plan in place for safe disposal of the collected material.
- Collecting old ITNs should not divert effort from core duties. If ITNs and packaging are collected, the best option is high-temperature incineration, not burning in open air. In the absence of appropriate facilities, they should be buried away from water sources and preferably in non-permeable soil.

WHO found that recycling and incineration were not practical or cost-effective in most settings at this time, confirming the results from PMI’s experience in piloting a recycling effort in Madagascar in 2010.<sup>55</sup>

Two important and potentially hazardous practices are: i) routinely removing ITNs from bags at the point of distribution and burning discarded bags and old nets, which can produce highly toxic fumes including dioxins, and ii) discarding old ITNs and their packaging in water, as they may contain high concentrations of residual insecticides that are toxic to aquatic organisms, particularly fish.

It is important to determine whether the environmental benefits outweigh the costs when identifying the best disposal option for old ITNs and their packaging. For malaria programs in most endemic countries, there are limited options for dealing with the collection. In most malaria-endemic countries,

---

<sup>55</sup> In 2010, USAID sponsored a recycling pilot in Madagascar. This looked at several key factors including recovery, transporting, and parameters for converting expired ITNs into a viable alternative product. It was determined that the technology required for this process was not available in Madagascar, and that the cost to ship ITNs back to the US for processing was prohibitively high. Outside of this one recycling pilot, there is no evidence that large quantities of ITNs have ever been collected for disposal, nor has evidence been presented that there is a positive outcome in collecting ITNs for disposal. Most expired ITNs remain at the site and are either repurposed or disposed of at a household level. Please see: Nelson, Michelle, Ralph Rack, Chris Warren, Gilles Rebour, Zachary Clarke, and Avotiana Rakotomanga. 2011. *LLIN Recycling Pilot project, Report on Phase II in Madagascar*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3. AND Nelson, Michelle, and Ralph Rack. 2012. *Madagascar: LLIN Recycling Pilot Project, Report on Phase III*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 7. Both reports can be downloaded at: [http://deliver.jsi.com/dhome/search?p\\_search\\_tok=madagascar+recycling&btnG=search](http://deliver.jsi.com/dhome/search?p_search_tok=madagascar+recycling&btnG=search)

recycling is not currently a practical option and high-temperature incineration is difficult and expensive. If plastic material is left in the community, it is likely to be re-used in a variety of ways. While the insecticide-exposure entailed by this kind of re-use has not yet been fully studied, the expected negative health and environmental impacts of leaving it in the community are considered less than amassing the waste in one location and/or burning it in the open air. Since the material from nets represents only a small proportion of total plastic consumption, it will often be more efficient for old ITNs to be dealt with as part of more general solid-waste programmes. National environment management authorities have an obligation to plan for what happens to old ITNs and packing materials in the environment in collaboration with other relevant partners.

## **Misuse**

Misuse is defined as the use of a viable ITN for purposes other than its intended use as a bednet. Misuse of ITNs is not acceptable under any circumstances and not only defeats the public health purpose of providing protection from malaria, but can also have negative environmental outcomes. The most ecologically damaging use of ITNs is for fishing. Pyrethroids can kill fish, especially young fish, aquatic crustaceans, and insects when leached from a viable ITN being used for fishing. The fine mesh of treated or untreated mosquito nets may also cause ecological damage by physically removing many small aquatic animals from an area. This is less of an issue in larger bodies of water but can be a significant problem in small streams and ponds. There are no other known misuses of viable ITNs that pose serious environmental risks. Evidence in the literature indicates that misuse of ITNs can be a problem, usually in fishing communities, and multi-sectoral efforts should be made to address these situations. However, there is “very little evidence to support claims of widespread misuse across Africa.”<sup>56,57</sup> A 2017 qualitative study in Malawi showed that the drivers of mosquito net fishing are a combination of a struggling economy and food insecurity, as people are forced to sell their belongings for money and/or food.<sup>58</sup> Other studies, such as those from lakeside communities in Lake Tanganyika and a refugee camp in the DRC reinforce the drivers identified in Malawi; ITNs are being sold to generate income to support immediate food needs.<sup>59 60 61</sup> While anecdotal reports of mosquito net fishing are growing, the magnitude of the problem remains unclear.

---

<sup>56</sup> Eisele TP, Thwing J, Keating J. Claims about the Misuse of Insecticide-Treated Mosquito Nets: Are These Evidenced Based? 2011, Plos Med 8(4): E1001019. DOI:10.1371/journal.pmed.1001019

<sup>57</sup> Koenker, H, et al, “What happens to lost nets: a multi-country analysis of reasons for LLIN attrition using 14 household surveys in four countries” 2014, Malaria Journal 13(464) DOI: 10.1186/1475-2875-13-464

<sup>58</sup> Berthe S, Jumbe V, Harvey S, Kaunda-Khangamwa B, and Mathanga D. 2017. Climate change, poverty and hunger: Drivers behind the misuse of ITNs for fishing in Malawi. Poster presented at ASTMH.

<sup>59</sup> Brooks HM, Jean Paul MK, Claude KM, Mocanu V, Hawkes MT. 2017. “Use and disuse of malaria bed nets in an internally displaced persons camp in the Democratic Republic of the Congo: A mixed-methods study.” PLoS ONE, 12(9):e0185290. doi: 10.1371/journal.pone.0185290.

<sup>60</sup> McLean KA, Byanaku A, Kubikonse A, Tshowe V, Katensi S, Lehman AG. 2014. “Fishing with bed nets on Lake Tanganyika: A randomized survey.” Malaria Journal, 13(1):395. doi: 10.1186/1475-2875-13-395.

<sup>61</sup> Short R, Gurung R, Rowcliffe M, Hill N, Milner-Gulland EJ. 2018. “The use of mosquito nets in fisheries: A global perspective.” PLoS One, 13(1):e0191519. doi: 10.1371/journal.pone.0191519

SBC interventions can address ITN misuse by expanding traditional messages about correct and consistent net use to show the shrinking sizes of fish species that may result from fishing with small mesh ITNs. However, opportunities also exist through collaboration with other entities (e.g., fishery conservation programs), as they can help enforce laws against illegal fishing gear, work to educate the fishing community about the threats to fisheries caused by small mesh nets and promote other strategies to support immediate food needs.

PMI has supported the development of a toolkit, *Identifying and Mitigating Misuse of Insecticide-Treated Nets for Fishing*. The purpose of this toolkit is to assist USAID Missions, donors, or implementing partners to conduct a rapid assessment in areas where potential ITN misuse for fishing has been observed.

### **Repurposing**

Repurposing is defined as the use of expired, non-viable ITNs for purposes other than as a bednet. Because expired ITNs likely have minimal ability to protect against malaria, repurposing is generally not an environmental hazard. There are numerous anecdotal reports on innovative and acceptable uses for expired ITNs. The only alternative use that is never acceptable is fishing. Although old nets likely have lower doses of insecticide, it is still recommended that care be taken in repurposing of nets. Old nets should not be used around food storage or in ways that would result in excessive contact with human skin such as bridal veils or for swaddling young infants.

In 2018, RBM issued a *Consensus Statement on Repurposing ITNs: Applications for BCC Messaging and Actions at the Country Level*<sup>62</sup> to provide National Malaria Control/Elimination Programs (NMCPs) and implementing partners with clear recommendations and key messages on three categories of repurposing: beneficial repurposing, neutral repurposing, and misuse:

- **Beneficial repurposing** is the use of inactive ITNs for purposes other than for sleeping under to protect against malaria infection. It is considered beneficial because the ITN material continues to act as a barrier against mosquitos. Examples of beneficial repurposing include using old or inactive ITNs as curtains, patches for holes in viable nets, stuffing eaves, and constructing window or door screening.
- **Neutral repurposing** is the use of inactive ITNs for household uses that do not prevent mosquito bites. Examples include covering latrines, protecting seedlings, fencing, transporting and storing crops, screening of poultry or animal enclosures, soccer goals, tearing into strips for tying objects, and other household uses.
- **Misuse** is the use of an active ITN for purposes other than its intended use as a bed net to protect against malaria infection, with added environmental harm. Using a new or old ITN—

---

<sup>62</sup> <https://endmalaria.org/sites/default/files/Consensus%20Statement%20on%20Repurposing%20ITNs.pdf>

one that is still useful for sleeping under—for another purpose is misuse. Using any ITN, whether new, old, or inactive, for fishing, is the prime example of misuse.

## Durability Monitoring

### *Introduction*

ITN durability monitoring aims to provide programs with information needed to optimize their procurement, delivery, and effectiveness. Monitoring allows programs to identify products that perform below expectations; it also provides useful feedback to manufacturers in their efforts to improve their products. While a rule of thumb that nets should be replaced every three years is commonly followed, field studies have shown that the durability of ITNs varies within and among countries, and that the durability of different types of nets may also vary. This variation is attributed to various behavioral, mechanical, and chemical elements so country-specific information is thus useful for guiding procurement and programmatic decisions made by NMCPs and PMI.

Similar to monitoring of drug efficacy and insecticide sensitivity, ITN monitoring must compromise between cost and optimal sampling. The diversity of ITN types, environmental circumstances, and cultural practices make exhaustive sampling impractical; however, it is possible and cost-effective to obtain representative data on the major types of ITN distributed.

ITN durability monitoring measures the effect of normal daily use on: attrition [as measured by the loss of nets for any reason as well as due to wear and tear from households]; physical durability [as measured by the number and size of holes in the net]; and insecticide effectiveness, [as measured by cone bioassays, tunnel tests, and chemical content analysis, depending on type of net]. These are best monitored in a prospective design linked to a mass ITN distribution campaign. Final results of durability monitoring (upon completion of 36-month report) are made publicly available via [pmi.gov](https://www.pmi.gov) and <https://www.durabilitymonitoring.org/>. All PMI-funded durability monitoring activities should follow the study protocols, questionnaires, and other tools available via <https://www.durabilitymonitoring.org/>

### *Should ITN durability monitoring be carried out?*

PMI funding may be used to support DM in the following circumstances:

- In countries that have never implemented durability monitoring (and large countries with expected differences due to ecological, social, etc.).
- In countries that have implemented durability monitoring and where significant issues with ITN durability have been identified.
- To monitor new types of nets (e.g., PBO synergist or dual insecticide ITNs). While there is little reason to believe that the physical durability of nets with new active ingredients will be different than that of standard nets in the same context, understanding how long the active ingredients

are effective on these nets is important. For these new types of nets, it will most likely suffice to monitor chemical and bioassay aspects (see below).

In general, PMI will not support durability monitoring of products for which data have already been collected in-country. If a country has carried out multiple rounds of durability monitoring in the past, the country team should engage the NMCP and other stakeholders to determine what questions remain for the country and to justify additional investment of resources. PMI recommends either monitoring one type of net in two locations or two different nets in similar settings. It is not recommended to concurrently monitor more than two net types nor undertake monitoring at more than two sites.

### ***Standard Durability Monitoring (“Tier 1”)***

ITN durability monitoring consists of four outcomes: attrition, physical integrity, insecticidal activity and insecticide content. Each outcome should be measured at baseline (within six months of distribution) and then annually for three years. Attrition and physical durability can be reasonably measured in a cohort sample of 250 marked nets. With this sample size, using 15 clusters of 10 households each where all nets are marked in selected households, countries will be able to detect approximately 20% variation in performance among products over a three year period, equivalent to approximately plus/minus 6-7 months of median net lifespan.

Measurement of insecticidal activity (both bioassays and chemical content testing) at baseline, 12 and 24 months should be done on nets from outside the main cohort of ITNs being monitored and at 36 months from the main cohort, whereby 30 nets are taken from the field for laboratory testing each year for three years. Nets collected at the baseline, 12 and 24 months may be identified through one of two methodologies, either: a) random selection from outside the study cohort; or b) tagging a separate bioassay net cohort at baseline. Each methodology has pros and cons and should be selected based on what is most appropriate within the country specific context. The nets taken from the field will need to be replaced by new nets. See [Entomological Monitoring](#) chapter for more information on bioefficacy monitoring of ITNs.

### ***Streamlined Durability Monitoring (“Tier 2”)***

In countries that have previously conducted durability monitoring on pyrethroid-only nets and are deploying new types of nets, PMI does not recommend another round of full durability monitoring, but rather monitoring focused on insecticide effectiveness (i.e., bioassays and chemical testing). This streamlined monitoring is expected to have a lower budget than the full durability monitoring package as the cost would be driven primarily by bioassay and chemical testing costs, plus the cost of net storage (for analysis in future rounds) and net replacement. Training could be targeted and remote, focused on a small core country study team. Fieldwork could be undertaken more quickly and with fewer personnel. Analysis would be led by in-country teams with remote support, if required. Note that a cohort would still be established at baseline to ensure that appropriate nets are sampled.

The activity should include, at a minimum:

- Data collection at two sites
- Collection of 45 nets per site, per time point (baseline, 12, 24, 36 months) for bioassays and chemical testing
- Physical integrity assessment conducted in a lab setting on frame (rather than hole counting in the field) before destructive sampling for bioassays and chemical testing
- Streamlined questionnaire [template forthcoming]

Chemical testing should be conducted at CDC or another qualified laboratory. If analysis of insecticidal content is to be done at CDC, engage your respective country entomology backstop to coordinate. Please consult with the PMI VMCT for further details.

If your country team has identified specific issues with ITN quality, **please contact your PMI HQ Operational and Entomology Leads and Supply Chain Team backstops**, who can help determine whether post-market surveillance may be most appropriate for the country context and concerns.

### ***Interpretation and use of the results of ITN monitoring***

WHO has provided clear cut-off points for WHO cone tests. Nets are considered effective if they cause  $\geq 80\%$  mortality or  $\geq 95\%$  knockdown in the WHO cone test. For nets that fall below these criteria, WHO recommends the use of the tunnel test to assess feeding inhibition caused by sub-lethal doses of insecticide. Nets are considered effective if they cause  $\geq 80\%$  mortality or  $\geq 90\%$  blood-feeding inhibition in the tunnel test. However, capacity to conduct the tunnel test is not currently present in most PMI countries. Therefore, as an alternative, nets are considered minimally effective if they cause  $\geq 50\%$  mortality or  $\geq 75\%$  knockdown in the cone test. If less than 80% of nets are minimally effective at any given time point, the ITN product should be replaced. Note that these alternative criteria may not be adequate for novel insecticides such as chlorfenapyr and PMI now recommends that countries develop capacity for the tunnel test.

Criteria for attrition and physical durability are less established but recent guidelines have been presented by the WHO Vector Control Advisory Group and the WHO Malaria Policy Advisory Committee. Nets should be considered in need of replacement if they have at least 1000cm<sup>2</sup> of damage (i.e., 642 pHI) (regardless of assumptions of shape of the hole). Population level survivorship curves can then be fitted to estimate an optimal replacement cycle.

Results of ITN monitoring can be used:

- To determine the median ITN life in a country and understand factors affecting attrition and ITN performance
- To inform improved procurement practices to ensure that ITNs bought provide as optimal performance as can be expected

- To inform countries to develop effective SBC to promote net care behaviors
- To provide information to WHO/PQ and manufacturers on the durability of different ITNs under different conditions to improve products and their specifications

Durability monitoring results can help PMI identify when an ITN product does not meet acceptable standards for integrity and insecticidal effectiveness. However, durability monitoring studies are not powered to determine if one product is significantly superior in quality to another and thus results should not be used to justify preference for procurement. PMI teams should explain this carefully to NMCP and malaria partners when results are presented. Guidance documents on what levels of ITN attrition, physical damage, and bioefficacy would constitute poor performance, and actions to be taken in response are posted on [www.durabilitymonitoring.org](http://www.durabilitymonitoring.org).

## Frequently Asked Questions for ITNs

### Q1. What are the side effects of insecticides used on ITNs?

A. The insecticides currently available for use on mosquito nets have low human toxicity (i.e., they are safe enough that a baby sucking on a net would not be harmed). That said, the ‘alpha-cyano’ pyrethroids such as deltamethrin or alphacypermethrin, can cause some irritancy on the skin or mucosal membranes when nets are first removed from their protective packaging. Workers assisting with mass campaigns who open and distribute many nets in a short timeframe report skin, eye, and nose irritation. Although this is temporary, they should not continue working directly with the ITNs. Countries may also choose to advise recipients of new ITNs to let the net air out for a day before using. Permethrin does not have the problem of potential irritancy and is therefore the active ingredient in shampoos marketed for lice and flea control, and the pyrethroid used for treating clothes, blankets etc.

### Q2. What are the environmental procedures and assessments that need to take place in order for ITNs to be procured and distributed with PMI support?

A. Insecticides used in ITN products are thoroughly evaluated in USAID’s [Integrated Vector Management Programs for Malaria Vector Control: Programmatic Environmental Assessment](#) (PEA)<sup>63</sup>; the PEA is routinely updated and the 2017 version is available on [pmi.gov](http://pmi.gov). The PEA found that ITNs show a low risk for negatively impacting human and environmental health. The PEA recommends the use of appropriate best management practices to avoid potential human contamination, and SBC on appropriate use during distribution efforts.

### Q3. Can PMI support ITN distribution in emergencies and other special circumstances?

---

<sup>63</sup><https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/integrated-vector-management-programs-for-malaria-vector-control-programmatic-environmental-assessment-2017.pdf?sfvrsn=5>

**A. Perhaps.** From time to time, PMI teams may be approached to support procurement of ITNs for separate, targeted distribution rather than as part of mass campaigns or routine distributions as programmed in the MOPs, or that are scheduled in national ITN strategic plans. Examples include distribution to refugees, communities affected by outbreaks such as Ebola or by flooding, and other special populations. In the context of a humanitarian emergency or other urgent public health situation - including a global pandemic - combining ITN distribution to a targeted population with other planned public health campaigns (i.e., IRS or immunization campaigns) may be a feasible distribution strategy. See the new section on [Malaria in Humanitarian Settings](#). In addition, NMCPs and partners may express interest in geographically-focused campaigns that integrate ITN distribution with those of vaccinations and other services. All have substantial logistical, funding, policy and strategic implications that could impact – positively or adversely – attaining both NMCP and PMI objectives. Please consult with the PMI VMCT team if a special circumstance should arise.

---

# INDOOR RESIDUAL SPRAYING

---

## **\*New/Key Messages\***

**Selection and Rotation of Insecticides:** Insecticides used for IRS should be preemptively rotated between classes about every two years. SumiShield 50 WG and Fludora Fusion both belong to the neonicotinoid class of insecticides, and thus switching between these two products does not constitute an insecticide rotation.

**Special Considerations for Deployment of Fludora Fusion:** While the use of Fludora Fusion does not need to be restricted in areas with deltamethrin resistance, it is not recommended for co-deployment in areas where deltamethrin-containing (standard or PBO synergist) ITNs have recently been or will be distributed.

**New IRS Insecticide Procurement Policy:** With two clothianidin-based products now WHO PQ-approved and available for PMI procurement (FludoraFusion and SumiShield 50 WG) PMI seeks to promote competition and a balanced market. To that end, no more than 66% of a procurement with a minimum volume threshold of 10,000 units, should go to one manufacturer, assuming two manufacturers are in the market. Exceptions may be made, in consultation with the HQ VMCT, based on country level data and context, such as resistance and efficacy data, product registration, co-deployment with new nets, etc.

## **Introduction**

Indoor residual spraying (IRS) involves the spraying of residual insecticide on the inside walls of houses prior to peak malaria transmission. It is designed to interrupt malaria transmission by either killing adult female mosquitoes when they enter houses and rest on the walls after feeding or by repelling mosquitoes from entering houses. IRS has helped to greatly reduce or eliminate malaria from many areas of the world, particularly where the mosquito vectors feed and rest indoors and where malaria is seasonally transmitted. As a best practice, PMI recommends that IRS campaigns should occur just before the peak of the transmission season, in order to provide the highest impact.

Successful IRS depends on the use of an insecticide that kills the local malaria vector(s) and the quality of spraying. Unfortunately, IRS successes are now being jeopardized by the spread and intensification of insecticide resistance. According to WHO, mosquito resistance to at least one class of insecticides has been reported from 68 countries with ongoing malaria transmission. PMI's own entomological data shows evidence of insecticide resistance to one or more classes of insecticides in all PMI-supported countries in Africa. While the majority of PMI-supported countries relied on pyrethroids for IRS in the early years of PMI, because of documented pyrethroid resistance, no PMI-supported IRS programs have used pyrethroids since 2015.

## Insecticide Selection

The choice of which insecticide class (or compound) to use in a particular setting should be made with expert consultation, including PMI HQ Operational and Entomology Leads, implementing partners, and in-country technical working groups during the planning period for spraying **at least eight months before the spray campaign** to allow adequate time for procurement, delivery, and receipt of insecticide. All decisions about the choice of insecticide should be done in consultation with the NMCP. PMI has specified the following factors that should be considered in the choice of insecticide class: vector resistance, duration of efficacy, and cost. The choice of insecticides that can be used for IRS is limited. Each has its own advantages and disadvantages as outlined in the following table.

**Table. Advantages and Disadvantages of IRS-Recommended Chemical Classes**

Chemical class	Advantages	Disadvantages	Cost/sachet or sachet equivalent
Pyrethroids	<ul style="list-style-type: none"> <li>● Low toxicity</li> <li>● Low cost</li> <li>● &gt;7 months duration for longer-lasting formulations</li> </ul>	<ul style="list-style-type: none"> <li>● Resistance</li> <li>● Used in majority of ITNs</li> </ul>	\$2-3
Carbamates	<ul style="list-style-type: none"> <li>● Medium toxicity</li> <li>● Less resistance</li> </ul>	<ul style="list-style-type: none"> <li>● Higher cost</li> <li>● &lt; 4 month duration****</li> </ul>	\$11*
Organophosphates**	<ul style="list-style-type: none"> <li>● Less resistance</li> <li>● CS formulation &gt;6 months duration****</li> </ul>	<ul style="list-style-type: none"> <li>● Higher relative toxicity</li> <li>● Higher cost</li> </ul>	\$16
Organochlorines (DDT)***	<ul style="list-style-type: none"> <li>● Low cost</li> <li>● &gt;7 months duration</li> </ul>	<ul style="list-style-type: none"> <li>● Management costs</li> <li>● Resistance</li> <li>● Supply</li> </ul>	\$4-\$6.70
Neonicotinoids**	<ul style="list-style-type: none"> <li>● Less resistance</li> <li>● Residual efficacy up to 10 months</li> </ul>	<ul style="list-style-type: none"> <li>● Higher cost</li> </ul>	\$14.50

\*The number of structures sprayed per bottle/sachet is approximately equivalent for all insecticides, however, the short residual life of current WHO-recommended carbamate formulations means that in areas of year-round transmission, two rounds of spraying are required, effectively doubling the price of carbamates.

\*\*Currently all PMI-supported spray programs utilize the organophosphate and/or neonicotinoid classes of insecticide.

\*\*\* DDT does not currently have a WHO PQ recommendation

\*\*\*\*Residual duration depends highly on the surface type.

It should be noted that not all the chemicals listed in the table above are currently being produced by WHO pre-qualified manufacturers. In fact, only one each of the carbamate and organophosphate classes are produced by WHO pre-qualified manufacturers (bendiocarb and pirimiphos-methyl, respectively). There are no organochlorines produced by WHO pre-qualified manufacturers. PMI can only procure

insecticides from WHO pre-qualified manufacturers. The updated PQ list can be found at: <http://www.who.int/pq-vector-control/prequalified-lists/en/>.

The five classes of insecticides for IRS in the table are neurotoxins that paralyze and subsequently kill the insect. The oldest of these, the organochlorine class to which DDT belongs, came into widespread use in the 1940s. The mode of action of the organochlorines, like that of the pyrethroid class developed in the 1970s and 80s, is on the insect neuron sodium channel, keeping it open and therefore preventing the nerve impulse to recharge. Carbamates and organophosphates inhibit acetylcholinesterase, an enzyme in insects and humans that terminates the action of the excitatory neurotransmitter (acetylcholine) at nerve synapses. Carbamates bind loosely and reversibly to acetylcholinesterase, whereas the organophosphates bind more strongly. The most recent class to receive a recommendation by WHO PQ for IRS are neonicotinoids. These nicotine-like compounds mimic acetylcholine, tightly binding the acetylcholine receptor to cause high levels of activation and overstimulation. Neonicotinoids are slow-acting insecticides that cause mosquito mortality at 72 hours, rather than the typical 24 hours observed for other classes. This delayed mortality requires extended residual efficacy monitoring, which can be a challenge in some countries. Another potential new class (making it the sixth class) of public health pesticide, the pyrroles, is currently registered by the U.S. Environmental Protection Agency for some indoor uses (e.g., commercial kitchens). Pyrroles are not neurotoxins, but act by disrupting mitochondrial ATP production, leading to cellular death and eventual insect mortality. One member of this class, chlorfenapyr, has been evaluated by the WHO for use on ITNs, and may be evaluated for use in IRS in the future.

The newest IRS insecticide on the market is Fludora Fusion, a combination insecticide containing clothianidin + deltamethrin. Data from Bayer, the manufacturer of Fludora Fusion, show that there is a complementary effect between the two insecticides and the formulation is designed so the mosquito comes into contact with both insecticides at the same time. Results from 19 field trials, including six WHO trials, indicate the product is expected to have a long residual life, similar to SumiShield 50 WG 50 WG and Actellic CS. Fludora Fusion trial data also indicates it to be effective in areas with deltamethrin resistance; as such, the PMI VMCT does not believe it is necessary to restrict the use of Fludora Fusion in areas with deltamethrin resistance. However, it is not recommended that Fludora Fusion be co-deployed in areas where deltamethrin-containing (standard or PBO synergist) ITNs have recently been or will be distributed.

The WHO-specified duration of effective action in Table 1 largely corresponds to results from WHO supported trials. However, PMI's operational experience has generally demonstrated effective action for the longer-lasting OP (pirimiphos-methyl CS) of at least six months on cement, mud, and wood surfaces in most countries. Operational experience to date with bendiocarb in most cases has not demonstrated effective action beyond 3-4 months, with residual activity of only 2-3 months on mud surfaces reported in five countries. However, a number of PMI focus countries in Southern Africa, West Africa and Ethiopia have shown significantly shorter residual life for several insecticides, with approximately 1-2 months

residual efficacy for bendiocarb and 2-3 months for pirimiphos-methyl CS. PMI began rolling out SumiShield 50 WG 50 WG in 2018 and to date it has been used for IRS in 13 countries, with current data indicating a long residual life, ranging from 6 to 9 months. PMI began deploying Fludora Fusion for IRS in 2019 and to date it has been used for IRS in 14 countries.

### ***Rationale for introducing an insecticide rotation***

There are now sufficient data from control programs in both public health and agriculture to state that using carefully chosen rotations of insecticides (switching classes each round), mosaics (the spraying of one compound on some surfaces and another compound on other surfaces), or mixtures of insecticides (analogous to combination therapy for drugs, using two insecticides on the same surface) work well in slowing down the rate at which operationally significant levels of insecticide resistance will be selected.

The WHO *Global Plan for Insecticide Resistance Management*<sup>64</sup> recommends rotations, mosaics, and mixtures to slow selection of resistant vectors. As there are now multiple, similarly-priced insecticide formulations available for IRS, PMI supports subnational rotation between insecticides with susceptibility, to the greatest extent possible. As a practical option to manage buffer stocks, it may be possible to spray some districts with insecticide A, and others with insecticide B, and switch.

**PMI strongly supports the phased implementation of insecticide rotations.** The WHO's *Global Plan for Insecticide Resistance Management*<sup>65</sup> recommends that in areas where IRS is the primary form of vector control, the insecticide used should be preemptively rotated between classes annually. Cross-resistance patterns between insecticides can be complex, but as a general rule, insecticides that share a common target site should not be rotated back-to-back. An ideal rotation would deploy insecticides with different modes of action rotated annually, however for practical purposes, rotating about every 2 years should suffice. Preemptive rotations are likely the best way to prolong susceptibility and maximize the long-term cost effectiveness of insecticides. However, there are operational challenges to fully implementing the recommendations of the *Global Plan for Insecticide Resistance Management*. In particular, there are limited, albeit a growing number, of options for non-pyrethroid, long-lasting insecticides. In addition, questions remain regarding how successful rotations will be in mitigating the development of resistance, or promoting the return of susceptibility in resistant populations. Therefore, as countries conduct preemptive rotations, the effects of insecticide rotation on insecticide resistance profiles should be closely monitored and evaluated. Country teams should engage the **PMI VMCT Operational and Entomology Leads** to discuss insecticide resistance management plans, including pre-emptive rotation of insecticide, to appropriately consider needed monitoring and support.

---

<sup>64</sup> [http://apps.who.int/iris/bitstream/10665/44846/1/9789241564472\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44846/1/9789241564472_eng.pdf)

<sup>65</sup> <http://www.who.int/malaria/publications/atoz/gpirm/en/>

It should be noted that SumiShield 50 WG and Fludora Fusion both belong to the neonicotinoid class of insecticides, and thus switching between these two products does not constitute an insecticide rotation as described above. Please note the following guidance on the selection and rotation of clothianidin insecticides for IRS:

- If neonicotinoids are selected for deployment in a country's spray campaign, then Fludora Fusion and SumiShield 50 WG should both be deployed in a country's IRS campaign each year to maintain market stability unless local data shows clear differences in either 1) residual efficacy, or 2) other factors that have the potential to reduce the relative impact of one of the insecticides .
- If country-specific data are currently available for only one or neither product, it is recommended that both Fludora Fusion and SumiShield 50 WG be procured and evaluated in a single spray campaign to determine any local differences in residual efficacy, acceptance, or other relevant factor, which are critical to inform future procurements.

### ***New IRS Insecticide Procurement Policy***

With two clothianidin-based products now WHO PQ-approved and available for PMI procurement (FludoraFusion and SumiShield 50 WG) PMI seeks to promote competition and a balanced market. To that end, no more than 66% [within a class, assuming] of a procurement with a minimum volume threshold of 10,000 units, should go to one manufacturer, assuming two manufacturers are in the market. Exceptions may be made, in consultation with the PMI VMCT Operational and Entomological Leads, based on country level data and context, such as resistance and efficacy data, product registration, co-deployment with new nets, etc. Currently, the price for both clothianidin-based products is identical, thanks to the agreement negotiated at the end of the UNITAID funded NgenIRS Project. However teams should note that freight costs are not identical and will vary due to the location of the manufacturing facility and the product weight (Fludora Fusion is a 100 gram sachet and SumiShield 50 WG is a 150 gram sachet). Also note that there may be slightly higher logistics costs for the implementing partner, in order to administratively process, clear, and transport multiple shipments.

### **Key Issues**

The IRS technical guidance below is organized by key issues, and addresses how best to implement IRS in the most cost-effective manner in different epidemiological settings. These issues are intertwined and should be considered together. Additional technical and programmatic resources regarding IRS can be found on the PMI website. For additional information on the combination of IRS and ITNs, please see the [Vector Monitoring and Control](#) chapter of the PMI Guidance. Another excellent source of information

on IRS strategy, management, and operational issues such as the safe use of insecticides and spray application guidelines, is the June 2015 WHO [Manual on Indoor Residual Spraying](#).<sup>66</sup>

### ***Key issue 1: IRS in various epidemiological settings***

- Historically, PMI prioritized support for IRS in areas with seasonal malaria, but with longer lasting insecticides available, PMI also supports IRS in perennial transmission settings as a means to rapidly reduce malaria transmission.
- PMI does not support IRS as an epidemic prevention measure in areas that may experience a malaria outbreak, followed by long periods without transmission. PMI also does not support IRS as an epidemic response measure. In most cases, the logistics and lead time for IRS is too lengthy to allow for rapid response, and often epidemics are over before IRS can be implemented.
- PMI does not typically support IRS in urban settings. However, IRS may be justified once local transmission is confirmed with entomological data, if there are unique circumstances (e.g., delayed LLIN distribution, sudden population shift, or hotspot identified) that can justify IRS, and if urban housing conditions allow for anticipated access with high levels of acceptance among urban community dwellers. When country teams are selecting new spray areas, for example because a decision has been made to expand or retarget the program, epidemiological data should be taken into consideration and the **PMI VMCT Operational and Entomological Leads** should be consulted.

### ***Key issue 2: Targeting IRS and blanket versus focal application of IRS***

IRS programs should aim for 100% coverage of all eligible structures in the area (sub-district, district, region, or other administrative unit) to be sprayed, although WHO guidelines state that coverage above 85% is sufficient to produce a community effect. After an area is selected for spraying, there are two ways to implement IRS: blanket spraying and focal spraying. Whereas blanket spraying is defined as the spraying of all houses within a targeted area (e.g., entire provinces or districts), focal spraying is defined as the spraying of living structures within selected, discrete geographic areas within an area targeted for IRS activities, based on epidemiologic or ecological parameters. Focal IRS requires precise epidemiological, environmental, and entomological information on households within an area. The goal of focal IRS is typically to cover epidemiological “hotspots,” which can be defined as a town, village, or geographic area that experiences regular seasonal increases (and thus not defined as an outbreak) in confirmed malaria cases or transmission activity in comparison to surrounding areas. This could be due to the proximity of mosquito breeding sites, variations in housing structure, particular resident behaviors, etc. Therefore, the scale of selection is much finer than that determined by an administrative or political boundary, while also being independent of such boundaries.

---

<sup>66</sup> <http://www.who.int/malaria/publications/atoz/9789241508940/en/>

- IRS should be targeted based on malaria disease burden and/or community parasite prevalence, malaria seasonality/epidemiological setting, population density, vector behavior and resistance status, and the presence of other interventions, particularly ITNs, and the presence of ecologically sensitive areas (i.e. organic farming or rivers, streams or wetlands). Stratification of the country can facilitate the decision-making process and assist countries in determining areas most suitable for spraying.
- Although focal IRS should theoretically decrease cost while maintaining impact, implementing it requires significantly more data collection, analysis, planning, and logistics than blanket spraying. Focal spraying would only be appropriate in countries where epidemiological data are sufficiently granular to accurately target sub-district areas for spraying. Inaccurate targeting of focal IRS can waste significant resources and leave high-transmission areas unprotected.
- If a country has already decided to re-evaluate the scope of its IRS program (i.e., shift from blanket spraying to focal spraying), care must be taken to ensure that newly targeted spray locations are selected in an evidence-based manner and that the localities targeted for IRS with focal spraying are large enough to achieve some level of public health impact. The **PMI VMCT Operational and Entomological Leads** should be consulted to help with these decisions.
- From 2015-2018, PMI conducted operational research in Zambia to assess the effectiveness and cost implications of focal spraying using three different targeting strategies: 1) Geographic concentration (i.e. density of structures), 2) Health facility-based (i.e. highest burden areas based on HMIS), and 3) Ecological (i.e. breeding sites identified by entomological studies). Study results found that ecological targeting was associated with a 13% reduction in malaria incidence compared to geographic targeting, while health facility targeting was associated with a 35% *increase* in malaria incidence compared to geographic targeting. **Given these results and the further study that's needed, countries that have not already initiated focal spraying should not plan to do so given the uncertainties.**

### ***Key issue 3: How long to spray and withdrawal of IRS***

- IRS should only be implemented as part of a long-term vector control or malaria elimination strategy.
- When new spray areas are being considered, areas of high transmission that require only one spray round per year to cover the majority of the transmission season, should be prioritized.
- While some countries use IRS-withdrawal thresholds of “after 3 years of implementation or reduction in burden by a certain level”, there is no universally accepted threshold that can be used to determine if a country can withdraw IRS. IRS withdrawal is often influenced by political or financial decisions, or the introduction of new interventions (i.e. PBO synergist and dual active ITNs); both the epidemiological and entomological context should be factored in when considering IRS withdrawal.

- Since IRS is typically implemented in the highest burden areas, we expect to see malaria transmission reduction in these areas, while other areas that previously had less transmission will now appear to have higher transmission relative to the initial area that is now protected with IRS. Thus, these expected changes should not automatically lead to discussions on how to move the IRS from one area to another.
- If IRS is withdrawn, it should be in the context of a malaria elimination plan or as part of a malaria control program using a “knock-down/keep-down” strategy (i.e. IRS is used to reduce or “knock-down” the malaria burden, and then effective ITNs (based on insecticide resistance data) are used to maintain or “keep-down” the burden), ensuring universal high ITN coverage. Ensuring the population is covered with an effective ITN, which in many cases may require next-generation ITNs, is a critical component of any IRS withdrawal strategy, as an increase in malaria burden when withdrawing IRS is expected. In addition, IRS should only be withdrawn if adequate access to malaria case management has been achieved in that area.
- To date, all PMI countries with IRS programs have withdrawn IRS from one area (i.e. district), and moved to another area, with varying levels of entomological or epidemiological rebound. If IRS will be withdrawn from an area, PMI recommends developing an IRS Exit Strategy with the NMCP, to document various considerations for removing IRS from an area, and incorporating recommendations and suggested partners for implementation. Considerations include: timing of a mass ITN distribution campaign, and the possibility of utilizing continuous distribution channels or new types of ITNs, if appropriate in the former IRS area.
- If IRS is to be withdrawn because of resource constraints or a shift in a country’s IRS targeting strategy, countries should ensure clear SBC messaging, high ITN coverage and use, strengthen malaria case detection and response systems, and closely monitor ACT and RDT stocks. It is prudent to expect and plan for an increase in malaria cases following the withdrawal of IRS. Additional commodities may be needed in the former IRS targeted areas, and entomological monitoring should be continued to monitor the impact of withdrawal on the vector population. If IRS is the main form of vector control in an area, it should continue to be implemented even as transmission drops.

The country team should consult with the **PMI VMCT Operational and Entomological Leads** when making changes to the country’s vector control/IRS strategy, and collaborate to submit adequate documentation to PMI leadership to justify the change in strategy, as needed.

#### ***Key issue 4: Costs of IRS implementation***

According to the PMI VectorLink Project cost analysis of IRS programs in 2019, in the majority of PMI-supported countries, insecticide costs average 26% of the IRS budget, depending on the insecticide class used. The three largest cost categories were spray operations (38% of all costs), insecticide (26% of all costs), and local labor (22% percent of all costs), constituting an average of 86% of all costs. Based on results from 2019 PMI-funded spray campaigns, the average cost per person protected was \$6.19 (range

from \$3.35 to \$15.56) and the average cost per structure sprayed was \$21.86 (range \$10.78 to \$45.43). There is considerable variation in the cost of IRS in PMI-supported countries based on factors such as program scale, cost of local labor, etc.

- For FY 2022 MOP planning and beyond, PMI country teams, together with NMCPs, should consider IRS programs in the context of the current resource allocations for vector control interventions from all sources, given the malaria burden, insecticide resistance profile, and actual program expenditures in each country, and make changes in upcoming years where necessary.

### ***Key Issue 5: Monitoring and Evaluation of IRS***

- All PMI-supported vector control programs should collect entomological data for data-based decision making, and for inclusion in the PMI/headquarters entomology database. See the [Entomological Monitoring](#) chapter for suggested indicators.
- PMI country teams are encouraged to support routine epidemiologic monitoring, including some measure of disease burden, in areas with PMI-supported IRS activities as a means of tracking malaria trends that will help guide policy decisions (e.g., scaling down, suspending spraying, or moving from blanket to targeted spraying).
- PMI recommends the use of existing routine health facility data for epidemiologic surveillance in IRS areas. Questions about the timing of spraying, whether a single round of spraying per year is sufficient to cover the entire transmission season, and/or the need to change from one insecticide or formulation to another are probably best answered by a review of routine entomological data from the area being sprayed.
- PMI supports the spraying of sleeping structures, and generally does not support IRS in non-sleeping spaces, such as latrines, fowl runs, grain storage, or animal shelters. If a country's national policy is to spray non-sleeping spaces in their IRS program, and the country would like PMI to support this, sufficient entomological evidence, including molecular identification of malaria vectors in these non-sleeping structures, must be documented in order to justify the added cost of extending spraying to these additional structures with PMI resources. Please engage the **PMI VMCT Operational and Entomological Leads** for further clarification.

### ***Key issue: New types of nets and IRS***

- There is little information on the use of new types of nets in areas where IRS is being conducted. In Tanzania, there was limited benefit found from the combination of Olyset Plus (PBO net) and annual Actellic IRS treatments.
- Additionally, some IRS insecticides, such as pirimiphos-methyl, are pro-insecticides, meaning they require a transformation of the product to become insecticidal. This occurs in the mosquito, usually an effect of oxidases. If PBOs inhibit oxidases, they may result in a decrease of the effectiveness of pro-insecticides. While further work is needed to understand whether this

effect results in challenges for co-implementation, this should be considered when choosing interventions.

- Generally, co-deployment of new types of nets (PBO synergist and dual insecticide ITNs) and IRS should be considered for use in the same areas only if there is unequivocal evidence of increased vector and disease suppression, and sufficient vector control is in place in the rest of the malarious areas in the country. In most instances, OR/PE will be required to generate this evidence. Country teams that plan to support co-deployment of IRS and new-types of nets should engage the PMI VMCT for further guidance.

## Frequently Asked Questions for IRS

### Q1. What is PMI's role in ensuring the quality of insecticides used in IRS?

**A.** As noted earlier, PMI procures insecticides from manufacturers who are pre-qualified by WHO. Typically, insecticides will arrive in-country with quality assurance documents from the manufacturer. However, to ensure due diligence, PMI requires its IRS partner to conduct independent, pre-shipment quality control evaluations. In countries where PMI conducts IRS but the insecticide was not procured by PMI, quality assurance testing must still be undertaken by PMI prior to use. Quality control testing of insecticide can be conducted at a number of qualified laboratories; please discuss with the PMI Headquarters IRS Technical Team for more information.

### Q2. Is there any level of resistance that would cause us to stop IRS?

**A. Yes.** If confirmed resistance, as defined by the WHO guidelines, were detected to all available IRS insecticides, we would discontinue IRS. At present, there are only a few reports from West Africa where the vectors are resistant to four of five classes of insecticide (but not necessarily all active ingredients in each class). Therefore, we should choose an insecticide that works, not just for transmission reduction, but also as a strategy to help manage resistance, remembering that the ITNs themselves can select for resistance.

### Q3. Does PMI use DDT in its spray programs?

**A. No, not currently.** In select countries, PMI has supported IRS with DDT starting first in 2006, but the emergence of high levels of DDT resistance has limited its use, and no PMI-supported IRS program has used DDT since 2012. Furthermore, there are issues regarding the supply of quality DDT. PMI will continue to provide technical assistance on the use of DDT where there is an approved supplemental environmental assessment (SEA) in place and when appropriate given susceptibility profiles, ensuring always that appropriate safeguards are in place to prevent leakage into the agricultural sector and mechanisms for safe disposal of unused DDT and DDT-contaminated materials exist. **These additional**

**safeguards are costly, and the supplemental environmental assessments for DDT should be initiated at least one year prior to use and require yearly revisions.** Any country using DDT for IRS should have signed and be in compliance with the Stockholm Convention for use of DDT<sup>67</sup>, including the requirement of prior notification of intent to use. For more information on the use of DDT in IRS programs, refer to the WHO position statement revised in 2011.<sup>68</sup>

#### **Q4. Who is responsible for monitoring human and environmental safety measures for IRS?**

**A.** It is the shared responsibility of in-country PMI team members (particularly the Activity Manager of the Vector Control partner), the Mission Environmental Officer, and the IRS Contracting Officer's Representative (COR) team to monitor environmental compliance and human safety. An independent environmental assessment should be conducted every three years through the Environmental Compliance Support (ECOS) mechanism. Countries should allocate ~\$45,000 for this assessment. If a country has documented repeated significant environmental deficiencies through the IRS implementing partner's internal systems, an external monitoring visit may need to be conducted sooner than every three years. This determination should be made in consultation with your **VMCT Operational Lead**.

Attention should be directed to ensuring that:

- Mitigation measures listed in the Safer Use Action Plan of the environmental assessment are being addressed
- Strict insecticide unit accounting methods are in place to prevent leakage
- IRS contractor(s) complete environmental compliance visits, and include findings in End of Spray Reports

The PMI Best Management Practices for IRS<sup>69</sup> manual was revised in 2020 and contains checklists for field evaluations to assist PMI managers and IRS implementing partners in monitoring compliance efforts. In addition, PMI through the PMI AIRS project has developed several supervisory tools and checklists.<sup>70</sup>

#### **Q5. How do I comply with USG Regulation 216 if asked to support non-PMI financed IRS operations?**

**A.** USAID has historically interpreted "the procurement or use of pesticides" clause under Reg. 216 to mean both direct and indirect forms of support (e.g., disposal of pesticides, provision of fuel to transport pesticides, technical assistance to pesticide management, etc.). This clause is of particular importance

---

<sup>67</sup> <http://chm.pops.int/Home/tabid/2121/mctl/ViewDetails/EventModID/7595/EventID/447/xmid/7598/Default.aspx>

<sup>68</sup> [http://www.who.int/malaria/publications/atoz/who\\_htm\\_gmp\\_2011/en/](http://www.who.int/malaria/publications/atoz/who_htm_gmp_2011/en/)

<sup>69</sup> [https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/2020-bmp-manual-revision-final-3-16-20-sxf-\(2\).pdf?sfvrsn=2](https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/2020-bmp-manual-revision-final-3-16-20-sxf-(2).pdf?sfvrsn=2)

<sup>70</sup> <http://www.africairs.net/wp-content/uploads/2012/08/AIRS-Supervisory-Toolkit.pdf>

for PMI because (1) as host-country capacity grows for IRS, PMI's role will likely shrink, and (2) as more countries prioritize IRS as a key component of malaria control, funds from other donors, the private sector, and NGOs will be used for IRS, and PMI may be called upon to play a more limited role, such as provision of technical assistance and supervision, etc.

In all cases, PMI-supported countries must document the specific actions a USAID Mission/PMI program is proposing to support in the form of a new SEA or an amendment to the existing SEA. The SEA or SEA amendment should be shared with the IRS COR team, Mission Environmental Officer, and Global Health Bureau Environmental Officer, who will collectively review and provide required clearances. Because countries need to allow time for completion and approval of the more time-consuming SEAs, below are illustrative lists of actions that must be included in a SEA or SEA amendment:

- Procurement, transport, storage, loaning, direct application, or disposal of insecticide
- Loaning of spray pumps or IRS related equipment (i.e., progressive rinse barrels)
- Provision of direct supervision
- Providing payment for spray personnel or fuel to transport insecticide
- Procurement of personal protective equipment
- Hosting/co-hosting training for spray operators, trainers, supervisors, environmental compliance inspectors, IEC mobilizers, and other technicians

Please contact the IRS COR Team for country-specific scenarios.

**Q6. Can PMI support IRS operations in refugee and internally displaced persons (IDP) camps/settlements?**

**A. Yes.** PMI can support the direct implementation of IRS and/or provide technical assistance to other entities conducting IRS in refugee and IDP camps/settlements, as long as the NMCP is supportive. Note that not all refugee and IDP camp structures may be considered eligible for IRS, as non-permeable tenting material may not absorb insecticide (see new guidance on [Malaria in Humanitarian Settings](#)).

---

# MALARIA IN PREGNANCY

---

## **\*Key Messages\***

With the release of the 2016 WHO ANC Guidelines, PMI country teams should work with NMCP counterparts to revise national ANC policies to ensure the timing of ANC visits promotes optimal dosing of IPTp, including an additional ANC contact at 13-16 weeks to ensure timely access to the first dose of IPTp-SP. See below for further details and clarification.

**IPTp3+ is now the primary indicator recommended by the RBM MERG.** PMI recommends tracking both IPTp3+ and IPTp2+ for MIP programming results. Additionally, PMI recommends collecting ANC4+ so that IPTp “missed opportunities” can be tracked using IPTp3 and ANC4 indicators.

SP resistance monitoring should be included in all PARMA countries with no information on molecular markers of SP resistance in the previous two years. In countries where TES is performed annually in different sites, and depending on baseline levels of SP resistance, consideration should be given to annual monitoring, as resistance markers can be quite focal. We encourage teams to discuss with the MIP Working Group as needed for questions.

Please ensure sufficient support for functioning national MIP working groups including tracking capacity and frequency of meetings.

## **Introduction**

Each year, approximately 125.2 million women living in malaria-endemic countries, including 30 million in Africa, become pregnant. For these women, malaria is a threat to both themselves and to their babies, with an estimated 10,000 maternal and up to 200,000 newborn deaths each year as a result of malaria in pregnancy. Pregnant women, particularly those in their first or second pregnancies, are particularly vulnerable to malaria as pregnancy reduces a woman’s immunity to malaria, making her more susceptible to malaria infection and increasing the risk of illness, severe anemia, and death. For the unborn child, maternal malaria increases the risk of miscarriage, stillbirth, premature delivery, and low birth weight - a leading cause of child mortality.

The impact of malaria infection on the health of the pregnant woman and her developing fetus depends to a large extent on the level of malaria transmission in the region where she lives. In low-transmission areas, women usually present with symptomatic malaria, which can result in severe illness for the mother as well as the potential for premature delivery or miscarriage. In these areas, WHO recommends the use of ITN by all pregnant women and prompt diagnosis and treatment with an effective antimalarial. Intermittent preventive treatment in pregnancy (IPTp) is not recommended for pregnant women living in areas with low levels of malaria transmission, such as in Asia or selected areas of Africa (e.g., Ethiopia).

In contrast, women living in areas of sub-Saharan Africa with moderate to high levels of malaria transmission may have asymptomatic infections during pregnancy, resulting in maternal anemia, which

can have severe consequences for the fetus and newborn. Maternal anemia and the presence of parasites in the placenta impair fetal nutrition, contributing to a range of negative pregnancy outcomes including low-birth weight.

In areas with moderate to high levels of malaria transmission, WHO recommends a three-pronged approach to reduce the burden of malaria infection among pregnant women:

- Intermittent preventive treatment of malaria during pregnancy
- Insecticide-treated nets
- Effective case management of malarial illnesses and anemia

PMI supports malaria in pregnancy activities through the antenatal care service delivery platform in collaboration with NMCPs and Reproductive/Maternal Health Programs.

To facilitate this collaboration and to ensure improvements in delivery and uptake of IPTp, PMI encourages countries to establish a national technical advisory body, such as MIP or ANC working groups. Coordination with other infectious disease programs (including HIV) are also important considerations for MIP services provided to pregnant women. For example, HIV infection lessens a pregnant woman's ability to control malaria infections and placental infection with malaria parasites doubles the risk of vertical transmission of HIV.<sup>4</sup>

## Intermittent Preventive Treatment in Pregnancy

IPTp is the periodic dosing of a pregnant woman with a curative treatment of an antimalarial, regardless of the presence of parasitemia, since placental infections may not be detected through standard methods. Currently, the only WHO-recommended regimen is sulfadoxine-pyrimethamine (SP), which has been shown to be safe and effective for use in pregnancy. The purpose is to clear (or substantially lower) the parasites from the placenta and to provide protection against new infections during the course of the pregnancy. This strategy has proven to be effective in preventing parasitemia and anemia in the mother, and in increasing the birth weight, and thus the chances of survival, for the newborn.

Since more than 70% of pregnant women in Africa attend ANC at least once during their pregnancy, and the vast majority of these women attend three visits, the provision of IPTp during ANC visits is an effective way to ensure that a majority of pregnant women receive a minimum of three doses of IPTp during pregnancy, provided that SP is given at each visit. PMI country teams should consider all possible efforts to increase uptake of IPTp with SP at ANC after the first trimester in areas with moderate to high transmission in Africa. IPTp should be incorporated into the routine ANC visit, and by definition, should be provided to asymptomatic women without testing for malaria.

In October 2012, WHO revised its policy recommendations on IPTp-SP to call for administration of **IPTp-SP at each scheduled antenatal care visit** starting as early as possible in the second trimester (13 weeks), provided that there has been an interval of approximately one month since the last dose of SP.<sup>71,72</sup> This change was made as a result of research demonstrating that providing IPTp at least three

---

<sup>71</sup> WHO Malaria Policy Advisory Committee and Secretariat (2012). "Malaria Policy Advisory Committee to the WHO: conclusions and recommendations of September 2012 meeting." *Malaria Journal* 11(1): 424.

<sup>72</sup> [http://www.who.int/entity/malaria/iptp\\_sp\\_updated\\_policy\\_recommendation\\_en\\_102012.pdf](http://www.who.int/entity/malaria/iptp_sp_updated_policy_recommendation_en_102012.pdf)

times during the course of pregnancy is more effective at preventing the adverse effects of malaria in pregnancy than providing only two doses of IPTp (absolute risk reduction for LBW was 33 per 1000 [95% CI, 10-52] for women receiving three or more versus 2 or less than two doses).<sup>73,74,75</sup>

---

**Current WHO IPTp Policy Recommendations**

- In areas of moderate-to-high malaria transmission, IPTp with SP is recommended for all pregnant women at **each** scheduled antenatal care visit starting as early as possible during the second trimester of gestation, provided these visits are at least one month apart. Ideally, IPTp should be administered as directly observed therapy (DOT).
  - SP can be given either on an empty stomach or with food.
  - Folic acid at a daily dose equal or above 5 mg should not be given together with SP as this counteracts its efficacy as an antimalarial.
  - SP should not be administered to women receiving cotrimoxazole prophylaxis.
- 

## WHO ANC Guidelines

The WHO ANC Guidelines, released in late 2016, call for a minimum of 8 contacts with a health provider, with one contact during the first 12 weeks gestation, and subsequent contacts at 20, 26, 30, 34, 36, 38 and 40 weeks gestation. The ANC guidance also notes that “frequency and exact timing of some of these ANC practices and interventions – especially related to malaria, tuberculosis and HIV – may need to be adapted, based on the local context, population and health system.” As highlighted in the RBM ANC brief, developed in close collaboration with WHO Reproductive Health and Global Malaria colleagues, in malaria endemic areas, **an additional visit at 13-16 weeks is recommended to allow for early provision of IPTp**. Ideally, this would mean that women would be given IPTp at **each** visit starting from 13-16 weeks, provided that the last dose of IPTp-SP was at least 4 weeks prior, as follows:

**Table. Adaptation of WHO Recommended ANC Contact Schedule to Include IPTp**

Timing of Contact	Dose #
1: Up to 12 weeks	ITN provided
<b>1a: 13-16 weeks</b>	<b>IPTp-SP dose 1 (additional contact)</b>
2: 20 weeks	IPTp-SP dose 2
3: 26 weeks	IPTp-SP dose 3
4: 30 weeks	IPTp-SP dose 4

<sup>73</sup> Filler, S. J., P. Kazembe, et al. (2006). "Randomized Trial of 2-Dose versus Monthly Sulfadoxine-Pyrimethamine Intermittent Preventive Treatment for Malaria in HIV-Positive and HIV-Negative Pregnant Women in Malawi." *J Infect Dis* **194**(3): 286-293.

<sup>74</sup> Kayentao K, et al, 2013. Intermittent preventive therapy for malaria during pregnancy using 2 vs 3 or more doses of sulfadoxine-pyrimethamine and risk of low birth weight in Africa: Systematic review and meta-analysis. *JAMA* 309: 594-604.

<sup>75</sup> Diakite, O. S. M., K. Kayentao, et al. (2011). "Superiority of 3 Over 2 Doses of Intermittent Preventive Treatment With Sulfadoxine-Pyrimethamine for the Prevention of Malaria During Pregnancy in Mali: A Randomized Controlled Trial." *Clin Infect Dis* **53**(3): 215-223.

5: 34 weeks	IPTp-SP dose 5
6: 36 weeks	No SP, if last dose received <1 month ago
7: 38 weeks	IPTp-SP dose 6 (if no dose in past month)
8: 40 weeks	

When implementing these recommendations, care should be taken to preserve flexibility- i.e., it should be made clear to providers that the 20-week visit can be conducted over a range of weeks, and not only at exactly 20 weeks, and that IPTp can be given at each visit, provided that the woman is at least 13 weeks pregnant, and at least 4 weeks have elapsed since the prior dose was administered. In training documents, one could consider highlighting that the visits should occur approximately monthly starting at 26 weeks, with biweekly visits starting at week 34 until the end of pregnancy.

Due to the revised WHO policy of giving IPTp at every ANC visit starting early in 2<sup>nd</sup> trimester, the RBM **MERG has recommended tracking the percentage of women receiving the 3<sup>rd</sup> dose (IPTp3)**. While PMI has historically tracked the 2<sup>nd</sup> dose and will continue to do so to continue monitoring trends over time, PMI will also track the 3<sup>rd</sup> dose of IPTp (and potentially additional doses as well) as countries start implementing the new policy.

Each dose of IPTp consists of three tablets of 500 mg sulfadoxine/25 mg pyrimethamine for a total dose of 1500 mg sulfadoxine and 75 mg pyrimethamine. All three tablets should be provided together, preferably under DOT at ANC, and may be given on an empty stomach. Co-administration of SP with other sulfa drugs, such as cotrimoxazole (Bactrim), is contra-indicated, as this will increase the risk of severe adverse events.

Women should receive IPTp each month starting in the 2<sup>nd</sup> trimester; there is no evidence of a negative health impact for either the woman or baby associated with receiving more than three doses of IPTp when doses are administered at monthly intervals. WHO recommends giving IPTp up to the time of delivery; there is no need to withhold SP in the month prior to delivery.

In all cases where PMI is procuring SP, only those drug products that are either produced in facilities in compliance with current Good Manufacturing Practices (GMP) as evaluated using International Conference on Harmonization, WHO, or stringent regulatory authority (SRA) guidelines, or approved for marketing by an SRA can be procured. In cases where countries are procuring SP themselves (i.e., not PMI procured), either from a local manufacturing facility or internationally but from a source where the quality standards and certification are unknown, teams should consider periodic testing of drug quality to ensure that high quality drugs are being used.

In the case, however, where PMI funds will be used to support the storage, distribution and/or usage of locally-sourced SP that has not been procured through PMI directly, the full consignment will be subject to 100% batch testing before release. In a drug quality survey conducted by WHO, 33 out of 127 (26%) samples of SP (from 25 batches, produced by 18 different manufacturers) were found non-compliant in tests of the content of active ingredients, and in one study in Kenya, 45% of SP was found to be

substandard. Depending on the manufacturer, SP has a reported shelf life of between 36 and 48 months.

Due to consistent demand and long lead times, PMI continues to look at options to improve procurement processes for SP. Importation issues and registration policies continue to be key challenges to ensuring access to SP in sub-Saharan African countries. The variety of SP presentations available for procurement (i.e., numerous different-sized unit bottles and various blisters pack options) has added an additional obstacle to the in-country registration processes, providing little incentive for manufacturers to register any one product over another. PMI-supported countries should plan on longer lead times (8-12 months) for SP commodity orders from quality-assured manufacturers and work with their in-country supply chain technical assistance partners to obtain importation waivers, if necessary. Currently, there are no WHO prequalified single-unit dose presentations of SP indicated for IPTp; PMI procures non-pre-qualified SP from wholesalers. To ensure only good quality products are sourced from reliable vendors, PMI continues to apply a robust QA/QC policy to every consignment of SP. Please refer to the [Sulfadoxine-Pyrimethamine](#) and [Lot Quality Assurance/Quality Control](#) subsections within the [Commodity Procurement](#) and [Supply Chain Management](#) chapters for more information.

In areas where IPTp-SP is currently being implemented, and transmission of malaria has been reduced substantially, IPTp should be continued; at this time, it is not clear at what level of transmission reduction IPTp should be abandoned as a strategy, and no alternate strategy has been demonstrated to be more effective or more cost-effective. **Caution should be exercised in recommending the cessation of IPTp as a strategy**, as there is not yet sufficient data from countries where transmission has fallen to show that such gains are long-standing rather than transient.

Although in some areas, particularly in East Africa, high levels of SP resistance have been documented, rendering SP ineffective as therapy for acute malaria infection, the available data suggest that there is still a benefit of giving IPTp-SP, and **WHO continues to recommend its use, irrespective of SP resistance**. Currently, there are no approved preventative treatment alternatives to IPTp-SP. WHO recommends continuing with the existing platform using SP rather than stopping and restarting with a different drug. At the present time, there is not enough evidence to recommend a wide scale policy change in favor of IPTp with dihydroartemisinin-piperaquine (DP), and WHO has recommended additional research to better understand the impact, safety, and operational feasibility associated with IPTp-DP, which would need to be delivered as a treatment course over three days rather than as a single dose at each ANC visit. PMI is supporting a study to further assess IPTp with DP in Malawi which has been completed and data analysis is ongoing. In addition, a multi-country study (Tanzania, Kenya, Malawi) funded by the European and Developing Countries Clinical Trials Partnership is expected to complete participant follow-up at the end of 2020 and provide results in 2021 to definitively address this question.

**Intermittent screening and treatment in pregnancy (ISTp)**, which involves screening with an RDT at each ANC visit and treating only women who test positive, has been evaluated in East and West Africa, and ISTp was not found to be superior to IPTp-SP even in areas with significant SP resistance. ISTp has also been evaluated against IPTp in Indonesia, where IPTp was more effective, except in the lower transmission setting, where IPTp was not significantly different from ISTp. In Africa, ISTp was associated with more maternal clinical malaria episodes, and was more costly than IPTp-SP, and therefore is not being recommended by WHO for use in any settings.

## Opportunities for Community-Based Programming

Although community-based delivery of IPTp with SP (c-IPTp) has not been approved by WHO, and WHO recommends that IPTp be delivered at routine ANC visits, WHO does support exploring partnerships to deliver some components of the proposed malaria prevention and control package to pregnant women at the community level. As such, "...community health workers may be effective at promoting the use of ANC services and ITNs and, with appropriate training and logistic support, could deliver IPT."<sup>76</sup>

Community MIP interventions appear to work best if community health workers/volunteers are specifically taught to focus on both ANC and IPTp-SP. One option that has been shown to be effective in improving IPTp uptake and ANC coverage is to promote IPTp and ANC attendance at community-level to ensure that women visit the ANC to receive their IPTp doses. Few studies have assessed the effects of community level delivery of IPTp-SP. These studies have shown mixed results with regard to ANC attendance. As we do not want to promote a policy to improve IPTp at the expense of ANC attendance, additional research is needed to assess whether delivery of IPTp-SP at the community level is cost-effective and can be achieved without compromising ANC attendance. A PMI funded study in Burkina Faso of community distribution of IPTp showed a significant improvement in the delivery of IPTp3 and IPTp4, as well as improved retention in ANC. A second study in Malawi was recently completed and the results will be available in 2021. Also, UNITAID has launched a new 4-country study to pilot community-delivery of IPTp with SP in DRC, Nigeria, Madagascar, and Mozambique. These studies will generate evidence for updating WHO's policy on community-based distribution of IPTp (c-IPTp). If countries wish to consider this option, PMI recommends that the approach be assessed with an operational research study before moving to wide scale implementation. Countries interested in exploring c-IPTp should discuss this with the PMI Headquarters MIP Team. An alternate implementation approach to increase uptake of IPTp for countries to consider would be to expand their facility-based ANC outreach services to include IPTp (along with delivery and promotion of the full ANC package) as a means of reaching pregnant women in remote, rural areas.

## Insecticide-Treated Mosquito Nets in Pregnancy

Use of ITNs during pregnancy is a key component of PMI's malaria in pregnancy strategy. In areas with moderate to high levels of transmission, the use of ITNs during pregnancy provides significant protection against malarial infection, illness, maternal anemia, and low birth weight. The provision of ITNs to pregnant women is part of the essential package of ANC services. ITNs should be provided to pregnant women as early as possible in pregnancy and their use should be encouraged for women throughout pregnancy and during the postpartum period. ITNs and indoor residual spraying (IRS) are the only interventions that protect women, during the first trimester. Ideally, **all women of childbearing age should sleep under an ITN**, as this will ensure protection even before the woman realizes that she is pregnant. PMI supports universal coverage of ITNs to ensure women of reproductive age sleep under ITNs early in their pregnancy; PMI teams are encouraged to identify additional novel distribution channels to ensure high coverage of nets to women of reproductive age, particularly adolescent girls. **With continuing support for universal ITN coverage campaigns and maintaining high ITN ownership, countries should not lose sight of the importance of providing ITNs to pregnant women at first ANC**

---

<sup>76</sup> WHO Regional Office for Africa: A Strategic Framework for Malaria Prevention and Control During Pregnancy in the African Region (2004).

**visit as part of the routine health services.** Although mass distribution campaigns are critical to ensure universal coverage is achieved, when planning a campaign, ensure that sufficient ITNs are available so that ITNs are not removed from the ANC clinics resulting in a prolonged period of unavailability following the campaign. The RBM Malaria in Pregnancy and Vector Control Working Groups and the Alliance for Malaria Prevention published a joint statement detailing the importance of maintaining LLIN coverage of vulnerable populations via ANC and EPI distribution.

## Case Management of Malaria in Pregnancy

Prompt diagnostic confirmation and treatment with a safe and effective antimalarial drug is a fundamental component of the WHO-RBM's strategy to control malaria. Antimalarial treatment shortens the duration of illness, and reduces the frequency of complications and the risk of death for the mother and fetus. This is particularly important in pregnant women, due to their increased risk of developing severe disease. Essential elements of the ANC package in malaria endemic regions should, therefore, include malaria diagnosis and treatment with antimalarial drugs that have an adequate safety and efficacy profile for use in pregnancy.

Women who present at routine ANC with fever, malaise, or other symptoms consistent with malaria should be tested by microscopy or rapid diagnostic test (RDT) whenever possible. If a pregnant woman is found to have malaria, she should be treated as outlined below. There is no contra-indication to the co-administration of SP with either quinine or artemisinin-based combination therapies (ACTs), thus IPTp may be administered or not. In all instances, she should be instructed to return for IPTp in one month. If a woman is tested and found to be negative, then she should be given IPTp as usual and followed-up as per country protocol.

For uncomplicated malaria, WHO continues to recommend that women in the first trimester should be treated with oral quinine for seven days (with or without clindamycin), however, the Technical Expert Group on Malaria Chemotherapy is expected to review the safety data and make a recommendation on whether ACTs can be considered equivalent to quinine for treatment of acute malaria in the 1<sup>st</sup> trimester of pregnancy in 2021. Until the recommendation is changed, however, ACTs should be used for treating uncomplicated first trimester malaria infections only if no other efficacious antimalarial treatments are available. In the second and third trimesters, ACTs are the preferred therapy. Quinine is associated with an increased risk of hypoglycemia in late pregnancy, and it should be used only if efficacious alternatives are not available. Primaquine and tetracycline should not be used in pregnancy.

For treatment of severe malaria in pregnancy, parenteral antimalarials should be given without delay; maternal mortality in severe malaria is approximately 50%, which is higher than in non-pregnant adults. Parenteral artesunate is preferred in the second and third trimesters while either parenteral quinine or parenteral artesunate are acceptable choices in the first trimester (the increased risk of death outweighs the uncertainties over safety).

**Table. Treatment of Malaria in Pregnancy**

Malaria Severity	1 <sup>st</sup> trimester	2 <sup>nd</sup> or 3 <sup>rd</sup> trimester
Uncomplicated malaria	Oral quinine for seven days (with or without clindamycin) or, if quinine is unavailable, ACT**	ACT*
Severe malaria	IV/IM artesunate or IV/IM quinine	IV/IM artesunate (preferred) or IV/IM quinine if artesunate not available

\* HIV infected individuals on zidovudine or efavirenz should avoid ACT regimens that contain amodiaquine.

\*\* Nearly all of the data on safety of first trimester ACT use is for artemether-lumefantrine, so this should be considered as the preferred option

## HIV-Infected Women

HIV infection reduces a pregnant woman’s ability to control *P. falciparum* infections. The risk and intensity of malaria infection during pregnancy is higher in women who are HIV-infected. Such women are also more likely to have symptomatic infections, respond less well to antimalarial treatment, and have an increased risk for malaria-associated adverse birth outcomes. While the risk of malaria in HIV-negative women is greatest during first and second pregnancies, in the presence of HIV infection, the risk associated with placental malaria is independent of the number of pregnancies. Given this increased risk, emphasis should be placed on ensuring that HIV-infected women sleep under ITNs every night.

**Intermittent preventive treatment is recommended for HIV-infected pregnant women living in areas with high levels of transmission only when they are not receiving daily trimethoprim-sulfamethoxazole (cotrimoxazole) prophylaxis, because co-administration of these drugs increases the risk of sulfa-related adverse effects, including Stevens-Johnson Syndrome (a severe skin reaction).** In addition, daily cotrimoxazole provides a similar protective effect to IPTp if doses are not missed. HIV-infected women who are not taking cotrimoxazole prophylaxis should receive a minimum of three doses of IPTp with SP during pregnancy to obtain protection similar to that received with two doses in women not infected with HIV.

Given that many HIV-positive women will not be eligible for IPTp due to concurrent cotrimoxazole prophylaxis, it is imperative that HIV-positive women receive an ITN and are encouraged to sleep under the net throughout their pregnancy.

Case management of malaria in pregnancy in HIV-positive individuals is the same as in uninfected individuals, with the exception that amodiaquine-containing ACT regimens should be avoided in patients on zidovudine or efavirenz.

## Prevention of Anemia in Pregnancy

Folic acid supplementation in pregnancy is important to prevent neural tube defects in the developing fetus as well as to prevent megaloblastic anemia in the mother. The recommended dose of folic acid for use in pregnancy is 0.4 mg/day or 400 micrograms per day, which is adequate to prevent neural tube defects in the infant. In many African countries, the higher (5 mg) dosage, which is used to treat megaloblastic anemia (anemia resulting from folic acid deficiency, which is rare in pregnancy), is

predominantly available. However, this higher dose should not be used in conjunction with IPTp, as it has been shown to decrease the efficacy of SP. In contrast, the 0.4 mg/day dose does not interfere with SP efficacy. **In countries where doses of folic acid greater than 1 mg/day are used for supplementation in pregnancy (notably Niger and Nigeria), PMI teams should work with the MOH to procure (or consider procuring) low-dose folic acid (or iron and folate combination tablets, with 60 mg/day iron and 0.4 mg/day of folate), which is recommended by WHO for use in pregnancy.**

## Improving Program Implementation for IPTp

A number of challenges to IPTp scale up have been observed in PMI-supported countries. These include issues concerning central and peripheral level stock-outs of SP, inconsistent malaria and maternal health guidance on IPTp administration, confusion among providers about timing and dosages, and lack of coordination between Reproductive/Maternal Health and NMCPs of their responsibilities for program implementation.

PMI country teams are encouraged to:

- Identify and assess potential issues and challenges to IPTp scale-up
- Foster coordination between Maternal Health Programs and NMCPs, with establishment of a national MIP working group or task force
- Review the current policy in country and work with the MOH, Reproductive Health, and NMCP to update the policy to conform to the revised WHO guidelines
- Update the HMIS and ANC registers to facilitate collection of data regarding the additional doses of SP (i.e., IPTp3, IPTp4, etc.)
- Disseminate revised guidelines widely, and ensure that they are available to health providers at the facility level (e.g., a simple memo from District Medical Officer followed by a supervisory visit may be an effective means to improve IPTp uptake)
- Develop an action plan for IPTp training and supervision of health providers
- Support SP supply chain and stock management, training, and logistics and procure SP in case of gaps
- Explore innovative means to reach out to CHWs, including the use of cell phone messaging to promote ANC attendance and IPTp awareness.
- Consider support for electronic based supervision and reporting forms to assess health worker performance
- Work toward ensuring proper folic acid doses are being administered

In addition, PMI teams are encouraged to reach out to other donors and partners, such as the U.S. Peace Corps, to help facilitate MIP activities including IPTp. For example, Peace Corps Volunteers can assist facility based health workers and community health workers to increase IPTp uptake through targeted SBC strategies including mobilizing community members through household visits, organizing women's and other community group discussions, engaging men, focus group discussions, etc. Peace Corps Volunteers could also be trained to do rapid MIP/IPTp assessments in communities where IPTp uptake is particularly low to identify some of the major bottlenecks. Please see the [SBC chapter](#) for additional guidance.

## Additional Resources

- WHO-Roll Back Malaria website: <http://mosquito.who.int>
- The updated WHO IPTp-SP policy and full meeting report (July 2012): [http://www.who.int/malaria/mpac/sep2012/iptp\\_sp\\_erg\\_meeting\\_report\\_july2012.pdf](http://www.who.int/malaria/mpac/sep2012/iptp_sp_erg_meeting_report_july2012.pdf).
- The full report from the Malaria Policy Action Committee meeting: <http://www.malariajournal.com/content/11/1/424>
- WHO updated policy brief published in April 2013: [http://www.who.int/malaria/publications/atoz/policy\\_brief\\_iptp\\_sp\\_policy\\_recommendation/en/](http://www.who.int/malaria/publications/atoz/policy_brief_iptp_sp_policy_recommendation/en/).
- The report from the Expert Review Group meeting: [http://www.who.int/malaria/mpac/mpac\\_sep13\\_erg\\_ipt\\_malaria\\_pregnancy\\_report.pdf](http://www.who.int/malaria/mpac/mpac_sep13_erg_ipt_malaria_pregnancy_report.pdf)
- *The epidemiology of malaria in pregnancy* (by Desai M, ter Kuile FO, et al) and other articles in the Lancet supplement (volume 7), February 2007.
- A broad range of useful documents is also available as part of the “Malaria during Pregnancy Resource Package” produced by the Maternal and Neonatal Health Project. This can be found on their website ([www.jhpiego.org](http://www.jhpiego.org)) and is also available on compact disk. Updated ANC guidance: [www.who.int/reproductivehealth/publications/maternal\\_perinatal\\_health/anc-positive-pregnancy-experience/en/](http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/)
- ANC guidance executive summary, including the list of the recommendations: <http://apps.who.int/iris/bitstream/10665/250800/1/WHO-RHR-16.12-eng.pdf?ua=1>

## Frequently Asked Questions for MIP

### Q1. If SP is no longer effective in children, why are we giving it to pregnant women?

**A.** The spread of resistance of *P. falciparum* to SP in eastern and southern Africa has raised concerns about the efficacy of SP for IPTp. However, even in areas where SP is not an effective therapy in children for treating uncomplicated malaria, it remains effective for IPTp. It is thought that a pregnant woman’s pre-existing immunity amplifies the effectiveness of SP in IPTp, whereas young children have no such immunity. IPTp is thought to work both by clearing existing asymptomatic placental malaria infections as well as preventing new infections for several weeks (due to the long half-life of SP). Even in areas of high level resistance to SP, this combination has been shown to provide a benefit against the adverse effects of malaria.

### Q2. What are the key findings from recent efficacy studies of IPTp with SP?

**A.** Some recent studies present mixed findings on the efficacy of IPTp with SP, however WHO recommends continuing IPTp with SP until such time as there is clear evidence that it is no longer effective or an effective alternative is recommended. There is evidence of decreasing efficacy of SP in Eastern Africa, specifically in studies from Tanzania and Malawi, suggesting that SP may be of reduced

benefit in specific regions of the respective countries.<sup>77,78</sup> Of particular concern are several studies in areas where the dihydropteroate synthase (*dhps*) A581G mutation has been identified on a background of the dihydrofolate reductase (*dhfr*) /*dhps* quintuple mutant, resulting in a “sextuple mutant.” However, the extent of this mutant remains limited, and data from areas without the sextuple mutant (even with high prevalence of the quintuple mutant) suggest that IPTp continues to provide benefit. In a study in Mozambique, Menendez et al. found a protective effect of SP against neonatal death despite a lack of protection from low birth weight or placental infection by histology, suggesting that there may be additional mechanisms through which SP provides protection.<sup>79</sup> Studies in areas with lower levels of SP resistance (West Africa) have found that IPTp with SP remains effective.<sup>80</sup> In addition, a recent meta-analysis of national survey data has shown that SP provides protection in a programmatic context (e.g., non-study setting). Similarly, a meta-analysis of data from eight delivery cross-sectional studies in six countries with varying degrees of resistance found no correlation between the effect of IPTp-SP and resistance strata. Consequently, WHO recommends continuing IPTp with SP until there is clear evidence that it is no longer effective or an alternative is recommended. Updated WHO policy recommendations are based on recent evidence and seek to reinforce the importance and appropriateness of SP for IPTp. PMI encourages routine monitoring of molecular markers of SP resistance.

### Q3. How can one be assured that a woman is in the second trimester?

A. The second trimester starts at the beginning of the 13<sup>th</sup> week of pregnancy. This can be determined by one or more of the following:

- Counting weeks from the first day of the last menstrual period
- Palpation of the uterine fundus: once the fundus can be palpated, the woman is definitely in the 2<sup>nd</sup> trimester, although an unskilled provider may not be able to palpate as early as 13 weeks

Quickening, which is defined as when the mother first feels fetal movements, and usually occurs at approximately 20 weeks gestation in the first pregnancy, and earlier (between 15-20 weeks) in subsequent pregnancies (given that this is well into the 2<sup>nd</sup> trimester, it is preferred that other methods be used to determine gestational age/ whether the woman is in the 2<sup>nd</sup> trimester).

---

<sup>77</sup> Harrington WE, et al: Intermittent Treatment to Prevent Pregnancy Malaria Does Not Confer Benefit in an Area of Widespread Drug Resistance. *Clin Infect Dis* 2011, 53:224-230.

<sup>78</sup> Feng G, et al: Decreasing burden of malaria in pregnancy in Malawian women and its relationship to use of intermittent preventive therapy or bed nets. *PLoS ONE* 2010, 5:e12012.

<sup>79</sup> Menendez, C., A. Bardaji, et al. (2010). "Malaria Prevention with IPTp during Pregnancy Reduces Neonatal Mortality." *PLoS ONE* 5(2): e9438.

<sup>80</sup> Maiga OM, et al: Superiority of 3 Over 2 Doses of Intermittent Preventive Treatment With Sulfadoxine-Pyrimethamine for the Prevention of Malaria During Pregnancy in Mali: A Randomized Controlled Trial. *Clin Infect Dis* 2011, 53:215-223

---

# SEASONAL MALARIA CHEMOPREVENTION

---

## **\*New/Key Messages\***

Seasonal malaria chemoprevention has been shown to be an **effective strategy** in reducing malaria morbidity in eligible countries of the Sahel and feasible to implement on existing platforms.

Planning for procurement of commodities should be done **at least a year in advance** given long lead times for delivery.

Without issuing new or updated guidance, the WHO-GMP has clarified to countries its support of a less restrictive approach to SMC implementation, especially regarding the addition of a fifth round of SMC where epidemiologically appropriate.

## **Introduction**

WHO issued a recommendation for the implementation of seasonal malaria chemoprevention (SMC) in March, 2012.<sup>81</sup> Seasonal malaria chemoprevention, formerly known as intermittent preventive treatment for children, is the administration of treatment doses of longer-acting antimalarial medications at monthly intervals in areas of exclusively seasonal transmission with the aim of maintaining protective drug concentrations in the blood throughout a complete transmission season. The current WHO recommendations consist of a treatment dose of amodiaquine plus sulfadoxine-pyrimethamine (AQ+SP) given to children between 3 and 59 months of age at monthly intervals during the period of peak malaria transmission. While historically implemented over a period of 3-4 months, recent models showing benefit of additional coverage in certain settings have led a few countries to plan for a fifth round of SMC in targeted geographies.

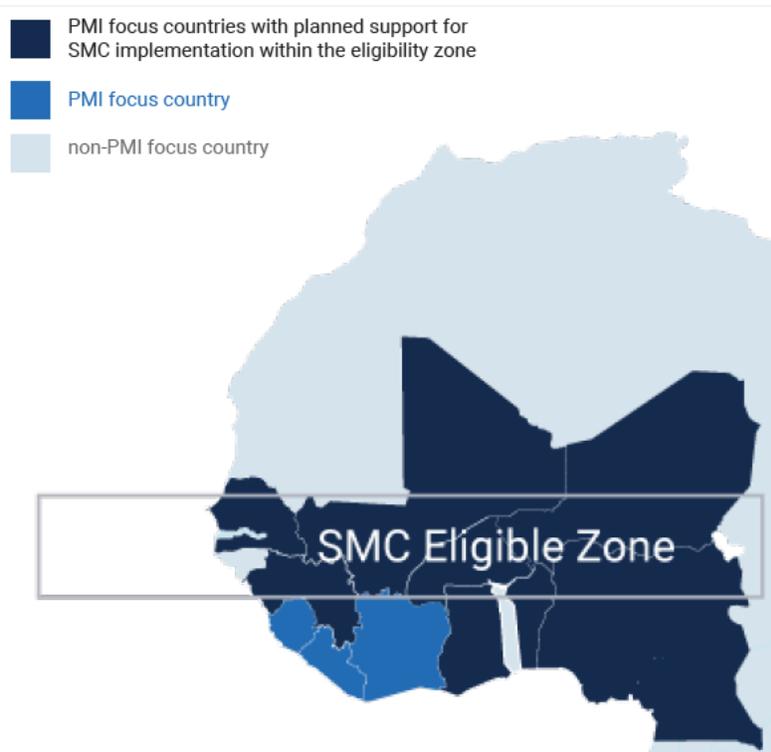
This approach is only recommended for geographic regions in which 60% of malaria cases occur within a short period of about four months. Seasonal malaria chemoprevention is not recommended for areas where high levels of resistance to either SP or AQ have been demonstrated. Based on these criteria, implementation of this strategy has only been recommended in countries or portions of countries in the Sahel region of West Africa, to date. WHO recommends that countries implementing SMC should not concurrently implement intermittent preventive treatment in infants (IPTi, which is the administration of a full treatment dose of SP to infants less than one year of age) in the same areas. PMI currently supports SMC activities in Benin, Burkina Faso, Cameroon, Ghana, Guinea, Mali, Niger, Nigeria and Senegal. Seasonal malaria chemoprevention with SPAQ is not currently being used in the seasonal

---

<sup>81</sup>[WHO Policy Recommendation: Seasonal Malaria Chemoprevention \(SMC\) for Plasmodium falciparum malaria control in highly seasonal transmission areas of the Sahel sub-region in Africa. March 2012](#)

transmission belt in Southern Africa, because intense SP resistance has been well documented in the area, and sufficient data on the safety, feasibility, and efficacy of alternative drugs for SMC programs are not yet available.

Seasonal malaria chemoprevention programs require a community-based structure to deliver this intervention. Many successful programs are built on existing CHW or iCCM programs, where available. Community health workers are often best placed to identify the children who qualify for SMC, distribute the medications, and follow-up to ensure adherence to dosing regimens throughout the rainy season. Results from the PMI-funded pilot implementation and evaluation of SMC in Mali and Senegal showed a 66% drop in parasite prevalence and a 50% drop in cases of uncomplicated malaria among children <5 following four rounds of SMC. The studies also demonstrated the feasibility of implementing through existing community-based platforms. Teams in relevant countries are encouraged to consult with the PMI Headquarters SMC POCs to determine whether and how to support country-level SMC strategies.



## Considerations

A number of technical and logistical considerations exist when supporting an SMC program. These are outlined below.

## ***Implementation issues***

Current WHO guidance does not provide details on the best strategies for delivery of SMC in the field. In many countries, the first dose of SMC is delivered door-to-door by community health workers, and the doses for the second and third day are left with the child's caregiver, along with instructions for administration. In other countries, a fixed-point approach is used for the first dose, with caregivers taking the additional doses for home administration. In fixed-point sites, there may also be community level 'mop-up' to reach children not seen at the distribution points. Some programs couple other interventions, such as nutritional supplementation, to SMC delivery. In most programs, SMC is given to all children who are present, but there are exceptions. For example, in Mali, malaria screening and testing is done prior to SMC delivery and children who test positive are treated with ACTs and do not receive SMC drugs. Countries have adopted different delivery approaches that are adapted to the specific country context. While no official guidance exists, the individual experiences of different countries have been documented in the scientific literature. For example, a PEER study funded by PMI documented that door-to-door distribution achieved higher coverage levels, but also increased costs for the program. Some countries, such as Senegal, are addressing concerns about adherence to day 2 and day 3 of SMC drug regimens by providing directly observed therapy (DOT) as part of the campaign. This comes with significant costs and is not recommended by PMI without clear evidence of low adherence for second and third doses. In most SMC campaigns, implementing partners are responsible for SBC and communication activities ([See Social Behavior Change - Special Considerations](#)). These activities can also be key to achieving coverage and adherence targets. PMI country teams are encouraged to reach out to other countries implementing SMC to better understand best practices.

### **Number of cycles**

WHO recommendations specify that seasonal malaria chemoprevention should be delivered once a month during the peak transmission season in settings in which the majority of clinical malaria cases occur within a short period of about four months. Some countries have questioned whether three rounds would be sufficient to provide a desired level of protection, while others have considered extending the season to five months. Countries or geographic areas with a documented transmission season shorter than four months may consider only covering the duration of the transmission season. However, shortening SMC to fewer than four months should not be considered as a cost-savings activity as sufficient data do not currently exist on the effectiveness of a shortened period of implementation. Modeling exercises have shown that in some settings the addition of a fifth round may lead to significant reductions in malaria mortality and morbidity. Additional data from countries or regions implementing a fifth round (such as coverage and adherence in round 5, adverse drug reactions, etc.) are needed to better inform policy.

### **Age groups**

The current WHO recommendation is for SMC to target children aged 3-59 months. These recommendations are based on clinical trials and pilot SMC projects which documented the effectiveness of the intervention to reduce malaria morbidity in this age group. Studies extending the age range for SMC up to age 10 years have been conducted in several countries, including a PMI-funded OR project. WHO has not yet published an evidence review or made a recommendation regarding this age group, however a systematic review will be conducted in 2021 to be considered for an update of recommendations. Countries wishing to use PMI funds to support expanded SMC coverage of older children should consult with the SMC technical team.

### ***Resistance monitoring vs. pharmacovigilance***

The deployment of a novel drug-based strategy such as SMC, even though it uses well-tested drugs, raises questions of efficacy and pharmacovigilance. The current WHO guidelines stress that systems to monitor both these issues should be instituted or strengthened in SMC zones. As with other malaria medications, PMI does not prioritize support for pharmacovigilance due to the well-established safety profile of AQ and SP. On the other hand, PMI does support monitoring of therapeutic efficacy for first-line malaria treatments, which can include testing for molecular markers of drug resistance for ACTs as well as AQ and SP. Therapeutic efficacy monitoring of AQ and SP is not conducted as it would be unethical to use either of these drugs as monotherapy for treatment of clinical malaria in a standard TES protocol. PMI is working with WHO and other partners to develop and implement molecular methods to monitor for resistance to these two drugs. Country teams interested in supporting resistance monitoring activities should consult with the Case Management team for guidance.

### ***Commodities***

One significant issue for implementing an SMC program is having the necessary quantities of quality-assured SP+AQ available in advance of the malaria transmission season. To date, there is one WHO prequalified manufacturer of the co-blister presentation of SP+AQ; another manufacturer has ERP approval but is not yet WHO prequalified, although a dossier has been submitted. PMI relies mostly on the WHO prequalified supplier but is also phasing in the ERP approved supplier with limited procurement to diversify the market. Limited supply base remains a constraining factor for other donors as well, and lead times for SP+AQ remain long (approximately 1 year). To overcome this challenge, PMI continues to use a pre-positioning strategy to ensure supplies are available to meet demand across the SMC community. Countries considering drug procurement in support of SMC campaigns should place orders as early as possible to ensure the drugs arrive in the country in time for the malaria transmission season, taking into consideration transport/distribution for pre-positioning to the intended point-of-care distribution locations. All PMI country teams planning to support SMC should work closely with the PMI Headquarters Supply Chain Team to ensure sufficient quantities of SMC drugs will be available when needed. Any SMC drug needs required for potential pilots or planned expansions should also be included in commodity planning figures. In the limited geographies implementing SMC to an expanded

age range, please note that the older children require two blister packs per treatment and plan accordingly.

If SMC is relevant to your country team and PMI is requested to procure commodities, orders must be submitted to GHSC-PSM or the PMI Headquarters Supply Chain Team as close as possible to one year in advance of planned campaign dates to ensure availability of the needed drugs in advance of the campaign. More information can also be found in the Commodity Procurement chapter.

In addition, the use of AS-AQ as a first-line malaria treatment is not recommended for SMC areas because AQ is used for SMC, so countries implementing SMC where AS-AQ is the first-line treatment must ensure a sufficient supply of a non-amodiaquine-based ACT (i.e., AL or DHA-Piperaquine) for first-line treatment either nationwide or in SMC areas.

It is recommended that countries do specific quantification for RDT and ACT needs during the SMC distribution rounds as part of the logistics planning in settings in which active screening and treating of febrile persons is part of the SMC implementation protocol.

### ***Surveillance, monitoring, and evaluation***

As a geographically targeted program, SMC presents some unique challenges for surveillance, monitoring, and evaluation. The first challenge is enumerating the target population of children 3-59 months. While most districts (or health zones, etc.) have estimates for this figure, precision is often difficult; some children will age into, and out of, this range during the period of implementation and older siblings or children from outside the SMC geographic area may present for treatment. Some SMC countries also have the added challenge of enumerating mobile populations and populations in insecure settings. Enumeration of the eligible population has implications for planning and procurement of drugs as well as for estimates of SMC coverage.

Tracking actual administration of the drugs is also a major challenge. The community health workers or other implementers tasked with delivering the drugs generally record the child's information and any reasons for non-administration of SMC in a standardized register. Most programs also provide caregivers with individual cards for each child, and each administration of SMC is recorded on the card. This allows tracking of the children over each month of SMC implementation. These data can then be aggregated by district to calculate coverage rates. However, these systems are fairly new and can be subject to incomplete data, especially in regards to why a child did not receive SMC during a particular round.

Currently, WHO recommends that countries collect only one indicator on SMC programs:

**Proportion of children aged 3–59 months (of those targeted) who received the full number of courses of SMC per transmission season**

This indicator is intended to be derived from routine systems such as those mentioned above. Despite this being the official WHO-recommended indicator, measurement details have not been fully finalized. Ideally, coverage would mean each child has received all three daily doses of medication each month, over the three or four months of the transmission season. In reality, routine data generally just reflect children who received the first dose through directly-observed treatment and whose caregivers were given the remaining two doses to administer at home. Most routine information systems are not able to capture actual administration of the second and third dose. However, PMI's pilot studies indicated that if a child received the first directly observed therapy dose, there was a very high likelihood of receiving the additional doses at home<sup>82</sup>. The number of rounds (months) of administration can vary by country and even by sub-national zone depending on a range of planning factors. Thus, countries should also report on the target number of courses (3, 4, or 5) and calculate this indicator accordingly.

In addition, it is important to monitor the proportion of children who meet the eligibility criteria (including residence in eligible zones) but who did not receive SMC due to refusals, presenting with malaria (in the case of Mali), etc. During the pilot phases of SMC scale-up, a number of programs used pre- and post-coverage surveys to capture direct data on coverage of the intervention. While large scale survey efforts are not necessary, low-cost rapid surveys are one tool that could be used to validate the administrative data on coverage and adherence. However, PMI does not recommend tracking coverage of SMC through national household surveys such as the DHS or MIS, because SMC programs are often only implemented in select districts and the sampling frame for these surveys is not representative at the district or lower levels. In addition, the timing of the survey work is not linked to the timing of the SMC activities. If data collection occurs before or during SMC implementation in a given year, the results could underestimate actual coverage.

A number of national programs and implementing partners have developed data collection tools to monitor program progress in their countries. The SMC Working Group, currently independently convened, is submitting a proposal to be considered as an official workstream of the RBM Country/Regional Support Partner Committee (CRSPC). An M&E taskforce has been created within this group to work on standardization of metrics and provide a platform for sharing tools and best practices.

## Additional Resources

- Additional information on the WHO policy recommendation can be found at: [http://www.who.int/malaria/publications/atoz/smc\\_policy\\_recommendation\\_en\\_032012.pdf](http://www.who.int/malaria/publications/atoz/smc_policy_recommendation_en_032012.pdf)
- A field guide for SMC implementation from WHO is available here: <http://www.who.int/malaria/publications/atoz/9789241504737/en/>
- An additional toolkit from MMV is available at: <https://www.mmv.org/access/tool-kits/seasonal-malaria-chemoprevention-tool-kit>

---

<sup>82</sup> Diawara F et. al. Measuring the impact of seasonal malaria chemoprevention as part of routine malaria control in Kita, Mali [Malar J.](#) 2017 Aug 10;16(1):325.

---

# VACCINES AND OTHER PREVENTIVE APPROACHES

---

## **\*New/Key Messages\***

Although WHO issued guidance to implement IPTi with SP in 2010, to date only Sierra Leone has adopted and implemented this policy.

WHO is conducting a **pilot evaluation of RTS,S/AS01 implementation** in three countries to assess feasibility, safety, and impact (mortality) in programmatic conditions. The vaccine implementation evaluation began in Ghana and Malawi in April 2019 and in Kenya in September 2019.

The 2018 WHO Evidence Review Group on **mass drug administration (MDA)** reviewed all recent studies and concluded that combined with vector control and case management, MDA may have short-term reductions on malaria transmission, but these reductions were only sustained in very low-to-low transmission areas and on islands. MDA or mass screen and treat activities can be considered within the context of operational research.

**Proactive community case management (ProCCM)** is a community-based intervention in which community health workers visit all households in their communities regularly, usually weekly or fortnightly, to actively seek out persons with fever, test them, and treat those that test positive for malaria. ProCCM is being scaled up in Senegal and Madagascar after operational research demonstrated effectiveness in decreasing malaria parasite prevalence and incidence. Non-PMI supported research is ongoing in Uganda and Mali. Although delayed by COVID-19, PMI is planning operational research to assess whether ProCCM can have an impact on reducing malaria transmission. Other proposals for pilots with enhanced monitoring could be considered on a case-by-case basis.

## **Introduction**

Although much progress has been made with the scale-up of PMI's core interventions, additional tools are being implemented or evaluated to either reduce malaria morbidity and mortality in high transmission settings or to interrupt malaria transmission in low transmission settings. This chapter will describe these ancillary interventions— their intended role, targeted settings, and level of current evidence. It is important to note that these interventions are intended to complement, not replace, core interventions in case management and vector control and should only be considered for PMI support once requirements for these core interventions have been addressed. Some of these interventions are appropriate for control/transmission reduction settings and others are intended as tools for elimination.

In recent years, WHO has approved new approaches involving anti-malarial medication for prevention (e.g., seasonal malaria chemoprevention or intermittent preventive treatment in infants) to further reduce morbidity and mortality in target groups in high transmission areas. In addition, the RTS,S

vaccine is being piloted in three countries as an additional tool to reduce morbidity and mortality in children in high transmission areas.

To accelerate the pathway to elimination or to interrupt transmission, other tools (e.g., MDA and MSAT) have been evaluated in various transmission settings. No matter the transmission setting, all of these ancillary approaches are intended as additional targeted activities and are not a substitute for a robust malaria control program based on vector control and strong case management practices. **For countries considering implementing any of these interventions, please consult with the PMI Headquarters Case Management Team or the PMI Headquarters Elimination Working Group.**

## Intermittent Preventive Treatment in Infants (IPTi)

In 2010, WHO issued guidance on the use of SP for intermittent preventive treatment in infants (IPTi). Intermittent preventive treatment in infants consists of the administration of a full treatment dose of SP to infants less than one year of age, living in areas at high risk of malaria, concurrently with the routine immunization schedule. The routine EPI scheduling varies by country but usually includes doses at 10 weeks and 14 weeks (with DPT vaccinations), and 9 months of age (with measles vaccination). IPTi has been approved by WHO for use in areas of moderate to high malaria transmission, where transmission occurs year-round, and where parasite resistance to SP is not high, which can be defined as areas that have less than 50% prevalence of *pfdhps* 540 mutations associated with resistance in the *P. falciparum* parasite. This strategy may be implemented at a sub-national level (e.g., at the regional or district level) when the extent of SP resistance is only known for a smaller geographic area.

In reality, most countries lack information on the prevalence of this mutation at the population level, making this strategy difficult to implement. To date, NMCPs have not prioritized IPTi in any country except Sierra Leone. Sierra Leone, after piloting IPTi in four districts in 2017, scaled up IPTi nationally to all 14 districts in mid-2018. UNITAID is planning an investment to generate further evidence to accelerate the adoption and scale-up of IPTi in moderate-high transmission settings. WHO recommends that countries implementing SMC should not also implement IPTi in the same areas. Any requests from NMCPs to support IPTi should be accompanied by evaluation of infant mortality and other potential benefits of adding this intervention, and must be discussed with the PMI Headquarters Case Management Team and PMI leadership.

Additional information on the WHO policy recommendation can be found at:  
[http://www.who.int/malaria/news/WHO\\_policy\\_recommendation\\_IPTi\\_032010.pdf](http://www.who.int/malaria/news/WHO_policy_recommendation_IPTi_032010.pdf)

## Malaria Vaccine

Research and development to produce a malaria vaccine has been ongoing for decades. The RTS,S/AS01 malaria vaccine (manufactured by GSK) was tested in a Phase III trial in 11 sites in seven African countries with different transmission intensities. The vaccine was tested in two age-categories: children

first vaccinated at 5-17 months of age, and young infants first vaccinated at 6-12 weeks of age. After approximately four years of follow-up, vaccine efficacy against clinical malaria in children was 36% and 28%, and against severe malaria was 32% and 1.1% when administered with and without a booster dose, respectively. In young infants, the vaccine efficacy against clinical malaria was lower at 26% with the booster dose and 18% without; no efficacy against severe malaria was observed. Despite moderate to low efficacy, impact, measured as number of cases averted, was high; 1,774 cases of clinical malaria were averted per 1,000 children vaccinated with booster, and 1,363 without booster. In young infants, 983 and 558 cases of clinical malaria were averted per 1,000 vaccinated with and without the booster, respectively. The Phase III trial demonstrated an increased risk of febrile convulsions within 7 days of vaccination. Additional important safety signals were noted but no causal link to the vaccine has been established: 1) an increase in meningitis in RTS,S/AS01 vaccinated children compared with controls; 2) in vaccinated children who developed severe malaria, there were more cases of cerebral malaria, and 3) among the low number of children who died, girls vaccinated with RTS,S were more likely to die than girls vaccinated with comparator vaccines.

The RTS,S/AS01 vaccine was reviewed by the European Medicines Agency in July 2015 and received a positive scientific opinion. Subsequently, a joint meeting of the WHO's Strategic Advisory Group of Experts and Malaria Policy Advisory Committee recommended to WHO that a large-scale Phase IV pilot implementation in operational context in 3-5 targeted countries in Africa be carried out to assess the feasibility of implementation of four doses of the vaccine in children 5-17 months of age, evaluate the vaccine's impact on mortality, and further assess the vaccine safety in the context of a routine immunization program. They also recommended an evaluation of adverse events following immunization, particularly on meningitis and cerebral malaria. WHO secured funding to support the initial malaria vaccine implementation programme (MVIP) with support from the Global Fund, GAVI, and UNICEF and put out a call for proposals (June 2017) to assess feasibility, safety, and impact (mortality). Ghana, Kenya, and Malawi were selected as the three pilot countries. The pilot began in Ghana and Malawi in April 2019 and in September 2019 in Kenya. Although PMI is not providing direct support for the implementation of these pilots, PMI is supporting scale-up and maintenance of coverage of vector control and case management interventions in the areas targeted by these pilots. PMI Resident Advisors in the targeted countries should be participating in country-level discussions to ensure coordination of these trials with PMI's implementation activities. PMI leadership will keep the field informed of any developments as these pilots are implemented. It is not anticipated, though, that PMI will have additional funding beyond what is already provided to countries to support evaluation of this vaccine in the pilot. The MVIP is expected to continue through 2023.

## **Mass Drug Administration**

Mass Drug Administration is defined as the practice of treating a targeted population in a defined geographic area for malaria, irrespective of the presence of symptoms and without diagnostic testing. As malaria control programs aspire to elimination, there has been a resurgent interest in MDA as a tool

to eliminate the remaining parasite reservoir in a given geographic area. Mass drug administration was a strategy used with mixed results during the eradication era of the mid-20<sup>th</sup> century. In some regions, such as the USSR and China, it was used for malaria control, parasite elimination, and epidemic response. In combination with vector control measures, MDA helped to eliminate malaria in select settings (e.g., small islands or highland settings).

Based on those eradication era experiences, WHO had discouraged MDA for routine malaria control because of its limited sustained impact on transmission and the high potential for the development of drug resistance. However, when artemisinin resistance was first detected in Southeast Asia, MDA was revived as a potential approach to eliminate the resistant strains of the parasite in limited geographic settings and targeted populations. In 2010, WHO convened an expert group to review the evidence for the use of MDA in the artemisinin-resistance containment project in Southeast Asia. The WHO Technical Experts Group concluded that there was no evidence of long-term benefits for MDA in large population groups. Two reviews found that while MDA can be successful at rapidly reducing parasite prevalence, once the activity is stopped, there is a strong tendency for malaria to rebound to previous transmission levels especially in higher transmission settings.<sup>83,84</sup> A consensus modelling study<sup>85</sup> noted that despite differing magnitude of effect depending on the transmission model used, all models predicted the percentage reduction in transmission to be temporary. The underlying assumption and the rationale for MDA is that subpatent parasitemia contributes substantially to malaria transmission and, therefore, must be treated if malaria is to be eliminated.

There were some limited examples of success, especially against *P. vivax* in seasonal transmission settings and small, isolated populations (such as on islands). However, many questions regarding the effective use and long-term effectiveness of MDA remain unanswered, including which drug regimens to use and for what duration, which populations to target, how best to achieve high coverage, and what combination of co- interventions is necessary for MDA to be effective.

In addition, in the context of the 2014 Ebola outbreak in West Africa, MDA was used as a strategy to reduce the prevalence of malaria in selected urban areas.<sup>86</sup> Temporarily reducing the burden of malaria on the health facilities allowed health workers to focus efforts on establishing critical Ebola diagnostic and treatment protocols.

Other partners, particularly the Gates Foundation and the Global Fund, have funded pilot studies in the Greater Mekong Subregion and other areas in Africa to assess the effectiveness of MDA, particularly in

---

<sup>83</sup> Newby, G. et. al., (2015). Review of mass drug administration for malaria and its operational challenges. *Am J Trop Med Hyg.*

<sup>84</sup> <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008846.pub2/full>

<sup>85</sup> Brady, O. J., et al. (2017). Role of mass drug administration in elimination of *Plasmodium falciparum* malaria: a consensus modelling study. *Lancet Glob Health* 5(7): e680-e687

<sup>86</sup> Aregawi, M., et al. (2016). Impact of the Mass Drug Administration for malaria in response to the Ebola outbreak in Sierra Leone. *Malar J* 15: 480.

the context of elimination efforts. Preliminary results of these studies have been mixed, both in terms of the coverage achieved (which often was well below the target) and in overall effectiveness. Some of the variation in study results appears to be related to transmission level and the coverage achieved and ongoing importation of malaria infections from outside the targeted area. Initial results from southern Zambia showed marked reductions in malaria prevalence and incidence across both control and MDA arms following aggressive efforts to achieve universal coverage of LLINs, IRS, and effective community case management.<sup>87</sup> In addition, focal MDA (MDA targeting households or small-scale foci) was not as effective or cost-saving compared to MDA.

In 2015, WHO convened an Evidence Review Group (ERG) to review all available evidence on MDA and presented their draft recommendations to the Malaria Policy Advisory Committee. In November 2015, WHO issued its recommendations stating that: *“Use of MDA for the elimination of P. falciparum malaria can be considered in areas approaching interruption of transmission where there is good access to treatment, effective implementation of vector control and surveillance, and a minimal risk of re-introduction of infection.”* The goal in this setting is to eliminate all remaining parasite carriers and fully interrupt transmission. WHO also recommends that MDA could be considered in the context of epidemics or complex emergencies to transiently reduce malaria prevalence and reduce the risk of severe disease and death, thereby reducing the burden on the health system. WHO developed a [manual](#) for organizing an MDA campaign including examples of tools, templates for developing job aids, training and communication materials, and data collection forms that may be useful. In 2018, WHO convened another ERG to review the role of MDA. Several trials and non-randomized studies across transmission settings were discussed including an update of the previous Cochrane review which includes more recent high-quality studies. Combined with vector control and case management, MDA may have short-term reductions on malaria transmission, but these reductions were only sustained in very low-to-low transmission areas and on islands. The effectiveness of MDA may depend on the coverage of the intervention, which can be improved by including multiple rounds and targeting additional rounds to individuals missed during the first round. Updated recommendations from the 2018 ERG meeting have been submitted to the Malaria Policy Advisory Committee. In addition, WHO has commissioned a series of new systematic reviews including MDA for burden reduction, MDA for transmission reduction, MDA in emergency settings, and mass primaquine treatment to inform the Guideline Development Groups.

PMI is not currently supporting MDA implementation in the context of elimination activities or routine program support. At this point in time, PMI support for MDA is in the context of operational research. PMI will be supporting operational research to compare targeted MDA versus reactive case detection in response to index cases in the elimination settings of Ethiopia and a MDA study in Senegal. Any country teams considering supporting an MDA intervention should consult with the PMI Headquarters Elimination Working Group and Case Management Teams.

---

<sup>87</sup> Eisele, T.P. et al. (2016). Short-term Impact of Mass Drug Administration with Dihydroartemisinin Plus Piperaquine on Malaria in Southern Province Zambia: A Cluster-Randomized Controlled Trial. *J Infect Dis*; **214**(12):1831-1839.

## Mass Screen and Treat

Mass screen and treat (MSaT) refers to screening all persons in a population with a malaria diagnostic test and providing treatment to those with a positive test result. The aim of this type of program is to reduce the parasite reservoir (and ultimately reduce gametocytemia) and decrease malaria transmission. By systematically testing a population and treating all positive cases, including asymptomatic infections, the hope is that the reservoir of parasites (and subsequent gametocytes) will be diminished beyond that which is possible by traditional case management.

At present, malaria RDTs are the only feasible option for conducting MSaT. However, the currently available RDTs are not sensitive enough to detect very low density parasitemias, which can comprise up to 50% of malaria infections found in a population. Evidence from Burkina Faso and Zambia, and from a PMI-supported study in Kenya, indicate that MSaT with conventional RDTs is insufficient to significantly reduce the human infection reservoir. While work to develop more field-friendly molecular tests are underway and a highly-sensitive hrp2-based RDT is commercially available, there is currently no evidence to indicate that such more sensitive diagnostic tests will improve the effectiveness of the MSaT approach. Evaluation of the performance of the high-sensitivity RDT for *P. falciparum* malaria in asymptomatic individuals from Uganda, Myanmar, and naïve human challenge infections showed a greater than 10-fold lower limit of HRP2 compared with conventional RDT.<sup>88</sup> Recent studies from Myanmar<sup>89</sup> and Ethiopia<sup>90</sup> observed higher sensitivities than the conventional RDTs but still only about 50% compared to the gold standard methods.

The 2015 Malaria Policy Advisory Group concluded that mass screening and treatment and focal screening and treatment for malaria are not recommended as interventions to interrupt malaria transmission. PMI is not currently supporting MSaT activities; however, the role of highly-sensitive RDTs was evaluated in Burma and Cambodia for reactive case detection with mixed results. Neither country plans to incorporate the uRDT into their program at this point. Any country teams considering supporting an intervention involving MSaT should consult with the PMI Headquarters Elimination Working Group and Case Management Teams in advance of any consideration of MOP support.

## Pro-active Community Case Management

Proactive community case management (ProCCM) is the deployment of CHWs to visit all households in the community to identify persons of all ages with fever or other symptoms consistent with malaria on a routine basis (generally weekly or every two weeks) in a targeted community. Persons identified with

---

<sup>88</sup> Das, S., et al. (2017). Performance of a High-Sensitivity Rapid Diagnostic Test for Plasmodium falciparum Malaria in Asymptomatic Individuals from Uganda and Myanmar and Naive Human Challenge Infections. *Am J Trop Med Hyg*

<sup>89</sup> Landier, J., et.al. (2018). Operational Performance of a Plasmodium falciparum Ultrasensitive Rapid Diagnostic Test for Detection of Asymptomatic Infections in Eastern Myanmar. *J Clin Microbiol.*

<sup>90</sup> Girma, S., et. al. (2018). Prevalence and epidemiological characteristics of asymptomatic malaria based on ultrasensitive diagnostics: A cross-sectional study. *Clin Infect Dis.*

febrile illness are tested with a malaria RDT. Those that are positive are treated with the appropriate first-line treatment (or referred if signs of severe disease are present). Such proactive community sweeps may be restricted to the high transmission season.

The most well-established example of this approach is the PECADOM Plus program in Senegal. Community health workers conduct weekly visits to all households in their catchment areas during high transmission season for malaria to identify and test (by RDT) anyone with recent fever or symptoms related to malaria. Treatment is provided to those who test positive. In villages in which PECADOM Plus has been implemented, there have been significant reductions in weekly prevalence of symptomatic, parasitologically confirmed malaria infection over the course of the transmission season, even while total numbers of cases identified and treated at the community level increased.<sup>91</sup> The approach, started in the highest transmission districts, was scaled to 40 of Senegal's 76 health districts by 2016, including higher transmission areas within zones of low-moderate transmission. Current efforts extend the period of implementation and increase the proportion of communities benefiting from this intervention.

Results from a recently completed study in Madagascar suggest that ProCCM was associated with decreased parasite prevalence among all ages and decreased anemia among women of reproductive age. PMI is exploring whether the ProCCM approach might be feasible and effective, both as a means of reducing severe disease and death and as a transmission reduction strategy, in other settings. Studies of ProCCM are underway in Mali and Uganda (some PMI funding), and one is planned for Zambia (PMI-funded). More evidence is likely to become available in the next few years. The ProCCM approach may be most appropriately deployed in areas where core vector control and passive case management interventions have been fully scaled up, where an existing iCCM program is in place, and where further reduction in burden is sought.

Any country considering deploying ProCCM should consult with the PMI Headquarters Case Management Team. For countries where studies have not yet been conducted, any pilots should have clear objectives for the program (objectives might include burden reduction, treating more cases at the community level, remedying poor or delayed care seeking, improving utilization of CHWs, strengthening the CHW platform, improving quality of community-based case management) and include enhanced monitoring that examines the intervention through the lenses of feasibility (including supervision and supply chain), quality of care, sustainability, and effectiveness in achieving the stated objective. Any ProCCM pilot will require enhanced supervision and supply chain reinforcement.

---

<sup>91</sup> Linn A, et al. Reduction in symptomatic malaria prevalence through proactive community treatment in rural Senegal. *Trop Med International Health* 2015.

---

# CASE MANAGEMENT

---

## **\*New/Key Messages\***

**Reformatting the Case Management section.** With input from field staff, the Case Management (CM) chapter has been re-formatted for easier use and reference. Each section in the CM chapter now has two components. The first component provides key technical information. The second component (shown in a gray highlighted box) that follows provides guidance on PMI priority areas for support for that specific technical section. The CM team also has added sections on “Recognition and management of febrile illness” and “Determination of first line ACTs.”

**Guidance document on the management of malaria rapid diagnostic test stock shortages.** PMI, in collaboration with partners, has developed guidance to assist National Malaria Control Programs in the management of short- to medium-term malaria rapid diagnostic test (RDT) stock shortages. A summary of the guidance is provided below in the sub-section “PMI Priorities Areas of Support for RDTs” and includes a link to the full document.

**Infections with parasites containing deletions in the *hrp2* gene, which produces the main antigen detected by *P. falciparum* RDTs, have been identified in a few sites in Africa.** Samples collected during therapeutic efficacy studies may be screened for the presence of *hrp2/3* deletions.

**Highly sensitive malaria rapid diagnostic tests (hsRDTs):** Although hsRDTs are now available, PMI does not currently recommend the use of hsRDTs for diagnosis of clinical malaria in any setting and will not support procurement of hsRDTs as a replacement for conventional RDTs.

**World Health Organization (WHO) notification on the use of artesunate-pyronaridine for treatment of uncomplicated malaria.** The WHO released a notification in October 2019 clarifying that artesunate-pyronaridine (AS-PYR) (brand name Pyramax) can be considered an efficacious and safe artemisinin-based combination therapy (ACT) for the treatment of uncomplicated malaria in adults and children weighing 5 kg or more in all malaria-endemic areas.

### **Case Management Resources**

Additional resources, including PMI treatment guidelines checklist, WHO technical guidelines and job aids, can be found at this link:

[https://drive.google.com/drive/folders/1h5eiTRgCMc\\_18YAYp!UnR9GEfyaM0kUP?usp=sharing](https://drive.google.com/drive/folders/1h5eiTRgCMc_18YAYp!UnR9GEfyaM0kUP?usp=sharing)

## PMI Priority Areas Supporting Comprehensive Malaria Case Management

A successful malaria case management program consists of several distinct but interrelated activities that should be implemented in concert. Priority areas for PMI support for case management include:

- Reviewing policies and guidelines on the management of fever and diagnosis and treatment of malaria, and harmonizing with WHO recommendations<sup>92</sup> and other relevant clinical policies and guidelines (e.g., integrated management of childhood illness guidelines);
- Supporting the accurate quantification and forecasting, and the consistent provision of equipment and supplies to assure appropriate diagnosis (e.g., blood sampling, microscopy, rapid diagnostic tests [RDTs], biohazardous material disposal);
- Supporting the accurate quantification and forecasting, and the consistent provision of antimalarial treatment for uncomplicated (i.e., artemisinin-based combination therapy [ACT]) and severe (e.g., parenteral artesunate, rectal artesunate) malaria;
- Supporting quality assurance of diagnostic testing programs including quality control of RDTs and their use, malaria microscopy, job aids, and training and supportive supervision;
- Supporting pre- and in-service training, supervision and mentoring of clinical staff and community health workers (CHWs) for the management of uncomplicated and severe malaria, including accurately recording and reporting malaria test and treatment results;
- Supporting integrated Community Case Management (iCCM) programs consistent with recommendations from UNICEF and WHO; and
- Supporting therapeutic efficacy monitoring of antimalarial treatments.

For additional details, see the specific “Key Technical and Programmatic” section below.

### Key Technical and Programmatic Guidance

#### *Recognition and management of febrile illness*

Infection with malaria parasites results in a spectrum of manifestations ranging from asymptomatic to uncomplicated illness to severe malaria. Among symptomatic patients that seek care, signs and symptoms of malaria typically include fever but generally are non-specific. Malaria therefore should be suspected clinically by a health worker (HW) primarily on the presence of fever or report of history of fever<sup>93</sup>. WHO also recommends that malaria be suspected in children with clinical signs or lab evidence of moderate to severe anemia (i.e., palmar pallor, hemoglobin <8g/dL). Despite this recommendation, recent evidence suggests that most patients with fever or history of fever who present for care are not suspected of having or tested for malaria, missing opportunities to diagnose and appropriately treat<sup>94</sup>.

---

<sup>92</sup> WHO Guidelines for Treatment of Malaria, Third Edition (2015) <https://www.who.int/publications/i/item/9789241549127>

<sup>93</sup> WHO Guidelines for Treatment of Malaria, Third Edition (2015) <https://www.who.int/publications/i/item/9789241549127>

<sup>94</sup> Plucinski MM, Guilavogui T, Camara A, Ndiop M, Cisse M, Painter J, Thwing J.

Appropriate assessment by HWs of all patients seeking care for signs and symptoms of malaria and providing parasitological testing of all patients with suspected malaria is important for both effective case management and transmission reduction. As malaria prevention and control efforts continue to drive down malaria prevalence, continued parasitological testing of all febrile patients will remain critical, especially as the percentage of positive tests continues to decline.

The initial management of a suspected malaria patient also should include an assessment of illness severity to correctly classify the patient as having uncomplicated or severe disease to guide case management, including appropriate diagnostic testing and prescribing effective treatment. Please see [WHO Guidelines for the Treatment of Malaria \(3rd Edition\)](#)<sup>2</sup>, [Integrated Management of Childhood Illnesses \(IMCI\) Chart Booklet](#)<sup>95</sup>, [Integrated Management of Adolescent and Adult Illness \(IMAI\)](#)<sup>96</sup>, and [Malaria Surveillance, Monitoring and Evaluation: A Reference Manual](#)<sup>97</sup> for guidance.

**Country case management policy and guidelines** on the clinical management of fever and malaria should be periodically reviewed, revised, and harmonized with WHO recommendations and other relevant clinical policies and guidelines (e.g., integrated management of childhood illness guidelines).

## Diagnostic Testing

### *Universal testing of all patients with suspected malaria*

**In 2010, WHO changed its recommendations on malaria diagnosis, calling for all patients with suspected malaria to undergo quality-assured diagnostic testing, with either RDTs or microscopy, and for treatment decisions to be based on test results.** RDTs and microscopy both are recommended for the diagnosis of malaria in patients with suspected malaria. Each testing modality has characteristics that make it useful in particular clinical situations or settings. WHO has published detailed guidance for lab procedures for malaria diagnosis and on the programmatic elements of a malaria diagnostics program, which should assist in the development of national policies and guidelines.<sup>98, 99, 100</sup> Diagnosis based on clinical signs and symptoms alone should only be used when diagnostic testing is unavailable.

---

How Far Are We from Reaching Universal Malaria Testing of All Fever Cases? Am J Trop Med Hyg. 2018 Sep;99(3):670-679. doi: 10.4269/ajtmh.18-0312. <http://www.ajtmh.org/content/journals/10.4269/ajtmh.18-0312>

<sup>95</sup> Integrated Management of Childhood Illnesses (IMCI) Chart Booklet (2012)  
[https://www.who.int/maternal\\_child\\_adolescent/documents/IMCI\\_chartbooklet/en/](https://www.who.int/maternal_child_adolescent/documents/IMCI_chartbooklet/en/)

<sup>96</sup> Integrated Management of Adolescent and Adult Illness (IMAI)  
[https://apps.who.int/iris/bitstream/handle/10665/68535/WHO\\_CDS\\_IMAI\\_2004.1.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/68535/WHO_CDS_IMAI_2004.1.pdf?sequence=1)

<sup>97</sup> WHO Malaria Surveillance, Monitoring and Evaluation: A Reference Guide  
<https://www.who.int/malaria/publications/atoz/9789241565578/en/>

<sup>98</sup> WHO Malaria Diagnosis website: <http://www.who.int/malaria/areas/diagnosis/en/>

<sup>99</sup> [Universal Access To Malaria Diagnostic Testing: An operational manual](#) 2011

<sup>100</sup> [Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: round 8 \(2016-2018\)](#)

## ***PMI priority areas for diagnostics in general***

### **Policy and Guidelines**

PMI has prioritized scaling up diagnostic testing for malaria with RDTs and microscopy in all focus countries with the goal that all persons with suspected malaria are tested, and only those with a positive test are treated for malaria and reported as confirmed cases. This requires that quality-assured diagnostic testing for malaria be available at all levels of the healthcare system, including at the community level, at all times. Each country must decide which of the tests should be used at which points-of-care and for what indications.

Policy and guidelines on the diagnosis of malaria should be periodically reviewed, revised, and harmonized with WHO recommendations, and should provide specific recommendations on when a diagnostic test is indicated and how the results of testing should guide treatment decisions. If diagnostic testing is to be carried out by non-laboratory personnel or volunteers, clinical guidelines should incorporate or reference standard operating procedures (SOPs) and job aides on how to perform the test and handle and dispose of blood and biohazardous materials.

Regulations and/or laws governing who is permitted to perform a diagnostic test and dispense antimalarial drugs and antibiotics may need adjustments. For example, the task of performing RDTs in health facilities may be shifted to hospital or clinic assistants once they have been trained to conduct these tests.

### **Training and supervision of laboratory staff**

In most countries, training and supervision of laboratory personnel will be delivered as an integrated package. It is the responsibility of the NMCP, the National Reference Laboratory, and/or the Laboratory Department of the MOH to ensure that training materials reflect the current state-of-the-art, that the trainers and supervisors have the appropriate level of skill and experience, and that supervisory checklists and laboratory records collect all necessary information, including any data required for appropriate monitoring. PMI can play a critical role in providing technical assistance to these efforts. Capacity also should be available to conduct refresher training when supervision identifies deficiencies in laboratory or HW staff performance. Training and supervision materials, SOPs, and bench aids developed by PMI can be adapted and tailored to the country context.

## ***Diagnostic testing: rapid diagnostic tests (RDTs)***

Because quality assured microscopy services are challenging to implement and maintain at scale, RDTs are critical tools in reaching universal diagnostic testing of suspect malaria cases in all levels of the health system, especially in settings without a laboratory.

### **RDT characteristics**

Malaria RDTs detect the presence of *Plasmodium*-specific antigen(s) in the blood. The antigens detected by malaria RDTs include histidine-rich protein 2 (HRP2), *Plasmodium* lactate dehydrogenase (pLDH), or aldolase. Some RDTs detect antigens for a single species (e.g., *P. falciparum* or *P. vivax*), either as a single or multi-antigen RDT. Other RDTs detect antigens for multiple species, and some distinguish between *P. falciparum* and non-*P. falciparum* infection.

The sensitivity of RDTs to detect parasite antigen varies by the antigen and by brand, with the lower limit of detection generally at least the equivalent of 200 parasites/ $\mu$ L blood, which is sufficiently sensitive for identifying parasitemia in patients with clinical symptoms. While many RDTs have been shown to accurately detect both *P. falciparum* and *P. vivax* infections, the accuracy of RDTs to detect other non-*P. falciparum* infections is poor. HRP2-based RDTs are the predominant type of RDT used to diagnose *P. falciparum* infections primarily due to their higher sensitivity and more stable storage conditions. The shelf-life of RDTs is approximately 24 months from the date of manufacture.

Because RDTs do not detect antibodies from the human immunological reaction to *Plasmodium*-specific antigen(s), the result is not affected by impaired immunity (e.g., malnutrition, human immunodeficiency virus infection). Nevertheless, because RDTs are designed to qualitatively detect the presence of antigens, they are not able to determine the density of parasitemia or monitor the response to treatment, and therefore should not be used in the management of severe malaria. RDTs may remain positive for two weeks or more after clearance of parasitemia (particularly those RDTs based on the detection of HRP2 antigen), and they therefore cannot be used to diagnose treatment failures.

#### **RDT program considerations: use, adherence and quality assurance**

RDTs are relatively easy to use following only a few hours of appropriate, high-quality training. Different RDT kits have different accessory components, including different blood handling devices and different procedures (e.g., different numbers of drops of buffer, different incubation times). If more than one RDT brand with different characteristics is used in a country, adequate information must be provided to HWs about how the tests differ.

RDTs are highly accurate in diagnosing symptomatic malaria when stored under the appropriate conditions and administered correctly. However, HW adherence to RDT results (e.g., providing an ACT only if the RDT is positive) is influenced by many factors and is variable. Ongoing quality assurance, including supportive supervision, is necessary to ensure appropriate use of RDTs and adherence to RDT results. Please see *Behavior Change and Case Management* section for additional information.

#### **False negative RDTs**

Although the occurrence of falsely negative RDTs among symptomatic patients is uncommon, as the use of RDTs expands, it is important to understand the multiple potential causes for false negative RDTs (or

RDT failure), including poor quality RDTs, poor storage and transport conditions, operator error during performance or interpretation, and low parasite density infections (which may mean that the illness is not due to malaria parasites). For RDTs based on the detection of HRP2 antigen, additional causes for false negative RDTs include having infections caused by non-falciparum species or parasites with *hrp2/hrp3* gene deletions. Many of the potential causes of false-negative results can be prevented or minimized by procuring good-quality RDTs, by improving the quality control of procured RDTs (e.g., lot verification) and by good training of users.

False negative RDTs should be suspected either when symptomatic patients with repeated negative RDTs and persistent signs or symptoms subsequently have other confirmatory malaria testing (e.g., quality assured microscopy, non-HRP2 antigen RDT), or when there is discordance between RDT and microscopy results with  $\geq 10\%$  higher positivity rates by microscopy during routine quality control by cross-checking or when both tests are performed on the same patients.

Please see WHO False-negative RDT Results and Implications of New Reports of *P. falciparum* histidine-rich protein 2/3 gene deletions<sup>101</sup> for specific guidance.

### [Hrp2/3 gene deletions](#)

Although the antibodies on the RDT are designed to recognize the HRP2 antigen, they may also cross-react with another antigen of the HRP family, namely HRP3, which is important in the context of *hrp2/hrp3* gene deletions.

Malaria parasites lacking the HRP2 and/or HRP3 antigens have recently been identified in Sub-Saharan Africa.<sup>10</sup> Although different research groups have reported detection of generally low rates of deletions in Angola, DRC, Mali, Uganda, Rwanda, and Ghana, the methods used and reliability of these reports are variable. However, there is strong evidence that *hrp2/hrp3* gene deletions occur at very high levels in Eritrea, and potentially neighboring countries.

An *hrp2/hrp3* gene deletion should be suspected if a patient sample gives negative results on an *hrp2* test line of at least two quality-assured malaria RDTs but a positive result on the pan- or Pf-pLDH test line when a combination test is used, and the sample is confirmed microscopically to be positive for *P. falciparum* by two qualified microscopists. If *hrp2/hrp3* deletions are detected or suspected, then follow-up investigations may be warranted, using a systematic approach<sup>102</sup> designed to characterize the prevalence of the deletion in a given region.

Current options for non-HRP2 based RDTs include multi-antigen tests and single Pan-LDH or Pf-LDH antigens. These RDTs were included in Round 8 of WHO product testing (2018), and were tested against

---

<sup>101</sup> [False-negative RDT results and implications of new reports of \*P. falciparum\* histidine-rich protein 2/3 gene deletions](#)

<sup>102</sup> <https://www.who.int/malaria/publications/atoz/hrp2-deletion-protocol/en/>

parasites with *hrp2* gene deletions. Two Pan-LDH RDTs met the procurement criteria, but none of the Pf-specific RDTs (Pf-LDH with or without HRP2) did. Thus, at this time, RDT options for regions with *hrp2* deletions remain limited and imperfect.

### ***Highly sensitive RDTs***

The next generation of highly sensitive RDTs (hsRDTs) have been shown to have a level of detection 10-fold more sensitive than conventional RDTs, and now are commercially available. However, as conventional RDTs remain sufficiently sensitive for identifying parasitemia in patients with clinical symptoms, WHO does not recommend the use of hsRDTs for diagnosis of clinical malaria in any setting. Highly sensitive RDTs may be useful for certain indications in elimination settings. Please see the [Elimination section](#) for more information.

### ***PMI priority areas of support for RDTs***

#### **Policy and guidelines**

Please see PMI Priority Areas of support for diagnostics in general for guidance.

#### **Equipment and supplies**

PMI procures WHO pre-qualified RDTs, with exceptions only in times of severe supply shortage. PMI does not procure specific brands of RDTs for countries ('sole-sourcing') – see Supply Chain chapter for more information. Country teams should reach out to the PMI supply chain team if your country has specific registration requirements.

PMI prioritizes procurement of HRP2-based RDTs and does not procure hsRDTs for diagnosis of malaria in clinical settings. PMI follows WHO recommendations which state that in countries in which *P. falciparum* infections are predominant (i.e., Zone 1 countries), only single-species *P. falciparum* tests be used. **All PMI-supported countries in Africa (with the exception of Madagascar and Ethiopia) should be procuring single-species *P. falciparum* RDTs.** In countries with significant *P. falciparum* and *P. vivax* malaria (i.e., Zone 2 countries), including Ethiopia, Madagascar, and the Greater Mekong Subregion, WHO recommends the use of multi-species RDTs.<sup>15</sup>

Despite these recommendations and guidance, some NMCPs in countries in which *P. falciparum* infections are predominant have requested that PMI procure multi-species RDTs, including Pan/Pf RDTs, with a rationale that NMCPs also want the capacity to diagnose non-falciparum species. At times, the rationale is based on data from population based cross-sectional household surveys (e.g., DHS, MIS) that identify a proportion of infections caused by non-falciparum species. PMI generally does not support this rationale because:

- Most non-falciparum infections in “Zone 1” countries are due to *P. malariae*, and the accuracy of RDTs to detect *P. malariae* is rather poor, which is at least partly explained by the very low parasite density of most *P. malariae* infections.

- Most *P. malariae* infections are detected in patients with concurrent *P. falciparum* infections, and mixed Pf/Pm infections are treated with ACTs, exactly as one would treat *P. falciparum*-only infections.
- The proportion of non-falciparum infections detected during population based cross-sectional surveys includes asymptomatic individuals, and therefore may overrepresent the proportion of symptomatic non-falciparum infections presenting for clinical care.
- Programmatically, single species RDTs are less costly (i.e., the unit cost of multi-species RDTs is up to 30% greater than single-species RDTs) and simpler to interpret (i.e., there is only one test line and one control line).

Exceptions to this guidance will be granted if there is credible evidence demonstrating ongoing local transmission of *P. vivax* infections of significant prevalence (at least 5% relative prevalence) or at least 5% prevalence of *hrp2* gene deletions amongst those presenting with symptomatic malaria.

Quantification of RDTs primarily is based on case data from routine health information systems or consumption data. Correct quantification of RDTs has been a significant challenge in most PMI-supported countries, and an internal PMI analysis of MOP gap tables found wide variability in estimating RDT needs. Country teams are encouraged to take an active role during annual quantification exercises to help improve estimations. Please see the Commodity Procurement and Supply Chain Management chapter for additional guidance.

RDT shortages also may be a periodic challenge for countries despite continued efforts to strengthen the supply chain. PMI, in collaboration with partners, is developing guidance to assist National Malaria Control Programs in the management of short- to medium-term malaria RDT stock shortages based on the anticipated duration of the shortage or stockout. The guidance aims to help with the prioritization of existing RDTs from the central level for situations in which RDTs will offer the most value to treatment decisions for symptomatic malaria patients and less overuse of ACTs. The guidance recommends accounting for the malaria context in the country and prioritization based on regions with lower malaria burden and among lower risk populations. Although not ideal, regions or populations not prioritized will have limited remaining or no RDTs, and suspected malaria cases therefore will need to be managed with presumptive treatment. The guidance will be shared separately once finalized.

### **Quality assurance**

PMI's centrally-managed supply chain partner procures RDTs and subjects them to quality control lot testing by WHO/GMP before they are distributed in the country. At this time, methods for quality control of RDTs at the point-of-service are somewhat limited, but should be considered. Facility- and community-level QA/QC should include, at a minimum, regular supervision at least every six months with observation of healthcare workers' performance of RDTs using a standardized checklist.

Laminated cards with pictures of positive, negative, and invalid RDT results also have been used to test HWs' skill at interpreting test results. Positive control wells (PCWs) with positive control antigens that enable end-users to determine whether the RDT kit they are using is performing properly are available

from a limited number of manufacturers for a limited set of products. Although PMI is not currently supporting the use of PCWs, further guidance on the appropriate piloting/use of PCWs will be issued once they are more widely available for procurement and global guidance on use cases is developed.

Rapid diagnostic tests require proper transport and storage to avoid damage that may be caused by extreme heat and humidity. In PMI's experience, RDTs have remained stable even at high temperatures and humidity, and post-deployment tests are only rarely warranted. In these cases, tests of RDT kit performance should be performed no sooner than 12 months post-deployment. Samples of test kits should be sent to WHO-approved laboratories for further lot testing and will be done at no cost beyond the cost of shipping the test kits. Although WHO and PMI do not recommend routinely comparing microscopy to RDT performance, a comparative assessment may be useful as a first step in an investigation of suspected poor quality RDTs.

The QA activities that are NOT recommended include cross-checking RDTs with blood slide microscopy, saving RDTs for re-reading, and conducting PCR as part of clinical management.

#### **Training and supervision of laboratory staff**

Please see PMI Priority Areas of support for diagnostics in general for general guidance.

#### ***Diagnostic testing: light microscopy***

Diagnostic confirmation by microscopy is obtained by identification of malaria parasites on thick and thin blood films. Thick blood films are more sensitive in detecting malaria parasites because the blood is more concentrated, allowing for a greater volume of blood to be examined. The lower limit to detect malaria parasites with microscopy is usually 50-200 parasites/ $\mu$ L blood in clinical settings. Thin smears are particularly helpful for malaria parasite quantification and speciation since the appearance of the infected red blood cells (RBCs) or parasite features in the RBCs can aid identification. Although not as easy as in a thin smear, quantification and speciation can be done with thick smears, and microscopists may be more comfortable using this modality for all three aspects (e.g., detection, quantification, and speciation).

Microscopy results are dependent on the competence and performance of laboratory technicians in preparing, staining, and reading blood slides, as well as the quality of the reagents and equipment. The system to support and maintain quality assured microscopy services can be challenging and costly to sustain, and quality assured microscopy services are not widely available.

#### ***PMI priority areas of support for microscopy***

Policy and guidelines on the diagnosis of malaria should be periodically reviewed, revised, and harmonized with WHO recommendations<sup>2,6,7</sup>. In most countries, microscopy is only available at the

hospital level and at larger health centers. Microscopy also should be available in settings where definitive care for severe malaria is provided.

### **Equipment and supplies**

Lists of necessary supplies, including those for blood sampling and safe disposal of biohazardous materials, and specifications for microscopes are widely available through WHO, CDC, and from PMI headquarters upon request. In most countries, procurement of laboratory supplies is handled by the same authorities that handle pharmaceuticals. In others, the central laboratory or individual regional or district authorities may handle procurement and/or distribution. In many cases, local quality-assured sources of these supplies may be procured more quickly and at lower cost than through global sources so, in certain circumstances, PMI supports targeted local procurement through the PMI central supply chain partner.

### **Quality assurance**

WHO has developed detailed guidelines on quality control of malaria microscopy<sup>103</sup>, which involves collection of a subset of slides from clinical specimens and re-examination of those slides by expert microscopists, which may be performed during a supervision visit or in a national, regional, or district reference laboratory. PMI supports the development or purchase of validated malaria reference slide sets with known species and parasitemia density for use in training and quality assurance. Purchasing a validated slide set may be preferable as developing a slide set is laborious and can take years to complete. On average, the development of a national archive of malaria microscopy slides costs and supplies. Because thousands of slides are produced during the activity, providing a wide and redundant range of parasitemia and species combinations (as applicable), this is largely a one-time expenditure for countries.

### **Training and supervision of laboratory staff**

Please see PMI Priority Areas of support for diagnostics in general for guidance. Additionally, the CDC malaria diagnostics bench aids and SOPs are available on the CDC DPDx website (<http://dpx.cdc.gov/dpx/Default.htm>), and a CDC-developed malaria microscopy training CD-ROM or digital download (in English) can be obtained from WHO Global Malaria Programme at: [http://www.who.int/malaria/areas/diagnosis/microscopy\\_cd\\_rom/en/](http://www.who.int/malaria/areas/diagnosis/microscopy_cd_rom/en/)

### ***Diagnostic testing: methods not recommended for clinical management***

Other diagnostic modalities, including nucleic acid amplification techniques (e.g., polymerase chain reaction [PCR]; loop mediated isothermal amplification [LAMP]) and serology are not recommended for clinical settings; they primarily are used for research or epidemiologic study purposes.

---

<sup>103</sup> WHO Malaria Microscopy: Quality Assurance manual. <https://www.who.int/malaria/publications/atoz/9789241549394/en/>

## Case Management

### *Treatment of uncomplicated malaria*

WHO recommends six ACTs as first-line options for the treatment of falciparum malaria<sup>104</sup>:

1. Artemether-lumefantrine (AL)
2. Artesunate-amodiaquine (AS-AQ)
3. SP-artesunate (SP-AS)
4. Mefloquine-artesunate (MQ-AS)
5. Dihydroartemisinin-piperaquine (DP)
6. Artesunate-pyronaridine (AS-PYR)

ACTs partner an artemisinin drug (i.e., artesunate, artemether, dihydroartemisinin) with a second antimalarial that has a longer half-life. Artemisinins rapidly reduce parasite density in the blood and control fever, but also are rapidly eliminated. The partner drug, such as mefloquine, SP, amodiaquine, lumefantrine, piperaquine, or pyronaridine, is longer acting and clears residual parasites providing protection against the development of resistance to the artemisinin component. Side effects are uncommon, and serious or life-threatening adverse drug reactions are exceedingly rare.

### *Antimalarial efficacy and treatment failure*

The efficacy of ACTs in sub-Saharan Africa remains high and a 3-day course, which is designed to cover two asexual cycles of the parasite, is usually curative.

Nevertheless, it is critically important that HWs and programs remain vigilant for potential evidence of antimalarial treatment failures. WHO defines antimalarial treatment failure as the inability to clear parasites from a patient's blood or to prevent their recrudescence after the administration of an antimalarial<sup>105</sup>. Incorrect dosing and poor patient compliance are more common causes for treatment failures, but poor drug quality, drug interactions and resistance to one or both active components of the ACT also must be considered. To help address incorrect dosing, poor patient compliance, and poor drug quality, please see *PMI priority areas of support for treatment of uncomplicated P. falciparum* below for additional details on training and supervision of HWs and quality monitoring of drugs.

### *Antimalarial resistance*

---

<sup>104</sup> [WHO Guidelines for the treatment of malaria, 3<sup>rd</sup> edition, 2015](#)

<sup>105</sup> [WHO: https://www.who.int/malaria/areas/treatment/drug\\_efficacy/en/](https://www.who.int/malaria/areas/treatment/drug_efficacy/en/)

Development of drug resistance has been evident with most antimalarial monotherapies, with the distribution and spread of resistant parasites consistent with geographic areas where specific antimalarial drugs had widespread use. In 2006, WHO began recommending ACTs as first line treatment for uncomplicated malaria globally to improve treatment efficacy and delay development of drug resistance by partnering two antimalarials with independent modes of action and different half-lives.

Southeast Asia is the geographic region in which antimalarial resistance is most prevalent. Recent studies identified the emergence and spread of *P. falciparum* parasites that have a reduced susceptibility to both artemisinin and the partner drug component of ACTs. Artemisinin resistance, which manifests as delayed clearance of parasitemia and is associated with point mutations in the propeller region of the *P. falciparum* kelch protein on chromosome 13 (*k13*)<sup>106</sup>, was reported first in western Cambodia, where resistance to previous first-line antimalarial drugs also first emerged. Artemisinin resistance has since spread, emerged independently, or both in other areas of mainland Southeast Asia. Evidence of artemisinin resistance outside Southeast Asia has been limited to Guyana<sup>107</sup>, India<sup>108</sup> and Rwanda<sup>109</sup>.

#### ***ACT characteristics comparison***

	<b>Artemether-lumefantrine (AL)</b>	<b>Artesunate-amodiaquine (ASAQ)</b>	<b>SP - artesunate (SP-AS)</b>	<b>Mefloquine - artesunate (MQ-AS)</b>	<b>Dihydro-artemisinin-piperaquine (DP)</b>	<b>Artesunate-pyronaridine (AS-PYR)</b>
<b>General comment</b>	Most widely used ACT in Africa	Mostly used in West Africa, not recommend where SP-AQ used for SMC	Limited use (India, Middle East) due to SP resistance	Recommend for areas with multidrug resistance (SE Asia, South America)	Predominantly used in SE Asia	WHO note <sup>110</sup> clarifying AS-PYR considered safe and efficacious
<b>Formulation</b>	Fixed dose tablets and pediatric dispersible	Fixed dose tablets	Blister packed tablets, not fixed dose	Fixed dose tablets	Fixed dose tablets and pediatric dispersible	Fixed dose tablets and pediatric dispersible

<sup>106</sup> Arie F et al. A molecular marker of artemisinin-resistant Plasmodium falciparum malaria. 2014. Nature. 505(7481):50-5.

<sup>107</sup> Chenet AM et al. Independent Emergence of the Plasmodium falciparum Kelch Propeller Domain Mutant Allele C580Y in Guyana. 2016. JID. 213(9):1472-5. doi: 10.1093/infdis/jiv752.

<sup>108</sup> Das S et al. Evidence of Artemisinin-Resistant Plasmodium falciparum Malaria in Eastern India. NEJM. 2018. <https://www.ncbi.nlm.nih.gov/pubmed/30428283>

<sup>109</sup> Uwimana, A., Legrand, E., Stokes, B.H. et al. Emergence and clonal expansion of in vitro artemisinin-resistant Plasmodium falciparum kelch13 R561H mutant parasites in Rwanda. Nat Med 26, 1602–1608 (2020). <https://doi.org/10.1038/s41591-020-1005-2>

<sup>110</sup> <https://www.who.int/publications/i/item/use-of-artesunate-pyronaridine-for-the-treatment-of-uncomplicated-malaria>

<b>Partner drug safety</b>	Ample evidence from SE Asia, sSA	Ample evidence from SE Asia, sSA	Ample evidence from SE Asia, sSA	Ample evidence from SE Asia, increased risk of neuropsychiatric effects with repeated dosing	Ample evidence from SE Asia, sSA	Relatively limited evidence; acute, reversible liver enzyme increases
<b>Partner drug half life, post treatment prophylaxis</b>	4-6 days, limited to ~14-21 days	~4-10 days, limited to 21-28 days	~4-8 days, limited to 21-28 days	14-28 days, post treatment to 42+ days	14-28 days, post treatment to 42+ days, reduced risk of recurrent parasitemia and severe malaria vs. AL or ASAQ	14-18 days, mixed results on post-treatment prophylactic benefit over AL
<b>Evidence of resistance to partner drug</b>	No prior monotherapy, limited evidence	Some prior monotherapy, focal areas with evidence	Widespread resistance	Primarily in SE Asia	Evidence in SE Asia, no/limited evidence in sSA	Limited evidence in SE Asia, none in sSA
<b>Partner drug molecular resistance locus<sup>111</sup></b>	<i>Pfmdr1</i> point mutations	<i>Pfmdr1</i> point mutations	<i>Dihydrofolate reductase (DHFR)</i> and <i>dihydropteroate synthase (DHPS)</i> point mutations	<i>Pfmdr1</i> copy number	<i>Plasmeprin 2</i> and <i>3</i> copy number, <i>Pfcr1</i> point mutations	Mechanism unknown

### Determination of first line ACTs: program considerations

All six ACTs are considered efficacious and safe (3-22). Most countries in Africa continue to rely on AL and AS-AQ as first- or second-line treatment options. However, some situations warrant the introduction of newer ACTs in addition to or instead of AL or AS-AQ including:

1. Seasonal Malaria Chemoprevention (SMC)  
Because SP-AQ is used for SMC, AS-AQ is not recommended as a first or second-line treatment in countries or parts of countries that conduct SMC.
2. Waning ACT efficacy  
Despite overall high efficacy of AL and AS-AQ in Africa, there are some instances where treatment efficacy appears to be waning. Efficacy should be monitored regularly for a significantly declining trend of treatment efficacy over time, even if not below the WHO-specified 10% failure rate for a change of ACT. NMCPs, in collaboration with WHO, PMI, and other stakeholders, should proactively plan to update policies and change drug procurement to an alternate antimalarial(s). Consideration should be given to known resistance patterns in the country when selecting a different antimalarial.

<sup>111</sup> [http://www.ajtmh.org/content/journals/10.4269/ajtmh.14-0031#html\\_fulltext](http://www.ajtmh.org/content/journals/10.4269/ajtmh.14-0031#html_fulltext)

### **Multiple first line therapies**

Although some modeling results have indicated that a strategy of deliberately deploying multiple first line therapies (MFTs) in overlapping geographic areas and time frame may be effective at delaying the emergence and spread of antimalarial resistance where it has not yet developed, the overall results of such approaches have been mixed<sup>112,113,114</sup>.

### **Single, low-dose primaquine for *P. falciparum***

In 2015, WHO updated its guidelines to recommend the administration of a single gametocytocidal dose of primaquine to be given in addition to an ACT for falciparum malaria **in low transmission areas**. See the *Elimination chapter* for details.

### **Treatments in development**

There are several other compounds/formulations in various phases of development, including triple ACT therapy. Given their R&D status, none should be considered during FY 2022 MOP planning. For the latest information, please refer to the Medicine for Malaria Venture (MMV) website (<https://www.mmv.org/research-development/mmv-supported-projects>).

### **Treatments NOT recommended**

Oral monotherapy, including with artemisinin drugs, is not recommended by WHO or PMI and has been banned by most countries because of the likelihood of promoting the spread and intensification of drug resistance. Artemisinin monotherapy with non-oral (i.e., intravenous, intramuscular, or rectal) for initial or pre-referral management of severe malaria is the exception; this initial or pre-referral treatment then is followed by a full ACT treatment course.

Artequick is an ACT (artemisinin 62.5mg + piperazine 375mg) produced by a Chinese pharmaceutical company that is NOT approved by WHO. Many PMI countries in Africa (e.g., Uganda, Malawi, Zambia) have reported Artequick donation offers made by a Chinese university. Countries are often encouraged to use the donated Artequick as part of MDA, even when the transmission setting may not be appropriate for MDA. In addition to the MDA-related issue, WHO (along with PMI) is concerned because of the unproven efficacy, possible side effects, and lack of quality assurance of this medication. If teams become aware of Artequick donation offers in their country, they are encouraged to contact the PMI Case Management Headquarters team, which has already been in contact with WHO about this issue.

---

<sup>112</sup> Boni MF, Smith DL, Laxminarayan R. Benefits of using multiple first-line therapies against malaria. *Proc Natl Acad Sci USA* 2008;105: 14216–21.

<sup>113</sup> Smith DL, Klein EY, McKenzie FE, Laxminarayan R. Prospective strategies to delay the evolution of anti-malarial drug resistance: weighing the uncertainty. *Malar J.* 2010; 9:217. doi:10.1186/1475-2875-9-217 PMID:20653960

<sup>114</sup> Nguyen TD, Olliaro P, Dondorp AM, Baird JK, Lam HM, Farrar J, et al. Optimum population-level use of artemisinin combination therapies: a modelling study. *Lancet Glob Health.* 2015 Dec;3(12):e758-66. doi: 10.1016/S2214-109X(15)00162-X. Epub 2015 Nov 4

## ***PMI priority areas of support for treatment of uncomplicated P. falciparum***

### **Policy and guidelines**

PMI recommends that national policy and guidelines on treatment for malaria should periodically be reviewed to ensure they are in line with WHO recommendations. Guidelines should be informed by the results of the latest therapeutic efficacy study (TES) and other relevant investigations (e.g., acceptability studies). In countries with a substantial private sector, the types and amounts of antimalarials being prescribed should be considered when selecting an antimalarial(s) for the public sector (Please see the “Diagnosis and Treatment in the Private Sector” section below for additional information).

PMI Headquarters has developed a checklist that can guide this process.

### **Equipment and supplies**

PMI supports the procurement of ACTs for the treatment of uncomplicated malaria as detailed in national treatment guidelines.

PMI does not recommend employing MFTs as a strategy to mitigate the development of antimalarial resistance based on the mixed results from modeling studies and consideration that the implementation of MFTs would result in higher costs and increased challenges with the supply chain, HW training, and social behavior change targeting beneficiaries. Pilots with support from other donors are currently underway to further evaluate the strategy of MFTs; PMI will review the results when they are available. In countries that list multiple ACTs as first-line therapy, PMI recommends deployment of only one ACT in a particular place and time.

Quantification of ACTs primarily is based on case data from routine health information systems or consumption data. Correct quantification has been a significant challenge in most PMI-supported countries, and an internal PMI analysis of MOP gap tables found wide variability in estimating ACT needs. Country teams are encouraged to take an active role during annual quantification exercises to help improve estimations. Please see the *Commodity Procurement and Supply Chain Management* chapter for additional guidance.

### **Quality monitoring of antimalarial drugs**

PMI supports quality monitoring of antimalarial medicines available in public and private sector outlets as part of a larger national strategic plan and longer-term strategy to build a robust national quality assurance program. PMI, through its implementing partners, use tools such as market surveys and mystery shopper assessments and collect readily available public and private sector antimalarial products for quantitative analysis at qualified laboratories to determine content and quality. Drug registration processes also are evaluated. Country teams are encouraged to invest in drug quality monitoring programs and should take into consideration information from various PMI or USAID Global

Health-supported technical assistance programs. Please see the *Commodity Procurement and Supply Chain Management* chapter for additional guidance.

### **Training and supervision of healthcare worker staff**

Training curricula for clinicians and CHWs should be periodically revised to align with the country's most updated malaria case management policies and guidelines, including integrated management of childhood illness guidelines. Whenever feasible, clinical training on malaria case management should be incorporated into training on the management of childhood illness. In addition, experience suggests that coordinated training of clinical and laboratory staff, in those facilities with laboratories, improves clinicians' understanding and interpretation of the diagnostic testing results. After training, periodic supportive supervision of clinicians and CHWs will be required. When possible, such supervision should be built into existing functional supervisory mechanisms, guided by structured checklists, and focus on real-time problem-solving. Generic training and supervision materials and checklists for facility-based clinicians are available upon request from PMI headquarters staff.

## ***Management of severe malaria***

### ***Facility level management***

Severe malaria is a medical emergency and should be managed with the immediate initiation of appropriate parenteral treatment. Based on evidence from a large, multi-center, randomized trial, WHO modified their treatment guidelines for severe malaria in 2011 **to recommend parenteral artesunate as the first-line treatment in children and adults, including pregnant women in all trimesters; if parenteral artesunate or artemether is not readily available, parenteral quinine should be used.**<sup>115</sup>

Parasitemia should be monitored at least every 12 hours during the first 2–3 days of treatment to assess the response. Once a patient has received at least 24 hours of parenteral therapy and can tolerate oral medications, treatment should be completed with an additional full 3-day course of an ACT.

Toolkits and other helpful information about severe malaria are available at <https://www.severemalaria.org/>, [WHO Guidelines for the Treatment of Malaria \(3rd Edition\)](#) and [WHO Management of Severe Malaria: A Practical Handbook \(3rd Edition\)](#).

### ***Peripheral health facility and community level management: pre-referral rectal artesunate***

Management of severe malaria cases at peripheral health facilities and at community level, where facilities are not equipped to manage such cases, should focus on administration of pre-referral

---

<sup>115</sup> Arjen M Dondorp et al. Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomised trial. *The Lancet*. [Volume 376, Issue 9753](#), 13e 376, Issue 9753w.sciencedirect.7.

treatment to reduce disease severity and rapid referral to an appropriate health facility for parenteral treatment and, if possible, microscopy to quantify and follow parasite burden.

WHO recommends rectal artesunate only for the pre-referral management of severe malaria in children aged 6 years or less. This guidance was re-emphasized in a subsequent WHO information note as some NMCPs still deviate from this guidance.<sup>116</sup> Children aged 6 years or less should receive a single rectal dose (10 mg/kg body weight) and immediate referral. Because severe malaria is life-threatening medical emergency, children should rather be over- than under-dosed, so that children weighing up to 10 kg should receive one suppository of 100-mg artesunate, and children weighing up to 20 kg should receive two 100-mg suppositories<sup>117</sup>.

Obstacles to widespread roll-out include inadequate pre-referral training for intramuscular (IM) treatment and rectal artesunate, and underdeveloped or non-existent community-based platforms for delivery and referral systems. Lack of follow up to the referred level of care can result in not obtaining a definitive diagnosis, the return of severe disease, and, in some cases, death. Therefore, the importance of completing timely referral following initial treatment should be strongly emphasized during training of health care workers and in communication with patients. In addition, the message that pre-referral treatment alone is not a substitute for management of severe malaria at a referral center should be included in the counselling by HWs and SBC materials. Groups such as Medicines for Malaria Venture and the Clinton Health Access Initiative have started to identify countries where “landscaping” evaluations will be performed to better characterize these obstacles and identify potential solutions.

### ***PMI Priority Areas of support for treatment of severe malaria***

Policy and guidelines on the diagnosis and treatment for severe malaria periodically should be reviewed to ensure they are in line with WHO recommendations. Before PMI will procure rectal artesunate, a country must update their case management guidelines to be consistent with WHO guidelines (e.g., indicated only for those younger than six years), update their training material to reflect WHO guidelines, or (preferably) both.

#### **Equipment and supplies**

PMI primarily procures injectable and rectal artesunate for treatment of severe malaria. PMI also may procure parenteral artemether or quinine if there is a specific country need (for example, procurement of IM artemether for health facilities that are not equipped for IV administration, or for countries that have still not shifted from quinine to artesunate for treatment of severe malaria in pregnant women). WHO-prequalified products are not available for either of these treatments, and lead times may be long. Please see the *Supply Chain chapter* for more information on lead times and quality considerations for these products.

---

<sup>116</sup> [Rectal artesunate for pre-referral treatment of severe malaria](#). WHO October 2017.

<sup>117</sup> <https://www.who.int/malaria/publications/atoz/rectal-artesunate-severe-malaria/en/>

For rectal artesunate, PMI will only procure WHO-prequalified 100-mg presentations. Countries that wish to procure the non-pre-qualified 50-mg or 200-mg presentations must contact the Case Management and Supply Chain Management headquarters teams to seek an exception and indicate how they are transitioning to the 100-mg presentation. Please contact the Supply Chain Team for supply chain specific questions related to rectal artesunate and other severe malaria medicines.

Correct quantification of antimalarial treatments for severe malaria have been a significant challenge in all PMI-supported countries because of the lack of complete and accurate consumption data for these products. Please see the *Commodity Procurement and Supply Chain Management* chapter for additional guidance.

### **Training and supervision of healthcare worker staff**

Training curricula for clinicians and CHWs should be periodically revised to align with the country's most updated malaria case management policies and guidelines. Recognition of signs and symptoms of severe disease has been found to be poor in many countries and should be included in training and supervision materials. After training, periodic supportive supervision of clinicians and CHWs will be required. When possible, such supervision should be built into existing functional supervisory mechanisms, guided by structured checklists, and focus on real-time problem-solving.

### ***Treatment of uncomplicated malaria in special populations***

Information on the management of uncomplicated and severe malaria in pregnant women can be found in the Malaria in Pregnancy chapter.

Infants weighing <5kgs should receive the recommended ACT at the same mg/kg body weight dose recommended for children weighing more than 5kg.

Please see WHO Guidelines for the Treatment of Malaria for guidance regarding HIV and other special populations.

### ***Case management of infections caused by non-P. falciparum species***

Among infections caused by non-*P. falciparum* species (*P. vivax*, *P. malariae*, *P. ovale*, and *P. knowlesi*), *P. vivax* is the most important, resulting in approximately 10% of malaria cases globally. Although prevalent in endemic areas of Asia, Central and South America, the Middle East and Oceania, *P. vivax* is uncommon in most of sub-Saharan Africa, except for the Horn of Africa, Mauritania, Mali, and the island of Madagascar (WHO Tx Guidelines).

Blood stage non-falciparum infections may be treated with chloroquine in chloroquine-susceptible regions, or with ACTs. Additional treatment of liver-stage infections caused by *P. vivax* and *P. ovale* is necessary for preventing relapses (i.e., radical cure). Medicines from the 8-aminoquinoline class, including primaquine and tafenoquine, are the only drugs effective for radical cure, but they are

associated with hemolytic anemia in individuals with G6PD deficiency. Before primaquine is administered for radical cure, the G6PD status of the patient should be assessed, unless the national policy differs. When G6PD status is unknown and G6PD testing is not available, a decision to prescribe primaquine should adhere to national treatment guidelines that should be based on a local assessment of the risks and benefits of adding primaquine. Treatment guidelines for radical cure of *P. vivax*, including options for primaquine dosing, can be found in detail in Annex 2 of the WHO “A Framework for Malaria Elimination” (2017)<sup>118</sup>, and the WHO policy brief “Testing for G6PD deficiency for safe use of primaquine in radical cure of *P. vivax* and *P. ovale malaria*” (2017).<sup>119</sup>

One qualitative product is currently marketed for point-of-care use in G6PD deficiency testing, BinaxNOW® G6PD screening test. The BinaxNow G6PD test is US FDA approved, but has not been used widely due to its requirement for venous blood collection, strict temperature range of 18°C to 25°C, and high cost of around \$25 per test. In addition, a quantitative point-of-care test, Standard G6PD Test manufactured by SD Biosensor, is currently approved by Global Fund’s Expert Review Panel Process for Diagnostic Products. PMI is currently supporting the evaluation of this test in Cambodia to support the deployment of primaquine radical cure. The SD Biosensor test is approved by the Global Fund ERP and a FDA decision is expected in 2021. Please contact the HQ Case Management team if your country is implementing G6PD testing and is requesting PMI to procure tests.

Tafenoquine received approval from the US FDA and the Australian TGA for single-dose radical cure of *P. vivax* infections and is now undergoing implementation pilots in Thailand, Ethiopia, and Brazil. It is a single-dose treatment, which will certainly improve adherence compared to the currently recommended 14 days of primaquine therapy. Unlike with the use of primaquine for radical cure of *P. vivax*, where individual countries have set their own policy on the need for G6PD testing, tafenoquine will require testing for G6PD deficiency using a quantitative test prior to administration. Registration in malaria-endemic countries is underway starting in Thailand. Two Phase III studies in adults and a trial in pediatric populations have been completed; however, the current label has not yet been updated to include a pediatric indication.

In countries with co-endemic vivax malaria, treatment strategies should be species-specific for the treatment of uncomplicated malaria and for malaria in pregnant women with a strategy for preventing relapses. Such guidance should clearly articulate when treatment is to be provided, at what level of care, what facilities and supportive services are required, and when referral is indicated.

---

<sup>118</sup> WHO “A Framework for Malaria Elimination, <https://www.who.int/malaria/publications/atoz/9789241511988/en/>

<sup>119</sup> WHO “Testing for G6PD deficiency for safe use of primaquine in radical cure of *P. vivax* and *P. ovale malaria*, <https://apps.who.int/iris/bitstream/handle/10665/250297/WHO-HTM-GMP-2016.9-eng.pdf>

## **Integrated Community Case Management**

Because facility-based services alone do not provide adequate access to care in most countries with high childhood mortality, especially during the most critical first 24 hours after symptom onset, the integrated community case management (iCCM) approach increases access to care at the community level for the most vulnerable populations. The iCCM approach provides diagnosis and treatment of pneumonia, diarrhea, and malaria (including the use of RDTs) through CHWs or health extension workers using standard algorithms. iCCM programs also provide a platform for facilitating referral of severe illness, including use of pre-referral rectal artesunate.

A number of studies have demonstrated that malaria diagnosis and treatment can be provided to children less than five years of age through community-based agents. WHO and UNICEF recommend implementation of iCCM for sick children less than five years of age as an essential method for improving access to malaria diagnosis and treatment. The iCCM program in each country should be tailored to meet country needs which include decisions on location of CHWs, whether CHWs will be paid (salary/stipend or other compensation) or volunteer, and what age groups the CHWs will serve.

More information on iCCM, including information on training, iCCM indicators, the latest research, and a tool kit is available on the Child Health Task Force website: <https://www.childhealthtaskforce.org/home>.

### ***PMI Priority Areas of support for iCCM***

#### **Policy and guidelines**

PMI encourages all focus countries to develop policies and support scaling-up of iCCM programs that are consistent with recommendations from UNICEF and WHO, including the use of RDTs for diagnosis and treatment of malaria. Policies and guidelines should clearly articulate what is and what is not permissible for diagnosis and treatment at community level and the qualifications and training required for CHWs.

PMI funding can be used to support integrated platform costs with the intention that this will be co-supported and co-funded by maternal and child health or community health partners.

PMI does not provide support for CHW salaries or stipends. PMI can support reimbursement of travel or other work-related expenses as well as for other incentives (e.g., bicycles, flashlights) as appropriate. For more information on incentives, refer to the *WHO guideline on health policy and system support to optimize community health worker programme*.

<https://apps.who.int/iris/bitstream/handle/10665/275474/9789241550369-eng.pdf?ua=1>

PMI supports iCCM services to children aged less than 5 years but will consider on a case-by-case basis support for expansion to older age groups. PMI is supporting operational research on expanded age ranges in two countries to understand some of these implications and help inform policy.

### **Equipment and supplies**

PMI supports the procurement of RDTs, treatment for uncomplicated malaria, and medicines for the pre-referral management of severe illness for use at the community level. PMI funding also may be used for training manuals, guidelines, and job aides for the full iCCM platform.

PMI funding can only be used to procure malaria commodities, but not for supplies or treatments for other diseases managed under the iCCM algorithm, including diarrhea, pneumonia, or malnutrition. PMI supports active engagement with Maternal and Child Health (MCH) and other Global Health colleagues to help strengthen iCCM overall including the provision of the non-malaria commodities. In this way, the community health worker system is strengthened and inappropriate diversion of malaria commodities may be reduced.

### **Training and supervision**

PMI supports the full iCCM platform, including integrated training and supervision. Please see the *PMI Priority Areas of support for treatment of uncomplicated malaria section* for details on training and supervision.

PMI strongly encourages the development of a systematic approach to the collection, processing, and reporting of all iCCM testing and treatment data to complement health facility data and strengthen routine health information systems. Additionally, as many PMI countries and programs are utilizing digital technologies in many aspects of their programs, PMI has launched a Digital Community Health Initiative to support the expanded use of digital technologies at the community level to further promote and improve data collection and use.

## **Diagnosis and Treatment in the Private Sector**

In many PMI-supported countries, a notable proportion of malaria cases are diagnosed and treated in the private sector. The private sector often includes non-profit and faith-based clinics and hospitals, for-profit facilities and providers, licensed retail outlets (including pharmacies and drug shops), and informal providers (both at fixed sites and mobile). In most countries, non-profit and faith-based facilities already receive support and oversight from the MOH, essentially functioning like an extension of the public health system. Other private providers may or may not be overseen by pharmacy boards or drug regulatory authorities, depending on the country.

The private sector can provide a significant percentage of malaria services at little to no cost to the public system, reducing the burden on the public sector. Therefore, appropriate case management in the private sector has the potential for substantial impact on malaria morbidity and mortality.

Many of the challenges with providing comprehensive malaria case management services in the public sector are amplified in the private sector. Because it remains essential to ensure that only high quality RDTs and ACTs are available, better monitoring and enforcement by drug regulatory authorities, intervention with importers and wholesalers, and subsidies that reduce financial barriers to retailers and consumers may be required.

Unlike the public sector, where diagnosis and treatment are often provided for free or at low cost, any private sector strategy must have a clear plan on appropriate pricing of diagnostic testing and treatment that takes into account the consumer's willingness to pay, the need of retailers and suppliers to make a reasonable profit, and the market prices of non-recommended treatments. The easy availability of alternative treatments for non-malaria fevers (e.g., antibiotics and antipyretics, such as paracetamol) must be considered, as it has been shown that inappropriate use of malaria treatment can be reduced if alternative treatments are available.

Like the public sector, any private sector intervention must be accompanied by good training, supervision, appropriate behavior change and communications activities for providers and patients, and collection and reporting of diagnostic and treatment data. It should be recognized that appropriate messaging for private sector case management is more complex. In addition to standard messaging to consumers to seek treatment for fever, those with fever must be encouraged to get tested, take treatment only if the test is positive, and consider other causes of fever if they test negative. An analysis of 12 studies on the introduction of RDTs in the private sector<sup>120</sup> is available for more information.

### ***PMI Priority Areas of support for Private Sector interventions***

#### **Policy and guidelines**

**PMI encourages all focus country teams to understand the scale and scope of private sector provision of malaria services and work with NMCPs to ensure this avenue of malaria services receives appropriate attention.** The first step is to clearly define which types of providers should be targeted. Registered private, for-profit facilities and providers, and/or private retail outlets are most commonly targeted, but this will vary by country.

PMI supports WHO guidance that all suspected malaria cases presenting at private sector outlets should undergo diagnostic testing with either RDTs or microscopy prior to receiving treatment. **PMI does not support private sector interventions that focus solely on providing malaria treatment in the absence**

---

<sup>120</sup> Theodoor Visser et al. **Introducing malaria rapid diagnostic tests in private medicine retail outlets: A systematic literature review.** March 2017 *Plos One* <https://doi.org/10.1371/journal.pone.0173093>

**of diagnostic testing.** As with the public sector, PMI recommends supporting the development of appropriate systems of accountability for commodities and supplies, quality services, biosafety, and data reporting. In some cases, this may require changes to regulations.

Country teams should seek the guidance of the PMI Headquarters Case Management Team early in the planning phase for such private sector interventions to ensure that PMI-supported private sector activities are in line with PMI Technical Guidance. Engaging appropriate country-specific working groups or advisors for USAID Mission-wide private sector strategies should also be considered.

### **Equipment and supplies**

Commodities (RDTs and ACTs) that are procured and donated by PMI currently cannot be sold for profit in the private or public sector; however, user or consultation fees for the package of malaria services may be acceptable in some situations. Finally, when working with the private for-profit sector, where the private sector themselves can not ensure a stable supply of quality RDTs and ACTs, teams are encouraged to seek support for procurement of RDTs and ACTs from other donors that provide subsidies and allow for sale of commodities, such as the Global Fund.

### **Training and supervision**

Private sector engagement can include training and supervision. Private sector providers may participate in training of public sector providers where appropriate or be engaged separately. There may be opportunities to partner with existing private sector structures, including pharmacy and/or medical societies or associations or common wholesalers or supply networks, to identify potential private sector partners and serve as platforms to support these efforts. Such networks also may play a central role in the supply of quality-assured commodities to private outlets.

For further questions about private sector interventions, please contact the Case Management team.

## **Case Management Surveillance, and Monitoring and Evaluation**

### ***Case recording and reporting***

Malaria case reporting should be built around diagnostically-confirmed cases with a positive RDT or blood smear microscopy test. Support to accurately record and report malaria test and treatment results and use routine health information system case management data should be incorporated into regular case management training and supportive supervision activities. Please see the Surveillance, Monitoring and Evaluation chapter for details on routine health information systems.

### ***Quality of Case Management Services***

Monitoring the quality of HW performance and of key diagnostic and treatment services is an important component of a comprehensive case management program. PMI encourages the analysis and use of data collected during supervision (e.g., assessment for fever and illness severity, ordering a diagnostic

test based on symptoms, correct performance of RDT steps, appropriate treatment based on test result) to monitor trends and identify gaps in the quality of care. PMI HQ is working on a list of suggested indicators for supervision checklists that will be available in 2021.

Other sources of data may include periodic health facility surveys that include indicators on the quality of malaria case management, such as the Service Provision Assessment, or ad hoc/tailored surveys designed to capture specific information on malaria services (e.g., testing practices, management of severe malaria). Please see the Surveillance, Monitoring and Evaluation chapter for details on the various health facility surveys.

### ***Monitoring the efficacy of antimalarial drugs***

Routine, periodic monitoring of the efficacy of antimalarial drugs is recommended for all PMI-focus countries using therapeutic efficacy studies (TES). A TES assesses antimalarial drug efficacy by evaluating clinical and parasitological responses to antimalarial treatment of uncomplicated malaria in controlled settings. Results from TESs then may be used by ministries of health to develop or update national treatment strategies and policies in a timely manner as indicated.

WHO recommends that all countries establish and maintain routine, periodic monitoring of the therapeutic efficacy of their first- and second-line malaria treatment. Countries that are anticipating the introduction of a new antimalarial drug into their programs may consider including that drug in TESs prior to its introduction. In countries with a substantial private sector, the types and amounts of antimalarials being prescribed also should be considered. Efficacy monitoring should be conducted once every 24 months<sup>121</sup>. To help sustain the capacity of national testing teams, NMCPs may conduct such efficacy monitoring at half the sites one year and the other half the following year. The WHO standard protocol is not designed for the evaluation of new or experimental medicines.

### ***PMI Priority Areas of support for monitoring the efficacy of antimalarial drugs***

#### **Policy and guidelines**

PMI supports WHO antimalarial drug efficacy monitoring recommendations. In collaboration with host country NMCPs, PMI provides support through technical and support staff based in-country, technical experts and PMI support staff based at headquarters, and implementing partner staff. This allows for regular technical interactions with local investigators conducting TESs and helps to ensure the quality and timely sharing of the final product.

PMI and the Global Fund have supported the majority of the TESs in PMI-supported countries in sub-Saharan Africa. In order to leverage institutional capacities to the fullest, PMI and Global Fund

---

<sup>121</sup> WHO Methods for Surveillance of Antimalarial Drug Efficacy.  
[https://apps.who.int/iris/bitstream/handle/10665/44048/9789241597531\\_eng.pdf;jsessionid=4C6CF37396573E8E9F7E25372673025D?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/44048/9789241597531_eng.pdf;jsessionid=4C6CF37396573E8E9F7E25372673025D?sequence=1)

leadership have agreed that PMI will now assume sole funding and technical responsibilities in PMI-supported African countries where Global Fund currently or formerly funded a TES. This transition will occur in conjunction with the Global Fund funding requests that are currently in development and it is expected to cause minimal disruption. This new TES funding arrangement will not impact WHO-funded TESs, which are currently implemented in a handful of PMI African countries.

PMI suggests budgeting \$75,000 per site, which includes costs for implementation and supplies. Costs of TES may vary based on the number of arms in the study and the addition of testing in response to results of previous studies such as day seven lumefantrine blood levels. There may be additional costs if molecular testing will be done in the country.

PMI recommends that *k13* and other molecular marker testing be conducted within the context of a TES because data on the presence or prevalence of *k13* mutations cannot be interpreted without accompanying clinical phenotypes. Activities to genotype *k13* outside the scope of TESs are considered operational research and require concept note and protocol approval by the OR working group. This pertains mostly to the Mekong region, where extensive efforts for *k13* monitoring are in place.

#### **Equipment and supplies**

Whatman 903 filter papers are recommended for dried blood spot sample collection for testing for recrudescence versus reinfection genotyping, and provide enough material for testing of molecular markers of resistance. The medicines to be used for TES may be procured by a PMI supply chain partner or requested from WHO or directly from the manufacturer. WHO-prequalified medicines available through the Central Medical Stores may also be used, as long as information on the manufacturer, batch number, and expiry date are available and the medicines are stored under acceptable conditions (generally <30°C).

#### **PMI-supported Antimalarial Resistance Monitoring in Africa**

The PMI-supported Antimalarial Resistance Monitoring in Africa (PARMA) network was established to support the monitoring of resistance-conferring *k13* mutations and other mutations associated with partner drugs in PMI countries in sub-Saharan Africa. Activities of the network supplement countries' routine drug efficacy monitoring efforts by characterizing molecular markers that may help to improve surveillance by adding genetic information to the clinical outcome data already generated by the study in addition to training laboratory staff in molecular monitoring techniques with the CDC Malaria Laboratory and partner laboratories in the PARMA network. CDC is implementing measures to shorten the time between completion of a TES and release of actionable resistance and efficacy information within a 6 month period. Thus, data results will be shared and programmatic implications discussed with NMCPs as soon as possible and will not await the corresponding manuscript for publication. Rapid public sharing with groups such as the WHO, the Worldwide Antimalarial Resistance Network also is strongly encouraged to enable potential decision-making in a timely manner. The PMI Headquarters PARMA Team will work with teams to ensure that protocols and transfer of samples conform to all U.S. and international ethical standards.

Expenses related to capacity building visits to CDC/Atlanta (i.e., a laboratory worker from the TES country learning the techniques and testing samples during a 8-week visit to the CDC) should be included in MOPs at an estimated \$12,000 per trainee with an implementing partner that can arrange travel, if the country prioritizes this for funding. Ideally, the PARMA trainee will already possess a

background in malaria laboratory techniques and be affiliated either with the national malaria control program or a well-established malaria laboratory. Once a country has participated in PARMA, there are several options for carrying out the resistance monitoring work in subsequent studies, depending on the laboratory capacity and human resources in the country. These options have different budgetary considerations which can be discussed with the TES/PARMA team at PMI headquarters.

## **Behavior Change and Case Management**

Communications and behavior change play an important role in encouraging best practices for case management, not only from the side of the patient/caregiver, but also for providers. On the patient side, key behavior change messages are often focused on the importance of prompt care seeking, acceptance of test results, and treatment adherence. Encouraging prompt care seeking is the first of many steps required for improved case management; without the patient first seeking care, messages on diagnosis and treatment are irrelevant. Once patients have sought care, it is important that providers follow national guidelines for diagnosis and treatment, as well as offering counseling not only on the diagnosis and treatment prescribed, but on appropriate prevention behaviors. Please see the Social and Behavior Change section for more information on PMI-supported approaches for provider behavior change to improve case management and service communication.

Historically in sub-Saharan Africa, almost everyone who presented to a health facility with fever was treated for malaria and mothers were encouraged to seek malaria treatment whenever their child had a febrile illness. Although parasitological testing has been in place for many years in many countries, appropriate use and adherence to the results of these tests remains a challenge. Patients and caregivers may demand ACTs even when tests are negative, and providers may not have full trust in the results when compared to their clinical diagnosis. Diagnostic testing must therefore be closely linked with communications and behavior change activities focused on changing the expectations and practices of providers, patients and caregivers.

Social and behavior change activities should be tailored to focus on either client behavior or provider behavior, and then further specified towards client groups (e.g., caretakers, pregnant women) and provider cadres (e.g., community health workers, clinicians). Although these objectives and approaches are different, activities to address them can be done concurrently. The Blueprint for SBC in Service Delivery details approaches to addressing specific behaviors for these groups.

<https://breakthroughactionandresearch.org/wp-content/uploads/2020/10/Blueprint-Applying-Behavioral-Insights-Malaria-Service-Delivery.pdf>

## **Health Systems Strengthening and Case Management**

Case management activities contribute to strengthening all recognized core HSS functions including medical products, vaccines, and technologies (e.g., strengthening forecasting, quantification and supply chain systems, consistent provision of supplies); human resources for health (e.g., pre and in-service

training); service delivery (e.g., supervision and mentoring), health finance; health governance (e.g., technical support to NMCPs); health information (e.g., support for data collection, reporting, analysis and use). Please see the HSS section for more details.

In support of health financing and efforts to achieve universal health care, PMI encourages all focus country teams to support countries in the design of their National Health Insurance strategies to ensure that they include appropriate coverage of malaria services and support structures to ensure and improve the quality of those services.

---

# HEALTH SYSTEMS STRENGTHENING

---

## **\*New/Key Messages\***

**PMI continues to significantly contribute to strengthened health systems through PMI's support for bringing and keeping at scale proven interventions with a priority emphasis on strengthening priority areas of the health system.** In fact, most, if not all, PMI-supported activities – whether intervention-specific or cross-cutting – contribute to health systems strengthening. PMI investments in systems that deliver health services at facility and community level, that ensure stable supplies of quality assured commodities, and that enable monitoring and evaluation of progress and impact of interventions are critically necessary for continued progress in malaria control. Therefore, PMI will continue to invest in strengthening priority areas of health systems across PMI's country programs including: (1) health information systems; (2) supply chain systems; and (3) community health systems that improve access to services for the most rural and high-risk populations, however guidance for PMI investments in these three priority systems are described in the technical intervention sections of this guidance and corresponding sections of PMI MOPs.

**PMI guidance for investment in: (1) Peace Corps; (2) Training and Capacity Building for NMCPs; and (3) Field Epidemiology Training Program (FETP) are included under this section.**

## **Introduction**

Stronger health systems are necessary to extend access to health services to the most vulnerable, to deliver sustainable improvements in health outcomes, and ultimately to contribute to countries' economic growth. Building capacity and strengthening health systems is identified in the *PMI Strategy 2015-2020* as a core area of strategic focus, which states that successful country-owned and country-lead malaria control programs are only possible when country programs possess appropriately-skilled human resources and the necessary infrastructure to plan, implement, and monitor progress of their malaria control activities. In addition, supporting countries as they advance on their journey to self-reliance is one of USAID's highest strategic priorities. Therefore, it is part of PMI's mandate to build capacity to enable countries to implement their own programs (rather than building parallel or stand-alone systems). This can include addressing gaps in country health systems in the key areas of supply chain management, training and supervision of health workers, health financing systems including effectively engaging with national health insurance schemes, and monitoring and disease surveillance systems as well as engaging communities to participate in malaria control. Most, if not all, PMI-supported activities – whether intervention-specific or cross-cutting – contribute to strengthening health systems.

PMI's support for HSS is aligned with [USAID's Vision for Health Systems Strengthening 2015-2019](#).<sup>122</sup> A revised **USAID Vision for Health Systems Strengthening 2030** is in the final stages of agency clearance now. Once finalized the link will be added to this newest visioning document. The agency's new Health Systems Vision shifts away from the prior emphasis on health systems building blocks to emphasis on health systems outcomes, including desired intermediate outcomes of equity, quality and resource optimization that lead to positive health outcomes in the countries we work.

PMI funding can be utilized to support activities that aim for or result in universal health coverage, but such activities must *directly* address key barriers to achieving PMI's goal and objectives. As with any proposed MOP activity, HSS activity descriptions should clearly describe the intended contribution to malaria control efforts. As with all intervention areas, HSS activities should be tailored to the specific country and operating context. Activities supported with PMI funding related to health financing must be directly related to an improvement in the countries' malaria control program strategy and goals, and if the financing goal is broader than malaria, malaria funding must be integrated with other funding streams. Activities supported with PMI funding related to the leadership and governance health system investment area must be directly related to an improvement in the countries' malaria program. PMI will not support the following: the hiring of public sector staff; the topping up of government salaries; construction or major renovation of buildings; or contributions to sector-wide approaches (donor common "basket" funding). However, although PMI does not support hiring of public sector staff as mentioned above, PMI can support technical and management capacity building approaches at national level and/or regional/provincial/zonal levels in the form of technical experts seconded to the NMCP or Ministry of Health Management Teams to work as integral members of these teams transferring knowledge, and skills and building capacity. When malaria technical/management secondments are supported with PMI funds, these secondments should have communication and reporting linkages directly with the PMI team, in addition to the NMCP.

## Integration with Other Health Programs

Where possible, PMI should look for opportunities to integrate malaria activities with other USG-supported health and development programs in-country. The *PMI Strategy 2015-2020* clearly articulates the importance of integration: "Whenever feasible and technically indicated, increase the level of integration of malaria activities with maternal and child health, HIV and AIDS, tuberculosis, neglected tropical disease activities, and the U.S. Government Global Health Security (GHS) activities". These efforts can include maximizing integration with USAID programming in health or other sectors, as well as with other USG Agency health program activities including but not limited to PEPFAR and Global Health Security activities implemented by USG Agencies other than USAID.

The GHS agenda aims to develop the capacity to conduct surveillance and adequately respond to public health threats through enhancing infectious disease surveillance, laboratory, information systems and

---

<sup>122</sup> <https://www.usaid.gov/what-we-do/global-health/health-systems/usaids-vision-health-systems-strengthening>

public health workforce. These activities can be leveraged with and can contribute to malaria prevention, control and elimination efforts by expanding their reach, efficiency and effectiveness. For example, GHS activities may contribute to PMI objectives by working to address artemisinin-resistance and multi-drug resistance in falciparum malaria parasites or identify the distribution of vector mosquitoes with resistance to synthetic pyrethroids and other classes of insecticide used for vector control. They may also contribute to strengthening routine health information or disease reporting systems. Where PMI aims to integrate PMI and GHS activities, the PMI team should designate an activity manager to engage regularly with the non-PMI funded aspects of the integrated efforts.

In addition, it is expected that many systems strengthening efforts, particularly those focused on health financing, leadership and governance, and workforce management, will be integrated across several health elements. Integrated programs should benefit all groups involved through improved coordination, increased cost-effectiveness, reduction of management workload, leveraging of resources, etc., while ensuring or enhancing achievement of malaria control objectives.

In proposing integrated activities, PMI should ensure that:

- Funding sources other than just PMI are contributing to the proposed integrated activity and describe these sources within the MOP
- For activities carried out by implementing partners with a mandate that extends beyond malaria:
  - That the implementing partners for these integrated activities have one or more staff members with expertise planning and implementing the malaria control interventions for which they are responsible
  - Malaria-specific objectives and targets are included in the M&E plan for the activity and within the partner's overall project scope of work and annual work plans
  - Partners are able to account for PMI funding and measure and report on PMI objectives and targets separately from other non-malaria activities
  - PMI staff review and concur with annual work plans and participate in monitoring for these mechanisms
- For activities carried out by staff or implementing partners of USG Agency other than USAID, PMI must identify an activity manager to provide oversight to the PMI funded and non-PMI funded aspects of the integrated activity to ensure maximum benefit to malaria and to ensure coordination across PMI's overall investment.

## **Promotion of Partnerships to Advance Malaria Control**

Achieving PMI goals at the country-level can best be served by close partnerships with civil society organizations, including non-governmental organizations (NGOs), community-based organizations (CBOs), and faith-based organizations (FBOs), and private and public sector entities, including academic

institutions. Non-governmental organizations have significantly contributed to PMI's successes to date and it is expected that they will continue to be strong partners in PMI efforts in the future.

## Peace Corps

### *Background*

On March 15, 2020 Peace Corps temporarily suspended all Peace Corps (PC) operations globally and evacuated all Volunteers, returning them to their homes in the United States due to COVID-19 pandemic. Prior to this suspension, the Peace Corps had over 3,400 total Peace Corps Volunteers (PCVs) in Africa, and over 2,400 PCVs in PMI countries in Africa across sectors (health, education Ag, etc.), and was thus well positioned to assist in the collective efforts of the USG to reduce the burden of malaria in sub-Saharan Africa. In November 2020, Peace Corps announced plans to begin the process of reopening programs with El Salvador announced as the first country to be reopened. Once the Peace Corps is able to reopen programs in Africa, the guidance below will continue to guide PMI's targeted investments with the Peace Corps.

The Peace Corps labels their overall malaria program efforts across all of their endemic countries in Africa as their *Stomping Out Malaria in Africa Initiative* – in short, referred to as STOMP. In 2011, PMI teamed up with PC to harness its reach and capacity in the fight against malaria in countries in sub-Saharan African where PMI and PC have a common presence. Funding for this is provided via a USAID Small Project Assistance (SPA) program, which supplements the Peace Corps' own appropriations.

In countries where there is PC-PMI collaboration, the expectation is that activities will be part and parcel to the larger malaria control effort led by the NMCP and the PMI platform will be used for coordinating such collaboration. Consultation between staff from the PC and PMI should occur prior to beginning any activity that is not already part of the national strategy and will ensure that efforts are complementary and technically sound. Collaborative activities are currently underway in 15 countries.

The PMI-PC collaboration includes two potential areas for PMI financial support funded through the MOP process: (1) funding for up to three PC Malaria Volunteers (MVs), and (2) funding to allow for malaria community projects and malaria training events, funded through SPA with a maximum of \$10,000 per year.

1. **Funding PC MVs:** PMI country teams planning to support 1-3 PC MVs should budget approximately \$10,000 per malaria volunteer per year. There are two potential mechanisms to support PC MVs: (a) the USAID-Peace Corps Interagency Agreement (SPA Agreement) managed by USAID/Washington, or (b) through a bilateral PMI implementing partner (appropriate when the PC MV's scope of work involves secondment to the implementing partner). The ~\$10,000 covers housing, operational support (e.g., laptop computer), basic work supplies, work related

travel, etc. Regardless of which mechanism is selected for PC MV support, the MOP should specify this support clearly in a line item in **Table 2**.

- 2. Funding PCV Malaria Community Projects and malaria training events through SPA Grants:**  
PMI can support PCVs malaria community projects (i.e. malaria prevention mural on market wall, or school based malaria messages) through a small grants process, budgeting maximum \$10,000 per year (assuming previous year's small grants pipeline has been spent down). Additionally, PMI can support training events of PCVs and their counterparts, however not just training events of PCVs alone. The counterparts involved in the training events must be direct malaria/health service providers (i.e. nurse at a clinic, community health worker, district health worker, etc.) or be linked directly to an NMCP intervention strategy such as school teachers involved in malaria SBC messaging or school based net distribution campaigns. Such trainings must be coordinated with and endorsed by the NMCP. PMI support to PC training events should also be budgeted at maximum \$10,000 per year.

The mechanism to support malaria community projects and training events through SPA grants is the USAID-Peace Corps Interagency Agreement managed by USAID/Washington. PCVs can access small grants through USAID Mission Program Office awards. PMI-funded malaria specific SPA projects range from less than \$100 to \$500. Funded activities typically include training or local community mobilization activities, such as a student song contest about malaria, painting a malaria mural at the health facility or school, Grass Roots Soccer games about malaria, etc. The PMI in-country team should participate in the application review and award process to ensure that proposed projects align with PMI and NMCP priorities. This will also enable the PMI team to follow the implementation of the projects and the use of these funds. PMI teams should assess whether it is to PMI's advantage to provide support for PCV malaria projects through a PMI implementing partner rather than through the Peace Corps SPA agreement. There may be situations where it makes greater programmatic sense to work with PCVs on a community project with the funding flowing through a PMI implementing partner to ensure the right technical expertise is available and the work is coordinated closely with PMI's overall program in country.

### ***Additional information – PC Malaria Volunteers***

Peace Corps Malaria Volunteers MVs are experienced PCVs either serving a third year in their initial country of assignment, or PC Response Volunteers (PCRVs) who may have already completed their initial two years of service and who have applied for another short-term assignment. A PCRV usually completed their initial service in a different country from their response assignment and may or may not have contiguous timing with their initial service. PCRVs are ineligible for PMI support if they have not already been a PCV.

Peace Corps MVs and PCRVs that were PCVs are expected to work closely with PMI in-country staff and the NMCP as well as collaboratively with other malaria partners active in the country to support national malaria control efforts. Both also play a coordination and mobilization role for malaria activities carried out by PCVs posted throughout his/her country of posting(including non-health sector PCVs).

The PMI-PC collaboration provides PMI and the NMCP with a network of volunteers experienced in community-level work, communities gain valuable malaria technical expertise, and the PC MVs and the larger network of PCVs working throughout the country acquire valuable first-hand technical and operational skills.

Examples of areas where PC MVs and/or PCVs have contributed include:

- Assisting with the organization and monitoring of ITN distribution campaigns at the district and community levels
- Helping PMI implementing partners with malaria interventions, such as preparing communities for indoor residual spraying or organizing and conducting training programs on community-based case management
- Designing and conducting SBC interventions, including working with community groups and local organizations
- Advising communities on malaria surveillance and monitoring and evaluation, including analysis and mapping of malaria data
- Supporting the logistics and implementation of priority operations research projects
- Documenting and sharing operational and community-based best practices within and across countries

PMI's country level collaboration with PCVs must be aimed at building local capacity of host country counterparts. Peace Corps Volunteer presence in communities can extend the reach of NMCP and PMI staff and implementing partners. However, **PMI funding should not be used to train PCVs** alone, but any PMI-supported malaria training should be part of PMI's ongoing malaria control and elimination in-country training aimed at building partner country capacity. PCVs taking part in PMI supported malaria training activities should be oriented to obtaining new knowledge and skills in order to work in their communities with local counterparts to carry out malaria control work.

### ***Training/country orientation***

Peace Corps historically conducted a comprehensive ten-day Malaria "Boot Camp" training in Senegal, funded by PC (not PMI), that provide MVs – those supported by PMI and those supported by PC directly - with a basic understanding of malaria disease, key program interventions, and how MVs/PCVs can support national strategies at a grassroots level. As of January 2018, Peace Corps transitioned to a new model, which prioritizes in-country trainings as well as virtual, online trainings. This country-focused model will facilitate capacity building of PCVs together with host country counterparts, while also

allowing for more participation by in-country malaria experts. The PMI in-country team is encouraged to collaborate with the NMCP and partners to coordinate and participate in these country-specific training for new PC MVs and their counterparts, as well as to assist with more in-depth orientation of PC MVs (i.e., sharing the NMCP Strategy, current status of malaria control nationally and sub-nationally, key country challenges, and priority activities).

### ***Supervision, communication, and assessment***

Peace Corps MVs work under the administrative supervision of the PC country office. PMI in-country staff, designated NMCP staff, and implementing partner staff should work together to identify the MV's day to day supervisor/mentor. If an implementing partner will be supervising a MV, then this responsibility should be indicated in the implementing partner's work plan. The MVs will develop their work plans with their supervisor, and ultimately seek PMI and PC approval of their work plan activities. During field trips, PMI in-country staff, in coordination with the PC country office, are also encouraged to visit MVs and other PCVs involved with malaria activities to provide opportunity for support, guidance, and mentorship. PMI staff and MVs should have at least quarterly updates, in-person or by phone, to ensure that volunteer activities are consistent with national guidelines, and that the MVs have the support and guidance they need.

Each MV will complete a report at the end of service that summarizes their accomplishments (e.g., malaria activities they supported, etc.) as they relate to supporting the NMCP/PMI's efforts. These reports should include indicators from the work plan and will be made widely available to the full PMI interagency team.

### ***Pre-service and in-service training***

In addition to working with the PC MVs, the PMI in-country team often participates in PC country-based pre-service, in-service, and even close-of-service training (to provide career guidance). Generic training materials are available to be adapted to specific country needs.

## **Training and Capacity Strengthening of NMCPs and Other Local Government Entities**

Capacity strengthening activities with national malaria control programs and other local government entities should be described in detail in relevant intervention sections of the MOP (i.e., training, on site supervision to strengthen diagnosis and treatment should be described in the case management section). Training activities for NMCP staff that do not appear within the technical intervention sections of the MOP, including FETP, should be described in the "Other HSS" section of the MOP.

As a part of efforts to strengthen national capacity in malaria control, PMI supports short-term training of NMCP permanent staff in areas that directly benefit the country's malaria program. Since other

donors and international organizations (e.g., Global Fund, World Bank, WHO, etc.) also provide funding for such training, PMI-supported efforts should be coordinated with those of other groups. Priority should be given to in-country training opportunities, followed by regional training programs, as workers will be absent from their jobs for shorter periods of time. Only under exceptional circumstances will training in Europe or the United States be considered and only when justification for this training is provided. As mentioned earlier, PMI also supports technical and management capacity building approaches at national level and/or regional/provincial/zonal levels in the form of technical experts seconded to the NMCP or Ministry of Health Management Teams to work as integral members of these teams transferring knowledge, and skills and building capacity. When malaria technical/management secondments are supported with PMI funds, these secondments should have communication and reporting linkages directly with the PMI team in addition to the NMCP.

Direct government-to-government (G2G) support to NMCPs and local government entities must be in accordance with [USAID G2G policy and regulations](#) and procurement guidelines regarding grants to governments. [USAID issued updated guidance that expands flexibilities for designing, negotiating, and implementing direct G2G funding with PEPFAR, USAID TB and PMI funding](#) (ADS 220, section 220.3.3.1.b(2)). Where used, direct grants to the Ministry of Health, NMCPs, or other local government entities may include support for financial management and tracking of the funds provided. Technical assistance and support to the Ministry of Health, NMCPs, or other local government entities to build their capacity can be part of the scope of work requested of PMI implementing partners, and should be described in MOP budget activity lines.

PMI supports and encourages NMCP staff to benefit from training opportunities and to participate in international conferences, particularly as presenters (oral or poster). Financial support for this engagement should be carefully reviewed by the PMI team to ensure that both the participants and the events are appropriate, that funds from other sources are leveraged if possible, and that outcomes of the participation are expected to be conveyed beyond the participants themselves in order to benefit the country program. Funding to respond to these opportunities may be programmed in the MOP as a component within HSS activities designed to build NMCP capacity, and/or within interventions related to a specific technical area. Malaria operational plans should not include a single budget line item for support for international travel for NMCP staff but instead should be a component of an activity aimed at further strengthening leadership and capacity of NMCPs.

## **Field Epidemiology Training Program**

PMI supports efforts to initiate and strengthen local epidemiologic and laboratory data collection, management, analysis, and dissemination capacity in PMI-supported countries. As one approach to strengthening the long-term capacity of this health system component, country teams may consider supporting training through the CDC FETP national level training efforts. In 2016, CDC reconfigured their FETP program to a three-tiered pyramid model consisting of frontline (short-term 3 month training), intermediate (9-12 months of training), and advanced two-year training. PMI support can be directed to

the advanced program, which consists of a two-year, full-time training program that helps MOHs build sustainable capacity for local detection and response to health threats, including sudden increases in malaria transmission. The aim is that over time, PMI investments in FETP will produce a cadre of public health workers that use science and data to identify, respond to, and manage acute health problems with appropriate strategies and policies and that this cadre will have positive impacts of malaria program efforts following completion of training.

PMI supports trainees in the advanced level 2-year program however, in PMI-supported countries where CDC is implementing frontline programs (whether via GHSA, PEPFAR, or other funds), PMI staff and partners should look to benefit from the new capacity of the district (or district-equivalent) managers benefitting from the frontline program. Frontline FETPs are basic level field epidemiology trainings, typically 3 months long with 12 days of didactic trainings/workshops, followed by on-the-job opportunities to apply the training. Frontline FETPs are currently operational in the following PMI focus countries: Benin, Burkina Faso, Cameroon, Côte D'Ivoire, DRC, Ethiopia, Ghana, Guinea, Kenya, Liberia, Malawi, Mali, Nigeria, Senegal, Sierra Leone, Tanzania, and Uganda.

Approximately 20-25% of the FETP advanced training program time is spent in classroom instruction and 75% on field assignments, with field assignments involving malaria control activities required. The training is competency-based with close supervision, didactic and inductive teaching which includes courses in epidemiology, communications, economics, and management. Trainees also learn quantitative and behavioral-based strategies for mitigating public health problems. The trainees provide epidemiologic services to the Ministry of Health during their training, including surveillance system assessments and outbreak investigations, and gain experience in reporting their findings and recommendations to high-level decision makers, stakeholders, and the media. Graduates receive a certificate or, in some advanced programs, a Master of Public Health degree.

FETPs are helping to realize the long-term health systems capacity development component of the USG's Global Health Security Agenda to which PMI aims to contribute. Currently, PMI is supporting FETP advanced program trainees in twelve countries: Angola, Burma, Cameroon DRC, Ethiopia, Ghana, Kenya, Mozambique, Nigeria, Rwanda, Tanzania, and Uganda.

Field Epidemiology Training Program residents/participants may be drawn from NMCP staff or from other applicants nominated by the Ministry of Health who have a medical or public health background. FETP residents/participants receive financial support from a variety of funding sources with new funding now provided through the Global Health Security Agenda. PMI country MOP funding can be prioritized for support for FETP. If support for FETP is prioritized, PMI country teams should work with FETP leaders to determine the appropriate PMI financial investment for FETPs within their respective countries within the financial parameters that define maximum funding for PMI support (see further below). In addition, PMI country teams must coordinate closely with FETP leaders to ensure support for PMI malaria-specific activities and training for FETP participants. For example, the PMI RAs may provide malaria focused

lectures to FETP participants, and mentorship on malaria-related projects. They also help to coordinate and promote the placement of FETP residents within the NMCP for training and field work and should take the lead in facilitating FETP resident collaboration with implementing partners on PMI-funded activities.

Each PMI-supported FETP program should expect to engage periodically in seminars organized by PMI CDC Headquarters staff for purposes of updating PMI (CDC and USAID) on malaria-related FETP projects and developing strategic approaches to strengthen this ongoing collaboration.

Although levels of financial support for malaria-focused FETP residents and the costs of training will vary by country, PMI has established budget guidance parameters for PMI support for FETP. PMI support for FETP trainees is external to salary provided by the Ministry of Health. PMI support contributes to the CDC program that includes two years of training per trainee and includes tuition towards a certificate or degree (if applicable), a modest training stipend, field site supplies, as well as travel expenses for didactic courses, field investigations, supervision, and scientific conferences. PMI funding for FETP cannot be used to support salaries of FETP RAs or salaries of any FETP residents or any other staff associated with the FETP program. PMI country teams proposing support for FETP trainees should budget between \$80,000 to a maximum of \$150,000 per trainee per two-year assignment (\$40,000 to \$75,000 per resident annually) to support the FETP program in their FY 2022 MOP budgets (please use country specific cost estimates when available without exceeding the maximum threshold allowed). No more than \$300,000 per year and four trainees at a time can be supported (two trainees in the new/starting cohort and two trainees in their second and final year of the advanced FETP training program). PMI country teams need to ensure that PMI funding is not displacing CDC appropriated, Global Health Security, or other USG funding supporting FETP program activities in-country. PMI country teams can explore requesting a PMI implementing partner with district level implementation focus to include support for training district level health officers through the CDC FETP frontline program in their annual work plan where CDC FETP frontline programs exist. Country teams should be careful to ensure that the training does not duplicate ongoing PMI supported training and capacity building efforts. If country teams choose to prioritize support for this training within a PMI partner's work plan, the PMI team should consult the in country FETP program for exact costs but it is expected that the implementing partner will need to budget no more than \$10,000 per student. Where PMI country team's prioritize support of trainees participating in a frontline/short-course FETP program will not be through AFENET, but through a PMI implementing partner. The majority of PMI implementing partners work at subnational levels and would be able to provide the necessary support needed for a successful partnership with the FETP Frontline programs.

PMI country teams should ensure appropriate indicators are in place to document the impact of PMI support for the FETP. PMI's decision to support FETP in the early days of PMI was taken with the expectation that graduates employment following graduation would be tracked in order for PMI to evaluate the extent to which FETP is building cadres of staff that remain within the MOH, to document

how PMI investments in this program continuing to have lasting impact. Countries are expected to annually update a PMI-FETP progress tracking spreadsheet which is sent to the countries for completion and then to USAID Washington per CDC IAA reporting requirements. The following indicators will be tracked:

- total number of FETP trainees enrolled and specifically, number of malaria FETP trainees enrolled
- total number of FETP trainees graduated
- total number of FETP trainees who are employed by the NMCP or other malaria programs after graduation (title and position) (PMI in country teams are to maintain a list of graduates and track annually their continued employment with the MOH)
- list of malaria projects completed with some details about the activity or response effort if a malaria outbreak investigation
- list of products (reports, publications and presentations) from malaria-related projects that were disseminated beyond the FETP program
- list of any malaria training conducted for FETP trainees
- success stories

---

# DIGITAL COMMUNITY HEALTH

---

## **\*Key Messages\***

**Digital tools used by health providers at the peripheral and community level have tremendous potential to improve case management and develop better and more timely program data for malaria program management.**

**A vision and operating principles for PMI investments in digital community health have been developed.** The vision and principles, along with the guidance in this section, are intended to help steer PMI's investment decisions in activities to expand the utilization of digital tools and systems to strengthen health services in the community.

**Expanding the utilization of digital tools for improving community health and malaria data remains a PMI priority. In FY20, there is not a directive for a specific funding amount into digital community health activities or a specific mechanism.** However, digital community health activities are encouraged to be incorporated into FY22 MOP planning and FY20 and FY21 reprogramming discussions and **entered in Table 2.** Flexibility exists at the country level to choose an appropriate mechanism to implement activities.

**Each applicable activity that leverages digital technology should include the term “digital”** within the activity description in Table 2 to allow for querying and tracking within M-DIVE. **For activities in alignment with the Digital Community Health Initiative, it is requested that the language “digital community health” or “DCH”** be included within the activity description.

### **Important Resources**

[USAID Digital Strategy](#)

[USAID Digital Health Vision](#)

[Principles for Digital Development](#)

[Principles of Donor Alignment for Digital Health](#)

[WHO Classification of Digital Health Interventions](#)

## **Background**

Public health is an ever-changing field, with new innovations and technologies constantly providing better and more efficient tools to increase the impact of life-saving interventions across populations. The ongoing global, digital transformation creates an opportunity to leverage technology to strengthen health services and revolutionize data collection and use. Therefore, PMI is prioritizing efforts to

sustainably incorporate the use of digital tools into malaria programming to improve service delivery and enhance data collection and use. In particular, this includes making strategic investments in the use of digital solutions to improve how malaria prevention and treatment services are provided at the community level and to improve the collection of data resulting from these activities.

As is reflected in the Case Management section of this technical guidance, investing in community health is a priority for PMI. This specifically includes supporting the training, mentoring and supervision of community health workers (CHWs) to provide high-quality testing and care for malaria in the community, accurately record and report testing and treatment data and encourage the adoption of prevention and treatment behaviors. As a component of this, it is a PMI priority to support and scale-up integrated Community Case Management (iCCM) programs to increase access to care in the community.

Due to community health being a priority, the ongoing digital transformation, and the potential that digital tools have to increase the impact of malaria programming, PMI launched its Digital Community Health Initiative in 2020. In order to jumpstart the initiative in the first year, the PMI Coordinator informed each PMI country of the requirement to invest a small portion of FY19 funds into this initiative via the Digital Square mechanism. Activities began in all PMI countries with a Foundational Assessment to analyze the current digital community health ecosystem and to identify country-specific priorities. These priorities will be viewed as a potential starting point for PMI to partner with country governments and others to expand the use of digital technologies at the community level to increase the impact of malaria programming. These priorities are certain to evolve over time.

This initiative aligns with the global push by USAID and many other donors to continue investing in digital health in a coordinated way to minimize fragmentation and to build more integrated and sustainable systems. In 2020, USAID launched its first [Digital Strategy](#), followed in December 2020, by its first ever [Digital Health Vision](#) to inform its digital health investments between 2020 and 2024. The overarching vision for PMI's Digital Community Health Initiative both aligns with and supports these broader, agency-wide frameworks.

## Digital Community Health Initiative Vision

Below is a description of the vision PMI has for this initiative, with which all investments should align.

**Vision:** Strengthen the delivery of health services at the community level in PMI countries, by investing in the scale-up of digitally-enabled community health platforms that:

1. Equip frontline workers with connected mobile tools to increase the effectiveness of case management (e.g. job aids, diagnostic tools/readers, support for care-seeking behaviors)
2. Improve access to near real-time, high-quality community data (that flows directly into country Health Information Systems at the most peripheral level)

3. Catalyze a cultural shift in the use of community data for decision making across all levels of the healthcare system
4. Facilitate the integration of services at the community level in alignment with the holistic needs and health goals of each country
5. Integrate and empower CHWs as a valued aspect of the national health system

For these purposes, the community level is defined as the lowest level health worker that is able and officially authorized to diagnose and treat malaria in each country.

## Key Investment Guidance

The FY19 funding directive into the Digital Square mechanism established a starting point for each country, which is sure to evolve as each country's local context changes with advancements in digital infrastructure and capabilities. Starting in FY20, digital community health activities will **NOT** be funded by a specific percentage of each country's annual budget directed by PMI leadership. Rather, these activities will be incorporated into the FY22 MOP process and ongoing FY20 and FY21 budget prioritization discussions to inform reprogramming decisions. This change from the FY19 funding directive does **NOT** indicate a shift in the attitude of PMI regarding the importance of support for digital community health. Each PMI country is expected to continuously identify and invest in priorities and opportunities that align with the vision for this initiative, integrating those opportunities into existing programs and technical areas, where relevant. To create in-country flexibility, countries should utilize the funding mechanism that is most appropriate for the digital community health activity(ies) they would like to support in a specific year. This can be a central mechanism or a country mechanism. Any future directed funding under this initiative will come via separate communication.

## Examples of Appropriate Investments

Each country's ongoing FY19 investment into Digital Square will identify appropriate priorities that can be funded moving forward. These should serve as a starting point when considering future investments. However, below are illustrative examples of activities that could be considered as part of this initiative.

- Develop scale-up strategies for existing, proven digital community platforms, including sustainable business models and costing components
- Support digitalization (e.g., development of digital applications or deployment of digital technology) of CHWs for case management and data collection support, and for systems supporting CHWs, including supervision, and performance or supply chain management
- Create a roadmap for systematic building of capacity for eHealth that includes community health workers and works along the continuum of health care service delivery
- Develop a national rubric for the assessment of digital community tools to adopt in-country, considering country specific context and sustainability

- Measure and evaluate the impact of 3-4 existing digital tools that have been deployed to determine which tool(s) to take forward at scale
- Provide support to establishing interoperability between digital community platforms and national health information systems
- Work with local government and others to establish the architecture for a community health information system (CHIS) and support planning and implementation of the architecture, ensuring it aligns with a national enterprise architecture
- Build out key reusable architectural components that will support the CHIS (e.g. registries, terminology service, interoperability layers, etc)
- Provide technical assistance to governments for incorporating digital community health into their information and communications technology (ICT) and/or eHealth strategy
- Develop and incorporate an iCCM module into an existing digital platform
- Develop and implement a digital capacity building plan for CHWs and their supervisors, taking into account training models that ensure sustainability
- Landscape and prioritize Global Goods<sup>123</sup> that align with the in-country architecture and NMCP priorities to support community case management and utilization of data
- Define and establish novel partnerships with private digital companies and/or universities to pursue development objectives aimed at improving community case management and data use
- Create and implement IT skills building curriculum to support placement of IT staff to support hardware and software needs for community health programs
- Drive behavior change activities that strengthen the use of community data for decision making across the health system
- Incorporate CHW skill building related to behavior change into existing digital tools to increase uptake of prevention and treatment behaviors

## **Principles**

When identifying activities for investment, countries should adhere to the following principles:

1. Digital systems/tools must connect with the country’s health information systems at the most peripheral level possible and ensure disaggregated community health data flows into the system.
2. Digital systems must integrate with and enable other health areas, to the extent practical, to drive sustainability and reduce system fragmentation (i.e. Do not invest in malaria-specific systems that create information silos). For malaria this would generally include iCCM, at a minimum.<sup>124</sup>
3. Build and expand on existing systems in-country instead of investing in separate, parallel systems.

---

<sup>123</sup> USAID’s Digital Strategy refers to Global Goods as any tool that is non-rivalrous, meaning use by one actor does not reduce the utility of the tool for use by another actor, and that is available for use by any actor. In the context of digital development, global goods are adaptable to different contexts, funded by multiple sources, and implemented by a large number of parties, and, in the case of software, interoperable across commonly used systems. They are often, but not always, open-source; however, “open-source” does not always mean “free of cost” or “free of intellectual-property rights.”

<sup>124</sup> It is recommended to closely coordinate with Mission colleagues in other health areas around digital community health investments to create alignment and opportunities for collaboration/co-investment.

4. Align with at least one of the priorities within USAID’s *Digital Health Vision*
  - Assess and Build Country Digital Health Capacity
  - Advance National Digital Health Strategies
  - Strengthen National Digital Health Architectures (inclusive of Community Health Information Systems)
  - Leverage Global Goods
5. Digital technology must be used responsibly by: 1) Prioritizing the rights of host governments and individuals to consent, privacy, security and ownership when using data to accelerate malaria control and elimination efforts and 2) Implementing values and practices of transparency and openness.
6. Ensure adherence to best practices established in the USAID-endorsed [Principles for Digital Development](#) and [Principles of Donor Alignment for Digital Health](#)

PMI HQ staff (Nathaniel Moller or Dean Sayre) are available to answer questions and discuss potential activities and projects with country teams during MOP planning and as they make funding decisions. .

## Incorporation of Digital Health Investments In Table 2

PMI has many investments that include digital interventions more broadly and is seeking to better understand and track these investments. Therefore, regardless of the level of the healthcare system (community, district, national, etc), mechanism and technical area (case management/community case management, SME/strengthening routine surveillance, etc.), all activities that include digital technologies should be clearly identified in Table 2. **Specifically, it is requested that each applicable activity that leverages digital technology<sup>125</sup> include the term “digital” within the activity description in Table 2 to allow for querying and tracking within M-DIVE. For activities in alignment with the Digital Community Health Initiative, it is requested that the language “digital community health” or “DCH” be included within the activity description.** In the scenario where a digital health component is being incorporated into an intervention in a specific technical area (e.g. scaling up an iCCM digital tool for CHWs), that should be included in the description for the applicable Proposed Activity (e.g. Community-based case management). If it is more of a cross-cutting digital health activity (e.g. develop an eHealth capacity building plan) it should be identified as a separate activity under the SM&E or HSS sections, as appropriate. This request is applicable to annual MOP planning and to Table 2 modifications as part of Reprogramming Memos.

---

<sup>125</sup> Only identify activities that utilize digital technology as a key component of health activities. These can be defined as activities that include the planning for, study, and use of digital systems and the data they generate to strengthen health institutions and outcomes through improved health information and delivery of care. This DOES NOT include general office use of desktop computers or laptops. For reference, the WHO has developed an extensive list of [digital health interventions](#) to provide some examples.

---

# SOCIAL AND BEHAVIOR CHANGE

---

## **\*New/Key Messages\***

**Prioritizing Behaviors:** To ensure the most strategic allocation of resources and the deployment of high quality, targeted SBC interventions, the SBC Technical Team recommends that country teams focus SBC efforts on no more than 2-3 specific malaria behaviors. That focus should be further refined by geography and target population and should support the National Malaria SBC Strategy and National Malaria Strategic Plan.

**Resources for National Malaria SBC Strategy Development:** A strong National Malaria SBC Strategy is critically important to ensuring a deliberate and harmonized approach to malaria SBC in a given country. Several new resources are available to help support National Malaria SBC Strategy development, including a standardized template, accompanying guidance document, and a toolkit aimed at facilitating development of the strategy.

**Malaria Behavior Survey:** The Malaria Behavior Survey (MBS) is a cross-sectional household survey designed to measure malaria-related behaviors and the internal and social factors associated with those behaviors using a theory-driven and standardized methodology. To facilitate strong, data-driven, theory-informed SBC interventions, the SBC Technical Team recommends countries conduct an MBS approximately every five years. There is both a standard questionnaire and a questionnaire for use in low-transmission settings.

**SBC Module for the MIS:** The RBM SBC Working Group developed an optional standard module of malaria SBC-related questions for use in all planned MIS surveys. The module includes nine indicators divided into the following categories: recall, knowledge, risk/efficacy, and norms, and should be included in all planned MIS.

**Larval Source Management:** There is insufficient evidence at this time to support the promotion of community removal of larval habitats. PMI funding should not be used for SBC activities specifically targeting the removal/drainage of Anopheles larval sites, outside of OR/PE. Furthermore, activities which have no biological link or evidence of impact on malaria risk, such as cleaning around the home or clearing vegetation, should not be included in SBC activities, nor supported by PMI funding.

**Zero Malaria Starts With Me:** Zero Malaria Starts with Me (ZMSWM) is a continent-wide advocacy campaign to increase ownership of, involvement in, and commitment to the fight against malaria. Given that ZMSWM is an advocacy campaign, it should not replace ongoing community-level, district-level, regional-level, and national-level SBC activities. PMI funding should continue to be used to support the

design and implementation of evidence-based, theory-driven SBC activities aimed at increasing the practice of specific behaviors.

## Introduction

Achieving and maintaining PMI and National Malaria Control Program (NMCP) goals depends on the acceptance and correct and consistent use of proven interventions (e.g., ITNs, IRS, RDTs, ACTs, IPTp, and SMC). When tailored to specific country contexts and needs, social and behavior change (SBC) activities play a critical role in promoting uptake of these interventions and achieving desired individual and public health impacts. Thus, to improve the overall quality of malaria control efforts that contribute to reductions in morbidity and mortality, PMI supports a range of SBC activities to increase uptake and correct and consistent use of key interventions.

## Key Areas of PMI Support for SBC

Key areas of PMI support for SBC include: (1) capacity strengthening, (2) design and implementation, (3) coordination with service delivery, and (4) monitoring and evaluation.

### *Capacity Strengthening*

To ensure sufficient host country capacity for malaria SBC activities, PMI supports capacity strengthening efforts related to the design, implementation, monitoring, and evaluation of SBC activities. Capacity strengthening activities should be directed toward NMCP staff and sub-national health staff, especially those directly involved with SBC activities, and may include Ministry of Health staff, such as those from a country's Department of Health Promotion.

#### National and sub-national capacity strengthening activities

PMI supports the following capacity strengthening activities nationally and sub-nationally:

- **Global and Regional Coordination and Collaboration:** Global and regional coordination and collaboration play an important role in ensuring high-quality malaria SBC activities. Participation in regional and global efforts allows for the exchange of ideas and best practices, as well as the sharing of tools and resources. PMI supports such activities and, when appropriate, facilitates and encourages the participation of NMCP and Ministry of Health staff in regional meetings and technical organizations such as the [RBM Social and Behavior Change Working Group](#).<sup>126</sup> PMI also strongly encourages engagement in online collaboration fora, such as the [Springboard for Health Communication Professionals](#).<sup>127</sup>

---

<sup>126</sup> The RBM SBC Working Group was formerly known as the RBM Communication Community of Practice. Additional information is [available online](#) and from the PMI SBC Technical Team.

<sup>127</sup> <https://springboardforsbc.org/>

- **Malaria SBC Technical Working Group:** Given the cross-cutting nature of SBC, a malaria SBC coordinating committee or technical working group is critical. Such a group facilitates information sharing and strengthens an NMCP's ability to coordinate SBC design, message harmonization, implementation, and monitoring and evaluation across and within ministries, donors, and non-governmental and private sector partners. PMI supports the establishment and ongoing maintenance of such a group, which should be convened regularly to share information, ensure alignment around the country's National Malaria SBC Strategy, and facilitate planning across various technical areas and partners.
- **Training and Development:** A critical component of the successful design, implementation, and monitoring and evaluation of SBC programs is ensuring there is sufficient trained and experienced staff to support such activities. For that reason, PMI supports the participation of NMCP and Ministry of Health staff at the national and subnational level in training and development activities. A number of training options exist, including local and virtual options, and can be found in the appendix of this chapter.
- **Technical Assistance:** PMI also supports targeted technical assistance (e.g., training, mentoring) to NMCPs, Ministries of Health, other relevant ministries, local civil society organizations, and implementing partners that contribute to SBC activities. Technical assistance is typically focused on planning, development, and monitoring and evaluation of SBC activities, including the selection of appropriate monitoring and evaluation indicators and review of existing data to inform SBC strategies and interventions.

### **Development of national malaria SBC strategy**

PMI supports the development or revision of a National Malaria SBC Strategy within a country's broader National Malaria Control Strategy. Such strategies are critically important as they guide the NMCP, donors', and implementing partners' SBC activities and help to ensure a deliberate and harmonized approach to malaria SBC in a given country. PMI should work with the NMCP to ensure the National Malaria SBC Strategy is evidence-based, clearly linked to national malaria control objectives, reflects global best practices, including those outlined in the [RBM Partnership to End Malaria's Strategic Framework for Malaria Social and Behaviour Change Communication 2018-2030](#),<sup>128</sup> and routinely used to guide implementation of malaria SBC activities. Several resources are available to assist countries in developing their National Malaria SBC Strategy:

- [RBM SBC Working Group Template for National SBC Strategy Development](#)<sup>129</sup> - This standardized template serves as a companion to the Strategic Framework for Malaria Social and Behaviour Change Communication 2018-2030 and reflects global best practices.

<sup>128</sup> <https://endmalaria.org/sites/default/files/RBMSBCCFramework2018-2030English.pdf>

<sup>129</sup> <https://endmalaria.org/sites/default/files/National-Malaria-SBC-Strategy-Template-2020-EN.doc>

- [RBM SBC Working Group Guidance for National SBC Strategy Development](#)<sup>130</sup> - This guidance, which accompanies the template above, outlines the key elements and considerations for the development of a National Malaria SBC Strategy.
- [National Malaria SBC Strategy Development Package](#)<sup>131</sup> - This toolkit serves as a step-by-step guide to completing the National Malaria SBC Template. Resources included are intended to facilitate development through a series of small group working sessions.

Technical assistance is also available from the Interagency PMI SBC Technical Working Team and should be utilized if there is not sufficient capacity in the country to support the development or revision of a National Malaria SBC Strategy.

### ***Design and Implementation***

At the core of PMI's approach to SBC is the use of data to design and implement high-quality, targeted interventions that reflect a comprehensive understanding of the multitude of factors that support or inhibit the practice of desired malaria prevention and control behaviors. This includes social (gender norms, social support, etc.), internal (attitudes, self-efficacy, etc.), and environmental factors (economic barriers, accessibility of services, etc.), and resulting interventions can be communication or non-communication-based.

Primary behaviors of interest include:

- Correct and consistent net use;
- Early and frequent ANC attendance;
- Acceptance of intermittent preventive treatment of malaria in pregnancy (IPTp);
- Prompt careseeking for fever; and
- Adherence to national guidelines for health workers.

However, to ensure the most strategic allocation of resources and the deployment of high quality, targeted SBC interventions, country teams must make decisions about the desired focus of SBC efforts in the countries they support. To make such decisions, country teams, with support from the SBC Technical Team and in collaboration with appropriate working groups in country, should regularly assess what is known about the practice of key malaria behaviors (such as the ratio of ITN use given access), alongside what is known about the internal, social, and environmental factors that influence the practice of those behaviors (such as country data that suggest that self-efficacy is associated with increased ITN use).

By triangulating data on behavioral outcomes with data on behavioral determinants and demographic information, country teams can make strategic decisions about the appropriate focus of malaria SBC

---

<sup>130</sup> [https://endmalaria.org/sites/default/files/National-Malaria-SBC-Strategy-Guidance-2020-EN\\_0.pdf](https://endmalaria.org/sites/default/files/National-Malaria-SBC-Strategy-Guidance-2020-EN_0.pdf)

<sup>131</sup> <https://drive.google.com/drive/folders/1paJiNjmiHdVtfl25BZSCfpk1HV61ygcl>

activities. PMI recommends that country teams ***prioritize no more than 2-3 specific malaria behaviors to focus efforts around***. This includes both community member and health worker behaviors. This focus should be further refined by geography (e.g., specific districts, zones, or provinces) and target population (e.g., health care providers, adolescent mothers, male heads of households, etc.), and should support the National Malaria SBC Strategy and National Malaria Strategic Plan.<sup>132</sup> Data sources for such an exercise can be quite varied and are outlined in more detail in the section on monitoring and evaluation.

When deciding which behaviors to prioritize, country teams should carefully consider the gains that are likely to be achieved through an SBC intervention. For instance, when reviewing the internal, social, and environmental factors influencing the uptake of a specific behavior, it may become clear that the most important factor influencing the behavior is related to access and a behaviorally focused intervention would be unable to successfully address that factor. Using a simple example, an SBC activity to increase patient demand for IPTp will have limited success if stockouts of sulfadoxine-pyrimethamine (SP) are widespread. Conversely, a situation in which SP is available at ANC clinics, but where there is a common belief among ANC providers that IPTp is ineffective, would indeed call for a well-designed SBC activity targeted to service providers. Similarly, this prioritization effort could reveal that uptake of certain desired behaviors is already quite high in a given country or region. In such an instance, especially if uptake of other behaviors is low, it might not make sense to focus PMI SBC resources on trying to achieve small gains for a behavior that is otherwise widely adopted.

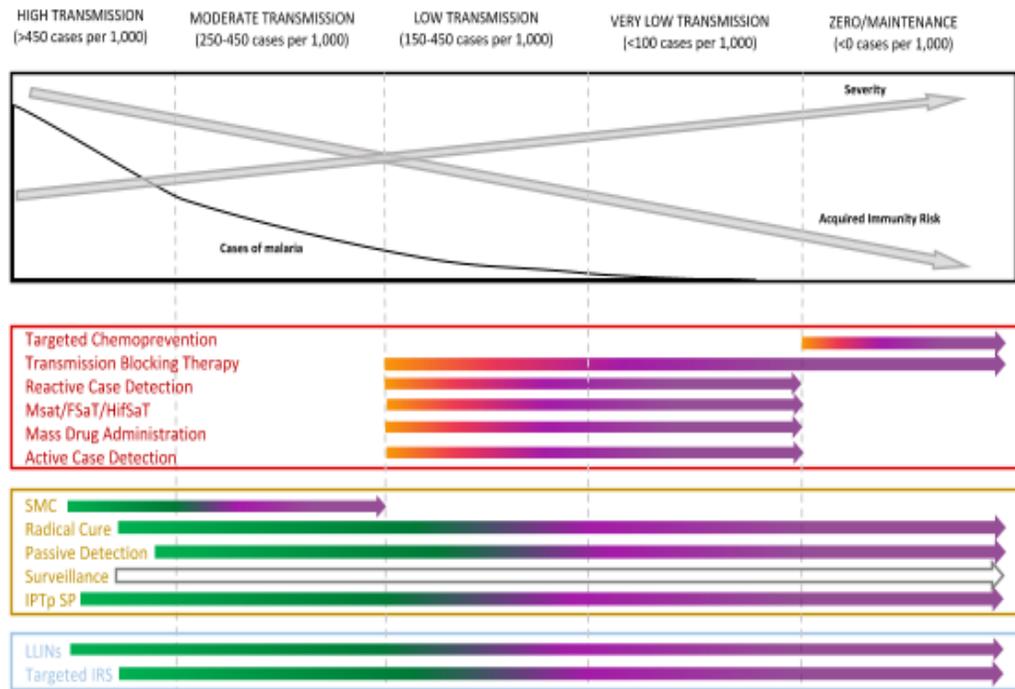
Country teams are also encouraged to consider where their country falls on the transmission continuum and the implications for the appropriate behavioral focus for their country. The figure below provides an overview of such considerations, which are described in Health Communication Capacity Collaborative's (HC3's) report titled [SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low, and Zero Malaria Transmission](#).<sup>133</sup>

---

<sup>132</sup> It is likely that the National Malaria SBC Strategy will have a broad behavioral focus and encompass all desired malaria control and prevention behaviors. However, to best focus PMI resources, PMI-supported activities should, to the extent possible, focus on a narrower subset of behaviors as identified through in-country discussions and the assessment process described above.

<sup>133</sup> <http://healthcommcapacity.org/wp-content/uploads/2018/01/HC3-Malaria-Elimination-Landscape.pdf>

**Figure. Malaria Transmission Intensity and SBC Focus**



**Recommended SBC Emphasis Across Transmission Settings**

Scale Up Use/Acceptance/Uptake of Core Behaviors	Accept Changes in Interventions	Maintain Behaviors
<ul style="list-style-type: none"> <li>Elevate perceived risk where malaria is considered normal</li> <li>Establish prompt careseeking, ITN use, IPTp uptake, IRS acceptance as normative behavior</li> <li>Establish and reinforce a culture of ITN use</li> <li>Establish acceptance of chemoprevention, explaining why treatment without signs of fever is being provided</li> </ul>	<ul style="list-style-type: none"> <li>Establish appropriate levels of perceived severity as malaria cases decline and perceived risk declines</li> <li>Introduce new case management interventions and establish trust among communities and service providers</li> <li>Ensure service providers are equipped with counseling skills to address concerns about fevers that increasingly test negative for malaria to avoid erosion of trust</li> </ul>	<ul style="list-style-type: none"> <li>Maintain prompt care seeking and explain contexts where treatment without a test is necessary</li> <li>Maintain high levels of ITN use</li> <li>Test new sampling methods and behavior change approaches where/when appropriate</li> </ul>

To assist country teams with discussions about the appropriate behavioral focus for their PMI SBC investments, the table below lists common behaviors associated with PMI-supported interventions. The behaviors are divided based on whether the behavior is one intended to be performed by community members or health workers. Please note, however, the list is only intended to serve as a starting point for discussions about the behavioral focus of PMI’s SBC investments. Ultimately, through a careful assessment of new and existing data and conversations with implementing partners, host country counterparts, and their PMI SBC Technical Team Backstop, country teams should identify 2-3 specific behaviors, as well as corresponding target geographic areas and populations, around which to focus PMI’s SBC investments.

**Figure. Common Focus Behaviors Associated with PMI-Supported Interventions**



Once specific behaviors, geographic areas, and target populations are identified, country teams, in collaboration with implementing partners and host country counterparts should begin the process of designing SBC interventions that are responsive to the behavioral determinants identified through the assessment process.

Drawing on best practices, as well as a [comprehensive evidence review conducted by Breakthrough Action](#),<sup>134</sup> PMI identified six essential components of malaria SBC activities:

- Formative assessments on barriers and facilitators;
- A theory-informed, strategic conceptual model;
- Audience profiles and segmentation into homogenous subgroups;
- Tailored interventions that utilize a mix of communication channels;
- Actionable, audience-specific, pre-tested messages; and
- Well-timed, programmatically useful monitoring and evaluation.

These components should be integrated throughout all PMI-supported SBC interventions. Country teams should review implementing partner workplans and deliverables and work with host country counterparts to ensure planned interventions thoroughly incorporate all key components. More details about each component are provided in the sub-sections that follow.

#### **Formative assessments on barriers and facilitators**

Designing SBC activities requires a thorough understanding of not only the target behaviors and audiences, but also the steps needed to practice the behaviors and the context-specific factors preventing or supporting the practice of those behaviors. SBC activities that resonate with target

<sup>134</sup> [http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report\\_Final.pdf](http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report_Final.pdf)

audiences through their cultural, interpersonal, and seasonal practices are more likely to influence desired malaria-related behavioral outcomes. As such, it is critical to conduct formative assessments to identify community-specific factors that prevent or support malaria-related behaviors. Formative assessments should also be used to inform decisions about the most strategic focus for PMI's SBC activities in a given country.

Formative assessments should involve a review of existing country-level quantitative and qualitative data on human behavior and malaria epidemiology and/or the generation of new data on desired malaria behaviors. Data sources might include information collected from national household surveys, like the Malaria Behavior Survey (MBS), Demographic and Health Survey (DHS), the Malaria Indicator Survey (MIS), and the Multiple Indicator Cluster Survey (MICS), as well as other relevant data sources, such as health facility surveys; knowledge, attitudes, and practices (KAP) studies; ethnographic research; and health information systems. Detailed information on data sources that can be used to inform SBC programming and described in more detail in the Monitoring and Evaluation section of this chapter.

#### **Development of a theory-informed, strategic conceptual model**

High-quality SBC activities must be based on a logical framework that identifies:

- Target behavior;
- Factors preventing or supporting the behavior in the target population (why people do *or* do not engage in the behavior);
- Behavioral and communication objectives to address these factors;
- Specific SBC activities to be undertaken;
- Expected outcomes.

Use of behavioral theories is critical to the development of a strong logic model. Examples of theories include: Social Ecological Model, the Health Belief Model, Stages of Change, and Social Learning Theory. These, as well as a number of other theories are described in more detail on the [National Institutes of Health's Office of Behavioral and Social Science Research e-Source](#).<sup>135</sup> It is important to remember, however, that there is no right theory to use. Behavioral theories can be adapted, modified, or combined to rationalize and communicate why certain approaches are used. The key is ensuring that a theory-informed, clear, and comprehensive logic model is used to guide SBC interventions. Health Compass' [How To Do a Logic Model](#)<sup>136</sup> provides guidance on the development of such a model.

#### **Profiling and segmentation of audiences into homogenous subgroups**

Audience analysis and segmentation is a critical component of any successful SBC intervention. It provides a systematic method for incorporating context-specific factors that prevent or support desired

---

<sup>135</sup> [www.esourceresearch.org/eSourceBook/SocialandBehavioralTheories](http://www.esourceresearch.org/eSourceBook/SocialandBehavioralTheories)

<sup>136</sup> [www.thecompassforsbc.org/how-to-guides/how-develop-logic-model-0](http://www.thecompassforsbc.org/how-to-guides/how-develop-logic-model-0)

behaviors, such as cultural practices or gender norms, into the development of activities, products, and messages. The first step in the audience analysis and segmentation process involves identification of the primary audience (individuals whose behavior needs to be changed) and the secondary audiences (individuals who influence the behavior of the primary audience). Decisions about the appropriate primary and secondary audience should be informed by data collected through the formative assessment process, as well as by decisions about the appropriate focus of PMI-supported SBC interventions. Once primary and secondary audiences have been identified, detailed profiles should be developed for each. A description of the characteristics that should be included in an audience profile, as well as step-by-step description of the audience analysis process can be found on Health Compass' [How To Do An Audience Analysis](#).<sup>137</sup>

Following audience analysis, audience segmentation, which involves dividing a larger audience into smaller groups with similar characteristics, can begin. For example, a target audience of health workers may need to be segmented by years of experience (junior vs. senior) or type of practitioner (doctor vs. nurse or outpatient provider vs. ANC provider). To ensure proper segmentation, clear criteria will need to be developed. These criteria should be based around traits that make groups significantly different from one another and which are likely to require different SBC messaging and/or interventions. Detailed information on audience segmentation can be found on Health Compass' [How To Do Audience Segmentation](#).<sup>138</sup>

### **Tailored interventions that utilize a mix of communication channels**

There are a variety of approaches that can be used to communicate with target audiences. Broadly, these approaches include mass media, interpersonal communication (IPC), community mobilization, and information and communication technology (ICT). The [comprehensive evidence review conducted by Breakthrough Action](#) recommends a transmedia approach to SBC that uses a mix of communication channels. The evidence suggests that a multi-channel, multimedia approach is needed to achieve high levels of exposure to SBC activities and that there is a dose-response relationship between the number of sources/messages recalled and the likelihood of adoption/maintenance of malaria-related behaviors.<sup>139</sup>

Within that framework, PMI has historically encouraged an approximately 70 percent/30 percent split between interpersonal communication and mass media activities. This reflects contributions from other donors – primarily the Global Fund – that have historically focused their support on mass media and PMI's investments have complemented that work. It is important to note, however, that the cost per person reached with IPC is considerably higher than with mass media and thus requires careful consideration of where and how to target. The table below summarizes key considerations related to

---

<sup>137</sup> <https://www.thecompassforsbc.org/how-to-guides/how-do-audience-analysis>

<sup>138</sup> <https://www.thecompassforsbc.org/how-to-guides/how-do-audience-segmentation>

<sup>139</sup> [http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report\\_Final.pdf](http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report_Final.pdf)

each of the communication channels identified above and provides insight into when a given channel might be appropriate. Ultimately, however, the appropriate mix of channels should be determined by country context, including epidemiology, situation analysis, behavioral analysis, audience analysis, as well as available budget and priorities of other SBC stakeholders. Additional guidance on selecting appropriate communication channels can be found on Health Compass' [How to Develop a Channel Mix Plan](#)<sup>140</sup> and by reviewing the [Malaria SBC Evidence Database](#).<sup>141</sup>

**Figure. Communication Channels**

Approach	Description	Channels
Mass Media	<ul style="list-style-type: none"> <li>Extensive reach, but one-way communication may be limiting for some behaviors</li> <li>Best for messages aimed at large audiences, such as for raising awareness about events</li> <li>Useful for reinforcing interpersonal communication, community-based, and ICT activities</li> <li>Allows for dissemination to diverse and hard-to-reach audiences, if sufficient media access</li> <li>Helps promote supportive social norms</li> </ul>	<ul style="list-style-type: none"> <li>Broadcast media (e.g., radio, serial dramas, game shows)</li> <li>Print media (e.g., magazines, newspapers, pamphlets, posters, and pamphlets)</li> <li>Outdoor media (e.g., billboards)</li> </ul>
Interpersonal Communication	<ul style="list-style-type: none"> <li>Face-to-face interaction, but costly and with limited reach</li> <li>Effective at converting knowledge to action and targeting behaviors that are more problematic or engrained and that require more sensitive communication</li> <li>Facilitates and encourages appropriate action, especially among marginalized populations, and helps people to discuss beliefs and feelings about their ability to take appropriate action</li> <li>Useful for targeting behaviors that involve multiple family members in the decision making</li> <li>Reinforces mass media, community-based, and ICT activities</li> </ul>	<ul style="list-style-type: none"> <li>Home visits</li> <li>Counseling</li> <li>School demonstrations</li> <li>Peer education</li> <li>Outreach</li> <li>Hotlines</li> <li>Provider (service communication)</li> </ul>
Community Mobilization	<ul style="list-style-type: none"> <li>Participatory process that stimulates community dialogue and motivates collective solutions</li> <li>Leverages social support, which can help shift social norms and fosters the adoption and maintenance of desired malaria prevention and treatment behaviors</li> <li>Reaches more people than interpersonal communication, but requires time and trust</li> </ul>	<ul style="list-style-type: none"> <li>Community dialogue</li> <li>Community drama</li> <li>Religious sermons</li> <li>Storytelling</li> </ul>
Information and Communication Technology	<ul style="list-style-type: none"> <li>Potential for interventions to be highly tailored and to engage younger individuals</li> <li>Able to share and adjust information quickly</li> <li>May allow users to engage in dialogue and share information, but control over messaging and content may be limited and many interventions require literacy</li> </ul>	<ul style="list-style-type: none"> <li>Mobile phone apps</li> <li>Online platforms and social media</li> <li>Interactive voice response</li> <li>SMS</li> </ul>

**Creation of actionable, audience-specific, pre-tested messages**

At the core of high-quality SBC interventions is the development and testing of messages. Well-designed messages: (1) include the information that is needed to encourage behavior change, and (2) have a clear behavioral and communication objective. Behavioral objectives reflect the behavior targeted by the SBC activity, while communication objectives reflect the behavioral factors that have been identified as influencing uptake of that behavior, sometimes referred to as an intermediate outcome. For example, a behavioral objective for an SBC activity may be to increase ITN use among pregnant women, while the corresponding communication objectives may be to increase the proportion of pregnant women who feel they are at risk for malaria and that the consequences could be severe. The appropriate corresponding message would likely focus on highlighting the risks associated with malaria for pregnant women and clear steps that pregnant women can take to avoid those risks, such as the use of an ITN.

<sup>140</sup> <https://www.thecompassforsbc.org/how-to-guides/how-develop-channel-mix-plan>

<sup>141</sup> <https://behaviorchangeimpact.org/malaria-landing-page/>

Evidence suggests that the inclusion of specific actionable steps that lead to improved outcomes is also a critical component of SBC messaging.<sup>142</sup> SBC activities that emphasize specific malaria-related behaviors (particularly behaviors associated with intervention use) are most likely to achieve substantial behavior change, compared to activities only focused on raising risk perception. Pre-testing is an important step in the message development process, and one that PMI recommends using consistently to assess whether the primary audience will find the messaging believable and appealing. Pre-testing is the process of bringing together members of the primary audience to react to materials and messaging before they are produced in final form, and it can save money, time, energy, and increase impact. The Health Compass' [How to Design SBCC Messages](#)<sup>143</sup> provides a step-by-step guide to the message development and pre-testing process, while [How to Conduct a Pre-Test](#)<sup>144</sup> provides detailed guidance on the pre-testing process.

### **Well-timed, programmatically useful monitoring and evaluation**

There is an increasing focus across PMI to develop more comprehensive and systematic data on the impact of SBC on malaria control and prevention. With this focus comes a greater emphasis on accountability and reporting of SBC activities, including the development of comprehensive monitoring and evaluation plans, the selection of appropriate indicators, and the measurement and tracking of those indicators. Given the importance of such activities, the role of monitoring and evaluation for SBC is explored in greater detail later in this section. It should be noted here, however, that a clear plan for monitoring and evaluating SBC activities should be developed at the time of intervention design.

### ***SBC in Service Delivery***

A growing area of focus for PMI's SBC efforts relates to health care provider behavior, service communication, and collaboration with service delivery stakeholders for malaria in pregnancy and case management services at the health facility and community levels. Utilizing an SBC lens to understand and address factors influencing provider behaviors, such as providers' sense of self efficacy, perceptions of the response efficacy of malaria diagnosis and treatment products/proven interventions (e.g., adherence to RDT results), attitudes, and norms, is essential for interventions aimed at improving the quality of service delivery. In addition, providers themselves are an important communication channel for complementing community-level SBC efforts through the use of existing service provision platforms to promote net use, prompt care-seeking, ANC attendance, and IPTp acceptance during the patient/provider interactions. Thus, from an SBC perspective, providers are both a target audience for SBC activities (provider behavior change) and a channel for communication targeted to patients (service communication). These concepts are explored in more detail below.

---

<sup>142</sup> [http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report\\_Final.pdf](http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report_Final.pdf)

<sup>143</sup> <https://www.thecompassforsbc.org/how-to-guides/how-design-sbcc-messages>

<sup>144</sup> <https://www.thecompassforsbc.org/how-to-guides/how-conduct-pretest>

### Provider-behavior change

Provider behavior change efforts focus on providers as a target audience for SBC interventions. There is widespread recognition that provider behavior plays a critical role in the quality and type of care patients receive and could be precursory to patients' decision to return for future services or maintain healthy behaviors. Without correctly understanding and targeting behavioral factors influencing health worker practices, achieving high coverage of service delivery interventions for case management and MIP will not be possible. Challenges related to provider behavior can manifest in a number of ways, including:

- Missed opportunities to provide IPTp and ITNs during ANC visits;
- Failure to provide the correct antimalarial in an appropriately diagnosed patient (e.g., treating uncomplicated cases with injectable treatments);
- Providing ACTs to patients with negative test results; and
- Misreporting, whether intentional or unintentional, and which can have a major impact on quality of routine data.

Provider-behavior change activities seek to positively influence provider behavior by addressing internal and social factors, such as personal attitudes and beliefs, social norms, personal and community values, status and recognition, that influence provider behavior. While behavioral drivers in the service delivery setting are complex, efforts are ongoing to leverage health facility-based data collection efforts, including supervision tools and health facility surveys, to fill knowledge gaps on drivers of provider behavior.

Activities to address these particular provider behaviors may benefit from coordination across SBC, service delivery, and surveillance, monitoring, and evaluation partners. Formative assessments will likely be needed to design SBC activities that effectively address the internal and social factors that influence provider behaviors and should be done in collaboration with service delivery partners who have valuable information on provider behaviors. Developed by Impact Malaria and Breakthrough ACTION, the [Blueprint for Applying Behavioral Insights to Malaria Service Delivery](https://breakthroughactionandresearch.org/wp-content/uploads/2020/10/Blueprint-Applying-Behavioral-Insights)<sup>145</sup> is a framework for understanding provider behavior that can be used when developing strategies for provider behavior change, or at any point during implementation of provider behavior change activities, to identify factors that influence behavior, develop appropriate, targeted activities, and conduct monitoring and evaluation.

Another promising approach is the application of behavioral economics methodologies to examine the decision-making pathways that influence case management practices (e.g., prescribing ACTs only to patients with test results that confirm malaria, mistrust in the efficacy of RDTs, etc.). Such a process can offer crucial insights into the factors that influence provider behavior, including values, professional

---

<sup>145</sup> <https://breakthroughactionandresearch.org/wp-content/uploads/2020/10/Blueprint-Applying-Behavioral-Insights>

norms, relationships. These insights can then be used to design, pilot, and scale up interventions targeting the identified behaviors.

### **Service communication**

Service communication is the use of SBC activities by healthcare providers to influence malaria-related behaviors among patients across the continuum of care at both facility- and community-based delivery points—before, during, and after services. Effective service communication can help improve the quality of provider-patient interactions, increase the adoption and maintenance of healthy malaria prevention and treatment behaviors, and contribute to creating a cycle of good provider/patient relations, which may lead to increased demand for, and use of, malaria control products and services. A helpful resource for developing SBC activities for health services is the [Service Communication Implementation Kit](#).<sup>146</sup>

Both service delivery and SBC actors play a role in service communication. Service delivery partners, for instance, may need to play a role in the implementation of SBC activities centered around improving service communication at the community or at facility level. As such, strong collaboration, coordination, and harmonization is essential. One way this can be achieved is by including service delivery stakeholders in a country's SBC Technical Working Group, which can serve as a forum for regular and ongoing engagement between service delivery and SBC partners. Monitoring visits that include both service delivery and SBC partners can also be beneficial and help to ensure service communication-related factors are addressed. Another approach is for SBC partners to contribute to service delivery partners' efforts to develop and deliver provider training and coaching modules focused on service communication.

### **Coordination**

Coordination between SBC and service delivery actors is essential to align supply (service provision) and demand (patient demand) efforts and can provide critical data to both sets of actors for monitoring the success of interventions. For instance, by sharing monitoring data across SBC and service delivery mechanisms, partners can gather important information that they might not otherwise be able to access. This, in turn, makes it possible for SBC programs to use service statistics to understand if their demand creation efforts are producing an effect, and allows service delivery partners to glean useful insights on provider and client beliefs, misconceptions, and norms. To that end, the SBC Technical Team recommends that country teams ensure there is close collaboration between all service delivery and SBC actors. Collaboration should include regular coordination meetings, message harmonization, information sharing, monitoring, and the development of joint strategies as needed.

### **Monitoring and Evaluation**

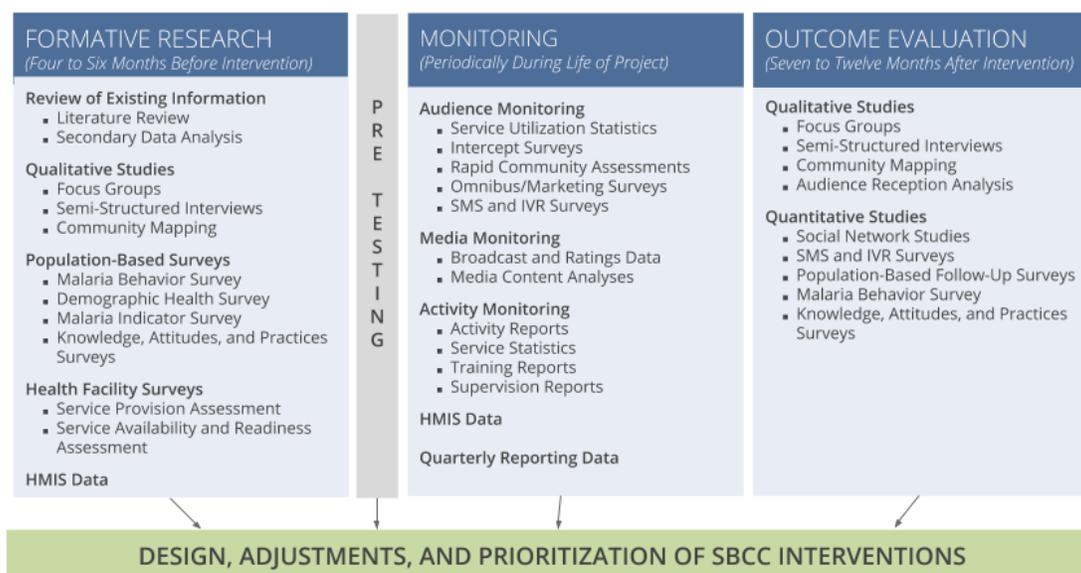
---

<sup>146</sup> <http://sbccimplementationkits.org/service-communication/>

There is a continued focus across PMI on the use of comprehensive and systematic data to make strategic programmatic decisions to strengthen implementation approaches. Central to this effort is the systematic evaluation of the impact of SBC on the acceptance, uptake, and maintenance of desired malaria-related behaviors. This, in turn, requires greater emphasis on monitoring and reporting of SBC activities, starting with selection of behavioral targets and selection of appropriate indicators, the measurement and tracking of those indicators, and the integration of adaptive processes that allow for programmatic adjustments on an ongoing basis.

Building compelling arguments around the impact of SBC activities requires data collection throughout the life of an activity. It is crucial that PMI country teams and partners factor in the time and budget required for proper monitoring and evaluation of SBC activities. This can be achieved through the development of a comprehensive and systematic monitoring and evaluation plan that draws on previously identified logic models and behavioral and communication objectives for the selected SBC approach. Monitoring and evaluation plans should use a practical framework to illustrate activities for formative assessments; baseline evaluation and indicator development; process and audience monitoring; and endline (outcome) evaluation.

**Figure. Framework for SBC Monitoring and Evaluation**



- Partner monitoring and evaluation plans for SBC activities should include the following components:
- Behavioral objectives, communication objectives, and a detailed description of the SBC activities designed to address those objectives;
  - Indicators for each objective, including operational definitions;
  - Targets for both the desired behavioral outcomes and the associated behavioral factors;
  - Timeline for data collection and analysis in relation to activity implementation (i.e., formative, baseline, midpoint, endline); and

- Information about the data sources that will be used to calculate the indicators, the reporting frequency, and responsible parties.

More details about each of these components, as well as guidance on developing a comprehensive and systematic monitoring and evaluation can be found in the RBM Partnership to End Malaria’s guidance titled [Developing Monitoring and Evaluation Plans for Malaria Social and Behavior Change Programs: Step-by-Step Guide](#).

#### **Data sources for monitoring and evaluation activities**

PMI recommends using multiple data sources for a comprehensive understanding of malaria-related behaviors. This may include the use of existing or new data sources, including national or sub-national household surveys (e.g., DHS/MIS; MBS; KAP), health facility surveys, routine data sources (e.g., HMIS, OTSS), and other relevant sources. Depending on the behavior of interest and target audience, each data source may be more or less relevant.

- **Malaria Behavior Survey:** The [MBS](#)<sup>147</sup> is a cross-sectional household survey designed to measure malaria-related behaviors and the internal and social factors associated with those behaviors using a theory-driven and standardized methodology. It provides critical data to inform the design, implementation, and evaluation of SBC interventions and can play a role in guiding decisions about the behaviors and behavioral factors programs should prioritize. To facilitate strong, data-driven, theory-informed SBC interventions, ***the SBC Technical Team recommends countries conduct an MBS approximately every five years.*** The timing and scope will need to be negotiated with the NMCP, in coordination with the SBC and SME Technical Teams, but some factors to consider:
  - **Timing:** From initial discussions to the dissemination of the final report, it takes approximately one year to complete an MBS, and data collection needs to take place during high transmission months. The ideal time to plan for and implement an MBS may be in preparation for a national strategy revision by the NMCP, in response to stagnation or lack of progress, or any other point where behavioral data are needed to guide programmatic decision making. However, the SBC Team recommends the MBS not be conducted in the same year as an MIS, MICS, or DHS. Due to the intensive nature of these surveys, the SBC Technical Team recommends that an MIS/DHS/MICS and MBS not be implemented within the same year, and ideally, be conducted a minimum of eighteen months apart. Given the SM&E Technical Team’s current recommendation that an MIS be conducted every two or three years in high transmission settings and every five years in low transmission settings, the timing of the MBS, which is recommended in all settings approximately every five years, must be carefully planned.

---

<sup>147</sup> <http://malariabehaviorsurvey.org/>

- **Scope:** For countries interested in implementing a nationwide MBS, the SBC Technical Team recommends selecting a sampling approach in close collaboration with the implementing partner. A number of considerations must be taken into account when deciding on a sampling strategy, including differences in malaria transmission throughout the country, cultural, religious, and linguistic differences, PMI target areas, and geographic zones of programmatic interest. Final decisions about the scope of an MBS will often be guided by budgetary limitations. In order to maximize MBS coverage, co-financing with other donors should be considered.
- **Implementation in Low-Transmission Settings:** The SBC Technical Team is working with Breakthrough ACTION to develop a questionnaire and implementation guidance tailored to low-transmission settings. The adapted questionnaire, which is being developed in collaboration with the Elimination Team, is intended to assess interventions implemented in low-transmission settings (e.g., active case detection and screening of travelers to and from high burden areas), as well as how behavioral determinants like risk perception shift in areas with low transmission. The adapted questionnaire will be piloted in CY2021 and ready for use in CY2023.
- **Other Household Surveys:** Core modules for the DHS and MIS include questions aimed at assessing recall of malaria SBC messaging and behaviors related to net use, ANC attendance, IPTp uptake, care-seeking, and testing and treatment. To supplement the core modules, the RBM SBC Working Group developed a [standard module of malaria SBC-related questions](#)<sup>148</sup> to help ensure that SBC questions included in the MIS are standardized, grounded in behavioral science, and backed by evidence so that the indicators can be used to help countries identify: (1) the populations/areas that need to be targeted, (2) the SBC approaches that are likely to be most effective, and (3) the kinds of messages that should be promoted to facilitate behavior change. The module also allows countries to compare results with countries that share similar transmission patterns or development contexts and facilitates the use of data for SBC program implementation. The SBC Team **encourages countries to consider including the optional module in all upcoming MIS surveys**. This standardized set of indicators should be the primary source of data about malaria SBC in MIS. The inclusion of additional malaria SBC questions is not recommended as the data generated by unvalidated and non-standardized SBC questions has the tendency to go unanalyzed and unused.

While the standardized MIS module is an important tool, data from the DHS and MIS have limitations that need to be considered when assessing their utility in a monitoring and evaluation plan for an SBC activity. For example, the DHS and MIS may not provide the subnational estimates required to measure outcomes of a specific SBC activity, especially if the activity is targeted to a limited geographic area. In addition, the DHS and MIS may not provide enough information on key

---

<sup>148</sup> <https://www.dhsprogram.com/publications/publication-MISQM-MIS-Questionnaires-and-Manuals.cfm>

behavioral determinants like risk perception, self efficacy, and social norms. Depending on the identified need, an MBS or KAP study may be preferable. KAP studies generally offer a more flexible alternative, however, there are no standard modules for such studies and thus they require expertise in questionnaire design, sampling, implementation, and analysis. Furthermore, KAP studies often do not collect systematic data on the full range of ideational variables that influence the uptake of malaria-related behaviors.

- **Health Facility Surveys and Routine Data Sources:** Data from health facility surveys or routine data collection systems can provide insight into various aspects of patient-provider interactions and can be useful for designing and assessing activities targeted towards health workers. Data collection methods include patient observation, patient exit interviews, provider interviews, and register abstraction. Additional efforts are being made to improve the data collected on health care provider behaviors (e.g., development of standardized questions to assess provider behavior in health facility surveys and a rapid behavioral diagnostic tool). Existing health facility data sources, such as routine data (e.g., HMIS, OTSS data, commodity inventories, etc.), also provide insight on provider behaviors and commodity availability. It is important to note, however, that there is currently no standardized protocol for health facility-based SBC data collection. As such, quality and completeness should be considered when interpreting the data.
- **Other Sources:** Tools used for durability monitoring and end process evaluations of mass net and SMC campaigns provide key information on behaviors related to ITN use and care and SMC adherence. Activity reports from implementing partners can also be used as data sources for monitoring and evaluation of SBC activities. Other monitoring tools, such as media monitoring for radio/television/social media, mobile phone surveys, media content analysis, and rapid exit surveys, can also be useful in an SBC monitoring and evaluation plan. For example, media monitoring can be commissioned from third-party organizations to ensure broadcasts are aired as planned. Omnibus surveys, which are regularly occurring large surveys conducted for marketing purposes, are another useful tool. Omnibus surveys can be used to track exposure/recall and assess changes in targeted behavioral factors. National or regional-level samples can be obtained but sampling strategies are not as robust as DHS and MIS surveys. For more details on the advantages and limitations of all data sources mentioned, please refer to [RBM Partnership to End Malaria's SBCC Indicator Reference Guide](#)<sup>149</sup> and [Breakthrough ACTION's SBC Monitoring Guidance](#).<sup>150</sup>

### **Formative assessments**

Formative assessments should be conducted prior to the design of SBC interventions. They should start with existing data sources and may include many of those referenced in the section above. However, depending on the depth and quality of information available, additional formative data collection

---

<sup>149</sup> [breakthroughactionandresearch.org/wp-content/uploads/2018/03/Malaria-SBCC-Indicator-Reference-Guide-ENG-2017-Sept.pdf](https://breakthroughactionandresearch.org/wp-content/uploads/2018/03/Malaria-SBCC-Indicator-Reference-Guide-ENG-2017-Sept.pdf)

<sup>150</sup> [breakthroughactionandresearch.org/resources/social-and-behavior-change-monitoring-guidance/](https://breakthroughactionandresearch.org/resources/social-and-behavior-change-monitoring-guidance/)

activities, such as an MBS, may be needed to fill gaps. After data has been gathered from a variety of sources, epidemiological data, data on behavioral determinants, and data on actual behavior should be triangulated to help inform the development of a strategy that clearly identifies priority malaria control and prevention behaviors; key behavioral determinants associated with those behaviors, and the most appropriate approaches to reach the intended audience.

### **Baseline evaluation and indicator development**

Baseline evaluations should be conducted following formative assessments to measure conditions before implementation. Some baseline data may already be available from formative assessment activities. However, during this phase, the development of indicators that can be used to monitor and evaluate the results of SBC interventions is critical. The selection of indicators for evaluation at baseline and endline should be based on an activity's behavioral and communication objectives and should include indicators that measure actual behavior, as well as those that measure behavioral determinants (e.g., knowledge, attitudes, self-efficacy, response efficacy, perceived risk, severity and norms). As appropriate, indicators for both beneficiaries and providers should be considered. For more information on indicator development and prioritization, please refer to the [RBM Partnership to End Malaria's SBCC Indicator Reference Guide](#), which was developed to ensure a rigorous standardized approach to SBC monitoring and evaluation efforts. The indicators included in the reference guide are not considered required reporting indicators for PMI. However, PMI partners are strongly encouraged to use the indicators to design, monitor, and evaluate SBC activities.

### **Process monitoring and audience monitoring**

Since endline evaluations only occur periodically (often only every 2-5 years), process and audience monitoring are essential for tracking whether activities are being implemented as planned and determining if desired changes are starting to emerge in the target population (e.g., changes in knowledge, attitudes, risk, efficacy, norms). This type of monitoring can and should be done using a variety of data sources as described above. If monitoring activities indicate that desired changes are not beginning to emerge, program adjustments should be made, including adjustments to channel selection.

### **Endline evaluation**

Endline or outcome evaluation should be conducted to assess and document changes in behavior and behavioral determinants as a result of SBC activities. It may not always be possible to attribute changes in behavior, and to an even greater extent, changes in health impact, to a specific SBC activity; however, descriptive behavioral outcome data, even in the absence of a statistically significant association, can suggest potential associations with SBC activities and be used to inform programmatic decision making. This association is strengthened even further if: (1) activities were implemented as intended, (2) the target audience was reached, and (3) the target audience demonstrated a change in targeted behavioral factors (e.g., risk perception, efficacy, attitudes, norms). The strength and confidence level of any measured association will depend upon data collection, sampling, and analysis methods. As mentioned

previously, the MBS is designed to collect systematic data on the full range of ideational variables and is intended to be used as a formative assessment tool *and* evaluation tool following the recommendation to implement approximately every five years.

## **Special Considerations**

### ***IRS and SMC***

Acceptance and uptake of IRS and SMC are distinct from many other malaria-related behaviors. They do not require maintenance of a specific behavior over an extended period of time. Rather, they rely on acceptance and uptake of an intervention at a specific point in time in a limited geographic area. The discrete nature of these activities means that large-scale, ongoing SBC interventions may not be needed or appropriate. Rather, targeted community mobilization efforts are often better positioned to address acceptance and uptake of IRS and SMC. In many instances, vector control or service delivery partners lead community mobilization efforts for IRS and SMC. The SBC Technical Team supports this approach and encourages country teams to work with their SBC partners to focus the bulk of their efforts on other malaria prevention and control behaviors. SBC partners should, however, be positioned to collaborate with vector control and service delivery partners and provide focused technical assistance on IRS and SMC when specific issues arise or when available data suggests there are significant challenges around acceptance of IRS or SMC.

### ***Larval Source Management***

As described in the [Vector Control chapter](#), there is a limited set of circumstances in which larval source management interventions may be appropriate. These interventions, which involve the destruction of larval habitats via draining or filling or through the application of larvicides, are designed to be systematic and require a high degree of rigor to have an impact on community-wide malaria transmission. Such programs are best implemented by vector control experts and do not rely on individual-level action by community members. However, in some countries, as part of their approach to larval source management, NMCPs have adopted or promoted individual-level actions. While these actions may be effective, there is a lack of evidence for community based larval control. Until better evidence is available, PMI funding should not be used to support any SBC activities aimed at encouraging community removal of larval habitats outside of the context of OR/PE.

### ***Changes in Transmission Settings***

As more countries move towards malaria elimination nationally and sub-nationally, the focus of SBC activities will need to shift. With declines in transmission intensity, countries will experience fewer and fewer cases of malaria and perceived risk is likely to decrease. Decreased natural immunity will, however, make cases more severe. In this context, SBC interventions will need to be adjusted to target different populations and behavioral factors, utilize new channels, and adjust how behavior change is

measured (see Figure 1 above). Behavior maintenance will also become more important, especially with regard to ITN use. There is no single correct approach for SBC in elimination settings. However, it is critical that countries understand how behavioral determinants, like risk perception and response efficacy, are different in low-transmission settings. To assist with this, and as noted above, the SBC Technical Team is developing a questionnaire and implementation guidance tailored to low-transmission settings. The SBC Section in the [Elimination Chapter](#) provides additional guidance, as does [SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low and Zero Malaria Transmission](#).<sup>151</sup>

### ***Malaria SBC During Public Health Emergencies***

Public health emergencies may greatly impact a government's ability to provide care and deliver malaria prevention products and services. It may also impact people's ability to seek care or preventive services and their confidence in the public health system. The COVID-19 pandemic and recent Ebola epidemics in West and Central Africa bear witness to that. However, during these difficult times, malaria remains an important public health issue. To this end, tailored approaches and systems should be developed or strengthened to ensure continued delivery of malaria interventions among communities, households, and individuals.

Specifically, approaches to malaria SBC must incorporate guidance developed by the World Health Organization (WHO) and host country governments to address public health emergencies, such as revised treatment policies, limits on public gatherings, handwashing guidelines, etc. Depending on the mechanism of transmission, public health emergencies may require the curtailment of IPC activities, including social mobilization, community engagement, community meetings, or household visits. If this occurs, malaria SBC interventions may need to be adjusted to utilize mass, mid-, digital, and social media approaches. However, if planned IPC activities are to be conducted in conjunction with life-saving malaria prevention, testing, or treatment activities (e.g., ITN mass campaign, IRS campaign, or SMC campaign), it may be appropriate to move forward with IPC at the community-level. This should only be done, however, after careful review of international and national public health emergency guidelines, discussions with relevant stakeholders, and careful consideration of the safety of those conducting and participating in community-level IPC activities. As with the COVID-19 pandemic, international organizations, such as WHO Global Malaria Programme and RBM SBC Working Group, may develop guidelines to assist countries in the implementation of malaria SBC within the limitations imposed by the public health emergency. See, for example, [Malaria SBC Program Guidance in the Context of COVID-19 Pandemic](#).<sup>152</sup>

---

<sup>151</sup> <http://healthcommcapacity.org/wp-content/uploads/2018/01/HC3-Malaria-Elimination-Landscape.pdf>

<sup>152</sup> <https://endmalaria.org/sites/default/files/Malaria-SBC-Guidance-in-the-Context-of-COVID-19>

## *Zero Malaria Starts With Me*

Zero Malaria Starts with Me (ZMSWM) is a continent-wide advocacy campaign for a malaria-free Africa co-led by the African Union Commission and the RBM Partnership to End Malaria. Implementation of ZMSWM is intended to contribute to increased political, private sector, and community commitment to and engagement in malaria control and elimination efforts, and in recent years, several PMI countries have endorsed the platform as a core component of their National Malaria SBC Strategy. It is critical, however, that participation in ZMSWM is accompanied by continued investments in the design and implementation of evidence-based, theory-driven SBC activities at the community, district, regional, and national levels given that malaria control and elimination requires individual behavior change in addition to broader advocacy efforts. Indeed, **ZMSWM and SBC are complementary approaches—and they should be implemented as such. ZMSWM should not replace ongoing community-level, district-level, regional-level, and national-level SBC activities**, and ongoing implementation of SBC activities should not preclude countries from adopting ZMSWM. PMI funding should be used to continue to support the design and implementation of evidence-based, theory-driven SBC activities aimed at increasing the practice of specific behaviors, not advocacy campaigns.

## *Operational Research / Program Evaluation*

Formative assessments to further understand a set of behaviors and the factors preventing or supporting those behaviors in the absence of existing data **are not** operational research and are expected. However, as PMI country teams confront SBC-related operational research questions, such questions should be discussed with relevant stakeholders for consideration of how to prioritize and address those questions. Country teams should also consider the [RBM SBC Working Group's Priority Research Areas and Approaches for Malaria SBC Programs](#), which outlines areas that need further research as malaria SBC interventions scale-up, and [Breakthrough Research's Research and Learning Agendas](#), which identifies research gaps related to provider behavior, as well as those related to the integration of multiple health issues within a single SBC program. Ultimately, as with other PMI-supported operational research activities, protocols should be developed in accordance with the process outlined in the [Operational Research and Program Evaluation](#) Chapter.

## *Peace Corps*

Guidance for collaboration with the Peace Corps is available in the [Health Systems Strengthening](#) chapter. However, as it relates to SBC activities, Peace Corps and Peace Corps Volunteers are a potentially great resource. It is recommended that PMI country teams ensure that Peace Corps' malaria SBC activities are aligned with NMCP SBC efforts, complement PMI-supported SBC activities, are evidence-based and theory-informed, and contribute to the behavioral and communication objectives outlined in the National Malaria SBC Strategy. Whenever possible, Peace Corps and Peace Corps

Volunteers should participate in existing or ongoing SBC activities rather than designing and implementing parallel SBC activities.

### ***Management and Budget***

PMI support for SBC activities should be commensurate with the overall PMI budget, the magnitude of the behavioral challenges, and the SBC investment by other stakeholders. As articulated in PMI Policy, and as with all PMI investments, PMI country teams are expected to actively manage and monitor SBC investments:

- In the event that the COR/AOR of a bilateral SBC mechanism or bilateral mechanism with a SBC component is not a member of the PMI country team, a member of the PMI country team should serve as an Activity Manager for the malaria SBC activities.
- For countries that buy into a central SBC mechanism, the PMI country team is expected to select a member of the country team to serve as a Mission-based Activity Manager for the malaria SBC activities regardless of whether the buy-in is across numerous health areas. The Mission-based Activity Manager will work with the headquarters-based Activity Manager to manage the malaria SBC activities.
- All PMI-supported implementing partners and projects are expected to coordinate and collaborate with PMI-supported SBC implementing partners and projects at the national and subnational levels. To ensure this occurs, PMI country teams are expected to help create strong linkages between SBC projects and other projects within the PMI portfolio. For example, SBC projects working to increase careseeking should be linked with service delivery projects working to improve the quality of malaria case management. These linkages are critical given the cross-cutting and supportive nature of SBC.
- PMI country teams are also expected to coordinate SBC activities with the Global Fund Principal Recipient and other implementing partners and donors to ensure the implementation of complementary and reinforcing SBC activities.

The SBC Technical Team at PMI/Headquarters is committed to supporting PMI country teams with design, implementation, monitoring, and evaluation of SBC projects and activities. Members of the SBC Technical Team can provide virtual, as well as in person support. Virtually, SBC Technical Team members can provide support to countries by reviewing workplans, strategy documents, or other deliverables, while, through a TDY, members of the team can provide project- or intervention-level operational support. They can also contribute to the design and assessment of countries' malaria SBC mechanism(s).

Each member of the SBC Technical Team is responsible for supporting specific countries on issues related to SBC.<sup>153</sup> Similarly, to facilitate communication with PMI/Headquarters, country teams are asked to identify a single SBC point of contact. The SBC point of contact (POC) will be the primary contact for the SBC Technical Team regarding SBC in-country. The SBC Technical Team at PMI/Headquarters will send periodic updates to the field-based SBC POCs and host periodic coordination calls with the field-based SBC POCs. The SBC Technical Team also encourages SBC POCs to reach out to their SBC backstop to request assistance related to SBC activities and to share SBC work plans and deliverables.

---

<sup>153</sup> For the name of the SBC backstop for your country, please contact any member of the SBC Technical Team at PMI/Headquarters.

## SBC Appendix 1 - Additional Resources

### General

Resource	Description
<a href="#"><u>RBM Partnership to End Malaria's Strategic Framework for Malaria SBCC</u></a>	Framework for malaria SBC that outlines a technical and advocacy agenda for the field.
<a href="#"><u>Springboard for Health Communication Professionals</u></a>	Online platform for exchanging knowledge, experiences, and resources about SBC.
<a href="#"><u>Health Communication Capacity Collaborative Online Learning Center</u></a>	Rich repository of information on SBC, including webinars, online trainings, and toolkits.
<a href="#"><u>Accelerator Behaviors</u></a>	Tool that identifies accelerator behaviors and proposes strategies.

### Strategy Development

Resource	Description
<a href="#"><u>National Malaria SBC Strategy Template</u></a>	Standardized malaria SBC strategy template that reflects global best practices.
<a href="#"><u>National Malaria SBC Strategy Development Guidance</u></a>	Guidance, which accompanies the template above, and outlines key considerations.
<a href="#"><u>National Malaria SBC Strategy Development Package</u></a>	Step-by-step guide to completing the National Malaria SBC Template in a small working group.
<a href="#"><u>Repository of National Malaria SBC Strategies</u></a>	Curated repository of national malaria SBCC strategies.

### Design and Implementation

Resource	Description
<a href="#"><u>SBCC Implementation Kits</u></a>	Collection of in-depth implementation guides on various topics related to malaria SBC.
<a href="#"><u>Health Compass How to Guides</u></a>	Step-by-step instructions on how to perform core SBC tasks.
<a href="#"><u>SBCC Quality Assurance Tool</u></a>	Easy-to-use tool to assess and assure the quality of SBCC activities.

## Monitoring and Evaluation

Resource	Description
<a href="#"><u>Developing Monitoring and Evaluation Plans for Malaria Social and Behavior Change Programs: Step-by-Step Guide</u></a>	Resource that introduces the elements of a monitoring and evaluation plan for malaria SBC programs.
<a href="#"><u>SBC Indicator Reference Guide</u></a>	A streamlined, standardized set of priority indicators for malaria SBC activities.
<a href="#"><u>SBC Monitoring Guidance</u></a>	Technical notes on monitoring methods that may be used for SBC programs.
<a href="#"><u>Malaria SBC Evidence Database</u></a>	Searchable database of literature documenting the impact of malaria SBC.
<a href="#"><u>Priority Research Areas and Approaches for Malaria SBC Programs</u></a>	Report outlining priority research areas and approaches that need to be explored and utilized as malaria interventions scale up.
<a href="#"><u>Breakthrough Research SBC Research and Learning Agenda</u></a>	Research and learning agendas for provider behavior and the integration of multiple health issues within a single SBC program.
<a href="#"><u>Checklist for Reporting on Malaria SBC Program Evaluations</u></a>	Checklist aimed at improving the evidence base for malaria SBC by outlining standard elements for program evaluation reporting.
<a href="#"><u>Malaria Behavior Survey Website</u></a>	Comprehensive website that includes standard questionnaires, implementation guidelines, and results from completed surveys.
<a href="#"><u>Standardized Malaria SBC Module for the MIS &amp; DHS</u></a>	Access to the questionnaire, interviewer instructions, and analysis plan for the standardized malaria SBC module.

## Specific Technical Areas

Resource	Description
<a href="#"><u>ITN Use and Access Report</u></a>	Provides an estimate of the proportion of the population using nets among those that have access to one within their household.
<a href="#"><u>SBC for Insecticide-Treated Nets</u></a>	Comprehensive guide on SBC activities for all types of net behaviors, including acquisition, use, and care.
<a href="#"><u>Monitoring And Evaluation For SBCC - Malaria Case Management</u></a>	How-to guide on monitoring and evaluating SBC components of malaria case management interventions.

<a href="#"><u>SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low and Zero Malaria Transmission</u></a>	Guide to scaling up and maintaining coverage of proven interventions in countries as transmission patterns change.
<a href="#"><u>SBC for Malaria in Pregnancy: Strategy Development Guidance</u></a>	Resource on the design of interventions for malaria in pregnancy, especially those interventions that target healthcare worker.
<a href="#"><u>Malaria SBC Toolkit for Community and Faith Leaders</u></a>	Guide for faith and community organizations aimed at building capacity for the promotion of malaria prevention and treatment behaviors.
<a href="#"><u>Blueprint for Applying Behavioral Insights to Malaria Service Delivery</u></a>	Framework for understanding provider behavior that can be used when developing strategies for provider behavior change.
<a href="#"><u>Malaria SBC Program Guidance in the Context of COVID-19 Pandemic</u></a>	Behavioral considerations and programmatic recommendations for the implementation of malaria SBC activities in the context of COVID.

## Online Training

Resource	Description
<a href="#"><u>Evidence-Based Malaria Social and Behavior Change Communication</u></a>	Introduction to malaria SBC theory, formative assessments, implementation, and monitoring and evaluation.
<a href="#"><u>Health Communication for Managers</u></a>	Course aimed at increasing learners' understanding of the basic principles of health communication.
<a href="#"><u>Health Behavior Change at the Individual, Household and Community Levels</u></a>	Provides introduction to conceptual tools needed to analyze health-related behaviors and the context in which they occur.
<a href="#"><u>Introduction to Human-Centered Design</u></a>	Introduction to the human-centered design process, which involves creating innovative solutions to real-world challenges

---

# ELIMINATION

---

## **\*New/Key Messages\***

**Strategy:** Although we anticipate changes to our elimination focus countries and approaches over the next 5 years to align with the new, forthcoming PMI strategy and as continued progress is made, the initial criteria for identifying PMI countries for elimination-specific support remain the same— a national strategic plan in support of elimination and a national/sub-national malaria prevalence of <5%.

In countries where malaria burden varies significantly, and thus sub-national elimination is being pursued, **priority for PMI funding should be given to supporting interventions to further reduce mortality and morbidity in high burden areas.** However, in such settings, limited support for elimination activities can be considered by PMI country teams, but should be balanced against the need to scale up core control interventions to achieve PMI's primary objectives to reduce morbidity and mortality.

New sections on prevention of reintroduction and malaria elimination certification aim to provide additional guidance for our last mile countries to develop a sustainable program in terms of cost and human capacity to prevent the reintroduction of malaria and to prepare for the WHO certification process. Certification of malaria elimination applies to an entire country and for all human malaria species and principally focuses on: 1) whether indigenous transmission of malaria has been interrupted throughout the country for at least three years and 2) whether a country's health system is adequate and capable of detecting and preventing the reintroduction of local transmission.

Countries/areas that have national strategies for malaria elimination (e.g., Burma, Cambodia, Ethiopia, Madagascar, Senegal, Thailand/Regional, Zambia, Zanzibar, Zimbabwe) should ensure that elimination goals, objectives and targets, and the geographic focus (e.g. list of target districts) of those efforts are included in their FY 2022 MOPs. Relevant elimination-specific components of the program inventory must be completed for the above-listed countries and are optional for all others.

**Entomological monitoring:** As countries approach elimination, entomological monitoring becomes more dynamic and should be part of an integrated approach to focus investigations that are driven by epidemiological data, social behavior change considerations, and environmental characteristics.

**Surveillance, Monitoring and Evaluation:** Timely, complete, and accurate recording and reporting of confirmed cases as passively or actively detected in the public and private sectors is the foundation for tracking progress and identifying cases and foci for further investigation and intensified response measures in elimination settings.

**New Tools:** The role of new tools and approaches, such as focal or mass drug administration, highly-sensitive diagnostic tests, or topical repellents, remains unclear and they are not recommended for routine implementation. Countries should propose these interventions in the context of operational research or program evaluation to help study their appropriate application and feasibility.<sup>154</sup>

---

<sup>154</sup> More information on mass drug administration can be found in the [Vaccines and Other Preventive Approaches](#) chapter of the technical guidance.

Tafenoquine, an 8-aminoquinoline like primaquine, was approved by the FDA in 2018 for the radical cure of *P. vivax* administered as a single dose, but is currently only registered in Thailand among PMI-focus countries.

## Introduction

In the past several years, as worldwide morbidity and mortality due to malaria have continued to decline, the global malaria community has increasingly embraced the feasibility of national and regional malaria elimination, and the longer-term vision of eradication. Over the past century, more than 100 countries, including the United States, have eliminated malaria from within its borders. Most recently, several countries in WHO's Eastern Mediterranean and American Regions, and the entire European Region have interrupted local transmission and have been or are being certified by WHO as having eliminated malaria. Although elimination is being achieved in many regions, most PMI countries in sub-Saharan Africa continue to focus on control and further reduction of malaria mortality. Within the context of this scale-up, a subset of PMI-supported countries have made tremendous progress in reducing malaria mortality and morbidity and are now building the systems required to move towards elimination.

In 2015, three noteworthy global policy documents were released—the WHO's Global Technical Strategy for Malaria 2016-2030, the RBM Partnership's Action and Investment to Defeat Malaria 2016-2030, and the multi-partner From Aspiration to Action: What Will It Take to End Malaria?—that advocate for countries to set goals for malaria elimination and for global eradication, and outline key operational, technical, and financial strategies to achieve the longer-term vision of malaria eradication. PMI shares the global, long-term vision of "A World Without Malaria."

The *PMI Strategy 2015-2020*, also released in 2015, sets as one of its three objectives: *To assist at least five PMI-supported countries to meet the WHO criteria for national or sub-national pre-elimination by 2020.* Pre-elimination phase, as previously described by WHO, includes areas where universal coverage of preventive and case management interventions has resulted in reduced malaria transmission to a level where monthly test-positivity rate remains less than 5% (of all febrile patients tested) throughout the year and health information systems are in place to track that progress. As we await the finalization of the next 5-year PMI strategy, we anticipate a continued focus on strategically driving towards elimination in an increasing number of PMI focus countries. The criteria for PMI considering elimination support in a given country will remain the same with 1. national (or subnational) parasite prevalence <5% and 2. the national malaria strategy contains specific goals and objectives related to malaria elimination.

In 2017, WHO released its updated *Framework for Malaria Elimination* that includes updated recommendations on terminology and classification of the stages as countries transition towards elimination. Among those changes, the term pre-elimination is no longer recommended for use. To align

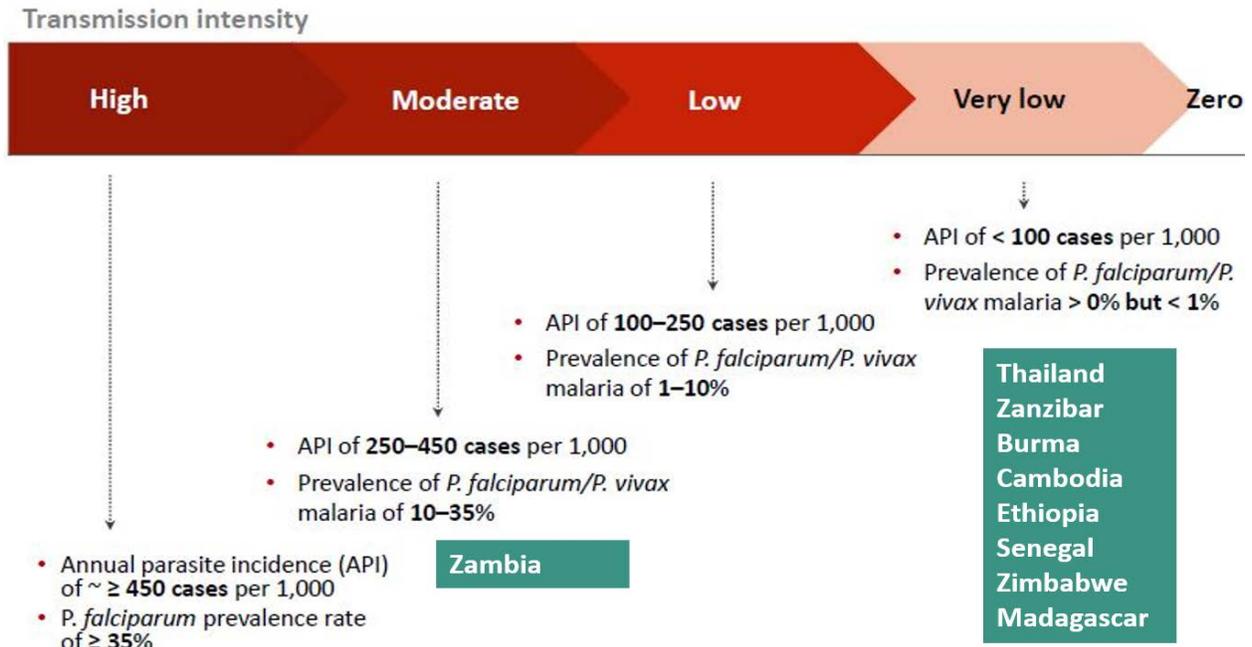
with this recommendation, PMI will only continue to use the term pre-elimination to monitor against the objective in its 2015–2020 Strategy. For other contexts, PMI HQ and country teams are encouraged to align terminology and tracking of country progress with WHO’s updated guidance along the lines of high, moderate, low and very low transmission where appropriate (see terminology in Table 2).

Malaria elimination builds on the foundation laid by intensive malaria control, with universal coverage of efficacious interventions for vector control among populations at risk and effective case management. As malaria-affected countries fully scale up core control interventions, it is likely that some areas will witness significant reductions in malaria burden while burden remains high in others. Therefore, malaria control and elimination activities must increasingly be tailored and focalized based on malaria risk stratification to address the specific needs of areas with differing epidemiologic profiles. This can only be accomplished if countries have the capacity to collect, analyze, and interpret real-time, high-quality health management information system (HMIS)/malaria surveillance information.

The WHO *Global Technical Strategy for Malaria 2016-2030* and the *WHO Framework for Malaria Elimination* emphasizes that the progression towards malaria-free status is a continuous process. It recognizes that countries, subnational areas, and communities are situated at different points on the path towards malaria elimination, and their rate of progress will differ and depend on the level of investment, biological determinants (related to the affected populations, parasites, and vectors), environmental factors, and the strength of health systems, as well as social, demographic, political, and economic realities. The new strategy lays out a pathway to malaria elimination that notes the increasing heterogeneity of malaria transmission as intervention coverage increases and the burden of malaria decreases and the performance of national health systems as a key determinant of the rate of progress along the path. More recently in 2019, the [Lancet Commission on Malaria Eradication](#) concluded that malaria eradication is possible, worthwhile, and affordable, and that the alternatives to eradication are untenable.

WHO’s *Framework for Malaria Elimination* revises the previous stages on the path towards elimination into three phases: the transmission-reduction phase with indicative transmission categories of high, moderate, low, and very low (which includes the previously-defined broad continuum from malaria control to pre-elimination); the elimination phase; and the prevention of reintroduction phase (**Figure below**). This reorientation emphasizes that all countries, regardless of where they lie on that continuum, should have a long-term vision of malaria elimination. It also belies the idea that parts of the country have very low transmission and can seek sub-national elimination while other areas of the same country have higher transmission levels. This concept is particularly relevant to the elimination countries in Africa e.g. Zambia, Madagascar, Zimbabwe, Senegal, and Ethiopia. This figure which spans a wide range of transmission intensity, is not as useful as countries drive down transmission as noted by the clustering of most of the PMI eliminating countries in the very low transmission category. To lend further granularity, PMI has adopted a modified strata to map transmission intensity across districts (**Table 2**).

**Figure. Indicative Categories of Transmission Intensity and Categorization of Relevant PMI Countries/Areas**



Source: WHO Framework for Malaria Elimination, 2017; World Malaria Report 2019

Several PMI countries have now set national or subnational goals of malaria elimination, scaled up control measures, and are improving their routine malaria information systems (see **Figure below**).

**Figure. Tracking Progress and Capacity in Reaching Elimination in PMI-supported Countries/Areas**

Country/Area	POLICY		IMPLEMENTATION		ROUTINE DATA*			
	Pre-/ Elimination Strategy	Risk Stratification	Cases investigated	Foci investigated	API	Test Positivity Rate	Case Confirmation Rate	HF Reporting Rate
Thailand	National	Recent	National	National	<1	<5	100	100
Myanmar/Burma	National	Recent	Sub-national	Sub-national	1-10	<5	100	100
Zanzibar	National	Recent	National	National	1-10	<5	100	98
Cambodia	National	Recent	Sub-national	Not done	1-10	5-50	100	100
Ethiopia	Sub-national	Recent	Not done	Not done	10-100	5-50	82	97
Zimbabwe	Sub-national	Recent	Sub-national	Sub-national	10-100	5-50	100	97
Senegal	Sub-national	Recent	Sub-national	Sub-national	10-100	5-50	99	98
Madagascar	Sub-national	Recent	Not done	Not done	10-100	5-50	100	95
Zambia	National	Recent	Sub-national	Sub-national	>100	>50	96	92

\*Limited to the public sector

Source: WHO World Malaria Report 2019 and FY 2020 MOPs

Color coding: Green- target achieved, Yellow- progress toward target, but target not achieved, Red- significant progress needed

As transmission levels decrease, programs should assess and strengthen systems needed to eliminate malaria. The following factors and associated indicators along with their necessary technical capacities will be important to consider for countries to assess readiness for elimination and to monitor progress towards elimination:

**Technical Feasibility:**

- Data that suggest successful implementation of malaria control interventions (e.g., having few reported cases of malaria)
  - *Relevant survey indicators: ITN/IRS coverage, treatment-seeking within 24 hours of fever onset, and malaria prevalence*
  - *Ability to classify the geographical areas or lower level administrative units according to factors that determine receptivity and vulnerability to malaria transmission (e.g., micro-stratification)*
- Availability of efficacious technologies and tools to eliminate malaria in a given eco-epidemiological setting

**Operational Feasibility:**

- A health system capable of accurate and timely diagnosis, treatment, and reporting of all malaria cases including imported cases:
  - *Relevant routine indicators: number of cases and deaths, Annual Parasite Incidence (API), test positivity rate, case confirmation rate, case investigation rate*
- Ability to ensure ongoing high-level coverage of vector control interventions.
- A surveillance, monitoring, and evaluation system able to identify, investigate, and control malaria hotspots, rapidly respond to malaria cases, and reliably measure elimination targets:
  - *Relevant routine indicators: completeness and timeliness of HMIS and malaria information system, proportion of cases and foci investigated*
  - *System has capability of moving from monthly/weekly routine reporting to case-based reporting from all facilities, in real-time.*
- Enabling environment with strong community engagement that includes targeted and tailored SBC approaches to address key behavioral factors, political commitment and collaboration amongst relevant ministries and key private sector stakeholders:
  - *Extensive community health worker (CHW) network of malaria workers who test and treat all age groups at the community level within 24 hours*
- Adequate human resources (including monitoring and supervision and clear reporting structures):
  - *Ability of health facility and district staff to analyze, investigate and rapidly respond to malaria cases in a timely manner (e.g., 24-48 hours)*

**Political Commitment / Financial Feasibility:**

- Strong political commitment evidenced by dedicated, sustained funding (both domestic and external) to achieve and maintain malaria elimination

- *Willingness and commitment of government and ministry of health to support elimination efforts, supported by a strategic plan*

PMI and other partners have developed new tools including Ethiopia’s Malaria Elimination Baseline Assessment Tool and the Madagascar health facility readiness assessment<sup>155</sup> that are intended to systematically assess the system and human capacity readiness at national and sub-national levels to move towards elimination. An evaluation of the technical and operational situation using such tools is an essential first step in planning and implementing elimination activities. The findings of assessments using such tools will provide programs with necessary information on what areas require further strengthening, which will enable better prioritization of PMI and country resources. Anyone interested in learning more about these tools and its potential adaptation and use in other countries can contact the PMI Elimination Working Group.

## Shrinking the Malaria Map

The worldwide malaria map continues to shrink with global economic development and increasing political and financial support for control and elimination. The specific measures to be applied in order to achieve malaria elimination and national goals and targets will always be governed by local conditions. Within its allocated funding envelope, PMI will support evidence-based national strategies and approaches. This will largely continue to focus on scaling up and sustaining control interventions. However, in applicable countries, additional support to pilot elimination activities in targeted districts, to further strengthen surveillance systems, digitize community-level data collection, and conduct operational research to determine cost-effective and feasible elimination approaches are permitted. **In countries where malaria burden varies significantly in different areas and thus sub-national elimination targets are being pursued, priority for PMI funding should be given to supporting interventions to further reduce mortality and morbidity in high-burden areas.** These control efforts focused on high-transmission areas will be crucial in limiting the exportation of cases to elimination areas within the country.

## Integrated Approaches to Malaria Elimination and Response

### *Malaria Stratification and Tailoring of Intervention Packages*

Globally, malaria programs are moving away from “one-size-fits-all” approaches. Sub-national stratification can help programs target interventions to areas where they are needed and where they will be effective, which will maximize program efficiency. While all malarious areas should continue supporting malaria case management and malaria surveillance, sub-national conditions should inform selection of other malaria-related intervention.

---

<sup>155</sup> Anand A, Favero R, Dentinger C, Ralaivaomisa A, Ramamonjisoa S, Rabozakandraina O, Razafimandimby E, Razafindrakoto J, Wolf K, Steinhardt L, Gomez P, Rabary M, Andriamananjara MN, Mioramalala SA, Rakotovoao JP. Malaria case management and elimination readiness in health facilities of five districts of Madagascar in 2018. *Malar J.* 2020 Oct 1;19(1):351. doi: 10.1186/s12936-020-03417-z. PMID: 33004061; PMCID: PMC7528237.

Within most PMI countries, transmission intensity is diverse. WHO's 2017 [Malaria Elimination Framework](#)<sup>156</sup> defines malaria transmission strata using annual parasite incidence (API) or prevalence of malaria caused by *P. falciparum*. Most countries can now assess annual malaria incidence sub-nationally using data from HMIS. Data quality (completeness, accuracy) should be monitored, but generally strata should be created using HMIS incidence data rather than survey-derived prevalence data because it is more timely, more geographically granular, and inclusive of more age groups. To help monitor smaller changes in malaria burden, and because different mixes and intensities of interventions may be required as geographic areas progress through WHO's "very low" stratum towards elimination, PMI suggests calculating some additional strata when incidence falls below 100 cases/1,000/year. Within MDIVE, PMI uses standardized incidence cut-offs for all PMI countries which may facilitate clearer, more granular visualization of the range of malaria transmission intensities for eliminating countries. To monitor progress and trends in elimination across PMI countries, PMI will use the following categories for district level incidence stratification:

- High >450
- Moderate > 250 and  $\leq$  450
- Low > 100 and  $\leq$  250
- Very Low > 10 and  $\leq$  100
- Extremely Low > 1 and  $\leq$  10
- Near Elimination > 0 and  $\leq$  1
- Zero

Although malaria transmission intensity (e.g., incidence) should form the foundation of stratification, as transmission decreases, stratification should incorporate ecological, entomological, and SBC data in order to determine the appropriate package of malaria interventions. WHO's [High Burden High Impact](#)<sup>157</sup> initiative includes sub-national stratification of the 11 highest-burden countries and modeling that incorporates factors like insecticide resistance, malaria receptivity, prevalence of improved housing, etc., to select intervention packages in order to optimize health impact. To further inform SBC implementation across transmission settings, countries may choose to implement the Malaria Behavior Survey for Low-Transmission Settings. This survey is intended to assess the extent to which behavioral determinants (e.g., risk perception, self-efficacy, norms, decision-making) shift across interventions in low-transmission settings (e.g., active case detection, screening of travelers) to improve targeting SBC activities (see [SBC chapter](#) for more information on the Malaria Behavior Survey).

Ideally, sub-national incidence will be monitored on an on-going basis to inform program decisions. Formal re-stratification and re-assessment of the intervention mix will be needed less frequently to inform strategic direction and funding decisions.

---

<sup>156</sup> A framework for malaria elimination. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

<sup>157</sup> <http://allianceformalariaprevention.com/wp-content/uploads/2020/01/4.-High-Burden-to-High-Impact-How-stratification-can-improve-targeting-of-vector-control-interventions-WHO.pdf>

## *High-risk Populations*

As malaria burden decreases in a country, spatial heterogeneity, as well as new demographic risk factors, will become increasingly relevant. It is not uncommon that certain groups may continue to carry a higher burden of malaria despite reductions in the general population. Examples of such emerging high risk groups include indigenous people in Central and South America, ethnic minority groups and forest workers in the Greater Mekong Subregion, and migrant agricultural workers in Ethiopia. These groups share some common characteristics, including geographic isolation from or reduced access to mass media and public health structures and preventive tools, lower wealth status and literacy, poorer housing, and increased movement for economic pursuits. In some instances, particularly in farm and forest workers, their work requires them to move from lower to high risk areas and to carry out activities, including working outdoors during peak mosquito biting times, which increases their risk of infection.

Reaching these populations can be particularly challenging, as they may only stay in one location for a few weeks or months or may be conducting unsanctioned work, which leads them to avoid contact with any government authorities or facilities. These groups also tend to have lower literacy or may speak a different language; are likely unaware of the availability of health services in their temporary locations, unless the farm or plantation provides those services; and may have varying levels of risk perception for malaria that influence their uptake in prevention behaviors. In some settings, traditional control measures, like standard LLINs and IRS, may not be appropriate for their living and work situations. Migrant and mobile populations may also be inadvertently excluded from net distribution or household surveys, as they do not appear on the local census which is used as a basis for population estimates in both situations.

Innovative approaches must be developed and tested to both identify and reach these high-risk populations. Examples of approaches that have been piloted in PMI focus countries include:

- Providing LLINs to farm/plantation owners to distribute to their workers
- Providing long-lasting insecticidal hammock nets (LLIHNS) for migrant/outdoor workers
- Setting up farm/plantation/forest clinics/workers or training mobile or work-site malaria workers
- Training taxi drivers to provide malaria messages and referral to services to migrant populations
- Using innovative sampling (e.g., snowball, respondent-driven, and time-location sampling) to conduct surveys of mobile/migrant populations
- Developing SBC materials in languages appropriate to the targeted population, including dual language or low literacy materials for use in cross-border settings
- Establishing border health posts
- Employing novel surveillance approaches to capture testing and treatment data so that these high-risk groups are accounted for in monitoring and evaluation efforts

## ***Foci Investigation and Response***

As malaria transmission declines, recalcitrant foci of transmission or hotspots may emerge. Under the new WHO framework for elimination, a “focus” is a defined and circumscribed area situated in a currently or formerly malarious area that contains the epidemiological and ecological factors necessary for malaria transmission. Foci are classified as active, residual non-active or cleared. Active foci are those where local transmission has not been interrupted. Foci with recent local transmission are considered residual non-active while those where local transmission has not been observed for at least three years are considered cleared.

Foci investigations should be tailored to the epidemiological situation. For residual non-active foci, investigations should be conducted to identify the likely location where the case(s) acquired malaria and any preventive measures that were available to and used by the cases. Reactive case detection may be done if transmission is suspected to be local or if there are concerns about onward transmission from the index case. Reactive case detection should also be done amongst co-travelers when the case was considered acquired outside the community. If transmission appears to be associated with certain occupations (e.g., forestry, mining, or agriculture), investigations should focus on identifying high risk behaviors and behavioral factors (e.g., attitudes, risk perception, self-efficacy, norms, etc.) in these workers and tools that might be effective in reducing work-related transmission. For instance, insecticide treated hammock nets are procured by PMI in Cambodia for such populations. SBC messages should be tailored to address identified behavioral factors to ensure populations at risk consistently use and care for LLINs, seek treatment promptly when sick, and other prevention behaviors, as applicable to the setting.

For active foci, more extensive investigations may be required. In addition to reactive case detection and assessment of coverage of vector control interventions among cases, availability of LLINs and access to prompt diagnosis and treatment should be determined for the entire focus area. Health facilities and village malaria workers should be adequately supplied with LLINs, RDTs and ACTs. Depending on the size of the focus and/or the number of cases, additional VMWs may be recruited to serve the population at risk. In addition to use of LLINs and access to health care, specific behaviors of community members should be assessed including travel history, particularly to areas with increased risk of malaria and activities that occur outdoors late at night (e.g. overnight stays at farms). As with residual non-active foci, SBC activities should address changes in risk perception, self-efficacy, community norms, and other factors that promote the uptake of malaria prevention and treatment behaviors.

If local transmission is determined to occur despite adequate coverage of LLINs and/or IRS, entomological investigations are required to identify the primary vectors, their susceptibility to insecticides used on LLINs or for IRS, their biting behaviors including the predominant times and locations of biting, and the distribution of potential larval habitats in the area. Assessment of mosquito behavior should be paired with information on basic human behaviors such as when they enter and exit their houses, what time they go to sleep and wake up and whether they used LLINs the previous night.

A detailed decision tree for entomological components of foci investigations can be found in module 9 of the [Malaria Elimination Toolkit: Entomological Surveillance Planning Tool \(ESPT\)](#).

In addition to responses indicated above, active foci where local transmission persists despite adequate coverage of LLINs or IRS may require additional, non-standard interventions that may not be appropriate in a control context, where broad scale coverage is needed. These may include interventions such as mass drug administration or larval source management as the rubric of ‘fixed, few, and findable’ may be less relevant in a severely circumscribed focus when the object is malaria elimination. The Malaria Behavior Survey in Low Transmission Settings<sup>158</sup> will further assess the behavioral factors that influence the uptake of these interventions to inform targeted and tailored approaches for SBC (See [SBC Chapter](#) for additional information). The aim of these combined approaches is to provide time-limited, intensive interventions to drive transmission to zero.

Where residual transmission may be occurring away from houses or outdoors, additional non-standard interventions to address residual transmission (e.g., insecticide treated clothing or repellents) may be requested, or even become part of the standard of care, in some countries. Direct procurement of these non-standard interventions is not currently supported by PMI without evidence that such interventions are effective in the specific geographic/ecological/epidemiological context and may require that such strategies first be evaluated through OR or program evaluation. **PMI may provide support for program evaluation or operational research to determine the acceptability, feasibility, and effectiveness of non-standard interventions. In addition, where appropriate, PMI may partner with NMCPs or other donors procuring or supporting the distribution of non-PMI standard interventions (e.g, topical repellents, etc.) to allow them to leverage existing PMI-supported implementation platforms currently being used to distribute other malaria interventions (e.g., LLINs in forest packs). In these instances, country teams should consult with the PMI HQ Elimination and/or Supply Chain Teams for additional guidance.**

## Entomological Monitoring and Vector Control

### *Role of vector control in elimination settings*

The common vector control interventions broadly scaled up in control areas – LLINs and IRS – should be targeted to areas where transmission is ongoing in elimination settings. It should be noted that even if a mosquito population shows tendencies to bite or rest outdoors, that indoor interventions can still have a significant impact on the population as a whole since indoor and outdoor biting populations are not distinct (i.e., within a mosquito’s lifespan it is likely to try to feed/rest for at least a short time indoors where it could come in contact with an insecticide treated net or surface). The role of vector control will also be dependent on where cases are coming from (e.g., locally within the village or being brought back from elsewhere e.g. the forest).

---

<sup>158</sup> The MBS for Low Transmission Settings will be piloted in CY2021 and will be ready for use in CY2023.

Although no clear criteria exist for stopping LLIN distribution, WHO recommends that vector control intervention coverage should be maintained at least until transmission has been fully interrupted (i.e., no indigenous cases) and, if feasible, beyond that point, to minimize the risk of reintroduction. If vector control measures are withdrawn, countries must ensure that malaria case surveillance systems are in place to monitor the situation closely.

### ***Role of entomological monitoring in support of vector control***

In high-transmission areas, longitudinal entomological monitoring via fixed sites is necessary and cost-effective given the likelihood of finding mosquito vectors at a particular site is high. Thus, where one samples is less important than sampling consistently and rigorously. In contrast, marked heterogeneity in malaria transmission within regions and even neighboring foci becomes apparent as transmission decreases. Furthermore, vector numbers may decline markedly, making mosquito collections more time-consuming and costly. Heterogeneity and sparse vectors as well as transmission often occurring away from villages (e.g., in forests, work sites, etc.) present challenges for entomological monitoring. Long-term trends may be more difficult to discern and sample sizes needed to assess insecticide susceptibility may be more difficult to obtain. To respond to these challenges, sampling sites for entomological monitoring should be guided by epidemiological data, by focusing on areas where transmission is likely to be occurring. Availability of such epidemiological data, assuming routine malaria surveillance is of good quality, is critical to focusing entomological monitoring in low transmission areas.

### ***Site selection for entomological monitoring***

In elimination settings, decisions about where to conduct entomological monitoring should be based on malaria burden data obtained from HMIS or, if necessary, from surveys. Entomological monitoring should concentrate on active foci of ongoing higher-level transmission. As a first step, collation and synthesis of existing published and unpublished entomology data will be needed to avoid unnecessary duplication of effort. As foci of higher transmission may be stable, it may be possible to conduct monitoring in the same foci for several years. However, the aim of such monitoring should be to identify gaps in vector control coverage (e.g. outdoor transmission) to identify supplemental vector control strategies (e.g. larval source management) that may be implemented to clear the focus. In residual non-active foci or cleared foci where transmission has been interrupted, continued entomological monitoring is likely to be of little value but targeted, time limited entomological investigations may be indicated as part of foci investigations. Nonetheless, limited longitudinal fixed site monitoring may be useful to maintain vector monitoring capacity and to train field staff. The PMI Headquarters Vector Monitoring and Control Team will help advise for specific elimination settings. For further information on the needed components of entomological monitoring, refer to the [Entomological Monitoring](#) chapter.

## Malaria in Pregnancy

The impact of malaria infection on the health of the pregnant woman and her developing fetus depends to a large extent on the level of malaria transmission in the region in which she lives. In low-transmission areas or epidemic areas, women may be less exposed, particularly when transmission is related to specific occupational risks. Consequently, pregnant women will have little or no acquired immunity, and are more likely to present with clinical malaria (although asymptomatic infection can still occur). They are also at an increased risk of anemia and severe malaria. Even in very low transmission settings, MIP is associated with spontaneous abortion, stillbirth, prematurity, and low birth weight. For these reasons, all PMI-supported countries, regardless of transmission levels, should continue to address prevention and control of malaria in pregnant women and ensure effective case management. PMI also considers pregnant women as an "easy access population" as a means of monitoring malaria transmission as transmission goes very low. Surveillance in this population is being evaluated in PMI's OR/PE studies and may be relevant for deployment pending the findings from the studies.

### *Prevention*

#### ITN

Countries proceeding towards elimination should continue to provide ITNs to pregnant women both through campaign distributions and through routine antenatal care depending on the country's distribution strategy. In countries, which do not currently implement IPTp, ITNs are the only preventive measure that can be applied throughout the pregnancy.

#### IPTp

In many PMI-supported countries, transmission has been substantially reduced due to effective prevention and control measures. Some PMI-supported countries (e.g., Kenya, Madagascar, and Zimbabwe) have opted to implement sub-national or focal IPTp policies targeting only moderate/high burden areas. As malaria burden decreases in countries, questions have arisen around the continued effectiveness of IPTp in low transmission settings. **The WHO currently recommends that countries in Africa that have reduced malaria transmission should maintain IPTp as a preventive strategy for pregnant women and PMI supports this recommendation.** Currently, there is insufficient data to determine a transmission threshold below which IPTp is no longer cost effective or efficacious. IPTp with SP remains safe, effective, and relatively inexpensive to implement. In addition, recent data has shown the deleterious effects of even low-level infections on pregnant women and their babies. Therefore, PMI will continue to support the implementation of IPTp-SP in all countries where it is currently part of the national strategy regardless of decreasing levels of malaria transmission.

Outside of Africa, there is not sufficient evidence to support IPTp-SP as a prevention strategy and countries are encouraged to focus on ITN provision to pregnant women and prompt health care seeking for fever.

## ***Case management of pregnant women***

As with all suspected cases of malaria, parasitological confirmation by RDT or microscopy is recommended. The treatment protocols for uncomplicated and severe malaria in pregnancy for very low transmission settings are the same as recommended for higher transmission or endemic areas. Appropriate management of vivax malaria during pregnancy needs to include, when feasible, strategies to prevent relapses without the use of primaquine e.g., weekly chloroquine for the remainder of the pregnancy.

## ***Other interventions: ISTp and MDA***

Recent studies have shown that ISTp is not as effective as IPTp-SP in reducing the malaria burden in pregnancy for African settings where *P. falciparum* is prevalent. ISTp was associated with more maternal clinical malaria episodes, and was more costly when compared to IPTp-SP. An ISTp study in Rwanda also showed that it was not superior to a clinical case management approach (i.e. only testing symptomatic women). In certain settings (e.g., Asia), where *P. vivax* is common and IPTp-SP has not been deployed, the alternatives are less clear and further evidence is needed. Although methods of detection of parasitemia (peripheral or placental malaria smear, RDT, or histopathology) underestimate the burden of malaria in pregnancy even in low transmission settings, available evidence indicates that if screening is done, it will be most effective early in pregnancy.

Care must be taken when deploying strategies such as mass drug administration<sup>159</sup> to avoid inappropriate treatment of pregnant women, particularly during the first trimester of pregnancy. This may pose a challenge since it requires the identification of women in early pregnancy who may not yet appear to be pregnant or may not disclose this information. Screening, including offering pregnancy tests and/or conducting an interview to ask about pregnancy status directly, may not be an optimal approach as many women may not wish to reveal their pregnancy status. Given that approximately 20% of the population is comprised of women of reproductive age who may be pregnant, the number of women who need to be screened for pregnancy is substantial across countries. In addition to privacy issues, costs of screening may be another barrier. Recent MDA pilots have excluded infants and pregnant women from receiving the intervention. It is also important to note that primaquine is contraindicated in pregnancy and lactating women. PMI-supported countries considering some of the newer approaches to control of malaria in pregnancy should consult with the relevant PMI Headquarters teams (Elimination, Case Management, and MIP) in the planning phases of such activities.

---

<sup>159</sup> [Please see Other Preventive Approaches for more detailed description of Mass Drug Administration.](#)

## Case Management

The Case Management chapter contains information relevant for diagnosis and treatment in all transmission settings. This section focuses on additional considerations for low transmission settings. As transmission decreases, it becomes essential to enhance case management to find all suspected malaria cases, confirm with a diagnostic test, treat all cases according to national treatment policies, conduct an investigation to collect case information, and determine the likely location of infection (i.e., local vs. imported), and report both testing results and case information.

### Diagnosis

As in any other setting, the diagnosis of a clinical case of malaria both at facility and community levels should be based on the result of a diagnostic test, either microscopy or RDT. When performed and interpreted correctly, both microscopy and conventional RDTs can detect parasites for *P. falciparum* and *P. vivax* in concentrations at or above 200 parasites per microliter, which is sufficiently sensitive for identifying parasitemia in patients with clinical symptoms. Highly sensitive RDTs (hsRDTs) are now available and may be useful for certain indications in elimination settings. The hsRDT developed by Abbott detects only the HRP-2 antigen and has a limit of detection of parasite density that is about 10–20 times lower than conventional RDTs. WHO does not recommend the use of hsRDTs for clinical diagnosis and indicates that further research is needed to determine the role of more highly-sensitive tests for case finding activities. Such hsRDTs may have a role, for example, in the context of reactive case detection. PMI has supported operational research on hsRDTs for reactive case detection in Burma and Cambodia, as well as in the setting of an IPTp study in Malawi. The results for the Burma and Cambodia studies along with other non-PMI funded studies show mixed results. Overall, RDTs with a lower limit of detection will give you more accurate estimates of ongoing disease, but at an individual study level the incremental accuracy and sensitivity will vary from site to site and the site-specific parasite species and density profiles. Use of the current Abbott uRDT or newer hsRDTs for elimination or malaria in pregnancy will need to be under the context of operational research or program evaluation. **Neither WHO nor PMI recommend the use of highly-sensitive RDTs for surveillance nor diagnosis of clinical malaria cases in any setting, and will not support procurement of these tests as a replacement for conventional RDTs.** For PMI guidance on non-HRP-2 based RDTs and detection of non-falciparum species by RDT, please refer to the case management chapter.

Other diagnostic modalities including nucleic acid amplification techniques (e.g., polymerase chain reaction, or PCR; loop mediated isothermal amplification, or LAMP) and serology, are not recommended for diagnosis of malaria in clinical settings, even in elimination areas. However, they may be useful for research or surveillance purposes.

In elimination settings, high priority must be placed on confirming every suspected malaria case, not only to ensure that all malaria cases are rapidly and correctly treated, but to enable accurate and timely

case reporting, investigation, and follow up. Therefore, in elimination settings where febrile illness is much more likely to be from a non-malaria source, clinical diagnosis should be discouraged, except when diagnostics are not available and in those cases where a delay in initiating treatment could increase the risk of severe disease or death. In those situations where treatment must be provided without a diagnostic test, effort should be made prior to commencing treatment to collect samples for testing at a later time. Testing could also be carried out as soon as is feasible after initiation of treatment to confirm the diagnosis although any delays in obtaining samples (e.g., more than 24 hours) would reduce reliability of a negative microscopic blood film examination. In contrast, RDTs will generally remain positive for days to weeks after clearance of parasites from the blood, particularly RDTs based on detection of the HRP-2 antigen.

As in higher transmission settings, microscopy is the preferred diagnostic test for patients with severe febrile illness, so that parasite density can be monitored, and also in cases of suspected treatment failure. In field settings, RDTs and microscopy are generally of equivalent accuracy in the hands of competent health workers.

One of the challenges in elimination settings is that the skills of laboratory technicians in malaria microscopy and RDTs can deteriorate as positive tests become increasingly rare and the parasite densities detected in samples from patients with clinical malaria are much lower than in higher transmission settings. Extra efforts must be made to maintain the skill of malaria microscopists, through periodic refresher training, frequent supervision, and establishment of a proficiency testing program. A proficiency testing program uses panels of well-prepared, well-characterized blood slides that are periodically sent to microscopists as unknowns. The microscopists are asked to read these slides and report results to the program administrator. The reported results are compared with the known results and errors in reading addressed through follow-up supervision or retraining, as appropriate. A validated national slide bank can be used to prepare such proficiency testing panels, as well as standardized training sets. PMI should prioritize support to ensure these skills are retained in these settings.

All PMI-supported countries, and particularly those moving towards elimination, should have such a slide bank. PMI is supporting development or procurement of slide banks in a number of countries. Standardized protocols for development of these slide banks are included in the updated 2016 WHO Malaria Microscopy Quality Assurance Manual.<sup>160</sup>

The highest priority must be placed on ensuring an uninterrupted supply of essential diagnostic and treatment commodities in elimination settings, as any delay in diagnosis or treatment of a malaria case increases the risk of progression to severe illness and also onward transmission of that infection. In addition to routine supply chain strengthening, there may be a need for an urgent resupply strategy using strategically located buffer stocks and clear notification systems. District-level buffer stocks and redistribution between sites in Cambodia have successfully prevented most stockouts in PMI targeted

---

<sup>160</sup> [http://apps.who.int/iris/bitstream/10665/204266/1/9789241549394\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/204266/1/9789241549394_eng.pdf)

districts. PMI should consider prioritizing support to help ensure these uninterrupted supplies, and understand that occasional expiration of small amounts of unused commodities is often unavoidable, particularly if the country is to be prepared for unexpected focal increases in malaria cases.

The need for rapid diagnosis, treatment, and response to malaria cases also necessitates quick and easy access to care for affected populations. In elimination settings, village or community health workers often become the foundation for both malaria case management and the subsequent investigations. Additional approaches, including mobile or migrant health workers, border clinics as in the E8 countries, health services provided in high risk settings (such as plantations in Cambodia or mining/forest camps) also have been used to facilitate access to care.

## **Treatment**

Curative drug treatment of uncomplicated and severe malaria cases does not differ in elimination settings from areas of higher transmission. When moving towards elimination, additional efforts are recommended to ensure treatment adherence and clearance of infection. Though costly, directly observed therapy (DOT), often in a modified form where each morning dose is observed by a CHW, and repeat testing with microscopy to document clearance of parasitemia after completion of treatment, is being used in some settings (particularly in the Greater Mekong Subregion, where treatment failures to ACTs have been identified and as an alternative to therapeutic efficacy monitoring in low transmission settings).

### **Single, low-dose primaquine for *P. falciparum***

In 2015, WHO updated its guidelines to recommend the administration of a single gametocytocidal dose of primaquine to be given in addition to an ACT for falciparum malaria **in low transmission areas**.<sup>161</sup>

---

#### **WHO Recommendation (2015)**

In low transmission areas, give a single dose of 0.25 mg/kg primaquine with ACT to patients with *P. falciparum* malaria **(except pregnant women, infants aged <6 months, and breastfeeding women of infants aged <6 months)** to reduce transmission. Testing for G6PD deficiency is not currently required.

---

The current WHO recommendation was updated from the previous 2012 recommendation, which excluded infants <1 year of age. Further recommendations include administration of single dose 0.25mg/kg primaquine on the first day of ACT treatment and with food to improve tolerability, and advice to individuals to monitor for signs of acute hemolytic anemia including dark urine and to seek medical attention should signs arise.

---

<sup>161</sup> Policy brief on single-dose primaquine as a gametocytocide in *Plasmodium falciparum* malaria, January 2015: [http://www.who.int/malaria/publications/atoz/who\\_htm\\_gmp\\_2015.1.pdf](http://www.who.int/malaria/publications/atoz/who_htm_gmp_2015.1.pdf)

Studies show that primaquine kills gametocytes and is the only widely available drug to kill mature falciparum gametocytes, which reduces the infectivity of *P. falciparum* malaria. Population-level reductions in transmission are only possible when a high proportion of patients are treated AND there is not a large asymptomatic human reservoir. Furthermore, modeling has shown that the addition of primaquine to first-line treatment of symptomatic falciparum patients in higher transmission settings would have no impact on transmission. Therefore, PMI recommends the addition of single, low-dose primaquine only in areas of low transmission and/or in a setting with confirmed artemisinin resistance.<sup>162</sup> Currently, single dose primaquine in addition to an ACT are the first-line treatments in the following PMI countries/areas (nationally or sub-nationally): all countries in the Mekong, Ethiopia, Senegal, Zanzibar, Zimbabwe. Procuring lower-dose tablets for pediatric use remains a challenge for programs. Medicines for Malaria Ventures is working with manufacturers to bring smaller dose tablets to market.

### **Treatment of asymptomatic infection**

Asymptomatic infections are rarely identified in a clinical setting, but rather through active case-finding activities that are carried out in elimination areas. This would include case finding around an index case (reactive case detection) or community surveys (proactive case detection).

In elimination settings, any detected infection, whether symptomatic or asymptomatic, is considered a malaria case and treated as such. Treatment for asymptomatic infections would be the same as that for uncomplicated clinical cases, including the addition of low-dose primaquine for *P. falciparum*, as guided by the national malaria treatment policy.

### **Treatment of *P. vivax* infections**

Countries outside of tropical Africa on the path to eliminating malaria will often have proportionately higher levels of non-falciparum infections, particularly *P. vivax*. Appropriate treatment begins with accurate diagnosis. Treatment of liver-stage infections caused by *P. vivax* is necessary for preventing relapses. Before primaquine is administered for radical cure, the G6PD status of the patient should be assessed, unless the national policy differs.

Tafenoquine recently received WHO PQ for radical cure of *P. vivax* infections and is now undergoing implementation pilots in Thailand, Ethiopia, and Brazil. It is a single-dose treatment, which will certainly improve adherence. It cannot, though, be given to patients with G6PD deficiency. Therefore, quantitative assessment of G6PD levels is required before administration. The drug is currently commercially available only in the U.S. and Australia though registration in malaria-endemic countries has begun starting in Thailand. See Case management for more information on treatment of *P. vivax*.

---

<sup>162</sup> Although the recommendations did not define low transmission, the recent WHO Elimination Framework defines very low transmission as areas having an annual parasite incidence of  $\leq 100$  and a prevalence of *P. falciparum*/*P. vivax* of  $\leq 1\%$ . It is also reasonable to use a health facility test positivity rate of  $<5\%$  as a threshold.

## Surveillance, Monitoring, and Evaluation

### *Household surveys*

PMI relies on household surveys to monitor coverage of interventions on a national or sub-national scale (for countries with large malaria-free areas), including ITN and IPTp coverage. As discussed in various chapters of this guidance, high-level coverage of these interventions will need to be sustained for elimination efforts to be successful. Therefore, PMI will continue to support periodic household surveys, every 3-5 years, as appropriate, to ensure that coverage of these critical interventions does not wane. In countries with high heterogeneity of transmission, sampling frames will need to be adjusted to ensure that surveys sample areas with malaria transmission risk. Other survey methodologies (e.g., respondent-driven sampling to monitoring persons with HIV. Piloted in Thailand and Cambodia among migrant workers, these methods, though, have been difficult to conduct and appear to be less applicable in the malaria setting where social networks are less well-defined and established.

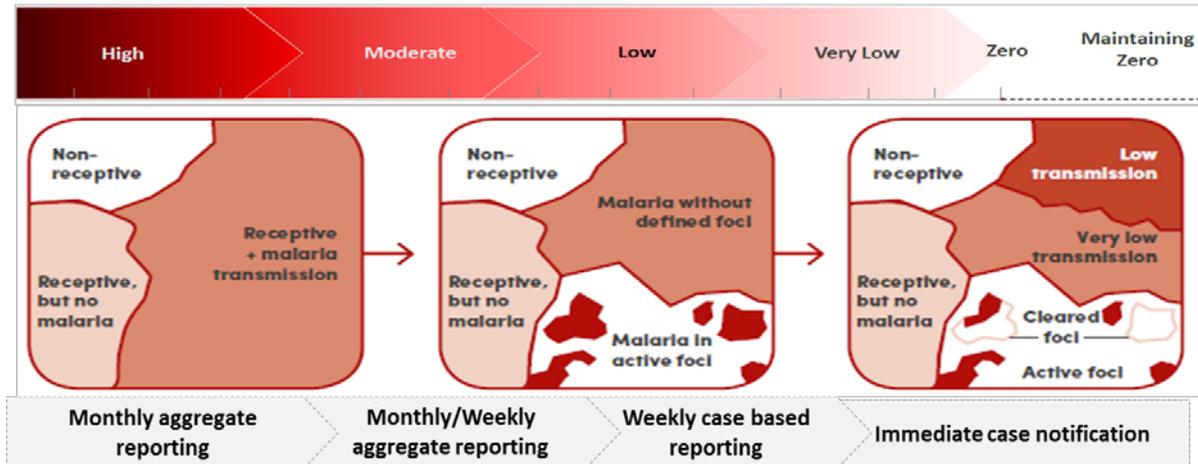
Although population surveys may still be needed in an elimination setting to monitor coverage of interventions, they become less useful for measuring morbidity. PMI has historically used national household surveys (e.g., MIS) to collect data on anemia and parasitemia, and DHS to track all-cause child mortality as impact indicators. For those countries moving towards elimination, national household surveys of a given sample size will become less sensitive to changes in parasitemia and malaria-related anemia as the prevalence of those conditions declines.

PMI recommends that in countries where parasite prevalence in children under five years of age is at or below 3% in two successive national surveys, collection of parasite burden by microscopy or RDTs and hemoglobin through national surveys should be discontinued. Exceptions can be made in countries where parasitemia has substantially declined in some regions of the country, but remains significantly greater than 3% in other regions. PMI should bear less of the financial and logistic burden of organizing the DHS surveys in elimination settings. **Countries transitioning to elimination should increasingly use longitudinal health facility- and community-based surveillance data, if of sufficient quality, to monitor seasonal and annual trends in malaria burden, as described in the surveillance section below.**

As a country or region approaches elimination, stratification of malaria risk will be more important to target interventions. In high-transmission settings, most national malaria risk maps are derived from a combination of parasite prevalence data from household surveys, routine health information systems, and data from various other sources on rainfall, temperature, and vector ecology. Countries approaching elimination with improved surveillance systems rely on their malaria incidence data to generate and update malaria risk maps to target appropriate interventions. Countries able to investigate their cases can further refine their risk maps to distinguish local from imported cases. Ecological, entomological, and social factors as well as robust surveillance data should be used by NMCPs to make strategic decisions regarding the deployment of various interventions, and to monitor progress towards elimination. (See section on stratification above.)

## Disease surveillance

Figure 2. Increasing spatial heterogeneity and frequency of malaria surveillance reporting as transmission decreases



### Surveillance system requirements for elimination

1. **Implementation of a national system to collect facility- and community-based data on confirmed malaria cases in order to reliably measure malaria incidence in all regions of the country:** Countries (or regions) approaching elimination will require a surveillance system capable of recording and reporting malaria incidence in increasingly smaller areas, timeframes, and other disaggregation (e.g. species, active vs passive, and public vs private). Such a surveillance system can quickly identify focal areas of continued or new malaria transmission and to facilitate rapid response to prevent outbreaks and/or epidemics. A comprehensive surveillance system will need to incorporate data from all sectors, including public, private, non-governmental organizations, military, etc.
2. **Ability to identify, investigate, and control foci of malaria transmission:** In the elimination setting, surveillance systems must be capable of timely (no less frequently than weekly) reporting of individual malaria cases by location of transmission. These should be analyzed for possible hotspots, or foci of transmission, to allow for targeted malaria control efforts. The investigation of a locally-infected index case and subsequent response measures (reactive case detection) could include testing and treatment of family members, co-travellers, and close neighbors. Geolocation is beneficial to identify areas of ongoing transmission and allow cross-referencing of control activities in the area to target additional efforts.
3. **Building disease surveillance and response capacity:** Building disease surveillance capacity should be supported in all PMI focus countries. In elimination settings, the capacity of local health authorities to rapidly identify, investigate, and respond to outbreaks is critical. In such settings, PMI will support the training and supervision of health workers and surveillance and

environmental/entomological officers to detect and report cases, investigate foci, and respond with appropriate control measures.

## ***Disease surveillance tools***

### **National disease surveillance systems**

In many PMI countries, multiple surveillance systems exist which collect malaria data at varying frequencies. In collaboration with the NMCP and MOH authorities, PMI teams should prioritize specific areas for programmatic support. In elimination countries or regions, the focus of PMI support to surveillance systems should be on developing the critical surveillance capacity necessary to achieve timely, complete, accurate, aggregate data. The following points should help in making these decisions.

Country teams should consider support to these systems based on the following conditions/contexts:

- **Integrated, health facility-based routine information systems (HMIS, Integrated Disease Surveillance and Response (IDSR)—for a more general description of these systems see [SM&E chapter](#)**: Health Management Information Systems (HMIS) typically report aggregate health-facility level data on a monthly basis. These data do not have the resolution or timeliness needed for targeted elimination efforts (e.g., case listing or detection of transmission foci). In some instances, case-based surveillance tools can be integrated into HMIS via an electronic platform such as DHIS-2. In general, countries nearing elimination should have well-functioning routine aggregate data systems and will focus investments on developing timely, case-based data systems for elimination certification.

Integrated epidemiologic surveillance systems, such as IDSR, provide timely alerts (weekly or even daily if necessary) though may lack the higher-resolution data needed for individual case investigation and response. IDSR systems could be used in outbreak detection and monitoring interventions in a timelier manner.

- **Stand-alone or dual-reporting malaria surveillance systems**: Some countries have stand-alone malaria surveillance systems with more frequent reporting (e.g., weekly) than routine HMIS systems. While PMI does not generally support national parallel surveillance systems for malaria, in some instances these systems may be necessary for targeted elimination areas. Any considerations of support for parallel systems should be discussed with the PMI Headquarters SM&E and Elimination Teams and PMI leadership.

It is important to understand that HMIS and IDSR are often managed by different departments within the MOH and may have different goals and reporting frequency. Consequently, it is possible that a national malaria control program may have limited, timely access to malaria data collected through HMIS or IDSR. In countries moving towards but that have not yet reached the elimination phase, weekly IDSR reporting is likely an adequate platform and the MOH must coordinate appropriate data access for

the NMCPs. However, some countries approaching the elimination phase may require a malaria-specific, supplementary surveillance system that builds on the HMIS/IDSR platform and reports directly to national or sub-national malaria control authorities with greater frequency. These countries in the elimination phase will likely require additional systems that can accommodate individual case data collection, reporting to the national and regional levels within days of diagnosis, and detailed investigations on every case. Systems and modules to support individual case reporting and tracking are being rapidly developed, including RTI's Coconut Surveillance platform used in Zanzibar and the DHIS-2 TRACKER being piloted in Zimbabwe and Burma.

### Hardware/software

There are no specific requirements regarding hardware and software for an effective pre-elimination surveillance system. However, the ability to rapidly share data is essential when approaching elimination and the use of computers and mobile phones/tablets will facilitate rapid reporting. The technology should be selected to address the data collection needs, the overall surveillance strategy, and the national telecommunication infrastructure and policies. Examples of surveillance tools and equipment that assist in rapid case notification, investigation and response include:

- SMS-based reporting: minimal case information can be entered and sent via SMS from CHW or local providers to surveillance staff to alert them to newly confirmed cases. This approach does not require a smart phone or data network to function as information is transmitted via cell phone network.
- App-based reporting: some electronic surveillance platforms support an integrated tablet-based or smart-phone based reporting and response system. These can be used to collect patient-specific information and direct surveillance officer investigations of newly diagnosed cases and case clusters. Officers can record exact response activities in real time and either transmit to the central surveillance system or upload when connectivity is available. These technologies can also facilitate geo-location of the cases through built-in GPS functions, but require a functional data network.

A landscaping of currently available mobile technologies and a roadmap for mobile solutions for malaria elimination surveillance systems was commissioned by the Bill & Melinda Gates Foundation and is available at <http://vitalwave.com/case-study/mobile-solutions-for-malaria-elimination-surveillance-systems/>.

### Surveillance approaches

The following are approaches to surveillance that can be supported through PMI funding where appropriate:

- **Passive surveillance:** Passive surveillance systems rely on data on individuals presenting for care within the health system. These data are aggregated and reported on a periodic basis (usually

monthly). In elimination settings, the system ideally should include all cases in a geographic area including public, private sector, and community-level data. Passive surveillance does not generally capture cases and deaths that occur outside of a health care setting, and thus might not provide a complete picture of malaria burden. In general, passive surveillance should be fully functioning (i.e., have high completeness and timeliness) and provide actionable data for a NMCP before pursuing active surveillance strategies.

- **Malaria mortality surveillance:** Monitoring changes in malaria-specific mortality is a challenge for malaria control programs. As programs approach elimination, accounting for deaths and confirming malaria infection will improve as all malaria cases are diagnostically confirmed and health information systems are strengthened. Generally, malaria mortality data from routine surveillance will become increasingly accurate and reliable. Furthermore, malaria deaths should become increasingly rare in elimination settings.
- **Active surveillance:** Active surveillance includes efforts to seek out additional cases of a specific disease and can take several forms. It can include community health workers or health workers visiting villages and going door to door looking for people with signs and symptoms of malaria, or testing all residents regardless of symptoms. Active surveillance is very resource- and time-intensive and is generally not considered until countries have a strong passive surveillance system and reach the elimination phase, when cases are few and health system capacity and resources allow. Active surveillance can be used in the elimination setting in several ways:
  - Identification of areas of high transmission or high-risk populations – finding cases or infections among groups where higher prevalence or outbreaks might be expected based on historical epidemiologic, vector, meteorological, and/or migration data.
  - Transit programs to screen individuals at high risk for malaria before they enter the country or low-prevalence areas within a country.

The effectiveness of active case detection in reducing disease burden remains unclear and such strategies should be carefully considered before they are implemented. Given the limit of detection of conventional RDTs and microscopy, especially in low-prevalence settings, teams need to balance the costs and potential benefits of this type of approach. Alternative approaches such as MDA are being evaluated as a strategy to reduce and interrupt transmission. See other preventive approaches chapter for more detail. In addition, it is strongly advised that if MDA activities are being considered, this should be done in consultation with the PMI Elimination Working Group and will generally be required to first be piloted as an OR study, assuming other evidence of effectiveness is unavailable, so that its effectiveness can be assessed.

- **Reactive case detection:** Elimination countries with robust health systems and capacity to investigate cases may employ various surveillance methods that combine passive and active

surveillance. Case notification, investigation, and response efforts, such as China's "1-3-7"<sup>163</sup> approach, fit in the category of reactive case detection. Cases are first identified by passive surveillance and reported within one day. A case investigation is completed within three days of notification, which includes both geolocating the case's residence and collecting personal, household, and environmental information that helps determine whether the case was likely to be locally-transmitted or imported. Further action is taken within seven days which often includes reactive case finding in a predefined radius around the identified case where the patient lives or works and treatment of additional confirmed cases.

Most countries targeting malaria elimination conduct some sort of reactive case detection activities. However, countries vary greatly in what triggers response measures, what diagnostic tests, if any, are used to identify additional cases and infections, whether testing is performed on asymptomatic persons or only symptomatic, the targeted radii, and the additional vector control and community education activities conducted in response. Countries use a wide range of response radii from the index household to up to 3km, often dictated by operational feasibility. Increasing evidence suggests that if local transmission is occurring, the likelihood of finding additional cases is highest in the index household and decreases rapidly beyond 200m from the index household. Determining the optimal radius for the area for case-finding activities should also be balanced by what is operationally feasible in the particular setting and by factors such as housing density and topography.

### **Draft PMI Elimination Indicators**

To track progress towards elimination, the following indicators are recommended for countries embarking on elimination:

Can be tracked through data elements that are currently collected through PMI quarterly reporting:

- Annual Parasite Index
- Test Positivity Rate
- Proportion of patients with suspected malaria who received a parasitological test
- Proportion of expected public health facility reports received
- Proportion of expected community provider reports received
- Annual blood examination rate
- Proportion of cases investigated and classified
- Proportion of foci investigated classified

Currently not tracked via PMI quarterly reporting:

- Proportion of patients with *P. vivax* or *P. ovale* malaria who received treatment for radical cure (limited to vivax-endemic countries)
- Proportion of patients with *P. falciparum* malaria who received single-low dose primaquine

---

<sup>163</sup> Cao J, Sturrock HJW, Cotter C, Zhou S, Zhou H, Liu Y, et al. (2014) Communicating and Monitoring Surveillance and Response Activities for Malaria Elimination: China's "1-3-7" Strategy. PLoS Med 11(5): e1001642. doi:10.1371/journal.pmed.1001642

- Proportion of malaria-endemic villages with access to community-level case management
- Proportion of expected private health facility reports received
- National stratification updated in the past year
- National Strategic Plan and Surveillance, Monitoring & Evaluation Plan for malaria elimination in place

## Social and Behavior Change (SBC)

In areas with high, moderate, low, and very low transmission alike, use and uptake of malaria interventions rely heavily on community awareness, demand, and acceptance of essential commodities and services. As such, SBC can play an integral role in malaria elimination through awareness raising for the specific strategies a country will implement, promoting the role that individual community members play in achieving this benchmark, and implementation of targeted approaches for specific populations. With transitions to malaria elimination, communities will experience fewer and fewer cases of malaria resulting in a decrease in perceived risk; however, the severity of malaria cases might increase. To address these shifts across transmission settings, SBC activities may also behavior maintenance will also become more important particularly with regard to ITN use.

Although there is no “one size fits all” approach for specific strategies and channels that should be used for SBC in elimination settings, key aspects of behavior change should be considered. To inform these SBC implementation strategies, country teams, with support from the SBC Technical Team and in collaboration with appropriate working groups in country, should regularly assess what is known about the practice of key malaria behaviors in these settings with what is known about the internal, social, and environmental factors that influence the practice of those behaviors (e.g., country data that suggest risk perception is associated with increased ITN use). See SBC section for an overview of behavioral considerations across the transmission continuum and are described in more detail in the [SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low, and Zero Malaria Transmission](#) report. Please refer to the [SBC Chapter](#) for more detailed descriptions of the approaches supported by PMI across all transmission settings).

### *Vector control*

Two of PMI’s main interventions – insecticide-treated mosquito nets (ITNs) and indoor residual spraying (IRS) – are aimed at controlling mosquito populations and are especially important in sub-Saharan Africa where nocturnal indoor-biting and resting behaviors are common. While these interventions are highly effective, the gains may be quickly reversed if net use or IRS acceptance falls. As such, the transient adoption of a behavior is not enough, particularly in an elimination setting; consistent use of ITNs and acceptance of IRS must be maintained at high levels.

While behavior maintenance for ITN use and acceptance of IRS is important in areas transitioning to low, very low and zero transmission, additional considerations should be made. For example, establishing or reinforcing net use in fixed or sedentary communities may function differently than in high risk

communities such as those that live in makeshift dwellings and/or sleep outside for months at a time, those with outdoor occupations (e.g., security guards, agricultural work), those attending outdoor community and religious ceremonies, and migrant populations. In these settings, monitoring shifts in human attitudes, perceptions and behaviors will be important. To better understand behavioral influences and barriers in these settings, formative assessments using new surveys and sampling techniques may also be required.

### ***Case management***

A key component of SBC for malaria case management is increasing treatment seeking behaviors especially through the public sector. In all transmission settings, SBC for case management at the community level should focus on establishing trust in the malaria test result and raising awareness of the broad spectrum of fever causes. It is equally important that SBC targeted at service providers focus on increased awareness of the broad spectrum of fever causes, emphasize adherence to national case management guidelines (for diagnosis and treatment) and improved communication for patients who do not receive treatment for malaria when presented with a negative RDT.

### ***Malaria in pregnancy***

At the community level, SBC should encourage consistent ITN use, ANC attendance, prompt testing and treatment seeking for fever, and promote the uptake of IPTp, when appropriate. Activities that target service providers should continue to encourage provider adherence to national guidelines for IPTp dosing (timing and frequency) and malaria case management.

### ***Surveillance, monitoring, and evaluation***

As countries shift to lower transmission and improve SM&E activities to capture robust data, special considerations to collect behavioral data on a routine basis should be made. For example, as active case detection is employed in low, very low and zero transmission areas, behavioral components could be incorporated into investigations to further understand and measure the uptake of the relevant behaviors as well as related behavioral factors. Refer to the [Malaria Social and Behavior Change Communication Indicator Reference Guide<sup>164</sup>](#), for indicators that can be adapted for elimination settings.

To measure malaria-related behaviors and the internal and social factors associated with those behaviors, the PMI SBC Technical Team recommends the implementation of the Malaria Behavior Survey (MBS). The tool is a theory-driven, cross-sectional household survey that will help to inform the design, implementation, and evaluation of SBC interventions. The tool is being adapted for implementation in low-transmission settings through coordinated efforts between the SBC and Elimination Technical Teams. The adapted tool will be piloted in CY2021 and will be ready for use in CY23. Please see [the SBC Chapter](#) for more detailed information.

---

<sup>164</sup> RBM Partnership to End Malaria. 2017. Malaria Social and Behavior Change Communication Indicator Reference Guide: Second Edition. Venier, Switzerland: RBM

While household surveys may still be used to measure behaviors of fixed populations (geographically and demographically), additional considerations for SBC SM&E activities include shifting to examining mobility as a system (e.g., monitoring human movement) and determining what effect the direction of that movement will have on malaria transmission. The Greater Mekong Sub-Region has implemented SBC interventions targeted towards mobile populations that have included net lending programs and interpersonal communication with travelers along known travel routes. Countries with mobile populations may wish to build off the lessons learned from experiences in the Greater Mekong Sub-Region. Please see your Headquarters country support for additional information about other PMI countries conducting research, SME and SBC efforts focused on mobile and migrant worker populations.

## Prevention of Reintroduction and Elimination Certification

### *Prevention of Reintroduction*

After malaria cases have been reduced to zero in a particular area or country, preventing the reintroduction and re-establishment of the disease becomes critical.

Based on WHO<sup>165</sup> guidance, re-introduction of malaria is defined as the occurrence of introduced cases (i.e., cases of first-generation local transmission that are epidemiologically linked to a confirmed imported case) in a country or area where the disease had previously been eliminated. Re-establishment of transmission is defined as the occurrence of 3 or more indigenous cases of malaria of the same species per year in the same focus for 3 consecutive years. Countries that have achieved elimination should develop a comprehensive program to transition from malaria elimination to prevention of reintroduction with a focus on the following objectives: 1) early detection and notification of all malaria cases and prompt diagnosis and treatment; 2) determination of the probable causes of the re-introduction of malaria transmission; 3) immediate action in the event of renewed local malaria transmission; and 4) determination of the risk of malaria reintroduction on the basis of assessment and regular monitoring of receptivity and vulnerability of the area.

It is essential for a country to have a robust and an effective national surveillance system throughout the country (and at this point generally should be integrated with reporting for other infectious diseases) to detect, notify, and report all malaria cases promptly. All malaria cases must be investigated in a timely manner and information compiled in a national register of malaria cases. Diagnostic capacity and quality of laboratory services should be maintained through consistent and integrated training and retraining of key personnel. Attention should also be paid to ensure adequate community awareness and vigilance about inevitable importation of malaria parasites.

In an increasingly mobile world, malaria imported by visitors (both foreign and domestic) and migrant workers carries some risk of re-establishment of local transmission of malaria in areas where *Anopheles* mosquitoes are still present and conditions for spread are favorable. Thus, receptivity and vulnerability will be key concepts to evaluate and monitor. Receptivity generally depends on the

---

<sup>165</sup> Regional Framework for Prevention of Malaria Reintroduction and Certification of Malaria Elimination (2014-2020), Regional Office for Europe

presence of local vectors and the existence of environmental and climatic conditions that are favorable to malaria transmission. As such, capacity for entomological monitoring of malaria vectors should be maintained. Vulnerability refers to the probability of importation of malaria parasites into a country or a particular area.

PMI recommends that countries or particular areas that have achieved malaria elimination or close to achieving malaria elimination should develop a sustainable program in terms of cost and human capacity to prevent the reintroduction and/or re-establishment of malaria.

### ***Certification of malaria elimination***

Certification of malaria elimination is an official recognition granted by WHO to a country for the achievement of having no indigenous transmission of malaria over the preceding and consecutive three years. The process of certification is initiated by a country requesting WHO to conduct an inspection of the malaria program. It is important to note that the elimination of malaria, defined as the interruption of local transmission throughout a specific country, does not require the elimination of all malaria vectors or that no malaria cases will be reported since imported cases from international travel can and should be anticipated.

Certification of malaria elimination applies to an entire country and for all human malaria species and principally focuses on: 1) whether indigenous transmission of malaria has been interrupted throughout the country and 2) whether a country's health system is adequate and capable of detecting and preventing the reintroduction of local transmission. WHO is in the process of developing a Malaria Elimination Audit Tool (MEAT) which aims to help countries identify and assess the key components needed in preparation for certification of malaria elimination.

As countries move towards national malaria elimination, it is anticipated that some areas of the country will have achieved key milestones along the path to malaria elimination faster than others. Countries should prepare and begin laying the groundwork for certification of national malaria elimination by starting at subnational levels. WHO does not provide specific guidance for subnational certification of malaria elimination, but the same principles should be followed and evaluated. A country considering certification of malaria elimination must demonstrate that it has 1) a high-quality and robust malaria surveillance system covering all areas of the country; 2) a national registry for malaria cases with rapid notification, investigation, and response for all cases from public, private, and communities, 3) an adequate system for detection and treatment of imported malaria cases; 4) high-quality and quality-assured laboratory services for parasitological confirmation of all malaria cases; and 5) a fully domestically-financed national strategic plan for the prevention of reintroduction of local malaria transmission

---

# SURVEILLANCE, MONITORING, AND EVALUATION

---

## **\*New/Key Messages\***

**Health management information systems (HMIS) are a key investment area for PMI.** Although a single partner may not be responsible for everything that needs to be done to strengthen routine health information systems, a checklist of PMI-recommended activities can be used to identify gaps across partners and prioritize support for activities (Box 1). To better document PMI support for HMIS strengthening plans, more information should be provided on the NMCP overall strategy, the level of support (region, district, facilities, and community), and the total number of areas being targeted and covered.

### **Nationally Representative Surveys: Recommended Frequency and Biomarkers**

#### **Household surveys will continue to be a key surveillance, monitoring, and evaluation (SM&E) activity:**

- In moderate- to high-prevalence areas, household surveys are recommended every 2-3 years
- PMI recommends that in countries where national parasite prevalence in children under 5 years of age is below 3% in two successive national surveys, collection of parasite burden by microscopy or RDTs and hemoglobin through national surveys should be discontinued.
- In countries with national parasite prevalence in children under 5 years of age at or below 3% at the national level, while it is recommended to discontinue the collection of parasite burden by microscopy or RDTs, household surveys are still recommended every 3-5 years to continue to assess intervention coverage.

**Health facility surveys (HFS)** such as the Service Provision Assessment (SPA) or Service Availability and Readiness Assessment (SARA) **are primarily used for program monitoring and help monitor readiness of a health facility to provide quality care and assess quality of care.** As a general rule, these HFS should not be repeated more than every 2-3 years to allow time for interventions and/or policy changes to produce measurable change. Note that there are many other facility survey tools that are used to conduct targeted investigations, operations research, assess data quality and check the availability of commodities (e.g. EUV).

## **Introduction**

Note: At the time of updating this guidance document (November 2020), a new PMI strategy is being developed for the next five years. In general, it is expected that the three objectives will continue to be

focused on mortality reduction, morbidity reduction, and moving countries toward elimination, but the targets and supporting focus areas will be adjusted.

The goal of PMI's updated strategy for 2015-2020 involves working with NMCPs and partners to accomplish the following objectives by 2020:

1. Reduce and document changes in malaria mortality
2. Reduce and document changes in malaria morbidity
3. Assist at least five PMI focus countries to achieve pre-elimination at national or sub-national levels

These objectives will be accomplished by emphasizing five core 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; and (5) building capacity and health systems.

## **PMI Surveillance, Monitoring, and Evaluation Principles**

### ***Coordination and partnership***

PMI is a member of the RBM Partnership and, as such, SM&E activities should, whenever possible, be carried out in coordination with other major partners and donor agencies, including the Global Fund, World Bank, WHO, UNICEF, DFID, etc. Surveillance, monitoring, and evaluation activities should also be in line with the principle of "The Three Ones" – one national malaria control coordinating body, one national malaria control strategy, and one national malaria control SM&E plan – by supporting national SM&E strategies and encouraging NMCP leadership in SM&E. PMI should seek ways to support and strengthen MOH and NMCP capacity in SM&E by providing appropriate technical and material resources to build human and system capacity at the various operational levels throughout the national health system. Collaboration with other USG partners such as PEPFAR, USAID MCH programs etc., should be sought.

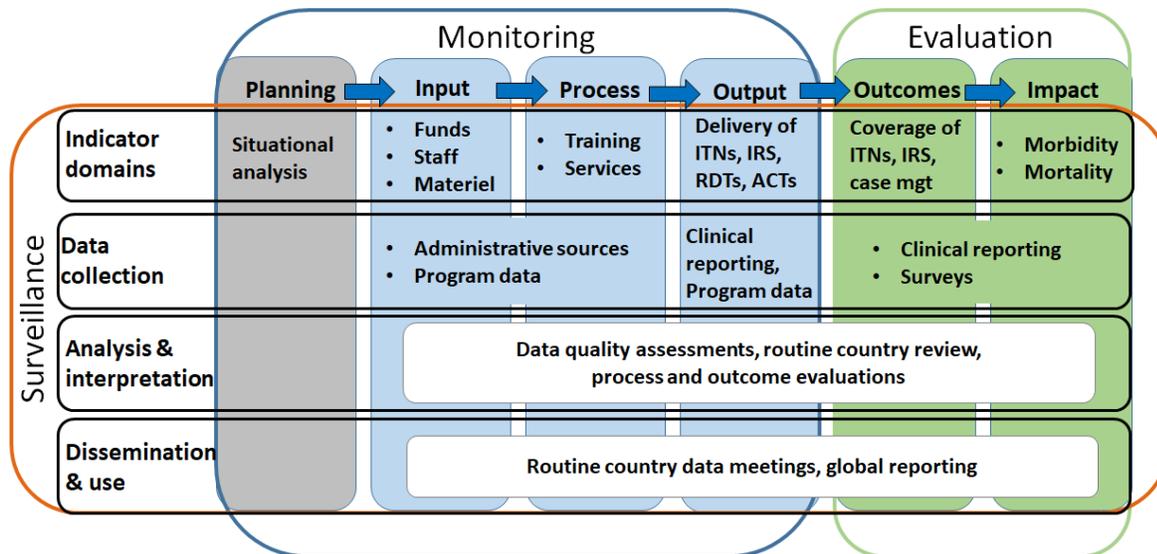
### ***Cost-effective, sustainable solutions***

The PMI Headquarters SM&E Team is cognizant that funding for malaria and SM&E activities is finite and therefore strives to ensure that PMI-proposed SM&E activities are the "best buy" for countries and donors. Surveillance, monitoring, and evaluation activities should provide cost-effective long-term solutions, and promote approaches and systems that are or can become sustainable with country resources. Although efficiencies in acquiring SM&E data and information for malaria may tempt the support of stand-alone malaria SM&E activities, every effort should be made to ensure that PMI-supported activities are integrated into larger public health needs, leverage other investments (e.g., PEPFAR, MCH), and build on local approaches and capacity.

## SM&E Framework

PMI follows the SM&E framework shown below in organizing its activities.

**Figure: Malaria Surveillance, Monitoring and Evaluation Framework**



## Measuring PMI Objectives

Determining progress toward the three 2020 objectives requires estimating malaria morbidity and mortality in each PMI focus country. For countries nearing elimination, subnational estimates are also required. The following sections correspond with PMI's objectives and focus areas and provide a general overview of what SM&E activities are expected to be included in the MOP and supported with PMI resources.

### Objective 1- Reduce and document changes in malaria mortality in PMI-supported countries

PMI has historically used DHS to track all-cause child mortality (ACCM) as an indicator of successful malaria control in high- and moderate-transmission settings. In settings with high malaria prevalence, trends in malaria mortality and ACCM are highly correlated. PMI will continue to rely on DHS as a primary source of ACCM data, and ACCM will continue to be a key indicator to assess the impact of the scale-up of malaria interventions in high- and moderate-transmission settings. But, as the fraction of all deaths attributed to malaria declines, trends in ACCM may be dominated by other diseases and may not reflect trends in malaria mortality. Also, as control is achieved, there can be a proportional shift in malaria morbidity and mortality from children under five years of age to older age groups. As malaria transmission diminishes and fewer deaths are attributable to malaria, use of ACCM will become less effective as a direct indicator for tracking malaria control success (for this reason, ACCM has never been a primary indicator for malaria in the Mekong countries).

Facility-based data collected by the ministries of health and the NMCPs through routine health information systems (RHIS) are a primary data source for hospital-based deaths from malaria. It is important to emphasize that hospital-based deaths grossly underestimate the actual number of malaria deaths because many deaths occur at home, or at facilities not reporting to routine systems. However, trends in mortality can be tracked through longitudinal facility-based data collection systems and, when controlling for factors such as increasing completeness of reporting and increases in health facility use, suggest changes in malaria mortality and case-fatality rates over time.

## **Objective 2 - Reduce and document changes in malaria morbidity in PMI-supported countries**

PMI has relied on population-based household surveys to measure malaria morbidity in the form of severe anemia (hemoglobin <8 g/dL) and parasitemia in children under five years of age. However, the cross-sectional nature of surveys makes it difficult to assess seasonal and temporal trends. Likewise, the large sample sizes necessary to obtain valid point estimates in medium- to low-prevalence areas are making surveys prohibitively expensive for national malaria control programs and donors in such settings.

To date, weaknesses in most routine health information systems have limited their use in following morbidity trends. The expansion of the District Health Information System 2 (DHIS-2) platform in many countries has contributed to more complete, accurate, timely, and accessible routine health data. As these systems continue to improve, routine health information will be critical to monitoring changing epidemiology, targeting resources and interventions, and measuring impact. Therefore, PMI encourages more investment in disease surveillance strengthening through routine health information systems; activities that include building the system and capacities to manage the system and improved data quality, use and visualization for decision making.

In most PMI-supported countries, RHIS data (increasingly captured via DHIS-2 platform) is the main data source for suspected and confirmed malaria cases, test positivity rates, hospital admissions, and deaths within hospitals. PMI recommends a strategy that addresses both increased analysis of RHIS data and overall strengthening of HMIS systems, such as improving data recording and reporting, use of digital tools, inclusion of relevant and up-to-date metrics, and inclusion of private and public facilities and community-level providers.

Measuring improvements in HMIS system strengthening can be challenging. The global malaria community (WHO/GMP, country government partners, donors (PMI, BMGF), implementing partners) has developed a standardized malaria surveillance assessment toolkit that can be used to assess the strength of the HMIS system using a set of core metrics that are comparable over time. The toolkit is being piloted in several countries and is undergoing review by WHO before being posted on the WHO website.

Additional guidance on these routine health information systems and population-based surveys is in the [‘Guidance on SM&E Approaches and Tools’](#) section below.

### **Objective 3 - Assist at least five PMI-supported countries to achieve pre-elimination at national or subnational levels**

WHO previously defined the pre-elimination phase as a monthly malaria test positivity rate of less than 5% among all febrile patients throughout the year. Thus, countries or subnational areas approaching elimination must have a highly functioning routine health information system that includes reporting of cases diagnosed at community level. Preferred impact indicators in settings moving towards elimination would then include test positivity rate and incidence estimates based on the catchment population of the health facility.

A detailed discussion on SM&E in the elimination setting can be found in the [Elimination chapter](#).

## **Five Areas of Strategic Focus**

The *PMI 2015-2020 Strategy* has five areas of strategic focus that support PMI’s three objectives. Focus areas need to be monitored to assess progress that will ultimately have impact on PMI’s objectives. See the *SM&E Framework* or more details on how these focus areas align with SM&E objectives.

## **SM&E for the PMI Strategy, 2015-2020**

PMI and the global malaria community have a long-term vision for the global eradication of malaria that is based on a progression through successive phases of malaria control, followed by sustained control, and elimination (high, moderate, low, very low, elimination, and prevention of re-introduction) within countries.

PMI recognizes that countries are progressing toward achieving intervention targets at different paces and face new challenges in reducing malaria burden. As transmission changes, data needs, data collection methods, and the frequency with which data are collected and reported will change. Countries’ epidemiological profiles and health system capacity should be taken into consideration when developing and carrying out national SM&E strategies. Planning and funding data collection activities should be based on how the data will be used, by whom, and with what frequency. As countries move from control to sustained control to elimination, emphasis on routine surveys will decline and routine systems will increase.

## **Guidance on SM&E Approaches and Tools**

### ***Malaria disease surveillance***

Malaria disease surveillance plays an important role in the monitoring and evaluation of malaria control programs. In the context of PMI, disease surveillance is the continuous systematic collection, processing, analysis, presentation, interpretation, and dissemination of malaria data from service delivery points to those responsible for malaria control to use for timely decision-making as well as feedback to the original service delivery points. Malaria surveillance data can be used to identify areas in need of more intensive interventions, targeted implementation research, and to measure the impact of interventions. When accurately recorded and reported, these data are important for monitoring changes in malaria over time. PMI recognizes that the country context – health system capacity, malaria epidemiology, implementing partner experience, among others – will determine how to best implement malaria surveillance.

For reference, the link to the WHO guidance on malaria surveillance for control areas is (<http://www.who.int/malaria/publications/atoz/9789241565578/en/>). For countries moving towards elimination, please contact the PMI Headquarters SM&E Team and Elimination Working Group for guidance. The 2017 WHO Framework for Malaria Elimination also has useful information on SM&E activities in elimination settings (<http://www.who.int/malaria/publications/atoz/9789241511988/en/>).

### ***Routine health information systems (RHIS)***

RHIS will be important for measuring the impact of PMI interventions going forward. The RHIS is based on clinical data passively collected from health facilities, and in some cases includes data collected from the community. The type of RHIS used by national programs will vary from country to country. The most common system used in PMI-supported countries is the HMIS. HMIS typically include a broad set of health indicators (including several malaria indicators) representing all health services provided at the health facility. A few country programs are also using the Integrated Disease Surveillance and Response system (IDSR). IDSR typically collects and reports on a limited set of indicators on a weekly basis for a small number of epidemic-prone diseases from health facilities. Both systems are affected by health-seeking behavior. The numbers of malaria cases reported through HMIS and IDSR may not be concordant due to differences in reporting time periods (e.g., monthly HMIS reporting versus weekly IDSR reporting), indicator definitions (country-dependent), and the number of facilities reporting into each system. In general, the HMIS is the preferred system for PMI support; however, the IDSR may be more appropriate in low-endemic areas for timely detection of unexpected changes in malaria that may indicate an epidemic.

The concern for many PMI-supported countries at this time is that data collected by health facilities (public, private, and community) and reported through the RHIS are not of sufficient quality (e.g., completeness, accuracy, timeliness) to be useful for monitoring or planning malaria control activities. Twenty-six of PMI's 27 countries are now utilizing a DHIS-2 software platform (either at national scale or

pilot stage) that is facilitating the timeliness of reporting and visibility of the RHIS data.<sup>166</sup> Issues of completeness and accuracy remain, but this should not keep countries from using information for tracking trends to inform programmatic decision-making while still checking data quality and completeness.

Countries should be supporting an integrated RHIS through MOP funding and technical assistance. In most cases, this will involve the HMIS on a DHIS-2 platform. In most countries, there are multiple stakeholders involved in these efforts. PMI should participate in necessary discussions with this broader set of stakeholders and promote the needs of malaria programs and identify opportunities for supporting activities that focus on malaria data, while assuring the stakeholders that our efforts also benefit the entire system. PMI should not be the sole funder of integrated reporting systems and PMI investments may be influenced by the ability to leverage other donors' support. Depending on country needs, capacity, and other donor activities, country teams may need to determine an appropriate balance of PMI support across routine systems (HMIS, IDSR, LMIS) in a country.

#### **Targeted approach for strengthening RHIS**

Resource constraints and the large scale of RHIS strengthening needs will prompt most countries to consider a targeted approach to RHIS support. A targeted approach refers to the following aspects of PMI support for RHIS strengthening: prioritization of passive surveillance in higher-burden areas of the country, selection of high-impact strengthening activities, and a phased approach to implementation across districts and facilities based on the malaria burden. In most instances, initial support should focus on districts with moderate/high malaria burden and overlap with other PMI-supported interventions where it will be important to monitor changes in burden, such as the addition or withdrawal of IRS and the monitoring of case management interventions. As targeted districts and facilities reach the end of their phased period, additional districts and facilities may be selected. The long-term goal of this targeted approach should be to strengthen RHIS and build capacity across all areas nationally in coordination with other partners. The time period of each phase should be determined based on country context and in collaboration with the MOH, NMCP, and all partners.

#### **Activities supported**

PMI support for RHIS activities may include those in Box 1. No one partner can support everything that needs to be done in RHIS, but this list of activities can be used to identify gaps and ensure support for all activities across partners.

---

<sup>166</sup> Note that there may be multiple reporting tools feeding into one reporting system. For example, the DHIS-2 is a common HMIS platform for many countries, and is capable of collecting, transmitting and reporting on a number of different diseases and frequencies. In some countries, the IDSR may also use the DHIS-2 platform.

**Box 1: SM&E activities recommended and supported by PMI at different administrative levels (this can be used as an internal checklist)**

<b>Central Level</b>	
Registers	<input type="checkbox"/>
Checklists, regular data quality activities	<input type="checkbox"/>
Tools (e.g. indicator glossary), job-aids (design, indicators, definition of data elements, system support)	<input type="checkbox"/>
Creation of a data dictionary to link specific RHIS elements with frequently used indicators and quarterly report requests.	<input type="checkbox"/>
Data quality assessments (separate from supervision – funding for travel to lower levels) Program monitoring and technical assistance (funding for travel to lower levels)	<input type="checkbox"/>
Training (funding for central level to conduct training at lower levels, capacity strengthening (i.e. mentoring, coaching, on the job training for central level staff)	<input type="checkbox"/>
Human resources (secondment of person in NMCP or central M&E unit for SM&E)	<input type="checkbox"/>
Data Use (analysis, interpretation, visualization (dashboards, bulletins), dissemination/feedback to lower levels, decision-making)	<input type="checkbox"/>
Policy guidelines and coordination (updating policies, guidelines, supporting sub-committee meetings, supporting participation in sub-committee meetings)	<input type="checkbox"/>
External relations/communications/outreach (support travel to international meetings and publications)	<input type="checkbox"/>
Support to annual operational plans for national malaria program	<input type="checkbox"/>
Desk review to catch “logic errors” in the system (provide TA to catch logic errors)	<input type="checkbox"/>
<b>Admin1 (regional-equivalent)</b>	
Registers for facilities and community health workers (warehousing, printing, distribution) and data collection tools	<input type="checkbox"/>
Data quality assessments (separate from supervision – funding for travel to lower levels)	<input type="checkbox"/>
Program monitoring and technical assistance (funding for travel to lower levels)	<input type="checkbox"/>
Training (funding for admin 1 staff to conduct training at lower levels, capacity strengthening (i.e. mentoring, coaching, on the job training for admin 1 level staff)	<input type="checkbox"/>
Human resources (secondment of person for malaria SM&E, office/team for SM&E)	<input type="checkbox"/>
Data use (analysis, interpretation, visualization (dashboards, bulletins), dissemination/feedback to lower levels, decision-making)	<input type="checkbox"/>
Adaptation of national policy guidelines and coordination (adapting policies, guidelines, supporting sub-committee meetings, supporting participation in sub-committee meetings)	<input type="checkbox"/>

Adaptation of checklists and job-aids	<input type="checkbox"/>
Participation in national meetings (support for travel costs)	<input type="checkbox"/>
Support to annual operational plans for admin 1 malaria program	<input type="checkbox"/>
<b>Admin2</b>	
Data entry, summary, and transmission (training, re-training, computers, internet, tools) Supervision (training, traveling, supervision tools/checklists, create/design system for organized/methodical supervision)	<input type="checkbox"/>
Data validation (data validation activities before monthly data submission - organize health facilities)	<input type="checkbox"/>
Monthly/quarterly data quality review meetings (venue, meeting support)	<input type="checkbox"/>
Data use (analysis, interpretation, visualization (dashboards), dissemination/feedback to facilities, decision-making)	<input type="checkbox"/>
Human resources (secondment of person for malaria SM&E, office/team for SM&E) Annual planning with admin 2 (support travel)	<input type="checkbox"/>
<b>Facilities</b>	
Data collection/entry, summary, and transmission (training, re-training, computers, internet, tools)	<input type="checkbox"/>
Digital tools for both job-aids and data collection and transmission (see Digital Community Health section)	<input type="checkbox"/>
Supervision of CHWs (training, traveling, administering supervision tools/checklists of community health workers)	<input type="checkbox"/>
Data use (analysis, interpretation, visualization (dashboards), dissemination/feedback to CHWs, decision-making)	<input type="checkbox"/>
Monthly/quarterly data quality review meetings (support for travel)	<input type="checkbox"/>
<b>Communities</b>	
Data collection/entry and transmission (training, re-training, tools)	<input type="checkbox"/>
Digital tools for both job-aids and data collection and transmission (see Digital Community Health section)	<input type="checkbox"/>
Data use (analysis, interpretation, decision-making)	<input type="checkbox"/>
Monthly/quarterly data quality review meetings (support for travel)	<input type="checkbox"/>

Data in a fully functional RHIS will move along a continuum: recording, reporting, processing, analysis, presentation, interpretation, use, and feedback. These activities also occur at different levels of the health care system. Thus, level of effort will vary depending on the status of implementation of the RHIS. A country that has just rolled out a DHIS-2 platform will need to focus primarily on data collection and processing. A country with 90% reporting would put additional effort into interpretation and use, while continuing to strengthen quality and timeliness of data collection. For countries where services

are provided by the private sector and/or at the community level, efforts to improve data completeness may be increasingly relevant. The intent would be to have a partner-coordinated, phased plan that strengthens the national RHIS over time.

### **Implementation**

Data of good quality from most facilities is more useful than perfect data from a few. The current PMI strategy includes a focus area on improving capacity to collect and use information. With resources available, this scale-up must be a phased approach. Facility- and community-level surveillance support should be part of a larger strategy targeting entire districts in a phased, partner-coordinated roll out, with PMI focused on districts with moderate/high malaria burden and other PMI-supported activities. The latter approach will also help build capacity at the district level for data use and decentralized decision-making.

PMI supports a phased and progressive approach to RHIS strengthening that encompasses strengthening activities implemented at the community level, across individual health facilities, as well as at district and regional levels, to improve data use. Implementation in individual health facilities should reflect an overall strategy to eventually cover an entire district or region, rather than several sites in isolation. PMI does not support sentinel sites, as defined by WHO, which are “established for the purpose of providing representative data, and deliberately involves only a limited network of carefully selected reporting sites.”<sup>167</sup> However, in the absence of a proven optimal strategy, PMI supports a range of RHIS-strengthening models. The timeframes for supporting RHIS strengthening at each facility will vary and must be guided by local circumstances; considering the level of improvement and the ability of the host government or other donors to provide the necessary support after PMI support to avoid regression. Evidence for RHIS strengthening should be presented in the MOP to document progress in performance and geographical coverage. Such evidence could be quantitative (e.g., numbers trained in specific activities or skills, changes in DHIS-2 coverage, numbers of facilities reporting to RHIS, or completeness of reporting to RHIS) or qualitative (e.g., instances of staff from supported facilities designing or leading SM&E training activities, or plans for supported facilities to train or advise other facilities). An essential component of documenting progress is clear documentation of denominators. For example, activities targeting the district level should include the total number of districts in the country, the number of districts intended to be reached by the PMI-funded intervention and those covered by other government or donor funds. In order to achieve the largest impact, emphasis should be placed on adding or expanding target areas.

To avoid potential confusion with support for sentinel sites or clinical strengthening, PMI requests only using the term RHIS strengthening (and not terms like “enhanced surveillance” or “malaria reference centers”). This does not mean that those sites will no longer be supported but that the MOPs should be clear in describing the overall strategy for RHIS strengthening efforts aimed at facilities, and how this will

---

<sup>167</sup> [http://www.who.int/immunization/monitoring\\_surveillance/burden/vpd/surveillance\\_type/sentinel/en/](http://www.who.int/immunization/monitoring_surveillance/burden/vpd/surveillance_type/sentinel/en/)

be rolled out to encompass surveillance at district, regional, and national levels with an overall long-term goal of nationwide reach of RHIS strengthening efforts.

To improve data quality at facilities, in some cases, the efforts will include improving diagnostics in addition to strengthening routine reporting. Improving diagnostics is critical to obtaining accurate malaria data, and integrating PMI activities across technical areas (e.g., case management and SM&E) almost always makes sense. In the country MOP, activities that support strengthening diagnostics should be included under the case management section while RHIS strengthening activities should be included under SM&E. If the same partner is implementing both activities, the level of effort must be estimated and budgeted accordingly.

Note that in moderate/high-transmission settings it is not necessary or cost effective for a national surveillance system to track and monitor individual cases. Case registry, aggregation, and mapping is appropriate at the level of a community health worker or health facility; however at the district and national levels, aggregate data are more appropriate for following trends and malaria risk stratification for intervention planning in the moderate/high-transmission settings. (See Elimination for details on individual case-level surveillance activities such as reactive surveillance.)

### ***Parallel malaria-specific efforts***

For surveillance purposes, PMI has supported both parallel malaria-specific surveillance systems and parallel malaria reporting systems. For clarity, here is a brief explanation of the difference between the two:

- **Parallel malaria-specific surveillance system:** This is a system operating outside of the RHIS used to collect specific malaria indicators. These systems employ their own data collection tools, reporting tools, management, and supervision structures. Sentinel sites, as supported by PMI in the past, are an example of such systems. PMI support to these systems in the past was important because routine data on malaria cases and deaths were not widely available from other sources. As routine systems have improved over time (with PMI and other partner support), PMI will no longer support parallel systems. The exception to this guidance is when RHIS (e.g., HMIS) is not functional or the data are of such poor quality that they cannot be used to inform programmatic decision-making. In such cases, supporting a parallel malaria-specific surveillance system could be a temporary solution as part of a larger strategy to strengthen RHIS. The decision to support or develop a parallel system should be clearly justified and made in consultation with the PMI Headquarters SM&E Team.
- **Parallel malaria reporting structure:** This is an alternate reporting route for RHIS malaria data to ensure the data are received by the NMCP. In some countries, it has been difficult for the NMCP to access routine data from the HMIS or IDSR in a timely manner (or at all). In such circumstances, PMI may support the NMCP to develop a reporting “work-around” where

districts or facilities report routinely collected malaria data directly to the NMCP in addition to the formal reporting mechanism for the RHIS. As above, PMI may provide this support as a temporary solution to NMCP data access issues, but again, only as part of a broader strategy to strengthen RHIS. The decision to support or develop a parallel reporting structure should be clearly justified and made in consultation with the PMI Headquarters SM&E Team.

In settings of low malaria burden, additional considerations for malaria surveillance strengthening may be warranted:

- **Epidemic-prone areas:**

A malaria epidemic is defined as a sharp increase in the incidence of malaria in populations in whom the disease is rare, or a seasonal increase in areas of low-to-moderate transmission over and above the normal pattern. Calculating the thresholds for determining a malaria epidemic is complex, and is detailed in the [WHO Malaria Surveillance, Monitoring and Evaluation manual](#).

In most cases, it would be optimal for a country to build a malaria epidemic surveillance system into an existing reporting system such as the HMIS or IDSR, rather than establishing a stand-alone malaria epidemic detection and reporting system. In areas with low malaria burden, if the HMIS cannot be adapted or the IDSR is not functional, a parallel system that reports on malaria cases more frequently than monthly may be required to detect sudden upsurges that could indicate an epidemic. As timeliness of reporting is critical, epidemic detection systems should be based on at least weekly summary reporting from facilities. Another key component is setting appropriate thresholds so that every seasonal increase is not investigated.

Countries should note that epidemic detection systems are meant for **LOW** burden areas (less than about 100 cases/1,000/year). Moderate/high malaria burden areas maintain levels of immunity that make epidemics much less likely. Countries should not use limited resources to investigate “outbreaks” in moderate/high burden settings. That does not preclude an ‘upsurge’ in malaria cases in these areas. Case counts (or incidence) along with reporting quality should be monitored on an on-going basis to assess trends and inform program activities. An upsurge in cases should be assessed to determine whether or not it is a data quality issue and whether adjustments to malaria control interventions may be necessary (e.g. ensuring that supply of ACTs/RDTs are able to meet the increased demand or distributing additional ITNs if coverage is suboptimal).

- **Elimination:** In situations where a country has transitioned into the elimination phase, either nationally or sub-nationally, a malaria-specific surveillance system may become necessary because individual case-level data is required to facilitate case investigations. See Elimination for more information.

Activities in support of malaria-specific surveillance may include surveillance system development, training, supervision, and communications. The decision to support malaria-specific surveillance systems in addition to routine information systems (HMIS/IDSR) should be informed by country context (e.g., need for epidemic detection, elimination considerations, leveraging other donor support). Implementation must be thoughtfully and realistically conceived and closely monitored to adjust and revise the approach as needed. PMI experience has shown that establishing such systems is often challenging and resource-intensive. In settings where routine data are already of poor quality, a separate surveillance system will have to overcome the same issues: lack of capacity, poor infrastructure, and competing priorities for healthcare workers, among others.

Support for models to predict epidemics is not recommended with PMI country funding. There are currently global efforts to develop improved models.

### ***ANC-based Surveillance***

Some countries routinely test pregnant women attending first antenatal visits for malaria. Previous research has shown that the prevalence estimates from this sentinel population can be used to monitor trends in malaria prevalence in the wider population<sup>168169</sup> (c. PMI is supporting Operational Research to explore the possible utility of the ANC platform for collecting data on coverage of malaria interventions as well as malaria parasite prevalence. Results from these studies will determine potential future use of this sentinel population as a standard source of data to inform our programs.

### ***Malaria stratification mapping***

Within most PMI countries, transmission intensity is diverse. Most countries can now assess annual malaria incidence sub-nationally using data from HMIS. Data quality (completeness, accuracy) should be monitored, but generally strata should be created using HMIS incidence data rather than survey-derived prevalence data because it is more timely, more geographically granular, and inclusive of more age groups. To help monitor smaller changes in malaria burden, and because different mixes and intensities of interventions may be required as geographic areas progress through WHO's "very low" stratum towards elimination, PMI suggests calculating some additional strata when incidence falls below 100 cases/1,000/year. Additionally, PMI suggests adjustments to strata at moderate-to-high incidence levels, where optimal intervention packages may depend less on precise incidence ranges and more on other factors. Using PMI's suggested incidence strata may facilitate clearer visualization of the range of malaria transmission intensities across PMI countries.

---

<sup>168</sup> Brunner, N.C., Chacky, F., Mandike, R. et al. The potential of pregnant women as a sentinel population for malaria surveillance. *Malar J* 18, 370 (2019).

<sup>169</sup> ASTMH 2018, Aaron M. Samuels: "Antenatal clinic surveillance for malaria accurately reflects community malaria infection prevalence in a high transmission setting in western Kenya"

Although malaria transmission intensity (e.g., incidence) should form the foundation of stratification, as transmission decreases, stratification should incorporate ecological, entomological, and SBC social and behavior change data in order to determine the appropriate package of malaria interventions.

WHO's High Burden High Impact (HBHI) initiative includes sub-national stratification of the 11 highest-burden countries and modeling that incorporates factors like insecticide resistance, malaria receptivity, prevalence of improved housing, etc., to select intervention packages in order to optimize health impact. WHO's HBHI initiative aims to improve the targeting of malaria interventions through better analysis and the strategic use of quality data in those countries with the highest malaria burden (which is determined by the number of malaria cases in a country, therefore is a factor of both population size and malaria endemicity). The targeted countries include: Nigeria, DRC, Mozambique, India, Uganda, Burkina Faso, Ghana, Niger, Cameroon, Mali and Tanzania. HBHI activities include stratification exercises during which available data are used to create maps of optimal interventions based on the district-level malaria epidemiology. PMI country teams have been encouraged to participate in HBHI activities which are typically funded by other partners. PMI-generated data, for example insecticide resistance data from entomological monitoring sites, can be valuable resources for these modeling exercises. Having a broad range of engaged stakeholders improves the quality of the stratification outputs. Note that some PMI-supported countries outside of the HBHI consortium (which include some countries with high malaria transmission but smaller national populations) have also invested in similar stratification exercises.

### ***Population-based surveys***

#### **National-level household surveys**

For PMI SM&E needs, conducting a national-level household survey, within established survey timelines set by the Ministry of Health and other partners, is recommended to assess coverage of interventions and, when needed, estimates of malaria prevalence and ACCM. For more information on the standard indicators available from household surveys, there is a Global Health eLearning course available: <https://www.globalhealthlearning.org/course/measuring-malaria-through-household-surveys>

In moderate- to high-transmission areas, a survey every 2-3 years might be appropriate; in low-prevalence areas, an interval of 3-5 years would be more acceptable. In general, timing between survey iterations should allow for interventions and/or policy changes to produce measurable change. The type of national-level household surveys supported by PMI will generally be a MIS, DHS, or MICS that includes the standard malaria module. While PMI has typically funded an MIS in full or in partnership with the Global Fund, the contribution from PMI to a DHS or MICS has typically ranged from \$350,000-\$500,000 but there are increasing requests from missions for larger contributions to the DHS or MICS. In light of these requests, the PMI contribution to the DHS or MICS should be comparable to the contributions from other health elements (MCH, PRH, NUT, etc.) at the country mission. In recent years, the frequency of such surveys has increased as donors seek evidence of the impact of their investments. There is also an increasing trend (not supported by PMI) towards removing malaria modules from DHS or MICS

surveys and advocating for a separate MIS the same year or within 18 months of the DHS/MICS. If a DHS or MICS is planned for a given year, PMI should support it and ensure that the appropriate malaria questions have been included, rather than supporting a separate MIS during the same year. If appropriate, the inclusion of biomarkers in these surveys may be negotiated with the survey planning teams. PMI does not support national-level household surveys that collect malaria indicators more frequently than every two years, regardless of donor source.

Some NMCPs and partners are requesting that national-level household surveys be expanded to obtain estimates with sufficient statistical power for sub-regions or population sub-groups (e.g., school-age children or people over 15 years of age). Per RBM Surveillance, Monitoring and Evaluation Reference Group (SMERG) guidelines, PMI has supported surveys with sample sizes large enough to estimate coverage of interventions by malaria transmission zones as defined by the Mapping Malaria Risk in Africa climate suitability index (usually 3-5 zones per country). To obtain reasonable estimates for sub-regions or for sub-populations outside of RBM-SMERG-recommended ones, sample sizes and survey complexity and cost will increase. These concerns, in addition to on-going efforts to ensure that the quality of survey data are maintained, PMI and RBM-SMERG currently do not support such survey expansions. If the NMCP and/or PMI country team believes it needs such estimates and is requesting PMI support, the PMI in-country team is asked to consult with the PMI Headquarters SM&E Team. In some situations, other cross-sectional survey methodology may be more appropriate.

#### *Biomarker measurements in population-based surveys*

The MIS is specifically designed to include measurements of parasitemia and anemia. The DHS also includes anemia as part of the nutrition module. However, the DHS does not routinely include parasitemia as the scope and logistics of the DHS often do not permit for prioritization of field work during the high malaria transmission season. Collecting malaria parasitemia prevalence estimates from surveys fielded at different times in the year with varying malaria transmission leads to challenges in interpreting trends. The UNICEF MICS does not routinely include any biomarkers, but technical assistance can be provided to include biomarkers to the MICS.

PMI supports parasitemia testing in children 6-59 months of age in countries with a national prevalence estimate of >3%. In general, PMI does not support parasitemia testing during household surveys outside of this age group, with the following considerations:

- PMI does not recommend parasitemia testing below six months of age. The number of children under six months of age that test positive for malaria parasites would be very small.
- Adding other age groups (i.e., school-age children, pregnant women) to be tested would make the survey process more labor-intensive and risk compromising the quality of the survey.
- Gaining access to school-aged children (5-14 years old) can be logistically difficult and costly. Often these children are at school when the surveyors come by the house, requiring repeat visits. The children that are at home may be the sick children, resulting in selection bias.

- Testing pregnant women for malaria parasites during household surveys raises ethical concerns and requires a much larger sample size to produce meaningful estimates. Survey protocols require appropriate treatment with ACTs for anyone testing positive for malaria during the survey. If women of reproductive age (15-49 years) are included in surveys, it presents the possibility of pregnant women in their first trimester (who do not know they are pregnant or are not disclosing they are pregnant) being treated with ACTs, which are not approved by WHO for treatment during the first trimester of pregnancy.
- PMI supports the guidance provided in the RBM MERG Household Survey Indicators for Malaria Control document regarding the use of RDTs  
[http://www.rollbackmalaria.org/files/files/working-groups/MERG/Reference%20documents/tool\\_HouseholdSurveyIndicatorsForMalariaControl.pdf](http://www.rollbackmalaria.org/files/files/working-groups/MERG/Reference%20documents/tool_HouseholdSurveyIndicatorsForMalariaControl.pdf)  
 Parasite prevalence should be based on the results of a high quality RDT where *P. falciparum* accounts for nearly all infections ( $\geq 90$  percent). PMI does not support the use of multi-species RDTs in surveys.

If a planned MIS or DHS contains parasitemia testing in age groups outside 6-59 month olds, PMI will support the survey (provided it has been approved by the PMI Headquarters SM&E Team), but will not fund the testing in the additional age groups.

As countries enter the pre-elimination phase of malaria control, the focus will shift to heightened surveillance systems that provide continuous information, rather than periodic nationwide household parasitemia surveys. **Therefore, PMI recommends that in countries where national parasite prevalence in children under 5 years of age is below 3% in two successive national surveys, collection of parasite burden by microscopy or RDTs and hemoglobin through national surveys should be discontinued.** Exceptions can be made in countries where parasitemia has substantially declined in some regions of the country, but remains greater than 3% in other regions.

### Combined national-level surveys

While collaboration with other groups conducting large-scale health surveys (such as a national census or an AIDS Indicator Survey) can be mutually beneficial, past experience has shown that there can be serious challenges when surveys are combined. The logistics for planning surveys is complex and combining surveys increases the complexities and introduces additional coordination issues across partners and technical areas, resulting in increased sample sizes, delayed surveys, and impacting overall data quality. If combined surveys are planned, it is recommended that PMI in-country teams consult with the PMI Headquarters SM&E Team to help negotiate with other stakeholders to ensure that PMI needs will be met, including an agreement such as a memorandum of understanding that outlines PMI's participation in the review of preliminary malaria data, as well as receipt of the full report and final

dataset within an agreed-upon time limit.<sup>170</sup> The standard malaria modules in the DHS, MICS, and MIS surveys are interchangeable. If concerns exist about the quality of any of these surveys, country PMI teams are encouraged to speak with the PMI Headquarters SM&E Team in the early stages of survey planning.

### ***Special cross-sectional surveys***

Special cross-sectional surveys (e.g., post-LLIN campaign surveys) can be designed to answer programmatic questions that pre-planned national-level household surveys cannot. Issues related to timing or a need for detailed data that cannot feasibly be added to a DHS or MIS may necessitate a separate survey. These surveys may focus on particular sub-populations or geographic areas of programmatic interest. They may, for example, be used to assess the result of a particular intervention strategy (e.g., LLIN ownership after a sub-national LLIN distribution campaign), or malaria burden in a sub-group of individuals (anemia and parasitemia in school-age children), or utilize malaria measures other than parasitemia or RDT (e.g., serology or PCR). PMI only recommends these surveys when a clear and necessary programmatic question needs to be answered and no other suitable data source for addressing the question exists. If the timing of a larger planned survey, such as DHS or MIS, coincides with the desired timing of a special survey, every effort should be made to utilize the planned DHS or MIS. Special surveys should be timed for optimal data collection based on the programmatic question they are intended to answer and should not be repeated annually.

If special surveys are proposed in country MOPs, country teams should provide concise descriptions of the activity that outline the programmatic question, scope, scale, and timing of the survey, in addition to how the information would be used to improve program implementation. A clear determination should be made whether the survey proposed is operations research; and in such cases coordination with the PMI Headquarters Operational Research Committee should be done.

### ***Health facility-based surveys***

Nationally-representative health facility surveys (HFS) are intermittent, comprehensive evaluations of health system function and are primarily used for program monitoring: establishing a baseline and assessing which aspects of the program require intervention or policy change, and then monitoring changes in relevant indicators after the intervention or policy has been implemented. Health facility surveys are useful in situations where routine information systems and household surveys do not provide all of the necessary information on case management practices, system readiness, and training and supervision to meet programmatic needs of the NMCP or PMI. As of 2020, there is no standard malaria-specific HFS. Health facility surveys should not be used as replacements for the routine HMIS.

---

<sup>170</sup> The DHS Program includes an MOU for all surveys (DHS and MIS) that agrees to provide public access to the dataset after the national dissemination of the final report. In surveys that are implemented by other partners and partially or fully funded by PMI, an MOU should be developed and negotiated for access to the dataset.

Instead, SM&E efforts should focus on strengthening routine HMIS and when facility readiness/performance data is not available, periodic HFS can be considered. **Investigations conducted in health facilities in response to a specific problem would not be considered health facility surveys. For example, discrepancies between actual case management practices and HMIS reporting are best investigated through smaller-scale investigations than through a nationally-representative HFS.**

**Methodology:** HFS typically capture cross-sectional data from health facilities on several aspects of the health system including availability of commodities, appropriateness/quality of case management, data reporting, record reviews, diagnostic capacity, health worker training, and other indicators critical to malaria programs. The type of information required, the level of detail, and other factors will determine the appropriate HFS methodology to be used. A HFS may also include assessment of data quality and reporting, although it is not part of some standard protocols.

**Scope:** Endemic countries should consider nationally representative HFS. In cases in which PMI is only working in part of the country or only parts of the country are endemic, sub-national HFS can be considered.

**Timing:** As a general rule HFS should not be repeated more than every 2-3 years, depending on the information required. More frequent HFS may be considered on a case-by-case basis but there should always be enough time between HFS to allow for interventions or policy changes to produce measurable changes. When possible, HFS should be carried out during the malaria season to obtain the most reliable assessment of malaria service readiness.

**Costs:** Costs will vary widely, from \$150,000 to over \$1 million depending on the sample size and method. In general, because health facility surveys can be very comprehensive and include many other health delivery systems, PMI should strive to work with other partners to fund HFS.

**Integration:** Children under five years of age with fever are evaluated in health facilities using integrated case management protocols. When a HFS includes an observation or re-examination module, case management of children should be observed and cases re-examined using an integrated protocol. Commodities, health worker knowledge and materials for IPTp (if IPTp is included in the country strategy) should be included in any HFS. In some situations, commodity or other data for other illnesses seen in facilities may be requested by other programs. As long as costs, timing and complexity of the HFS are not increased, integration of that type may be considered. Co-financing should be sought from other programs requesting data from a PMI-supported HFS.

**Outpatient/inpatient:** An HFS can include outpatient and/or inpatient assessments. Most HFS that PMI supports are outpatient assessments for which standardized protocols already exist and can be applied with minor adaptation. Inpatient assessments are generally more complex and require additional expertise from trainers, surveyors and supervisors, as well as data processing and interpretation.

Inpatient care can vary widely by type/level of inpatient facility making their assessment more complicated. Consult with the SM&E Team when considering inpatient assessments.

**Modules:** The type of modules used in a HFS will depend on objectives, but may include:

- Health worker and/or supervisor interview
- Health worker and/or laboratory technician observation
- Record review
- Re-examination of sick child
- Facility readiness checklist
  - Infrastructure
  - Diagnostics
  - Medications
  - Reporting forms
- Caretaker exit interview
- Surveyor observations
- Mystery patients

In some situations, an additional module on data quality and reporting may be included.

**Reports:** HFS data (e.g., commodities) can rapidly become non-actionable, so consideration should be given to generating analyses and reports as fast as possible. Generally, the larger or more complex the survey, the longer it may take to generate a report.

**If you are planning an HFS for the first time, consult with the SM&E Team for additional information.**

### *Examples of health facility surveys*

There are several types of health facility survey protocols, which vary in the aspects of the health system on which they focus, the overall cost and complexity, and how the results can be interpreted. For PMI purposes, HFS that produce estimates quickly – within three to six months – should be favored as commodity and case management data become increasingly non-actionable if there are significant delays between the survey and the sharing of results.

### *Service provision assessment (SPA)*

Note: At the time of updating this guidance document, a process to revise the SPA and develop a standardized and improved Quality of Care (QoC) survey is underway through the DHS-8 Program. The goal is to field the new tool in 2021 with standardized indicators and questions across the health sector.

Service provision assessment surveys examine the supply side of health care and the strengths and weaknesses of a country's public and private services. A SPA is one of the most complex facility surveys and collects data from a large sample (often in the hundreds) of health facilities on the readiness and availability of specific health services and commodities as well as quality of services. The SPA focuses on nine key services: (1) child health; (2) maternity and newborn care; (3) family planning; (4) sexually

transmitted infections; (5) HIV/AIDS; (6) malaria; (7) tuberculosis; (8) basic surgery; and (9) non-communicable diseases. The SPA includes assessment of health provider practices in each of the key services through direct observation, health worker interviews and exit client interviews. Instruments typically used in a SPA are:

- Health worker interview
- Caretaker exit interviews
- Health worker observation protocols
- Facility inventory

The tool can be found at: <http://dhsprogram.com/What-We-Do/Survey-Types/SPA.cfm>

### **Service availability and readiness assessment (SARA)**

Service availability and readiness assessment (SARA) surveys are designed to assess and monitor the service availability and readiness of the health sector and to generate evidence to support the planning and managing of a health system. The SARA generates tracer indicators of service availability and readiness. The SARA has been developed by WHO in conjunction with global partners to fill critical data gaps in measuring and tracking progress in health systems strengthening. While the SARA is not malaria-specific, it is possible to include a patient exit interview module to assess malaria case management practices; an optional data quality assessment module can also be added. Instruments typically used in a SARA are:

- Staffing matrix
- Inventory of inpatient and observation beds
- Facility infrastructure audit
- Inventory of available clinical services
- Diagnostic capacity assessment
- Inventory of medicines and commodities
- Interviewer's observations

The tool can be found at: [http://www.who.int/healthinfo/systems/sara\\_introduction/en/](http://www.who.int/healthinfo/systems/sara_introduction/en/)

### **Integrated management of childhood illness health facility surveys (IMCI HFS)**

Integrated management of childhood illness health facility surveys collect health facility data exclusively on childhood diseases including pneumonia, diarrheal disease, and febrile illnesses (malaria, including trigger points for management and referral for severe malaria). This survey produces findings within 12 weeks of start of implementation and can be adapted to different sample sizes. Instruments typically used in the IMCI HFS are:

- Health worker observation checklist
- Exit interview – caretaker of child

- Re-examination of sick child
- Equipment and supply checklist
- Health worker interview (optional)

The tool can be found at: [http://www.who.int/maternal\\_child\\_adolescent/documents/9241545860/en/](http://www.who.int/maternal_child_adolescent/documents/9241545860/en/)

### ***End-Use verification tool***

The EUV is a commodity assessment tool, rather than a health facility survey. Guidance on its use can be found in the [Supply Chain](#) chapter.

## **Evaluation**

Evaluation is a critical component of any national malaria control program and should be integrated into national SM&E strategic plans. PMI supports both program and impact level evaluations at the country level, however there are a number of considerations to take into account when programming funds for evaluation activities.

As part of overall malaria control impact evaluations, PMI generally does not support evaluations aimed at establishing/researching a WHO-recommended specific intervention's impact on morbidity or mortality (WHO recommended malaria interventions include but are not limited to IRS, ITNs, IPTp, Case Management, and SMC). PMI is based on a principle of implementing **already-proven interventions** and thus does not support individual country programs to test/research any one intervention or package of interventions to assess its impact on malaria morbidity or mortality outside of approved Operations Research (see Operations Research section. Also, given PMI's success in increasing coverage of multiple interventions across countries, conditions do not lend themselves easily to evaluate the impact of single interventions.

As interventions are being scaled-up, PMI encourages evaluations in countries where these interventions are not resulting in the expected outcome. These evaluations can help to identify ways to improve the effectiveness, coverage, or service delivery of individual interventions.

### ***Program evaluation***

There may be a number of times in a program's lifecycle when an evaluation is necessary to inform further programming decisions. Some examples of when a program evaluation might be useful include evaluating a pilot to inform decisions about scale-up of interventions, evaluating the effectiveness of one programmatic approach against another, or evaluating project achievements at the end of an activity before a programmatic redesign process.

Malaria program reviews per WHO methodology include program evaluation components and are generally supported by PMI. Malaria program reviews should be carefully planned and coordinated with

all partners (ideally timed to precede a country's new 5-year National Malaria Strategic Plan), last less than one year, not be repeated more frequently than every four years, and produce actionable data and information. No more than \$100,000 of PMI resources should be budgeted in total for a malaria program review.

<https://www.who.int/malaria/publications/atoz/whomprmalariaprogramperformancemanual/en/>

### ***Impact evaluation***

Evaluations of impact are generally good practice; however, PMI will not be funding these evaluations in every country. Impact evaluations are used to determine whether supported activities have had the desired effect on morbidity and mortality under operational conditions. Generally, evaluations of impact should be carried out only when interventions have reached sufficient coverage to expect impact, and evaluation questions are clearly defined. Globally-accepted methodologies preferably sanctioned by the WHO or the RBM SMERG

([https://endmalaria.org/sites/default/files/Framework%20for%20Evaluating%20National%20Malaria%20Programs%20in%20Moderate-%20and%20Low-Transmission%20Settings\\_FINAL\\_tr-19-334.pdf](https://endmalaria.org/sites/default/files/Framework%20for%20Evaluating%20National%20Malaria%20Programs%20in%20Moderate-%20and%20Low-Transmission%20Settings_FINAL_tr-19-334.pdf)) should

be used to ensure consistency and comparability across time and countries. Evaluations of impact should be transparent and participatory. Many stakeholders, both within malaria control and without, should be encouraged to participate in the design, analyses, and production of reports. The PMI Headquarters SM&E Team will reach out to countries that should consider an evaluation of impact to help plan and support it.

## **Activities No Longer Supported By PMI**

### ***Demographic surveillance system sites***

PMI does not provide direct support for demographic surveillance sites to monitor births, deaths, and health in geographically-defined populations continuously over time. It is possible, however, that PMI support might provide some limited support for data analysis of existing data in the context of impact evaluation activities.

### ***Verbal autopsies***

Following several pilots of the use of the verbal autopsy procedure, PMI has taken the decision to no longer use verbal autopsies to assess impact on malaria-specific mortality. The specificity and sensitivity of verbal autopsies for several fever-associated diseases, such as malaria, is low and verbal autopsies cannot be used to determine malaria-specific mortality within acceptable bounds.

## SM&E Appendix 1: Minimum System Requirements at Various Health System Levels During Control and Elimination Phases

	Control (e.g., TPR >5% amongst all febrile patients)	Elimination (e.g., TPR <5% amongst all febrile patients)
Community Health Worker	Test and treat malaria appropriately Document and report all cases Receive supervision and feedback	Test and treat malaria appropriately Document and report all cases Receive supervision and feedback
Health Facility	Test and treat malaria appropriately Document malaria cases, diagnostic testing results, and case management in registers Cases are graphed monthly to quarterly to identify trends Aggregated data transmitted monthly to district and higher ideally electronically Receive supervision and feedback	Test and treat malaria appropriately Registers of individual malaria cases, diagnostic testing results, and case management documented Cases are graphed daily to weekly to identify trends that may require focal response Data transmitted weekly to district and higher ideally electronically Receive supervision and feedback
Admin 1 and 2 levels	Aggregate data of uncomplicated cases, severe disease, and deaths summarized monthly to allow an understanding of the burden by district and health facility catchment levels Analysis of data Data used to set priorities for interventions	Aggregate case and death data summarized weekly or monthly to allow an understanding of the needs by health facility catchment or village level to help set priorities for interventions Register of severe cases and deaths maintained and case investigations performed to identify program breakdowns and needs Provide supervision to health facilities and receive feedback
National	Monthly to quarterly tabulation of cases and deaths to assess control efforts and prioritize activities Analysis of data Data used to set priorities for interventions	Weekly tabulation of cases and deaths to assess control efforts and prioritize activities

## SM&E Appendix 2: Key Reference Manuals

1. [WHO Malaria Surveillance, Monitoring & Evaluation: A Reference Manual](#)
2. [Household Survey Indicators for Malaria Control \(English\)](#)
3. [Household Survey Indicators for Malaria Control \(French\)](#)
4. [Monitoring and evaluation of malaria-related routine data during the COVID-19 pandemic \(English\)](#)

---

# DATA INTEGRATION

---

## **\*New/Key Messages\***

PMI leadership considers “advancing global and PMI specific analytic capabilities” in order to optimize data-driven decision-making as the highest priority initiative.

PMI has established a new **Quarterly Report** activity, wherein PMI partner countries are requested to report malaria-related health data, disaggregated by month and by district, on a quarterly basis.

PMI’s **Malaria Data Integration and Visualization for Eradication (M-DIVE) platform** (formerly PMI Data Lake) serves as a platform to ingest, house, analyze, and visualize data (supply chain, financial, entomological, demographic, COVID-19, climate, etc.) from various sources, including the data reported from countries on a quarterly basis for use in-country and at HQ.

PMI country programs are required to contribute technical inputs and funding to the development of the M-DIVE platform and for better quality data. (Please see November 22, 2019 email from the PMI Coordinator).

PMI countries in sub-Saharan Africa are required to hire one additional PMI dedicated team member - a **Malaria Data Specialist** - to ensure PMI programs are appropriately staffed and to support the new data-related priorities. This is not a requirement at present time for the three small, subnational, targeted programs in Asia.

## **Introduction**

In 2018, PMI leadership determined that “advancing global PMI-specific analytic capabilities” is the highest priority initiative. This priority builds on more than a decade of extensive use of data for decision-making and impact-monitoring across PMI and partner country program efforts.

To spearhead advancing PMI’s data efforts, PMI leadership established the PMI Data Integration Team to work closely with both in-country and headquarters staff and partners to systematically link PMI’s different datasets and establish key questions for analysis. The PMI Data Integration Team is not focused on collecting or generating data at country level, but instead on supporting systematic, frequent, and strategic use of what PMI already has, including exploring what useful data insights PMI can push to field staff and NMCP end users.

As part of the PMI Quarterly Reporting requirement, PMI partner countries are requested to share monthly district-level malaria-related health data on a quarterly basis. The goal of this Quarterly

Reporting process is to better support NMCPs through more regular use of data for decision-making and to better monitor the impact of U.S. government investments in malaria control interventions (see “Frequently Asked Questions” at the end of this section for more details on the Quarterly Reporting process).

## Background

After experiencing a period of unprecedented improvements in malaria control, progress recently appears to have stalled -- with several countries reporting alarming increases in malaria cases, including eight countries that witnessed an estimated increase in malaria deaths of more than 20% compared with 2015. Perhaps even more concerning than the increases in cases, is the fact that neither countries nor the broader malaria community knows whether the plateauing is due to reduced effectiveness and coverage of vector control interventions, increased rainfall or increased case reporting.

PMI, the Global Fund and other development partners have been supporting MOHs in the collection and reporting of national malaria-related data, such as service delivery data from the HMIS, supply chain data, entomological monitoring data, as well as financial, climate, demographic, behavioral, and intervention coverage data from population-based surveys such as MIS and DHS.

At both country and global levels, this massive amount of data is generally **fragmented** and disparate, which makes the development of insightful analytics to inform decision-making unnecessarily time consuming. MOHs and PMI country teams often do not have the resources to make sense of siloed datasets.

At PMI Headquarters, the various malaria-related and program data have historically been maintained from the 27 PMI focus countries in separate spreadsheets and siloed databases that do not exchange information. Data collection, reporting, and **triangulation** has proved **cumbersome** and **labor-intensive**. Given the sheer scale and complexity of the PMI program, the Initiative’s currently limited ability to learn iteratively from the triangulation of existing, routine malaria-related data presents a significant management risk.

At the country level, the gradual transition from paper-based to digital health information systems (HIS) means more and better data can be used to inform decision-making. In addition to the widespread adoption of software such as DHIS2 for reporting malaria cases, countries have also prioritized investments in other HIS sub-systems such as eLMIS and the use of digital technologies for frontline workers. At PMI Headquarters we have also started making programmatic data easier to analyze by standardizing and geographically disaggregating the way we plan funding levels by key intervention.

## Goal and Vision for Data Integration

Goal: Integrating more advanced data analytics into malaria programming by accelerating processes for data utilization, sharing and integration across multiple, currently siloed data sources (from global and country programs and partners) -- shortening the data-to-action cycle for PMI and our partner governments.

Vision: Granular data from key sources (from global and country programs and partners) flowing regularly into an open digital environment for systematic use to inform decisions on resource allocation and to track progress.

## M-DIVE Platform

To optimize data-driven decision-making, PMI has developed and continues to expand a web-based Malaria Data Integration and Visualization for Eradication (M-DIVE) platform. The M-DIVE decision-support tool is designed to integrate previously siloed data, and automate the triangulation and analysis of relevant datasets, including epidemiological, supply chain, entomological, climate, demographic, programmatic, and financial data.

Since the M-DIVE platform is designed to be used at both global and country levels to facilitate more data-informed resource allocations, in support of NMCPs, each PMI country program is required to contribute at least 0.75% of their overall budget to support the development of the platform via the PMI project named: Malaria Data Integration and Visualization (M-DIVE). (Please see November 22, 2019 email message from the PMI Coordinator).

## Data-Specific Staffing Requirements on PMI Country Teams

To ensure PMI programs are appropriately staffed to support the new data related priorities, including the new Quarterly Report, missions in sub-Saharan Africa are required to hire a Malaria Data Specialist Foreign Service National (FSN) using the standard position description template. The role of the new Malaria Data Specialist will be primarily focused on boosting PMI's data management, visualization, reporting and use efforts as outlined in the PD. This new position will be 100% funded from each country's Malaria Operational Plan budget. This requirement has been communicated by the PMI Coordinator to Mission leadership (see October 22, 2019 message from the PMI Coordinator). Missions that have constraints to immediately follow through on this requirement should discuss with the PMI leadership team and are encouraged to contact headquarters to discuss a revised timeline for implementation of the requirement.

## Access to Data Created or Obtained with PMI Funding

Timely access to relevant data at appropriate levels of granularity allows for better tailoring of programs, reprogramming of resources, and measurement of progress – all of which become even *more* crucial as a subset of PMI focus countries and subnational areas move towards elimination. PMI is therefore committed to working with leadership among the global malaria community and leadership at the highest levels of host country governments to rally support for a culture of openness, a commitment to data transparency, and data driven decision making. Over the last ten years, USAID and the U.S. Government at large have made significant progress in driving program effectiveness and innovation of development programs by fostering a culture of openness. USAID has been a U.S. Government leader in advancing open data and currently publishes hundreds of datasets each year via the [Development Data Library \(DDL\)](#).

USAID’s standard award provision “Submission of Datasets to the Development Data Library” (DDL clause) describes the responsibilities of PMI funded partners for managing and sharing USAID-funded data. USAID partners have an obligation to submit to USAID data “created or obtained in performance of this award”. To ensure that PMI funded partners are able to implement this award provision, it is important that they manage data as a critical asset and deliverable.

PMI recognizes the importance of and sensitivities around country-level data ownership. PMI also supports implementation of the Open Data U.S. Presidential Executive Order, which requires that data created or obtained with funding from the U.S. Government shall be made freely available in open, machine-readable formats, while appropriately safeguarding privacy, confidentiality, and security.

USAID COR/AORs and PMI activity managers can work with implementing partners to help plan for high-quality data management. Some tools and best practices that organizations have found helpful for managing data include:

- create and maintain an inventory of datasets and documentation that are required deliverables per award provisions and guidelines;
- ensuring that data-related legal agreements and informed consent procedures document data access and re-use rights;
- validating that the partner has the capabilities to store and manage data responsibly and to create rich documentation that describe data and analyses;
- ensuring that the partner has the capabilities to document and manage any privacy and security risks associated with the data;
- documenting and describing procedures for (including timelines) submitting data and related documentation to a USAID-managed or approved digital repository, such as the Development Data Library and M-DIVE;

- As a part of the Monitoring, Evaluation, and Learning (MEL) Plan, drafting a Data Management Plan (DMP) that includes the inventory of datasets and describes the information outlined above.

Since different datasets have different levels of sensitivity, PMI has different expectations for access to data based on the data collected:

1. **Access to data generated from nationally-representative surveys must be publicly availed.** Access to datasets from household surveys (e.g. Demographic and Health Surveys, Malaria Indicator Surveys, Malaria Behavior Surveys) funded in part or entirely by PMI and implemented through the DHS Program remain standard, as countries that participate in the DHS Program authorize access to their data via memorandums of understanding, and all data is publicly availed as both survey results and datasets. However, access to data from an MIS, funded in part or entirely by PMI and implemented through other partners, has occasionally been problematic. Where PMI partially or entirely funds an MIS or other nationally-representative survey, access to the data (both survey reports and datasets) should be negotiated and agreed upon during the planning stages of the activity and before funding commitments are finalized.
2. **Access to malaria-related data generated from routine data systems should be formally negotiated by PMI.** Where PMI alone, or in collaboration with other USAID Mission health funding, supports efforts to strengthen routine data systems—technical assistance for HMIS and LMIS implementation and strengthening efforts, etc. —PMI access to these routine data (in de-identified, aggregated form) should be discussed and formally negotiated as part of expectation setting conversations. The minimum requirement for PMI support is for host governments to share data on routine indicators disaggregated by district and by month as part of the PMI Quarterly Report. Data sharing between PMI as a part of the information systems strengthening and overall PMI investments efforts is expected.
3. **Access to operational data (e.g. from ITN and IRS campaigns) and data generated from other surveys (e.g. EUVs and health facility surveys), studies (e.g. therapeutic efficacy studies and operational research), and other monitoring efforts (e.g. entomological monitoring and durability monitoring supported by PMI) should be publicly availed at appropriate levels of aggregation.**

PMI teams must raise these expectations around open data at the country-level during conception of an activity receiving PMI support and PMI leadership should be notified if challenges are encountered regarding ensuring adherence to this policy requirement. In this spirit, PMI is prepared to work with partner countries to develop formal data sharing agreements, with guidance from the USAID General Counsel, to ensure data sharing is properly (lawfully) negotiated with host country governments.

## Quarterly Report Process - Frequently Asked Questions

- 1. What is the purpose of the PMI Quarterly Report?** PMI has decided to implement a Quarterly Report in order to strengthen its data-driven approach within individual countries and across multiple countries and help shorten the data-to-action cycle. The immediate aim is to increase PMI accountability and stewardship of US Government funds. However, the purpose of the PMI Quarterly Report (QR) is multi-pronged:
  - 1.1. Monitor trends and learn across regions.** PMI believes that the timely evaluation of change within a country and the ability to sum across countries will increase our accountability and stewardship of US Government funds.
  - 1.2. Amplify and build on existing systematic data reporting and analytical efforts.** Many countries are already implementing either monthly or quarterly reports (e.g. monthly bulletins). For such countries, PMI would like to augment in-country efforts by integrating data that they can use (such as survey and funding data) to triangulate with the data they typically use for their reports. For countries that do not currently systematically analyze their data, the analytical output of the QR can serve that purpose.
  - 1.3. Track progress of implementing partners.** The quarterly report will involve an effort to standardize indicators reported by implementing partners for each technical area and benchmarking programmatic results. Because US foreign assistance budgets are under ever-increasing scrutiny, PMI needs to improve our capacity to track progress and setbacks and demonstrate that we can address all issues in a timely fashion.
- 2. Who is the audience?** Since the immediate aim is to increase PMI accountability and stewardship of US Government funds, the primary audience for this QR is PMI. However, as we continue to learn with countries and improve the way we integrate and visualize data submitted through the QR, there will be multiple audiences including NMCPs and PMI, and in the long-term, if MOHs agree to share findings with the broader community, local stakeholders, and development partners.
- 3. Who will have access to the data?** PMI takes data security and ownership very seriously. Data submitted by countries will not be shared outside of PMI without the approval of the host country governments. These data will be combined with data that is housed at PMI-HQ or available publicly (i.e. PMI financial data, PMI-procured commodities, Satellite Imagery, Climate, DHS, MIS) to develop the reports. NMCPs will also have access to the underlying raw datasets behind QR dashboards for their respective country.
- 4. How will analytical outputs produced by PMI HQ be shared with countries?** The visualization tool used for the QR analytical output will be via interactive dashboards -- housed on PMI's Malaria Data Integration and Visualization for Eradication (M-DIVE) platform. NMCPs will be able to directly access these QR dashboards together with the underlying raw datasets via the PMI-supported M-DIVE platform. The M-DIVE video tutorial (available [here](#)) provides an overview of the data integration platform and Quarterly Report dashboards using simulated data.
- 5. Is PMI rolling out a parallel data reporting system?** No. PMI is requesting NMCPs to share data from existing systems. PMI is deliberately not creating a parallel system to collect data at decentralized levels. Most countries already have their own data reporting systems (often DHIS2) that enable data flow from facilities to districts to central levels. PMI is not asking countries to collect those data in a new manner or to collect

additional data elements. Countries should use their own national reporting systems to download data to produce the PMI QR. **Since M-DIVE is interoperable with DHIS2, PMI's Data Integration will be working towards helping as many countries to automate the HMIS component of QR data transmission. Interoperability can also be established with eLMIS databases for more seamless data exchange.** (To learn more about the process of connecting M-DIVE to DHIS2 connection to transmit PMI Quarterly Report data, please view the tutorial video: [How to facilitate data exchange between DHIS2 & M-DIVE](#)) Until these database connections are established in your country, QR data do not need to be entered into the PMI QR template; the template is intended to serve merely as a tool for outlining which data and levels of disaggregation are desired, and secondarily, for countries unable to extract the data directly from their HMIS, as a template to be filled out. For example, the MOH's national DHIS2 instance can and should be used to generate a report containing the requested data on malaria cases and deaths disaggregated by district and by month, and the in-country PMI team can submit this same report to PMI HQ for the quarter. The MS Excel-based PMI QR data entry template is meant to serve as a tool to be completed at the central level -- only if other tools cannot be used to generate reports disaggregated by district. The PMI QR data entry template is not meant for district health officers to report their data.

6. **What types of capacity building efforts will accompany the QR?** PMI will continue to support MOH and NMCP efforts to strengthen data reporting systems (e.g. HMIS, LMIS, entomological monitoring). PMI continues to explore ways to improve capacity.
7. **What approach should countries use to gather the QR data for submission to HQ?** In-country PMI teams are strongly encouraged to work closely with their NMCP counterparts and, wherever applicable, other relevant MOH departments (e.g. HMIS unit or Central Medical Stores) to generate reports with the required data elements. In addition, in most countries, PMI is funding M&E and supply chain advisors through its various implementing partners, and these individuals can be tremendously helpful in generating the required reports. Ideally, the person most familiar with the national HMIS or LMIS database would play a role in generating the report.
8. **Once the data are submitted to HQ, who is producing the QR?** PMI HQ will be responsible for reviewing the data submitted and producing the data visualizations for the QR. Additional data will be provided from HQ levels (e.g. financial, climate, procurement and supply chain) for these visualizations, which we are continuously working to improve by incorporating more data sources and listening to your feedback. Working closely with their NMCP counterparts, it is anticipated that PMI in-country teams and NMCPs will also have a role in providing feedback into the analytical frame and in interpreting results from the analyses.
9. **What data use processes will be supported at HQ and country levels?** Collecting data from countries and even creating dashboards does NOT inherently result in better data use for decision-making. Through the QR process, organizational processes must be put in place to ensure data received from countries are analyzed and discussed with country teams, and that insightful feedback via QR dashboards are provided to countries -- with a recognition that appropriate analytical interpretation can only be performed by individuals who work in the nearest proximity to where the data originated for decision-making. At country levels, PMI will continue to support monthly or quarterly data review meetings at national and district levels.

10. **The new QR requirement will necessitate that PMI staff at country and HQ levels spend additional time on data gathering, cleaning, analysis, interpretation and acting on findings. Will this new Quarterly Reporting effort be met with additional financial and human resources?** Yes, an additional Malaria Data Specialist locally-employed staff will be hired in each country to join in-country PMI teams in support of this new effort. PMI is also investing in the development of the M-DIVE platform for data warehousing and analytics and to automate data ingestion, integration and visualization processes required by the new QR.
11. **Why not implement semi-annual reports?** Most of the countries we work in have highly seasonal malaria transmission. There are at least four times a year when we should explore, based on available data, whether PMI should be making changes or stay the course because there were no changes from previous years. Implementing QR allows PMI to become more responsive to changing situations in the countries it supports.
12. **Why are we asking for sub-national data (district level of disaggregation)?** In most countries, there is great variability in how malaria occurs geographically. Collecting geographically-disaggregated data will allow for more focused analysis and better allocation of resources. Moreover, PMI increasingly needs to become better at tracking the performance of PMI-supported country programs.
13. **Are we asking for results for both PMI-supported and non-PMI-supported programmatic results?** To achieve a better, more comprehensive understanding of malaria control interventions implemented, the QR has evolved to now focus on both PMI-supported and non-PMI supported programmatic results (e.g. IRS and ITN Mass campaigns). Over time, it is anticipated that the more comprehensive data on programmatic results supported by NMCPs, PMI and other donors will help countries and the broader malaria community improve the way the impact of interventions is measured and resources are allocated while also showing whether investments are adequately distributed.
14. **Do we run the risk of taking power away from NMCPs by collecting this data?** PMI's primary purpose is to strengthen NMCPs. By working together closely on collecting and analyzing the data for the QR, PMI intends to build on NMCPs existing efforts to improve data-driven decision-making and strengthen national malaria surveillance. To further inform national efforts, PMI HQ also intends to complement existing datasets available in-country with some of its other data sources (e.g. population-based survey MIS and DHS, funding levels by district, commodity procurements, IRS and insecticide resistance data from centrally-funded implementing partners) as well as provide insights into what is happening in neighboring countries. PMI intends to enhance NMCPs' existing efforts to use data to make decisions by integrating data sets that previously have been difficult to synthesize (e.g. population-based survey MIS and DHS, funding levels by district, commodity procurements, IRS and insecticide resistance data from centrally-funded implementing partners). NMCPs can use these integrated data sets and visualizations in the quarterly reports to inform their decisions.
15. **If we believe data quality is poor and/or the monthly data has not been validated by the country, should we still submit to HQ? And will there be opportunities to re-submit validated data at a later stage?** Recognizing that countries continually make efforts to address data quality issues, PMI HQ still firmly believes that insights can be gained by systematically compiling and analyzing data. Local context will be used to interpret results from these analyses. Each quarter, countries will have an opportunity to provide updated datasets (even if these were previously submitted).

---

# OPERATIONAL RESEARCH AND PROGRAM EVALUATION

---

## **\*New/Key Messages\***

**New OR Mechanism:** PMI INFORM is a new central operational research (OR) and program evaluation (PE) mechanism with the objectives of implementing OR and PE activities, supporting an annual OR prioritization process, and tracking and disseminating findings to inform programs and policies.

**Updated OR Prioritization Process:** Beginning with FY21 funding, the annual OR prioritization will include broader input and funding where relevant from additional stakeholders, e.g., PMI INFORM, Bill and Melinda Gates Foundation, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, in addition to country and technical team input. Annually, the U.S. Global Malaria Coordinator will announce a narrow set of approved OR/PE priorities for core-funded OR/PE and MOP-funded OR.

**MOP-funded PE Review Process:** MOP-funded PE priority topics should be identified by country teams and do not fall within the annual PMI OR prioritization process. Once the OR Committee approves the concept note for a MOP-funded PE, the study can move forward as appropriate. OR Committee review is not required for MOP-funded PE protocols unless a full protocol review is specifically requested by the OR Committee, OR Management team, or PMI senior leadership.

**MOP-funded OR/PE:** All proposed OR and PE topics should be captured under the OR/PE heading in both the narrative and Table 2 and at minimum include a clear question, proposed study design, study implications, allocated budget and mechanism.

**Research Determination Process/ Human Subjects Review:** All OR and PE supported by PMI (for both core and MOP-funded OR/PE) must undergo human subjects review. If CDC staff persons are involved in the study, then the review must include CDC. The review process to the extent feasible will be streamlined to a single institutional review.

## **Introduction**

Over the past 15 years, PMI has strived to generate evidence through both operational research (OR) and program evaluation (PE). Both PE aimed at improving ongoing program activities in the local setting and OR to generate generalizable information have been critical in improving the successful implementation of PMI malaria control strategies and in achieving PMI's goals (See Table 1 below for distinguishing PE from OR). Since 2006, PMI has supported over 100 OR studies addressing a range of programmatically-relevant topics and continues to do so.

The guidance below focuses on objectives and priorities, guiding principles and processes for proposing MOP- or core-funded OR or PE for PMI country teams and headquarters interagency technical teams.

## PMI OR and PE Objectives

PMI will support program- and policy-relevant OR and PE that will:

- Improve effectiveness of existing interventions and increase scale-up and quality, including assessing combined interventions (e.g., ITNs and IRS)
- Evaluate ways to mitigate insecticide and drug resistance
- Identify and assess improved and cost-effective approaches to monitoring changes in malaria epidemiology, particularly for documenting impact of malaria control efforts
- Identify and assess approaches to improve the capacity of health systems to optimize delivery and quality of malaria interventions
- Assess new interventions that offer the potential for use by PMI-supported programs in the near future
- Assist in optimizing program efficiency by addressing bottlenecks in malaria prevention and control

## PMI OR Priority Setting Process

Beginning in FY2018, the U.S. Global Malaria Coordinator announced a new process for setting OR/PE priorities. The OR/PE priority setting process aims to generate a strategically narrow, focused set of scientific and OR/PE priority questions based on PMI senior leadership, technical team, and country consultation each year. Beginning with FY2021 priorities, this process will evolve to include input and funding where relevant from a broader set of stakeholders including: national malaria control programs (NMCPs), Bill and Melinda Gates Foundation (BMGF), and Global Fund to Fight AIDS, Tuberculosis, and Malaria (GF), to be coordinated by the new PMI OR implementing partner.

### *Annual OR Prioritization*

The annual OR/PE prioritization process applies to all core-funded OR and PE proposals as well as MOP-funded OR. Country-specific, MOP-funded PE proposals should be based on country priorities and fall outside the prioritization process. All MOP-funded, country OR or PE proposals will be included in the country MOP or reprogramming request submission and captured under the OR/PE cost category in Table 2. PMI technical teams will be requested to convene each year to identify, discuss, and prioritize critical operational and implementation bottlenecks that require core OR/PE funds. Each technical team will be asked to submit a ranked priority list of up to two proposals to the OR Management team near the end of the MOP season (early CY Q4). Approval of the MOP that includes OR/PE funding does not necessarily constitute approval of the MOP-funded OR or PE proposal.

The list of proposed ideas for core-funded OR/PE and MOP-funded OR priorities submitted by the PMI interagency technical teams and country teams will be reviewed by the OR Management team and the

OR Committee. An annual consultative meeting will be convened to review submitted PMI priorities as well as priorities from other stakeholders with the aim of generating an annual prioritized list of topics for PMI-funding alone as well as co-funding with other donors, e.g., BMGF and GF. The outputs of this meeting along with the recommendations from the OR Management team will be reviewed with PMI senior leadership. Ultimately, the U.S. Global Malaria Coordinator will approve and announce the core-funded OR/PE and MOP-funded OR priorities and identify an initial overall funding envelope for the year.

### ***Guidelines for Proposing OR/PE Activities for PMI Funding***

The following guiding principles were developed to assist PMI interagency technical teams and country teams when considering ideas for OR/PE priority submission (MOP or core-funded). These guidelines apply to all PMI-funded OR/PE activities. In general, as previously mentioned, OR/PE funded with PMI country-specific MOP funding responds to country-specific priorities and needs while core-funded OR typically addresses broader issues that are relevant across PMI's programs. Core-funded OR may be conducted across multiple countries and may address fundamental questions to achieve optimal impact from proven interventions.

#### ***Guiding principles for country-led (MOP-funded) research:***

Country-led (MOP-funded) study ideas should be oriented towards PE and improving:

1. Coverage of population infected/at-risk
2. Quality of intervention
3. Efficiency in intervention delivery

Country teams can also propose other ideas but should provide justification on the broader applicability of anticipated study results.

In the MOP submission, any OR or PE proposals must at minimum include a clear OR/PE question, proposed evaluation design, implications of either a positive or negative finding(s), proposed mechanism for implementing the study, and a complete budget.

#### ***Guiding principles for core-funded research:***

Core-funded study ideas should focus on:

1. Better reducing malaria transmission, disease burden and/or mortality;
2. Testing effectiveness of new or evolved priority interventions and strategies or combinations thereof;
3. Exploring new metrics and mechanisms to assess the impact of interventions.

Additional considerations for OR/PE priority submissions include:

- Is the idea strategically important to PMI (weigh against guiding principles)?
- Which/how many countries are struggling with issues that this research will help address?

- How would the anticipated results of the research be used (what specific strategies, policies, guidelines, funding decisions, etc. will be informed)?
- Has this been funded by PMI in the past?
- Are there other groups already doing this research?
- Are there other donors that would be interested in collaborating to fund this?
- What research are other donors funding on this topic and how does it relate with the scope?
- The estimated time from study conception to likely time of intervention implementation, result dissemination, and/or policy change.

Initial proposals (<1 page) from technical teams, should at minimum include a clear OR/PE question, proposed evaluation design, implications of either a positive or negative finding(s) on our malaria control and elimination programs, proposed mechanism for implementing the study, and a notional budget.

Although PE/OR should be relevant to country needs, completed in a timely manner, and prepared to disseminate/use results within 2-3 years, it is recognized that some high priority OR/PE activities may take several years to complete. Therefore, PMI does not impose restrictions on study length nor likely time from study start to intervention implementation for PMI OR studies. However, when considering which of several high priority studies to fund, the time from study start to likely time of intervention implementation and policy change will be considered, recognizing that research itself can accelerate the timeframe to policy adoption and intervention implementation.

## Funding Sources and Channels for PMI Operational Research and Program Evaluation

Funding for PMI OR/PE activities may come from two places within the PMI budget:

- **PMI country/MOP budgets:** PMI OR/PE studies funded with country MOP funding are generally conceived and designed by PMI country teams in consultation with NMCPs and local partners, and they are frequently implemented by local research groups. These tend to be shorter-term studies (duration of 12-24 months) aimed at generating results primarily applicable to the country context. The amount of country funding proposed for country-specific OR/PE activities vary by country and by year.
- **PMI core funds allocated for OR/PE priorities:** PMI OR/PE studies conceived of and funded centrally with PMI core funding generally address broader issues applicable across many PMI countries and tend to be larger studies with higher budgets than country-generated OR/PE activities. They may involve two or more PMI countries and/or require several years to complete. The amount of core funding made available for priority OR/PE activities varies from year to year depending on several factors including the overall total PMI budget, other PMI core budget priorities, the number of interagency core funded concept notes proposed and prioritized for funding, and the incremental funding needs (e.g., mortgages) for multi-year studies funded in previous years.

Most PMI support for OR/PE is in the form of funding directed to implementing partners to carry out the research study. PMI support also includes in-kind support for commodities (see “Commodities for OR” section below) and interventions and PMI headquarters and field staff time. Please consult the section titled “What is considered under PMI support for OR/PE?” for details.

Whether the source of PMI-supported OR/PE studies is core- or country- (MOP) funding, a variety of mechanisms and technical collaboration and oversight by PMI staff are available to carry out PMI funded research. Which mechanism(s) is selected depends on a variety of factors including the research question, country partner context, level of engagement of PMI technical staff, etc. Often several mechanisms might be needed to implement a study, e.g., the field implementation partner, GHSC-PSM for any procurement needs, and CDC IAA for any TDY TA or laboratory support.

Options include:

1. PMI’s new OR/PE-specific central mechanism: PMI Insights for Malaria (INFORM);
2. USAID country bilateral and central implementing partner mechanisms including USAID mechanisms that provide direct funding to local research institutions;
3. Research collaboration involving CDC and/or USAID headquarters technical staff and a USAID country bilateral or central implementing partner mechanism. For USAID Central mechanisms not managed by PMI, PMI staff would need to be directly engaged in protocol development, research implementation oversight, data analysis, etc.;
4. Use of the CDC Interagency Agreement to support OR/PE activities conducted by CDC (see important restrictions against third party transfers below).

For option (1) above, please reach out to PMI INFORM AOR with questions regarding project scope and timeline. PMI INFORM will be the default mechanism for all **core-funded** OR/PE unless a strong rationale exists for an alternative mechanism. PMI INFORM can also accept field support for MOP-funded OR/PE.

The CDC Interagency Agreement (IAA) includes policy restrictions for USAID appropriated funding to pass to CDC and on to a third party. If a third party transfer under the CDC IAA is being considered by PMI teams, early discussion is needed to determine whether or not the conditions exist to request an exception. Prior approval of an exception request is required before OR/PE study planning moves forward. The relevant IAA language states: *“All transfers of USAID funds under this agreement to third parties, including partner country government entities, are prohibited unless approved in writing by the AOR/COR.”* In particular, exception requests for PMI supported OR/PE through CDC, including with a third party transfer (to a non-government entity), can be considered if there is not a bilateral or global USAID mechanism that can carry out the proposed OR/PE. As there is now a dedicated, central mechanism to support OR/PE activities (PMI INFORM), the OR Management team does not anticipate exception requests for third party transfers under option four during the PMI INFORM award timeframe or when an existing bilateral/global USAID mechanism exists. Direct funding of MOH/NMCP/host

country governmental institutions (G2G) can be considered only through a USAID G2G mechanism and only following the completion of appropriate financial management system audits etc. Funding MOH/NMCP/host country government institutions (G2G) through CDC with USAID appropriated funding (PMI or all other types of funding) is prohibited by USAID agency-level policy restrictions. (See PMI Policy, 'CDC Interagency Agreement' section.)

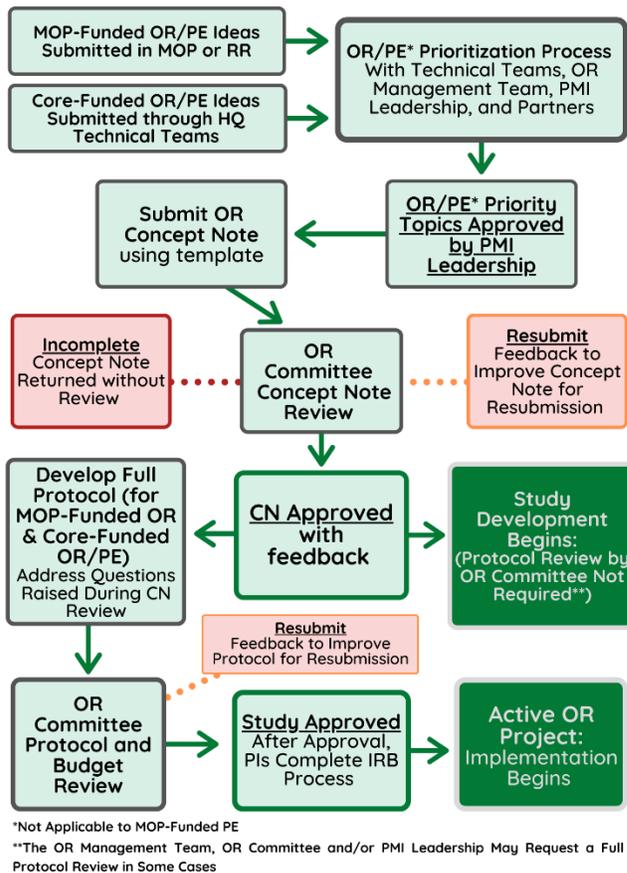
It is expected that CDC will be a key implementer of PMI-supported OR, as specified in the Lantos-Hyde Act, whether an exception is approved to rely on CDC staff and their research collaboration with a PMI country local partner or through CDC staff research collaboration with the research partner(s) accessed through a USAID mechanism. As with all PMI supported activities, PMI supported OR will be implemented with an interagency approach.

## **Co-funding of OR Activities**

PMI co-funding of OR/PE activities with other donors and organizations occurs and is highly encouraged, co-funding opportunities will be explored proactively with BMGF and GF as part of the new, annual OR prioritization process. Co-funding can include funding received by USAID from another donor that USAID obligates into an OR/PE mechanism or funding programmed in close collaboration/parallel to other donors to the same implementing mechanism/organization. Specifically, parallel funding involves two or more organizations agreeing to jointly fund a study with an implementing partner(s), but with each funding organization flowing funds through their unique agreement/mechanism separately, supporting defined elements of the study. When OR/PE activities receive funds from multiple sources, the concept notes should clearly explain which components of the study are being covered by PMI and the specific cost(s) associated with these components as well as summarize the co-funding from other sources for the study. The concept notes should clarify the mechanism through which each source of funding will flow. Even if contributions are limited to PMI staff time or provision of commodities, these are considered as PMI support and a concept note outlining these contributions in the context of the full study must be submitted.

## **Study Development, Review, and Approval Process**

**Figure. OR Committee Review Process**



### ***MOP-funded PE/OR inclusion in the MOP and concept note development***

Under the new OR/PE prioritization process, MOP-funded OR priorities will be announced by the U.S. Global Malaria Coordinator each year. Following the announcement of the OR priorities and budget, the OR Management team will solicit concept notes for MOP-funded OR ideas approved in the annual prioritization process or PE ideas approved in the MOP review process from country teams (PE/OR Concept Note template provided in OR Appendix 1). **concept notes are required for both MOP-funded OR and PE studies.** Only concept notes for approved MOP-funded OR priorities will be accepted. Please contact the OR Management team if a topic that has not been approved by leadership arises in the country prior to concept note development. For **new** MOP-funded PE proposals to be funded with reprogrammed funds, country teams must obtain reprogrammed request approval prior to concept note submission. Note that reprogramming approval does not constitute approval for the PE proposal. When developing concept notes country teams should ensure that they will address a pressing country need (i.e. programmatic and/or implementation bottlenecks), are feasible to answer considering the budget and length of time required, and align with the country operational research strategy or priorities.

Concept notes will be reviewed by the OR Committee and appropriate technical team staff designee(s), as needed, during a single review period each year. Deadline reminders for concept note submission are sent out PMI-wide one month in advance. Although ad hoc reviews for new proposals are possible, all planned OR/PEs should aim to submit their concept notes by the annual submission deadline.

The concept note will first be screened by the OR Management team for completeness within **one week** of submission. Incomplete concept notes will be returned without review. Complete concept notes will be sent to the OR Committee (or designee) for technical review and feedback and a response returned to the study point of contact (POC) within **two to three weeks** of the submission due date.

Concept notes reviews can have one of two outcomes:

1. **Approved:** The OR Committee and Management team review determines that the proposed study will provide valuable information and is technically sound and can proceed to protocol development which must incorporate any outstanding questions or issues identified during the review; or
2. **Resubmit:** The OR Committee and Management team review determines that the concept has significant problems with the study design as proposed and recommends that the concept note be revised and resubmitted, providing extensive feedback to help guide revisions. Status of concept notes, protocols and budgets allocated to each study will be reviewed quarterly with PMI senior leadership.

**MOP-funded PE studies are not required to submit a protocol for OR Committee review, unless specifically requested by the OR Committee, OR Management team or PMI senior leadership, and can proceed to implementation following concept note approval.**

### *Protocol review of MOP-funded OR studies*

Protocols for MOP-funded OR must be submitted to the OR Management team for OR Committee review prior to submission to relevant Institutional Review Board approval(s). Protocols will be reviewed to ensure the study is technically sound and is consistent with what was proposed in the concept note, including study budget and timelines. Outstanding questions or issues identified by the OR Committee during concept note review must be addressed in the protocol. Any changes to the study research question/objectives, design, methods, etc. that have occurred between concept note approval and protocol submission must be explained. Protocol review feedback will be returned to the study POC within three weeks of the protocol submission due date.

## **Core-Funded OR/PE**

### *Core-funded concept note development process*

Relevant HQ interagency technical teams and country teams along with PMI INFORM (if applicable) will co-develop concept notes for core-funded OR/PE priorities approved by PMI senior leadership. If the idea is cross-cutting, all relevant interagency technical team representatives should be included.

Study teams will submit the concept note to the OR Management team for technical review by the OR Committee. The OR Management team will communicate timelines and due dates for core-funded concept notes with the PMI interagency team.

Concept notes reviews can have one of two outcomes:

1. **Approved:** The OR Committee and Management team review determines that the proposed study will provide valuable information and is technically sound and can proceed to protocol development which must incorporate any outstanding questions or issues identified during the review; or
2. **Resubmit:** The OR Committee and Management team review determines that the concept has significant problems with the study design as proposed and recommends that the concept note be revised and resubmitted, providing extensive feedback to help guide revisions.

Once the concept note is approved, study teams will submit a full OR/PE study protocol and budget that addresses questions raised, if any, during the concept note review to the OR Management team for OR Committee review. Protocols can be approved or requested to be resubmitted.

Upon approval of the protocol and budget, the core-funded OR/PE project is considered active and can be submitted to relevant ethical review boards prior to implementation commencing. Status of concept notes, protocols and budgets allocated to each study will be reviewed quarterly.

## Distinguishing Operational Research and Program Evaluation

The goal of the OR Management Team is to ensure all PMI-funded OR and PE are conducted in a scientifically and ethically sound manner. The distinction between research (systematic investigation designed to develop or contribute to generalizable knowledge) and program evaluation (systematic investigation designed to assess a specific public health action(s) to improve its outcome and impact) is principally about the primary intention of the generated information. PMI's authorizing legislation, the Lantos-Hyde Act<sup>171</sup>, defines OR as the "application of social science research methods, statistical analysis, and other appropriate scientific methods to judge, compare, and improve policies and program outcomes from the earliest stages of defining and designing programs through their development and implementation with the objective of the rapid dissemination of conclusions and concrete impact on programming." Operational research is not different in principle from "research", but is focused primarily on service delivery and effectiveness, feasibility at scale, cost, and other such factors. PE is

---

<sup>171</sup> Lantos-Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act, 2008.

primarily informing the local setting with known/proven tools, whereas, OR is primarily informing more generalizable knowledge about new tools or strategies. This does not mean that the information from PE is not relevant elsewhere; nor does it mean that the OR generated knowledge is not also relevant to the setting where the work is being done.

PMI undertakes many monitoring and evaluation (M&E) activities which include standardized surveillance and M&E/PE approaches that are repeated across countries (e.g., TES, MIS, DHS, entomological assessment tools, LLIN durability monitoring, MBS, project midline and end-line evaluations, etc.) and are routine. These do not require OR committee review unless study components are added that would shift them toward research (see below guidance for health facility surveys).

With the recognition that PMI undertakes a broad spectrum of activities to inform and improve our programs from routine monitoring to OR, the table below provides guiding principles for distinguishing routine monitoring (exempt from OR Committee review) from PE and OR. Exemption or level of review by the OR Committee may not always align with the review needs of an ethical review committee. Study investigators' initial assessment of research vs. non-research (or OR vs PE for OR Committee review purposes) must be submitted for review and concurrence by an appropriate human subjects body.

**Table. Distinguishing monitoring, evaluation and research**

	Monitoring	Program Evaluation	Operational Research
<b>Definition</b>	A continuous process used to track, understand, and correct activities and programs as they are implemented.	A periodic activity to assess whether specific activities or interventions, or an entire operational program have reached their intended goals and have resulted in the desired outcome and/or impact.	The application of social science research methods, statistical analysis, and other appropriate scientific methods to judge, compare, and improve policies and program outcomes from the earliest stages of defining and designing programs through their development and implementation with the objective of the rapid dissemination of conclusions and concrete impact on programming.
<b>Purpose</b>	To improve the performance or activities and programs (continuous).	To evaluate an established program with known/proven tools to inform the local setting.	To assess new tools or strategies to generate generalizable information to inform programs/policies.
<b>Research/ Human Subjects Review?</b>	No*	Yes/No	Yes
<b>CN reviewed by OR Committee?</b>	No	Yes	Yes
<b>Protocol reviewed by OR Committee?</b>	No	Core funded PE: Yes MOP funded PE: No, unless requested by the OR team during the CN review	Yes

Although most routine monitoring activities are not submitted to institutional review board(s), human subjects review is required for any **CDC staff** persons intending to publish these results. To this extent, CDC Malaria Branch has developed a “blanket” non-research determination protocol to help encompass these activities reducing the burden of submitting each activity separately. Please work with the OR Management Team to ensure all needed prior review is appropriately sought.

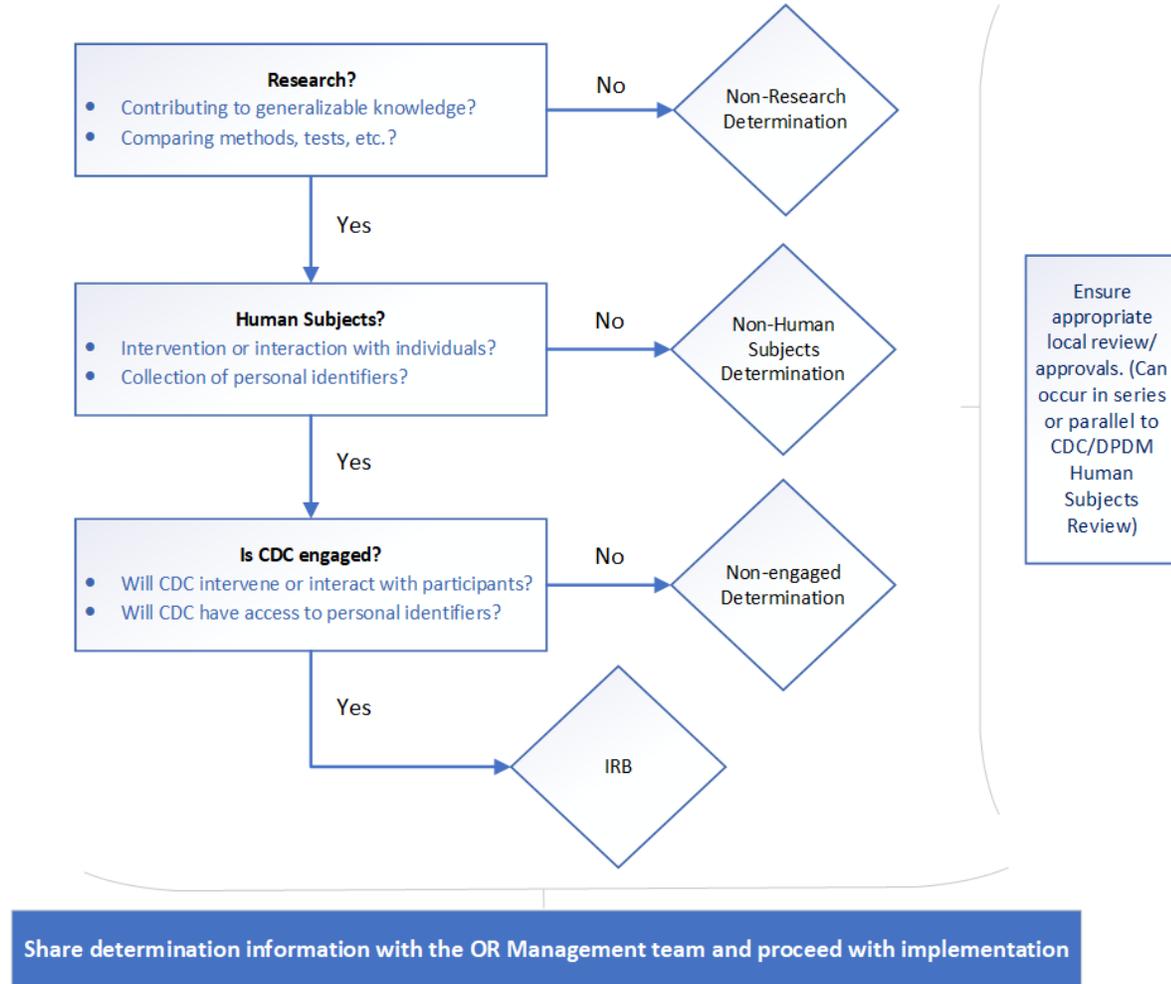
## Research Determination Process

Research determination is the systematic evaluation of whether a proposed activity constitutes research and involves human subjects and is undertaken by an independent ethical review board/unit. There is an ethical and legal obligation to ensure that individuals are protected in all public health research activities. As much as possible, PMI-funded studies should streamline this review to rely on a single Institutional Review Board (IRB). All PMI-funded OR and PE are required to undergo appropriate human subjects review by a relevant IRB. In most cases, CDC staff person(s) will be involved in the OR/PE projects requiring that this review include CDC which has an established Federal-wide Assurance (FWA) and IRB for ethical review. USAID does not maintain its own IRB and relies on implementing partners to follow appropriate regulations and obtain the necessary approvals to ensure the protection of human subjects.<sup>172</sup> The appropriate CDC staff as part of the study team must ensure submission of the protocol, consent forms, research determination form and all other relevant supporting documents to the Division of Parasitic Diseases and Malaria (DPDM) Human Subjects Office for review and human subjects determination. The figure below outlines the key questions that guide the DPDM Human Subjects Office’s human subject determination process. Ultimately, the study team will be responsible for communicating to the OR Management team the final research determination from an ethical review board. All studies determined to be research by an ethical review board will need to submit their full protocol for review by the OR Committee even if they were initially submitted as MOP-funded PE.

---

<sup>172</sup> Please refer to ADS chapter 200 “Protection of Human Subjects in Research Supported by USAID” for more information: <https://www.usaid.gov/sites/default/files/documents/1864/200mbe.pdf>

**Figure. Guiding questions for CDC’s Human Subjects Review**



## Facility Surveys and Blood Collection in the Context of OR/PE

PMI supports periodic health facility surveys for a variety of reasons, most often to assess the current status and quality of service delivery and to inform improvement activities. Survey designs that follow standard health facility survey practices (observations, exit interviews, record reviews, slide re-checking, etc) do not need OR Committee Review and are not considered OR. However, the addition of secondary blood collection for confirmatory diagnostic testing or molecular investigation is NOT considered standard. Methodologies involving blood sample collection as part of a facility survey are subjected to the OR/PE review process.

PMI-supported analysis of blood samples collected with external support (i.e. PEPFAR surveys, non-PMI funded studies) may also qualify as OR/PE and be subjected to the OR/PE process. Please consult with the OR Management team for a determination of whether the proposed PMI-supported analysis will require OR committee review or is considered to be a monitoring activity.

## What is Considered Under PMI Support for OR/PE?

All OR/PE activities receiving PMI support need to be tracked by the OR Management team. Support includes use of PMI MOP or core funds by an implementing partner to carry out the study, as well as use of PMI-procured commodities, deployment of PMI interventions for the express purpose of the study, and dedication of PMI field and/or headquarters staff time to the development, implementation, and/or analysis of the study. In such scenarios (e.g., the recent CDC International Task Force funded COVID-19 proposals where PMI support is limited to staff time and commodities), the study concept note and/or protocol will need to be submitted to the OR Management team for review by the OR Committee, if appropriate, and senior leadership detailing the level of PMI engagement/contributions to the study, relevance of the study and collaboration with PMI, the institutions involved, and the status of IRB review including CDC Human Subjects Review, if applicable. Semi-annual OR/PE updates will be requested for these activities by the OR Management team.

## Commodities for OR

For OR studies that require commodities (including RDTs, ACTs, ITNs, etc.), it is recommended that orders are placed through the PMI supply chain project so that quality of the commodities can be assured. Once a concept note is approved, the PMI point of contact(s) must inform the Supply Chain Team of the anticipated order and study timeline as soon as possible, to facilitate timely placement of the order and arrival of supplies in country. Contact can be made directly with the Supply Chain Team or through the OR Management team. **The study budget in the concept note should include specific lines and estimated costs for commodities that will be purchased through the supply chain project.** For core-funded OR commodity needs, the estimated funding for commodities outlined in the study budget will be directed to the centrally-managed malaria commodities procurement project. For MOP-funded OR commodity needs, country teams should specify at least two mechanisms for the OR study – the mechanism implementing the research and the PMI centrally-managed malaria commodities procurement project with the estimated commodity costs directed to the commodity procurement mechanism. Please consult the commodity ordering lead time table available in the Supply Chain section for procurement lead times and plan accordingly.

## Study Budget

The OR Committee review of concept notes requesting PMI funds covers technical and budgetary aspects of the concept note. A well-thought out budget (using the template provided in Appendix 1) is therefore required prior to submitting the concept note to the OR Management team. The expectation is that there should not be a significant difference between the budget proposed in the concept note and the protocol budget. A significant difference is defined as a difference greater than 10% between the original concept note budget and final protocol budget. If a protocol budget is greater than 10% of the budget proposed in the concept note, the study POC must submit a justification (less than half a page) to the OR Management team along with the

protocol. Efforts must be made to develop a detailed budget at the concept note stage since study budgets are required for OR Management team and OR Committee review.

Any changes in the technical approach (including research questions/objectives, design, study sites, and methodology) or the budget (exceeding 10%) of **approved protocols/ongoing studies** requires re-submission and re-approval by PMI Senior Leadership. PMI Senior Leadership approval is required before additional funds are requested for ongoing MOP-funded studies through reprogramming or action memos for core-funded studies.

## Responsibilities of the OR Management Team and OR Committee

The PMI Senior Leadership Team (U.S. Global Malaria Coordinator, Deputy Coordinator(s), USAID Malaria Division Chief, and CDC Malaria Operations Unit Lead) is responsible for providing overall annual budget guidance and approval of OR/PE priorities.

Responsibilities of the OR Management team include:

- Coordinate with PMI Senior Leadership Team on OR priorities
- Coordinate with GF and BMGF on Workstream OR
- Manage the new OR central mechanism
- Manage OR communications to PMI HQ and Country teams
- Manage concept notes, track proposals/protocols/reports/budgets and report to PMI senior leadership on a quarterly basis
- Report out on OR priorities, results, and developments to PMI's internal and external stakeholders
- Oversee appropriate dissemination of findings and their decision implications at relevant technical fora

The OR committee includes representatives from various PMI technical teams. Key responsibilities of the OR committee include:

- Coordinate with technical teams and OR Management team to develop a prioritized list of OR/PE priority ideas yearly
- Review concept note, protocols, and budgets to support the development of scientifically strong OR/PE studies

The OR Committee or the OR Management Team is not responsible for handling study implementation or study roll-out challenges. Principal investigators of PMI-funded studies must be fully qualified to implement the work stipulated in the protocol, oversee budget and staff, and comply with all local requirements for research including IRB clearances. OR Committee or Management team members should not be involved in study implementation and/or negotiations of implementing partners in their OR Committee or Management capacity. OR Committee or Management team members can provide technical input in their technical capacity as a member of the PMI team at large and/or a specific PMI

interagency technical team if asked but such advice should not be considered OR Committee/Management team guidance or a substitute for OR Committee review and approval of a concept note or protocol. If an OR Committee or Management team member is involved in study design or implementation, they are recused from Committee deliberations regarding the study in question.

## **Dissemination**

Most PMI-funded completed and on-going OR studies are searchable through an external website hosted by [MesaTracker](#). For all PMI-funded studies, a dissemination plan should be outlined early in the concept note stage ensuring timely sharing of findings for action by NMCP/other implementers and encouraging use of results even before the final publication.

### ***Reporting Requirements for Ongoing OR/PE Activities***

PMI-funded OR/PE activities are required to submit **semi-annual progress reports** regardless of funding mechanism. Progress reports must provide information regarding study activities for the preceding six months. A report covering activities March-August will be due in September; a report covering activities September-February will be due in March. A template to guide preparation of the progress report can be found in OR Appendix 2. Information submitted in progress reports will be used to monitor study implementation including any delays, e.g., impact of COVID-19, coordinate among studies, and for internal or external updates including the PMI annual report, Research Reports to Congress, the PMI.gov website, and MesaTracker. A completed study questionnaire found in OR Appendix 3, is required at study completion in addition to other study outputs (e.g., final report, data presentation). The completed study questionnaire aims to capture any programmatic implications or policy changes as well as any capacity built in the country as a result of the study.

**Conference abstracts and manuscript drafts resulting from the study must also be submitted for PMI Policy Clearance prior to conference/journal submission (see Section A for additional guidance on clearance) AND final versions sent to the OR Management team upon acceptance.** Please note that submission of abstracts and manuscripts to the OR Management team is not for review but for notification purposes only. Only PMI headquarters or country staff can submit a manuscript or abstract for clearance (i.e., manuscripts of PMI-supported partners must be submitted by the PMI headquarters or country point-of-contact for that project). If there are CDC co-authors, please ensure that the document has been fully cleared by CDC before submitting for PMI Policy Clearance.

### ***Authorship of Publications Resulting from OR Activities***

PMI strongly encourages staff publication of work. Early discussion of authorship with all parties involved in the design, implementation, data analysis, interpretation, drafting, and revision of

manuscripts resulting from PMI-funded OR/PE activities is necessary. A widely accepted International Committee of Medical Journal Editors guidance on defining roles of authors and contributors is available [online](#). Securing funding alone does not merit co-authorship.

Prior to preparing manuscripts and abstracts for submission to scientific peer-reviewed journals and conferences, authors should consider reviewing and adopting the reporting guidelines developed for different study designs such as:

- CONSORT for randomized trials ([www.consort-statement.org](http://www.consort-statement.org))
- Clinical Trials (<https://clinicaltrials.gov/>)
- STROBE for observational studies (<http://strobe-statement.org/>)
- STROME-ID extension of STROBE for Reporting of Molecular Epidemiology for Infectious Diseases ([http://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(13\)70324-4/abstract](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(13)70324-4/abstract))
- PRISMA for systematic reviews and meta-analyses (<http://prisma-statement.org/>)
- PRISMA-P for systematic reviews and meta-analyses protocols (<http://www.prisma-statement.org/Extensions/Protocols.aspx>)
- STARD for studies of diagnostic accuracy ([www.stard-statement.org/](http://www.stard-statement.org/)).
- SRQR Standards for reporting qualitative research: a synthesis of recommendations (<http://www.ncbi.nlm.nih.gov/pubmed/24979285>)
- CHEERS Consolidated Health Economic Evaluation Reporting Standard Statement ([http://www.ispor.org/Health-Economic-Evaluation-Publication-CHEERS- Guidelines.asp](http://www.ispor.org/Health-Economic-Evaluation-Publication-CHEERS-Guidelines.asp))
- Reporting guidelines for implementation and operational research (<http://www.who.int/bulletin/volumes/94/1/15-167585/en/>)
- Gather for studies that calculate health estimates (<http://gather-statement.org/gather-statement/>)

### ***Guidelines for Listing PMI and Agency Affiliations for Publication***

Author affiliations should correctly indicate for all PMI staff (country and HQ) both their agency affiliation (i.e., CDC or USAID) and U.S. President's Malaria Initiative. Staff from PMI/USAID supported projects should include the Project name in their affiliations, not just their agency, e.g., PMI AIRS Project, Abt Associates. Standard language for PMI staff:

- For USAID HQ staff: U.S. President's Malaria initiative, USAID, Washington DC.
- For USAID field staff: U.S. President's Malaria Initiative, USAID, City and County of post.
- For CDC HQ staff: U.S. President's Malaria Initiative, Malaria Branch, US Centers for Disease Control and Prevention, Atlanta, GA.
- For CDC field staff: U.S. President's Malaria Initiative, US Centers for Disease Control and Prevention, City and Country of posting
- For Implementing Partner staff: Project Name, Institution, City and Country (example: PMI

VectorWorks Project, Johns Hopkins University Center for Communication Programs, Baltimore, MD USA)

For manuscripts, PMI's financial support is acknowledged either in a funding or acknowledgments section (depending on the journal's guidance). Standard text could include: "Financial support for this study was provided by the US President's Malaria Initiative." In addition, the following standard USG disclaimer should be included in all manuscripts: "The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the U.S. Agency for International Development."

**OR Appendix 1: [Concept Note Template for PMI Operational Research and Program Evaluation \(for both MOP or core-funded OR/PE\)](#)**

**OR Appendix 2: [PMI OR/PE Study Update Form](#)**

**OR Appendix 3: [Completed OR/PE Study Questionnaire](#)**

---

# COMMODITY PROCUREMENT AND SUPPLY CHAIN MANAGEMENT

---

## **\*New/Key Messages\***

PMI's supply chain was adversely affected by COVID-19 including production and logistics delays, and increased freight costs. RDT prices increased around 40 percent. We anticipate that the supply chain will continue to be constrained in 2021. Countries should place orders early to account for longer lead times, adjust supply plans to keep inventory levels closer to their maximum level, and use the updated commodity cost table, which reflects the latest freight and commodity costs.

PMI will procure new types of ITNs (e.g., PBO synergist or dual insecticide ITNs via the New Nets Project) where supported by insecticide resistance monitoring data. PMI ITN's procurement strategy continues to emphasize standardization of ITNs in size, shape, color, material, accessories, and package artwork.

PMI will only procure the 100mg formulation of rectal artesunate suppositories moving forward to align with WHO recommendations and prequalification status. Please see severe malaria section for details.

PMI will no longer allow sole source procurement of RDTs. PMI recommends that countries in sub-Saharan Africa procure RDTs that test for *P. falciparum* only with the exception of Ethiopia and Madagascar, where *P. vivax* is common.

Direct warehousing and distribution costs should be included as a separate line item in the MOP from both the commodity and the technical assistance activities. The EUV costs should be included as a separate line in the MOP with the Proposed Activity listed as Pharmaceutical Management Systems Strengthening and the Description of Proposed Activity focused on the EUV.

PMI supports GS1 standardization across the supply chain. PMI is requiring, in a phased approach, that its vendors include GS1 barcodes on products it procures. Country teams should consider supporting country regulatory authorities to require GS1 standards to eventually improve track and trace capabilities. PMI also supports technical assistance to countries interested in implementing GS1.

PMI is implementing a **stockout reduction initiative**. All PMI country teams are being asked to review their commodity procurement and support for supply chain technical assistance and prioritize those supply chain investments that are most likely to have an impact on reducing stockouts in the near term. In FY 21 GHSC-PSM is finalizing a playbook to be used by GHSC-PSM in FY21 and in future years all supply chain IPs. This playbook is designed to assist supply chain technical assistance partners to prioritize their proposed activities around the objectives of the initiative and subsequently to assist PMI country teams with prioritizing PMI investments. FY2022 MOPs and FY2021 reprogramming should be informed by and respond to the initial recommendations coming from the work done by supply chain partners who have worked on the initiative in FY 21.

---

# COMMODITY PROCUREMENT

---

## Introduction

Under the PMI strategy, one of the five key areas to achieve our objectives is the continued scale up of proven interventions, all of which are predicated on the availability, in one way or another, of high-quality commodities. In addition, FY 2022 holds the promise of a number of new malaria control tools including new types of ITNs, tafenoquine, and new G6PD diagnostics. Careful planning for introduction and monitoring of deployment for new types of ITNs is required. While we await approval from a stringent regulatory authority, country registration, and NMCP adoption, any introduction of tafenoquine and new G6PD diagnostics would be considered OR/PE and would follow PMI-supported OR/PE procedures. Please refer to the [Case Management](#) chapter for further updates on these two new tools.

Prior to MOP visits, country teams should work with their NMCPs and partners to update national-level gap analyses – typically using information from stakeholder-coordinated forecasting and supply planning efforts and/or Global Fund concept notes – for all key malaria commodities in order to have a thorough understanding of the priority commodity needs looking forward. In the estimated commodities costing sheet, found at the end of this chapter, the cost of commodities includes the costs of goods plus estimates on freight, insurance to port, clearance, and required quality assurance testing. *Note that the reference price used by Global Fund is based on the commodity cost only.* Country teams should also take into account the difference in planning requirements for warehousing and distribution needs of the various commodities when preparing order requests and build in the additional funding to the appropriate partner if needed. **Countries should be aware of product lead times**, which include order processing, production, quality assurance testing, shipping and customs clearance; the procurement of many malaria commodities require a lead time of eight months to more than a year. (Refer to Commodity Appendix 2 for product and country specific lead times).

## Types of Commodities

Commodities procured by PMI include: ITNs, ACTs, SP (for IPTp), AQ+SP (for seasonal malaria chemoprevention), drugs for severe malaria, other malaria pharmaceuticals (e.g., chloroquine, primaquine, and quinine tablets), laboratory equipment, microscopes and supplies for microscopy, RDTs, insecticides for IRS, spray equipment, and related personal protective gear. For IRS-specific commodities, please refer to IRS chapter, as this chapter will not address IRS commodities. Additionally, most commodities necessary to implement national surveys (e.g., Malaria Indicator Survey) do not fall within the scope of PMI's malaria commodity procurement partner and alternative arrangements should be made. Please contact the GHSC-PSM TO2 COR as soon as possible when discussions around the procurement of these malaria-related commodities for national surveys begin. Please also consult the SM&E chapter for greater detail around the procurement of those commodities (particularly RDTs and

ACTs). As with all procurements, lead times can be lengthy so any research or studies that require commodities should plan sufficiently in advance (see Commodity Appendix 2).

### ***Insecticide-treated nets***

Current [PMI policy](#) requires that ITN products, at minimum, be on the WHO [Prequalification \(PQ\) list of Prequalified Vector Control Products](#) to be eligible for PMI procurements. PMI also reserves the right to apply additional criteria related to label claims, past performance, financial viability and programmatic consistency to qualify ITN products for PMI procurements. Furthermore, for those ITN products that have been deemed to be “equivalent” through the PQ conversion process, PMI specifically requires that they have a PQ listing and have demonstrated field effectiveness according to label claims (e.g., against resistant mosquitoes). The PMI VMCT will review evidence pertaining to non-inferiority (blood-feeding and mortality indicator) to inform PMI procurement policies.

Currently, there are 21 PQ-approved ITNs available to be procured with PMI funding. This list includes six PBO synergist ITNs, the Interceptor G2 net, a dual-insecticide net that includes chlorfenapyr in addition to a pyrethroid and Royal Guard, a dual-insecticide net that includes pyriproxyfen in addition to a pyrethroid. Please see ITN section to see the complete list.

The PBO nets have a WHO policy recommendation (September 2017) that now makes them eligible for PMI procurement. The ITN chapter of this guidance outlines PMI’s approach to implementing the policy, including the criteria to meet in order to make them eligible to procure. Most PBO nets cost between \$2.65 and \$2.80 (commodity cost only), around \$0.80 more per net than a standard pyrethroid-only net.

Neither the Interceptor G2 nor Royal Guard ITNs currently have a WHO policy recommendation, however, PMI is able to procure Interceptor G2, with a co-payment via the New Nets Project. G2 nets with the co-payment cost approximately \$1.00 more per net (commodity cost only) than a standard pyrethroid-only net. Further guidance is provided in the ITN chapter.

To date, PMI has procured over 20 different types of ITNs across dimensions, shape, color, and material. The variation has been driven, in part, by net user preferences. However, a PMI-funded analysis demonstrates that while net users do have preferences, these preferences do not impact use.<sup>173</sup> The analysis showed that the biggest factor in use was sufficient access to a net, not that it met user preferences. With this analysis, the supply chain team worked to identify opportunities to rationalize ITN procurement to achieve best value. The Supply Chain team reviewed the ITN market including conducting an ITN cost of goods analysis, discussed the market and procurement approaches with other global ITN procurers (Global Fund and UNICEF), and conducted a survey of ITN manufacturers.

---

<sup>173</sup> Koenker, H. and Yukich, J.O. Effect of user preferences on ITN use: a review of literature and data. *Malaria Journal* 16:233 (2017) (<http://rdcu.be/tal2>; accessed, August 2017)

The landscape analysis highlighted that while ITN prices have dropped significantly over time, there were additional lead time and cost savings that could be gained through greater standardization. Additionally, standardization would lead to greater interchangeability allowing flexibility in moving nets across orders/countries to meet unanticipated demand, and smoothing out production for manufacturers, which also leads to cost and time savings. The need to demonstrate greater efficiencies and value for money is even more important in the current funding environment and with the need to secure the additional resources to deploy more costly, new types of ITNs to combat growing pyrethroid resistance.

The standards for PMI procured ITNs effective beginning with FY 2018 MOP orders has been, and continues to be:

1. Standardize shape to rectangular
2. Standardize ITN height to two heights: 150 cm and 170 cm (Note: there is flexibility in other dimensions, but most countries procure 190 cm width and 180 cm length)
3. Standardize ITN color to white (no other colors)
4. Do not include hooks and nails in ITN package
5. Do not restrict competition based on material
6. Limit packaging artwork to PMI logo, standard language (e.g., not for retail sale) and pictorial instructions

Requirements for procurement of ITNs with specific insecticides will be considered and will be reviewed in coordination with the PMI Vector Control Team. See ITN section, *Selection of ITNs in Context of Pyrethroid Resistance* for more information on using entomological monitoring data to guide ITN selection.

If a country needs to deviate from these standard specifications for regulatory reasons, they must justify the additional cost in consultation with the PMI Headquarters Supply Chain and ITN Teams and be granted an exceptional approval from PMI Agency Leads.

PMI requires that all ITNs procured for continuous distribution include individual bags. To eliminate waste, campaign ITNs may be procured in bulk packaging as these are usually brought close to the end user and distributed within a limited amount of time. However, if a bale were to be opened in a continuous distribution system, it could take weeks or months to hand out the nets from that bale at the facility. During that time, these nets are more vulnerable to dirt, rodents, or moisture than individually packaged nets. Furthermore, if the ITN is distributed at a central point, like a health center or school; and then transported some distance to individual homes, there is a risk that the ITN might be damaged before it is hung. For this reason, programs should procure ITNs using individual bags for use in continuous distribution. If a country feels they have a reason to procure ITNs in bulk packaging for a distribution system other than campaign, a justification must be submitted with the order request.

ITN campaigns often require very early planning, ordering, delivery, temporary storage, and significant numbers of nets, all of which must be considered in order for the timely arrival of nets, for manufacturers to be able to meet production demand and in-country storage and transportation. In contrast, continuous ITN distribution often requires planning for more regularly spaced orders, adequate permanent warehousing options, and more consistent net quantities. See Commodity Appendix 2 for average lead times.

### ***ACTs, other antimalarial medicines, and essential medicines***

While PMI prioritizes the procurement of a country's first-line drug, if necessary, PMI-financed alternate first-line or second-line therapies are allowable if first-line needs are fulfilled. Exceptions to this policy require discussion with the Case Management HQ and PMI Supply Chain HQ teams to talk through the case management and supply chain impacts. Although PMI procures a range of antimalarial drugs, consistent with WHO malaria treatment and prevention guidelines (as well as aligned with IMCI guidelines under PMI's iCCM rubric), PMI does not procure ACTs without *either* an approval through a stringent regulatory authority (SRA)<sup>174</sup> (such as the US FDA) or the WHO PQ Program.<sup>175</sup> Stringent regulatory authorities employ a robust drug dossier review to consider the safety, efficacy, and quality of pharmaceuticals intended for human use.<sup>176</sup> PMI also procures WHO PQ ACTs to ensure sufficient supply to meet demand. While the WHO is not a regulatory body, their PQ for artemisinin-based and other products indicated in the treatment of malaria applies a robust dossier and manufacturing site review process, resulting in approved products of known quality, safety, and efficacy.<sup>177</sup>

Currently, there are three ACT products approved by a stringent regulatory authority, two of which have been procured with PMI funding: Novartis' Coartem<sup>®</sup> (artemether-lumefantrine), Alfasigma's Eurartesim<sup>®</sup> (dihydroartemisinin-piperaquine), and Shin Poong's Pyramax<sup>®</sup> (pryonaridine/artesunate).<sup>178</sup> There are also several fixed-dose combination ACT formulations with approval through the WHO PQ. The PQ approval process operates on a rolling basis, which means new products are approved periodically. Several fixed-dose combination formulations of artemether-lumefantrine, artesunate-amodiaquine, and dihydroartemisinin-piperaquine (including dispersible formulations) have been approved by WHO PQ and therefore added to the WHO prequalification list<sup>179</sup> over the recent years.

---

<sup>174</sup> Currently, the drug regulatory authorities of the European Union, Japan, USA, Canada and Switzerland have implemented International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and are considered stringent regulatory authorities. There are also various industry organizations from the aforementioned countries who hold SRA status, and some member states with observer status. For more information, visit <http://www.ich.org/about/membership.html>

<sup>175</sup> <http://apps.who.int/prequal/query/ProductRegistry.aspx>

<sup>176</sup> The ICH is an internationally recognized body comprised of representatives from regulatory agencies and pharmaceutical companies globally to help develop standards around drug registration with an objective to harmonize interpretation and application of technical guidelines.

<sup>177</sup> Historically, the WHO PQ approved only ACTs antimalarials (co-blistered products and now co-formulated). Recently, however, non-ACTs used in SMC have been approved through the prequalification program.

<sup>178</sup> PMI has yet to receive a request from any PMI focus country to procure Pyramax.

<sup>179</sup> <http://apps.who.int/prequal/query/ProductRegistry.aspx>

PMI can procure these products subjecting them to the same testing requirements as other non-SRA approved pharmaceuticals procured with PMI funds.

Since 2015, there have been a number of new fixed-dose combination formulations of artemether-lumefantrine approved through the WHO PQ. Specifically, there are now several different co-blister oral presentations: 80 mg artemether/480 mg lumefantrine, 60 mg artemether/360 mg lumefantrine, and 40 mg artemether/240 mg lumefantrine. These new presentations are intended to improve compliance relative to the previous 20 mg/120 mg presentation, which placed a relatively heavy pill burden on the recipient. Unlike the older historical 20/120 tablet presentations, these newer formulations do not allow for weight band substitution. Like any newly procured pharmaceutical, please take into consideration the registration status and the potential need for an importation waiver if the product is not registered. For more information on the selection of ACTs PMI procures, please refer to Case Management.

PMI policy to procure either SRA-approved or WHO-prequalified ACTs is one element of ensuring quality of pharmaceutical products procured with PMI funds. Despite this, ensuring good quality non-ACTs and other essential medicines, continues to be challenging. For example, PMI sources products such as primaquine and most SP from pre-approved wholesalers.<sup>180</sup> The wholesaler agencies are routinely evaluated against internationally accepted quality assurance standards by a USAID-led team, comprised of USAID in-house pharmacists, QA implementing partners, and consultants with significant experience in both current good manufacturing practices and US FDA practices. Wholesalers are required to employ strict QA/QC measures with their vendors. Re-evaluation with site visits and desk audits is routinely carried out. Product testing is conducted at qualified (either ISO-17025 compliant or WHO prequalified) laboratories.

### ***Sulfadoxine-pyrimethamine***

PMI supports the procurement of SP for IPTp to ensure a quality product and to contribute to filling any identified gaps in the country's annual SP quantity needs. To date, there is only one WHO PQ approved option for SP indicated for use in IPTp;<sup>181</sup> as such, PMI sources most SP orders from pre-approved wholesalers.<sup>182</sup> The Medicines for Malaria Venture is working with several SP manufacturers located in Africa to meet WHO PQ standards.

**Historically, SP lead times have been lengthy.** In addition to long lead times, issues around lack of registered products in the presentations required by PMI-supported countries and acquiring the appropriate importation waivers contribute to complications in sourcing the product. The PMI Supply Chain team is looking into sourcing options to lower lead times but as country teams quantify national

---

<sup>180</sup> Please see most recent ADS 312 for more information on currently approved wholesalers.

<sup>181</sup> SP is included in two co-blistered presentations currently approved through the WHO PQ. However, neither of those presentations is indicated for use in IPTp.

<sup>182</sup> Please see most recent ADS 312 for more information on currently approved wholesalers.

level SP needs during operational planning visits for IPTp, consideration must still be given regarding lengthy lead times.

### ***AQ+SP for seasonal malaria chemoprevention***

Since the 2012 WHO policy recommendation regarding SMC, several PMI countries in the Sahel have begun implementing SMC programs. The current WHO recommendations consist of a treatment dose of amodiaquine plus sulfadoxine-pyrimethamine (AQ+SP co-blister) given to children between 3 and 59 months of age at monthly intervals during the period of peak malaria transmission season. While historically implemented over a period of 3-4 months, recent models showing benefit of additional coverage in certain settings have led a few countries to plan for a fifth round of SMC in targeted geographies. Please refer to the [SMC Chapter](#) for more details regarding the number of rounds and age ranges served. Over the past three years, PMI regularly procured AQ+SP for SMC campaigns in up to nine countries. Currently, there is only one manufacturer producing WHO prequalified co-blister presentations of AQ+SP (i.e., packaged in a blister pack together for ease of use), in both dispersible and non-dispersible formulations. However, another manufacturer recently received Global Fund ERP approval so in order to encourage diversity in the constrained market, PMI is phasing in this manufacturer in limited capacity, taking into consideration country registration and a rigorous QC policy to ensure quality. Historically, the limited production capacity has led to challenges in implementing SMC in PMI-supported countries. For countries implementing SMC, please note that there is a section in the MOP template including commodity gap tables for AQ+SP, which the PMI Supply Chain team relies heavily on in order to plan future procurements in coordination with other global donors.

Given the time-sensitive nature of SMC campaigns (i.e., administration of SMC medicines takes place only during the rainy season and peak malaria transmission), commodity procurements must take place well in advance, taking into account lengthy lead times of these medicines and the need to pre-position commodities where they are geographically needed. The PMI HQ Supply Chain Team is ready to collaborate directly with the subset of PMI country teams where SMC is appropriate as well as to facilitate coordination with other donors to enable PMI-supported access to sufficient quantities of the globally-limited supply of qualified product.<sup>183</sup>

**If SMC is relevant to your country team and PMI is requested to procure commodities, orders should be submitted to GHSC-PSM or the PMI HQ Supply Chain Team as close to one year in advance of planned campaign dates as possible to ensure availability of the needed drugs in advance of the campaign.** PMI employs a pre-positioning strategy in order to ensure supply availability to meet demand across the SMC community as production capacity closer to campaign dates are often booked by other donors or governments. If updated commodity needs are identified or even under discussion at any point after submitting the order, the team should alert the PMI HQ Supply Chain Team immediately so that every possible action can be taken to try and fulfill needs, despite the current market constraints.

---

<sup>183</sup> There are several dossiers for additional SP/AQ products currently under review by the WHO Prequalification Program, including two for dispersible formulations (one of which also has ERP approval through the Global Fund).

### ***Severe malaria medicines***

PMI is able to procure any of the three available WHO prequalified injectable artesunate presentations (30-, 60- and/or 120-mg formulations). There are also three different strengths of rectal artesunate suppository presentations available (50-, 100- and/or 200-mg formulations). Only the 100-mg preparation has approval through the WHO prequalification program (through two separate vendors) and WHO recommends the use of the 100-mg rectal artesunate suppositories. For these reasons, **PMI is only procuring the 100-mg formulation** moving forward. Countries that wish to procure the non-pre-qualified 50-mg or 200-mg presentations must contact the Case Management and Supply Chain HQ teams to seek an exception and indicate how they are transitioning to the 100-mg presentation. Please see the Case Management chapter for additional information. Injectable artemether and quinine are also available for procurement, although neither has approval through the WHO PQ. As demand for these products has decreased, lead time and quality issues have increased so procurements need to be planned far in advance in order for them to arrive when needed. Please see the Case Management chapter for further information on the appropriate selection of injectables. Please work closely with your in-country supply chain implementing partner during supply and demand planning for these and all malaria-related commodities. For additional information regarding commodities for severe malaria treatment, please see Commodity Appendix 3.

### ***Rapid diagnostic tests***

PMI now requires WHO PQ for *P. falciparum*, *P. falciparum/P. vivax*, and *P. falciparum/Pan* RDTs given there are a number of WHO-PQd suppliers of these three types of RDTs. Two criteria must be met in order for PMI to procure an RDT for any given country:

1. The RDT is appropriate to the country's detection settings and epidemiology. (PMI recommends that countries in sub-Saharan Africa procure RDTs that test for *P. falciparum* only with the exception of Ethiopia and Madagascar where *P. vivax* is common; see Case Management).
2. The product has received WHO pre-qualification.

An analysis of procurement data has shown that prices for RDTs that are sole-sourced are up to twice the price of the same RDT when there is open competition. An additional analysis undertaken by MalariaCare found that all countries either were using multiple brands of RDTs concurrently or had switched brands. Health workers were able to manage multiple RDT brands or switching brands without significant issues in use. Supervision and job aids supported health workers in managing the change. As such, **PMI no longer allows sole source selection of RDTs based solely on health worker training concerns beginning with FY 2018 MOP orders**. The Case Management team will help countries work through the implications of this new policy including supporting the development of training and job aids focused on managing different RDTs rather than a single RDT. Please work with the PMI Supply Chain team if your country has specific registration requirements for RDTs.

WHO has identified malaria parasites with HRP-2 deletions in limited areas of sub-Saharan Africa (see Case Management chapter for more details). In settings where HRP-2 deletions are greater than five percent (5%), HRP-2 RDTs may no longer be accurate, and RDTs using non-HRP-2 antigens may be needed. Single-species tests that detect two *P. falciparum* antigens (HRP2 and pLDH) with two test lines are now available. These tests are difficult to interpret in the case of conflicting results and do not generally provide a diagnostic advantage in detecting symptomatic malaria. **Given the challenges in interpretation and the limited settings experiencing prevalent HRP2 deletions, PMI will not procure two line multi-antigen RDTs for *P. falciparum*.** Some manufacturers also produce a single line RDT that contains antibodies to both HRP-2 and pLDH. It is hoped that this type of test might be a programmatic solution in countries with HRP-2 deleted parasites in limited areas. These tests, though, have not yet been validated against HRP-2 deleted parasites (although WHO is pursuing this validation) and, therefore, cannot at this time be recommended for use in areas where HRP-2 deletions have been identified. **Countries that either have evidence of HRP-2 deleted parasites or that suspect that such deleted parasites exist in their countries should contact the PMI Case Management Team for guidance on methods to document the presence of these parasites and for recommendations on alternative RDTs if such deletions are detected. Please also refer to WHO guidance (<http://apps.who.int/iris/bitstream/10665/258972/1/WHO-HTM-GMP-2017.18-eng.pdf>).**

RDTs that test for glucose-6-phosphate dehydrogenase (G6PD) deficiency have recently been developed by a couple of manufacturers. A PMI-supported field test of one brand of this RDT (CareStart®) demonstrated that they can detect major G6PD deficiencies, but can miss some minor deficiencies. There are several quantitative G6PD tests under development, most of which require a device (i.e., not an RDT). One of these has come to market and is being field tested in Ethiopia. As G6PD testing is not required prior to administration of low-dose primaquine for blocking the infectivity of gametocytes for *P. falciparum*, such testing is only indicated prior to radical cure treatment for *P. vivax*. Therefore, requests for procurement of G6PD tests will be considered on a case by case basis only from PMI countries with ongoing *P. vivax* transmission. If relevant in your country programs, please contact the PMI HQ Supply Chain and Case Management Teams to discuss the planned indications and deployment of these G6PD RDTs.

### **Lab supplies**

Lab supplies (microscopes, reagents, slides, additional parts etc.) are rather specific and can require significant time to procure; please plan orders accordingly. For information on procuring entomological supplies, see Entomological Monitoring chapter.

### **Lot Quality Assurance/Quality Control**

Quality, safety, and efficacy issues continue to be a concern and, therefore, a continued priority in the procurement of all malaria pharmaceuticals, RDTs, and ITNs. All pharmaceuticals approved by non-SRAs, including those approved through the WHO PQ, must be tested prior or concurrent to shipment (depending on how they were approved and on historical volumes procured) in accordance with PMI

standard operating procedures and work instructions (detailed documents developed by PMI's QA partner). For all pharmaceuticals, there is a quality testing strategy, with WHO-prequalified and wholesaler-sourced products requiring compendial testing based on potential risk. For the latter group, the timing of testing – either pre-shipment or concurrent – is dependent upon PMI experience with the product and manufacturer. Additionally, while routine testing of SRA-approved products is not necessary, PMI's QA strategy includes an annual sampling of retain samples for all SRA-approved products, based on volumes procured, which includes compendial testing.

Historically, RDTs have been subjected to 100% quality control lot testing at WHO-supported laboratories to ensure appropriate test performance and long-term stability. PMI is now implementing a risk-based strategy based on volumes procured (with related QC compliance), and WHO prequalification status. Additionally, there will likely be a transition in 2021 regarding laboratory testing facilities, although this is not expected to have a significant impact on RDT deliveries, etc. Once the new arrangements are finalized, updated guidance will be circulated.

ITNs undergo a physical inspection at the manufacturing site to identify any defects prior to release for shipping. Additional mechanical and chemical testing based on global standards is undertaken on samples at qualified testing facilities concurrent to shipping. PMI has worked with the Global Fund and UNICEF to harmonize pre-shipment inspection and testing protocols for ITNs.

All test reports (of pharmaceutical, RDT, and ITN quality) are kept on file electronically with PMI's quality assurance partner and with the PMI Headquarters Supply Chain Team. These may be obtained upon request by PMI country teams and regional advisors. If there are requests from external parties for specific quality control test results, please contact PMI's in-house clinical pharmacist as these data are considered sensitive.

Products will not be released until results are received by the QA/QC team and deemed as passing (i.e., in compliance with industry and internationally accepted QA/QC standards). For products eligible for concurrent testing, PMI's procurement partner will confirm that products can be quarantined upon arrival in-country while awaiting results of the testing if it has not been completed prior to arrival.

## **Emergency Commodity and Financial Accounts**

Country teams, with the assistance of supply chain/pharmaceutical management implementing partners, are requested to monitor the availability of all key malaria commodities (i.e., ACTs, SP, RDTs, ITNs, and related drugs and supplies for severe malaria) procured and distributed in country, regardless of donor, and take action when disruptions in supply are likely. Fluctuations in donor funding, commodities availability, and resulting stock outs have been a recurrent problem for country programs and may continue with potential decreases in donor contributions. PMI has observed that transition to a new Global Fund grant has posed supply risk in the past, however, urgent orders can receive advance

payment before grants are finalized. If a PMI focus country will be transitioning to a new grant, the country team may consider some contingency planning for potential delays in Global Fund initial orders.

As in previous years, several PMI-supported countries have experienced difficulties with funding leading to disruptions in the supply of key commodities. In these situations, country teams should be aware that PMI directs its SC partner to hold an emergency commodity funding account that can be utilized by countries to help avert stockouts of key malaria products and maintain flexibility in commodity funding.<sup>184</sup> Additionally, PMI with its SC partner has developed an ACT stockpile, which holds a relatively small cache of buffer stock, including all four original weight bands for artemether/lumefantrine<sup>185</sup>. Countries may access this buffer stock to help mitigate pending ACT stockouts, albeit quantities are relatively limited so large-scale emergency procurements are not possible. While PMI monitors the stockpile to ensure rotation of stock in order to maintain higher shelf life, the stockpile stock can still often fall under countries' importation shelf life requirements of 75 to 80 percent remaining shelf-life. As the stockpile stock is typically drawn on when countries are facing stock shortages and the amounts provided are typically only 1 to 2 months of stock, countries can accept lower shelf-life products without risk of expiry. For example, if a country is experiencing a stock out and is provided with a 2 month supply stockpile stock with 50% shelf life (12 months or more remaining shelf life), this stock will be used before it expires in a year. As such, country teams are encouraged to work with NMCPs and drug regulatory authorities to seek waivers for the importation of lower shelf-life products in these situations.

In addition, PMI leadership is committed to assisting country teams with high-level donor or Ministry negotiations in cases of major bottlenecks or program disruptions.

## Commodity Theft, Diversion, and Expiry

PMI implements stringent methods to try and ensure that all malaria commodities procured arrive to the intended country and user. However, malaria commodities, especially ACTs, are considered of high street value and most have relatively shorter shelf lives compared to other pharmaceuticals. Although PMI is ever vigilant to combat and avoid all forms of theft, diversion, and expiry of our malaria commodities, these issues can still occur. If your country is aware of, suspects, or hears of any form of loss of malaria commodities whether through theft, diversion, or destruction (e.g., fire), it is crucial to immediately report the incident **to the USAID Office of the Inspector General and to USAID/Headquarters (including the PMI USAID Agency Lead) and the PMI Headquarters Supply Chain Team (listed below)** with any information such as photos, lot numbers, location where the loss took place, etc. PMI is required to report to the Inspector General any type of loss or theft. In addition, it is crucial to understand any potential issues for our programs in country. Such issues require immediate

---

<sup>184</sup> Given the typical quantities of LLINs, long lead times, method of transportation and sheer physical bulk (necessitating shipment by sea only), the emergency commodity funds are only used rarely for the procurement of LLINs.

<sup>185</sup> PMI no longer holds an AS/AQ emergency stockpile, but the Supply Chain Team will work with its implementing partner to address any urgent needs of AS/AQ.

attention as they indicate that there may be a broader systemic issue in the country, represent a loss of U.S. tax dollars, and mean fewer people are protected from and treated for malaria. Countries should identify options to mitigate the risk of theft, including regular inspection of storage facilities, review of inventory records, comparison of logistics and case management data to identify significant discrepancies between reported cases and consumption, and strengthening in-country logistics management information systems. PMI is working with other USAID health supply chain programs to support a more proactive approach to risk management including systematically identifying potential risks, quantifying them and sharing mitigation approaches and tools across countries. This will be rolled out in CY 2021. Countries should also work to strengthen the national regulatory authority.

With regards to expiry, PMI and its procurement agent, manufacturers, and wholesalers aim to deliver medicines into country with the maximum shelf life possible. At times, delays with manufacturers and/or freight forwarders, combined with poor infrastructure in country and a lack of prepared distribution plans, collectively can lead to commodities arriving with shorter than preferred shelf-life. Because most countries also have a minimum required shelf-life for pharmaceuticals and related medical commodities, they may reject product on this basis. All methods to avoid expiry of any malaria pharmaceuticals should be tried before allowing expiry. PMI should be informed well in advance if there is potential for expiration, as USAID/Washington may be able to find ways to support emergency re-distribution to areas that could use the needed commodities. If expiry does occur, PMI should be immediately informed and a report will need to be documented for the record regarding the expiry as expiry of US-donated commodities falls under waste/fraud/abuse statutes.

## Central Commodity Mechanisms

While PMI has two central procurement options available to Missions for procurement of non-IRS commodities, the central procurement and supply chain management agent (listed first below) is the required mechanism for pharmaceuticals and other non-IRS commodities unless prior approval is sought and granted by the U.S. Global Malaria Coordinator (exceptions have been granted to allow UNICEF to procure ITNs when/where it makes programmatic sense).

1. Global Health Supply Chain – Procurement and Supply Chain Management (GHSC-PSM) Malaria Task Order (TO2) – The GHSC-PSM IDIQ and Malaria task order were awarded to Chemonics in April 2015. The malaria task order supports USAID’s implementation of malaria programs through the procurement, management and delivery of high quality, safe, and effective malaria commodities; the provision of on-the-ground logistics, supply chain, and related systems strengthening technical assistance and implementation capacity; provides technical leadership to strengthen the global supply, demand, financing, and introduction of existing and future malaria commodities. PMI focus countries are required to use PMI’s central mechanism for all non-IRS commodity procurement needs. The requirement (unless granted an exception) to work with PMI’s central procurement agent is due to PMI’s stringent quality assurance and quality control standards for all pharmaceuticals and related commodities procured as well as some pre-negotiated contracts to

obtain the best pricing, based on volume and pooling of orders. The central procurement agent also has flexibility in accommodating last minute order changes and the ability to handle in-country logistics, clearance procedures and if necessary, distribution needs. Their familiarity with USAID regulations and requirements is an added advantage; other procurement agents' lack of familiarity can translate into significant delays in the arrival of commodities. The mechanism's scope also covers in-country supply chain, pharmaceutical management, and logistics for malaria commodities. To further visibility and realistic budgeting, the in-country direct warehousing and distribution costs should be included as a separate line item in the MOP from both the procurement and the technical assistance activities. If you are uncertain of how to best estimate these costs, please contact your supply chain backstop.

2. UNICEF Umbrella Grant—As stated above, and only with prior approval from the U.S. Global Malaria Coordinator, PMI teams may choose to use the UNICEF Umbrella Grant to procure specific malaria commodities (e.g., ITNs for a joint campaign where UNICEF is already procuring a portion of ITNs for the campaign) where UNICEF has a country presence and is already engaged in malaria commodity procurement.

Regardless of the mechanism used, no PMI funds may be used to procure products of questionable quality; this typically precludes local procurements of commodities.

## **Government-to-Government Funding for Commodities**

In March 2012, USAID/Washington released the *Global Health Implementation and Procurement Reform Commodities Procurement Guidance* to better explain the Agency's role under the USAID Forward Initiative as it relates to the procurement of health commodities. In response to a growing interest by some countries to move toward a greater level of self-sufficiency in maintaining national health commodity supply chains, USAID/Washington may be supportive of the procurement of health commodities by host country governments through local systems. The Implementation and Reform guidance sets forth specific criteria for malaria commodities to be considered for local procurement. These include successfully completing a Public Financial Management Risk Assessment to identify fiduciary risks, as well as an additional programmatic risk assessment, the development of an associated risk mitigation strategy, and the inclusion of specific QA/QC measures at the level PMI employs for the procurement of its own commodities. These criteria must be met and require discussion between PMI headquarters and host-country USAID missions in order to move this new process forward while meeting all USG, PMI, Mission and country regulations, requirements and needs. To date, no PMI resources have supported local procurement by partner governments.

## **Global Standards through GS1 Implementation**

PMI, in coordination with other USAID health supply chain divisions, is preparing the USAID global supply chain system to implement global standards for product identification and track and trace using GS1. While these standards are being implemented globally in markets like Argentina, Turkey, the

United States, and the European Union, adoption has been low in developing and emerging markets to date.

Current global health supply chains are a collaborative effort between multiple donors including USAID, Global Fund, UNICEF, etc. What often starts as a network of disparate global supply chains managed by different donors and procurement agencies, often converge when products reach a country's central warehouse. These supply chains rely on trading partners to share data. However, the current approach to managing and sharing supply chain information undermines the value and use of global health supply chain data. Implementing GS1 enables visibility through the supply chain in the areas of product and location identification, data capture, and master, transactional, and event data exchange. On a global level, this increases PMI's ability to maintain updated product data from suppliers. In addition, other donors such as Global Fund are looking at implementing GS1 into their supply chain, enabling smoother data exchange for the future when looking towards coordinated supply planning. GHSC-PSM is also working with suppliers for their products and packaging to be GS1 compliant, which includes a GS1 barcode for automated identification and data capture to decrease time and mistakes, therefore lowering overall costs, when shipping and receiving products in warehouses both at the global and in-country levels and ultimately at facilities if country systems have adopted these standards. It also increases exchangeability of products between countries.

PMI also supports technical assistance for implementation of global standards in the country to improve visibility including identification of counterfeit products and eventually moving towards a full track and trace system. As at the global level, this is a multi-year endeavor. It depends largely on the maturity of the supply chain system and commitment of country stakeholders in driving use and adoption. It also relies on a well maintained product master data to fully realize the benefits that GS1 implementation can provide. Given the relatively new position of global standards as a component of systems strengthening, it is recommended that country programs consider a Learn – Assess – Plan – Pilot – Scale approach to develop a plan that looks towards building an enabling environment for future implementation.

---

# SUPPLY CHAIN MANAGEMENT

---

## Introduction

According to the Council of Supply Chain Management Professionals, “supply chain management encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third-party service providers, and customers.” The success of health programs is dependent on their ability to reliably and consistently supply, and thereby allowing improved access to essential medicines and commodities through a well-functioning supply chain management system. Working closely with ministries of health and NMCPs, PMI supports strengthening supply chain management systems to ensure an uninterrupted supply of safe, quality-assured commodities. Supply chain management of malaria commodities poses unique challenges due to special characteristics, including relatively limited products and typically with shorter shelf lives, complex dosing requirements, and varied demand due to the seasonality and dynamic epidemiology of malaria.<sup>186</sup> These characteristics and other considerations need to be taken into account when allocating PMI resources for activities to strengthen supply chain management systems.

PMI supports the provision of technical assistance to strengthen in-country supply chain management systems and strongly recommends leveraging supply chain strengthening support by other health elements and donors. It is essential to avoid fragmentation of supply chain system strengthening support to realize sustained supply chain systems strengthening results. Malaria-only supply chain technical assistance investments must be avoided unless malaria resources are the only element/donor resources available. Even then, a systems approach to address the key bottlenecks preventing malaria and other commodities from routinely reaching end users needs to be taken. Where other resources are available (e.g., PEPFAR, PRH, MCHN, etc.) and where other health elements are relying on government systems, PMI investments must be coordinated with other USG health supply chain investments. Additionally, Global Fund recently restructured, merging its strategic sourcing and supply chain departments into a single unit with a lead that reports to the Executive Director. Country teams should be aware of Global Fund’s supply chain plans for PMI countries and identify what impact they may have on PMI supply chain investment.

## PMI’s Stockout Reduction Initiative

To achieve consistent and meaningful change in malaria commodity availability, PMI is taking a new

---

<sup>186</sup> Guidelines for Managing the Malaria Supply Chain. <https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/guidelines-for-managing-the-malaria-supply-chain.pdf>

approach to optimizing PMI's supply chain investments, starting in CY 2020. PMI plans to operationalize a Stockout Reduction Initiative with a program to guide PMI country investments towards achieving a clear, time-bound target for improved commodity availability at service delivery points. The program will establish the target to be used across PMI, and develop a playbook, which will provide PMI country teams the assistance required to evaluate past investments, identify root causes of stockouts and potential solutions, and prioritize areas of future investments to reach the availability target. Activities to support PMI's stockout reduction initiative have been included in all of the FY2021 GHSC-PSM workplans for PMI countries utilizing GHSC-PSM for technical assistance. The exercises laid out in the playbook will also inform development of PMI FY2022 MOPs and prior year reprogramming, as well as FY2022 workplans for supply chain implementing partners in all PMI countries. PMI country teams are requested to keep this program in mind when allocating funding across all PMI interventions during the development of the FY 2022 MOPs to ensure that PMI investments will address each country's most critical issue(s) impacting commodity availability.

## **Logistics Management Information Systems**

A logistics management information system (LMIS) is the foundation of a supply chain management system. Improving data visibility along the entire supply chain is critical to improving overall supply chain performance, forecasting accuracy, optimizing inventory levels, and improving supply chain accountability. Strengthening LMIS and warehouse management systems is the second highest USAID supply chain investment only following commodity procurement in terms of cost. Country teams should prioritize strengthening LMIS in their supply chain funding.

An LMIS is the system of records and reports that is used to collect, organize, and present logistics data gathered across all levels of the system. An LMIS enables logisticians to collect the data needed to make informed decisions around procurement that affect product availability for health service delivery. LMIS data can be used to track trends in overall consumption, enabling more accurate forecasting and allowing adjustments to be made to country procurement plans and to in-country distribution plans. LMIS data can also be used to identify trends in dispensing practices or to detect anomalies in consumption practices. When used together with HMIS data, LMIS data can provide insight around expected correlations between services data and logistics data. In fact, PMI has country examples where correlating HMIS and LMIS data has led to detection of ACT theft at facility levels, which only underscores the importance of using these two data sources together when possible.

PMI provides technical assistance to NMCPs and other stakeholders to ensure the capture and consistent use of LMIS data. PMI country teams are encouraged to participate in discussions concerning the consistent use and improvement of an LMIS. Given that LMIS systems are integrated, multiple stakeholders are involved in these efforts and PMI should coordinate support and participate in discussions with these other stakeholders. PMI country teams should avoid supporting the creation of vertical malaria only LMIS systems. Electronic LMIS (eLMIS) systems have been established in some PMI-supported countries. The time and budget required to implement an eLMIS is dependent on the

existence and level of functionality of a paper based LMIS already established in-country. Multiple LMIS software options are available to countries interested in an eLMIS but the business processes, including clearly defined roles and procedures, should drive the choice of technology. PMI country teams should participate in discussions on whether to transition to an eLMIS to ensure all key issues are taken into consideration.<sup>187</sup> For example, leadership support from the MOH or other local group, internet access, IT support, current supply chain SOPs, computer access, etc. should be taken into account when transitioning to an eLMIS system.

Based on the maturity of a country's LMIS, PMI's investment should evolve. For example, countries with weak or no systems efforts should focus on establishing a basic system of recording and reporting logistics data, and then build in automation (eLMIS) as far down the supply chain as feasible. With a system in place the focus may shift to, improving reporting rates through supervision, and using data visualization (e.g., dashboards) to improve supply chain decision-making.

## Product Selection

In addition to epidemiologic considerations for product selection, a number of other key factors must be taken into consideration when selecting products to procure. These include whether a product is part of the country's National Essential Medicines List and is registered by the National Drug Regulatory Authority (in the absence of current registration, a waiver will be needed, and if approved, is a lengthy process that could delay arrival and distribution of commodities). Other issues to consider relate to logistics. What are the storage requirements of a product at the central, health facility and community level? Is there sufficient capacity within the country to distribute and manage the products? Do they require a cold chain during storage and distribution? What is the shelf-life of the product? Have the requisite health care workers been properly trained in the management of the commodity? PMI country teams should work with NMCPs and stakeholders to ensure both epidemiology and logistics are considered in selecting products for the program and/or building the logistics and technical capacity to accept and appropriately use the product.

## Quantification

Quantification is the process of estimating the quantities and costs of the products required for a specific health program (or service), and determining when the products should be delivered to ensure an uninterrupted supply for the program. This is usually done in two steps. First forecasting total need and then developing a supply plan that builds in existing inventory, current orders, and available funding from all sources. The supply plan determines the quantity and frequency of orders/shipments. Countries may use a variety of tools, including the RBM forecasting tool, which is often used for Global Fund concept notes. Tools such as Qunatimed (forecasting) and Pipeline (supply planning) are available for these quantification exercises through PMI's supply chain implementing partners. PMI and other health

---

<sup>187</sup> eLMIS Selection Guide :Electronically Managing Supply Chain Information. <https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/elmis-selection-guide-electronically-managing-supply-chain-information.pdf>

elements are supporting the development of a new tool called Quantification Analytics Tool (QAT) for forecasting and supply planning, which should be available CY 2021 and replaces the Quantimed and Pipeline applications. Three types of data can be used for forecasting: consumption data, services data, and demographic data. PMI supports use of all three types of data for quantification and forecasting. Demographic data tends to provide an upper estimate whereas consumption and services data are influenced by data quality in the LMIS and HMIS, respectively, and can misrepresent need due to stockouts and misuse, although of the two, consumption data is preferred. Quantification is not a one-time event; it requires continuous monitoring and regular updating of the supply plan to adjust for changes in consumption, actual deliveries and planned procurements. **It is important that PMI country teams participate in ongoing quantification exercises. Quantification exercises should also include Global Fund representation so there is one national quantification.**

PMI provides technical assistance to build the capacity of the NMCP and other country stakeholders to lead and take ownership of the quantification. In most PMI-supported countries, this remains an area for ongoing priority attention. In general, countries should conduct annual commodity forecasts, ideally with quarterly updates of the supply plans. These forecasting exercises are also part of the Global Fund concept note preparation. PMI country teams should participate in the process of quantifying for malaria commodities, including Global Fund forecasting activities, as NMCPs are often intimately involved along with national supply chain units and PMI input from regional advisors is appropriate. Most countries either have an established Supply Chain Technical Working Group or a Logistics Management Unit<sup>188</sup> that is charged with this responsibility, in addition to general coordination of malaria supply chain management.

PMI teams should use the country's annual quantifications as a starting point when preparing the MOP gap analysis tables. Please see PMI's MOP guidance for updated instructions for compiling the information presented in the FY2022 gap analysis tables.

## Warehousing, Storage, and Distribution

The purpose of a storage and distribution system is to ensure physical integrity and safety of products and their packaging as they move from the central storage facility to service delivery points. A sound system will preserve quality of products and will protect products from excessive heat, direct sunlight, moisture, water, pests, pilferage, and expiry. A sound system will have sufficient warehousing space that meets Good Distribution Practices standards, for all products at all levels of the system. Policies will be in place to prevent expiries (e.g., first-to-expire, first-out or procedures for what to do with short-dated stock, etc.) Procedures and policies should also be in place for waste, management, disposal, and product recall.

---

<sup>188</sup> Logistics Management Units: What, Why, and How of the Central Coordination of Supply Chain Management. <https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/logistics-management-units-what-why-and-how-of-the-central-coordination-of-supply-chain-management.pdf>

PMI supports the use of local in-country warehousing and distribution systems, usually through a government-owned or parastatal central medical store. As part of agreements between the USG and country governments, USG-funded commodities are exempt from all taxes. With prior approval, PMI resources can be used to pay for service fees related to warehousing and distribution of malaria commodities if there are clear agreements that describe the use of these funds. Fees for storage and distribution range from between 5 and 15 percent based on services provided (e.g., some central medical stores only deliver to the provincial or district level while others clear, store and deliver to the health facility level). Payment of these fees to a parastatal requires contractual approval through a Determinations & Findings (D&F). Where transparency and accountability is in place, PMI uses government owned or managed warehouses and distribution systems (e.g., central medical stores). In these cases, PMI will provide technical assistance to ensure supply chain management systems maintain or improve their performance, efficiency and accountability.

Where accountability and transparency are not in place or where storage and distribution systems do not meet Good Distribution Practices standards, PMI will support the use of parallel warehousing and distribution mechanisms that are outside of government owned or government managed systems. Use of parallel systems should be coordinated with other health elements, where appropriate. Approval from the U.S. Global Malaria Coordinator is required for PMI-supported countries to shift from reliance on government systems to supporting private and/or parallel warehousing and distribution systems particularly given PMI's priority for strengthening government capacity and systems, and the often significant increased costs of supporting particularly parallel systems. While using private mechanisms, PMI provides technical assistance to strengthen the capacity of public mechanisms, with the long term goal of transferring PMI funded commodities into strengthened public systems.

A number of countries are moving away from directly operating warehousing and distribution for the public health supply chain and instead are outsourcing these services to private logistics providers. **PMI encourages use of the private sector for supply chain.** Where countries have shifted to outsourced supply chain services, technical assistance focus should shift from building public sector warehousing and distribution capacity to strengthening contract management of third party logistics providers and oversight of the supply chain.

Funding for direct warehousing and distribution services, either paid to parastatals or implemented by a supply chain partner, should be included in a separate line from commodity or pharmaceutical management technical assistance costs.

PMI recognizes that the physical characteristics of ITNs and the uniqueness of their associated programming, in both routine and campaign distribution environments, often requires separate warehousing and transportation. PMI continues to fund the logistics for ITN warehousing and transportation but seeks, where feasible, to decrease the amount of funding allocated to the warehousing of campaign ITNs with MOP FY 2021 funding. Warehousing infrastructure is increasing in many of PMI's countries as is countries' ability to appropriately manage temporary

storage of campaign nets. Countries teams are encouraged to work with their supply chain implementing partners to assess country capacity, and weigh the risk of country-managed warehousing (e.g. ability to safely secure the nets) and how to mitigate the risk. Based on the assessment, PMI should work with programs to help them identify sources of temporary warehousing for campaign ITNs and support them to manage these arrangements. This would be an investment in the recipient country's journey to self-reliance. Funding for in-country ITN distribution should be included as a separate line in the MOP (i.e. separate from ITN procurement and separate from distribution of other commodities).

Pending availability of additional data, storage of ITNs in shipping containers for periods in excess of two weeks after their initial delivery in-country, without the containers being modified, is not recommended, given the potential risks of distributing ITNs that have become substandard as a result of exposure to high temperatures and/or humidity. No World Health Organization (WHO) pre-qualified (PQ) ITN supplier recommends storing their nets in containers. For more details, see: [Use of containers to store insecticide-treated nets: operational concerns and considerations](#).

## Quality Monitoring

As described above, quality, safety, and efficacy issues continue to be a major concern and top priority in the procurement of all malaria pharmaceuticals. Quality is important not only prior to shipment, but throughout the supply chain and logistics cycle, through to the end user. PMI country teams should work with NMCPs to ensure that QA standards are adhered to throughout the logistics cycle and any concerns are addressed. While significant resources have gone toward ensuring only good quality products enter malaria public supply chains, support for drug and RDT quality monitoring of products once in circulation is also critical. Historically, PMI support toward this has focused on surveillance for both antimalarial availability and quality, in both the private and public sectors.

An important component of the quality assurance continuum is post-marketing surveillance (PMS), which can provide general information not only on the relative quality of medicines circulating in the market, but also help pinpoint weaknesses with the supply chain. When considering whether this is an appropriate use of PMI funds, country teams should take into account the scope/scale of interest, sampling methodology, private vs public market, and as importantly, intended use of data after collection and the longer term strategy for implementing a PMS activity. As a one-off activity, data collected will have little use, unless used to highlight an acute known or suspected problem (e.g., collaboration with USAID's OIG, for example). Moreover, there are a limited number of partners whose relevant scopes of work that can accommodate these activities.

It is also important to distinguish PMS from pharmacovigilance. Pharmacovigilance is a complex series of processes generally used to establish causal relationships between a previously unknown adverse drug reaction (or any drug-related problem) and a specific drug once the drug is circulating among the

general population.<sup>189</sup> And while a critical part of both a mature drug regulatory system and meaningful public health program, even nascent pharmacovigilance activities require substantial financial and human capital; it should not be confused with basic post-marketing surveillance activities. To establish and maintain a functional pharmacovigilance system requires significant support over an extended period of time.

PMI typically does not prioritize pharmacovigilance because of the well-established safety profiles of the antimalarials procured and distributed. As new antimalarials are introduced in PMI countries, requests to support pharmacovigilance activities may increase. When considering pharmacovigilance as part of the introduction of a newer ACT, please contact the PMI Case Management and Supply Chain Management teams so that pharmacovigilance efforts may be coordinated with other donors and existing country systems and infrastructure.

## Monitoring and Supervision

To ensure optimum performance, supply chain systems should be monitored and evaluated on a regular basis. PMI country teams should work closely with program managers and supply chain managers to review data across all levels of the system to improve system performance. The Supply Chain Technical Working Group or LMU is a good venue to facilitate monitoring and evaluation of supply chain system performance. In addition to typical monitoring and supervisory tools recommended for all supply chains (e.g., LMIS reports, supervisory checklists, etc.), PMI uses malaria-specific tools to routinely monitor the supply chain system.

- **The Procurement Planning and Monitoring Report for malaria (PPMRm)** provides data on central-level stock availability for critical malaria commodities (ACTs, SP, injectable artesunate, and RDTs). The report describes stock status of anti-malarial products on a country-by-country basis and is produced quarterly by PMI’s central procurement and supply chain management mechanism. Data are used by PMI to highlight and address needs and potential supply challenges, including stockout situations through the provision of critical emergency shipments. All PMI-supported focus countries are required to provide data for the PPMRm, and PMI country teams should routinely review their countries’ PPMRm reports to flag low stocks, overstocks both in the near and far term. The PPMRm can be accessed at [www.ppmrm.org](http://www.ppmrm.org).
- **End-Use Verification (EUV) Survey:** PMI must ensure that USG-procured malaria commodities are reaching health facilities and are available to end users. The EUV Tool, or another tool that monitors the availability of malaria commodities at the facility level, should be used in a sample of health facilities in all PMI-supported countries two to four times a year. Stockouts of key malaria commodities should be followed up and quantification, procurement, and logistic issues resolved as soon as possible. Depending on how the sample is taken, nationally representative estimates are possible. When not representative, the estimates produced by the EUV Tool in a

---

<sup>189</sup>WHO defines pharmacovigilance as “The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.”

given quarter/semester are meant to give a general picture of malaria commodity availability at district or sub-district levels and encourage timely action to correct problems. Countries are encouraged to reach out to the PMI HQ EUV team and their supply chain technical assistance partner to discuss the best sampling approach, while also keeping in mind costs. Please consult with PMI headquarters to determine if there is another tool in use in country that provides this information or to discuss any changes in EUV methodology. Any decisions to stop the EUV and use another tool must receive approval from the PMI HQ EUV team and Agency Leads. Countries requesting to stop the EUV must have another system of providing routine commodity availability data from health facilities to PMI HQ.

- **Task Order Malaria (TOM) Table:** PMI monitors the status of its commodity orders through the Task Order Malaria (TOM) table produced bi-weekly by PMI's central procurement mechanism. The TOM table provides information on each active order (i.e., orders remain on the TOM table until two weeks after delivery), including order quantities, agreed delivery dates, and expected delivery dates by country. PMI country teams are encouraged to review orders on a regular basis and reach out to its supply chain backstop with any questions.

## Supply Chain Assessments

Countries may periodically need to assess their supply chains. This is often done for evidence-based investment and planning or for performance management. Supply chain assessments should be integrated across health elements and not be malaria specific. There are various tools that can be used to conduct a supply chain assessment. One such tool is the National Supply Chain Assessment (NSCA), a comprehensive toolkit that assesses the capability and performance at all levels of a health supply chain. There are three parts to an NSCA: supply chain mapping, capability maturity model, and key performance indicators (KPIs).

## Capacity Building

The performance of supply chain systems is reliant on adequately trained and motivated personnel. Without properly trained supply chain management personnel, system breakdowns can occur resulting in poor performance of the system or product stockouts. To ensure supply chain systems staff are properly trained, PMI provides technical assistance to build the capacity of supply chain management personnel. Activities can include providing technical assistance to update in-service training content for pharmacy personnel and health workers. PMI also provides technical assistance to build capacity of health facilities and community health workers in supply chain management. PMI country teams are encouraged to work with the NMCP and other stakeholders to identify and address human resources constraints that can negatively affect malaria supply chain systems.

## [Commodity Procurement and Supply Chain Management Appendix 1: Commodities Costing Table](#)

## [Commodity Procurement and Supply Chain Management Appendix 2: Average Lead Time Table](#)

## **Commodity Procurement and Supply Chain Management Appendix 3: Assumptions for Quantification of Parenteral Severe Malaria Drugs**

Regarding the procurement of intravenous, intramuscular, or rectal preparations of antimalarials indicated in the treatment of severe malaria, individual treatment dosages are weight-based, which can create challenges in quantifying the total number of units needed. Country teams will have access to population data, stratified by age (and an understanding of estimated weight bands), which must be used when calculating severe malaria commodities needs. For parenteral artesunate, the general rule of thumb for number of vials needed per treatment is:

- <25 kg: 1 vial
- 26 - 50 kg: 2 vials
- 51 - 75 kg: 3 vials
- 76 - 100 kg: 4 vials

Average weights for healthy toddlers, children, young adults and adults can be found at both the WHO website and the CDC website ([http://www.cdc.gov/growthcharts/who\\_charts.htm#](http://www.cdc.gov/growthcharts/who_charts.htm#)). With the case of parenteral artesunate, as an example, one would need four (4) vials of parenteral 60-mg artesunate for an average man weighing 170 pounds, or about 77 kilos (where 1 kg = 2.2 pounds) as an **initial loading dose**. As the WHO treatment recommendation calls for a **total of three (3) parental doses over 24 hours**, the dosing schedule in this example would therefore be four vials initially, followed by the second dose of four vials 12 hours later, followed by the third and final dose 24 hours after the initial dose, again of four vials. That would be a total of 4 vials x 3 doses = 12 vials total to treat one average sized man using the 60-mg preparation.<sup>190</sup>

For rectal artesunate dosing, WHO treatment guidelines, third edition, recommend a 10 mg/kg pre-referral dosage. Per the October 2017 WHO information note, if using a 100 mg suppository, this would be one suppository for children 2 months up to 3 years and two suppositories for children 3 years up to 5 years. Available preparations include 50-, 100- and 200-mg capsule suppositories; however, WHO and PMI recommend 100 mg capsules. As a reminder, rectal artesunate is indicated in children less than six

---

<sup>190</sup> Injectable artesunate has two administration routes: intravenous (as a bolus) or intramuscular. Also of note: although there are three WHO-prequalified strengths of injectable artesunate, only the 60- and 120-mg dosage formulations are available for public sector procurement. The 30-mg dosage formulation is only offered for private sector procurement by the WHO-approved manufacturer, Guilin.

years old; use in older children and adults directly contradicts WHO treatment guidelines. Again, country teams will have to make estimates based on available population data. Calculations for pre-referral needs, however, are likely further confounded due to a lack of complete information on extent of roll out and patient population accessing pre-referral services.

For other injectables, such as quinine and artemether, both will also rely on patient weights. When country teams are putting together requisition order forms in advance of procuring parenteral severe malaria commodities, the PMI Headquarters Supply Chain Team (which includes a clinical pharmacist) can be available for consultation to help prepare accurate requests (based on available data).

---

# PRIVATE SECTOR ENGAGEMENT

---

## **\*Key Messages\***

**Strengthening engagement and partnerships with the private sector represents a significant opportunity to build more sustainable and scalable programs.** This includes engaging with private health providers, where a significant proportion of malaria cases are diagnosed and treated, but also expands to other private sector segments where **significant untapped resources exist**.

**Strengthening malaria services in the private sector is a PMI priority, as referenced in the Diagnosis and Treatment in the Private Sector section of the FY22 guidance.**

Private sector engagement can involve a broad range of activities, with examples including supporting private corporations to strengthen data sharing with the public sector, partnering with telecommunications companies on messaging campaigns, working with national health insurance schemes to include malaria, training and supervision of private providers and many others.

### **Important Resources**

[USAID Private-Sector Engagement Policy](#)

[USAID PSE Points of Contact](#)

## **Background**

In December of 2018, USAID launched a [Private-Sector Engagement \(PSE\) Policy](#) as an agency-wide call to action to expand work with the private sector in identifying and pursuing areas of shared value across its programs. This mandate signaled the Agency's strategic shift to pursuing market-based approaches and investments to accelerate countries' journeys to self-reliance. Within this policy, USAID defines the private sector as "for-profit, commercial entities and their affiliated foundations; financial institutions, investors and intermediaries; business associations and cooperatives; micro, small, medium and larger enterprises that operate in the informal sectors; American, local, regional, and multi-national scale businesses; and for-profit approaches that generate sustainable income (e.g., a venture fund run by a non-governmental organization (NGO) or a social enterprise).

Engaging with the private health sector to strengthen malaria services is a PMI priority, as seen in the *Diagnosis and Treatment in the Private Sector* section of this guidance. This section complements that effort, largely focusing on PMI's approach to catalyze and leverage non-PMI resources, both financial and non-financial, in alignment with PMI and country-approved malaria priorities in PMI-supported countries. This approach includes the private health sector, but expands to the broader definition above.

Examples of other segments include information and communications technology (ICT), mining and extraction, banking and financial services, education, agriculture and many others.

Illustrative examples of engaging with the private sector include, but are not limited to:

- Working with national health insurance schemes to include malaria services
- Improving the quality of diagnostics and treatments available in the private market
- Supporting private companies and associations to strengthen data sharing (related to malaria activities) with the public sector
- Strengthening public-private dialogue in support of mobilizing private resources and coordinating malaria activities
- Providing TA to a corporation in support of workforce protection from malaria and supporting health needs (including malaria) of their employees
- Partnering with a telecommunications provider to enable behavior change communication messages for malaria campaigns
- Training and supervision of private service providers

In alignment with USAID's PSE Policy, PMI is focused on expanding country-level engagement with private sector actors to drive towards country self-reliance in malaria, and in-country ability to maintain gains in malaria control and sustainably work towards malaria elimination. Furthermore, PMI's objectives of identifying, defining and prioritizing PSE opportunities within the specific bounds of PMI's goal to control and eliminate malaria in its priority countries align closely with the strategic pillars outlined within the Global Health Bureau's PSE Plan:

1. Strategically engage with private sector in coordination across USAID and USG
2. Build GH staff's capacity and confidence on private sector engagement
3. Support Missions with responsive and proactive technical assistance
4. Develop and implement a learning agenda for PSE and disseminate lessons learned

Specifically, PMI HQ is supporting an implementing partner to: (1) conduct a comprehensive landscape analysis of relevant private sector segments, activities and value drivers in four PMI focus countries (Côte d'Ivoire, Democratic Republic of Congo, Liberia, Uganda); (2) develop recommendations on priority opportunities for strategic partnerships with the private sector in those countries; and (3) create a PSE toolkit with resources tailored to build the capacity of PMI in-country teams and national malaria programs' staff broadly to identify, pursue and establish PSE opportunities. Upon completion of these activities in 2021, learnings and the toolkit will be shared across PMI to support expansion of PSE in all countries. Additionally, PMI HQ is developing a tool to allow PMI to better track its in-country private sector partnerships, along with other non-traditional partnerships, to identify gaps and priority opportunities to expand its portfolio of partners.<sup>191</sup>

---

<sup>191</sup> [PMI Announces Emergency Loan Guarantee Facility to Shore Up Private Sector Health Care for Malaria During COFID-19](#)

In another example of private sector engagement, PMI, with support from USAID’s Center for Innovation & Impact (CII), partnered with the Development Finance Corporation (DFC) and the Health Finance Coalition (HFC) to mobilize a ~\$20 million loan guarantee to unlock up to \$35.5 million from the Medical Credit Fund (MCF) in working capital loans for small and medium-sized healthcare providers in Ghana, Kenya, Nigeria, Tanzania, and Uganda. This financing will enable healthcare providers to stabilize operations, procure PPE or other equipment, and continue providing essential health services – including Malaria diagnosis & treatment. These loans will be paired with digital training resources from SafeCare on COVID-19 and Malaria.<sup>192</sup>

PMI encourages all PMI countries to think creatively about how they can engage private providers to improve overall malaria outcomes as well as leverage private sector resources to expand funding for malaria in countries. For those internal to USAID, additional resources and support can be found on [USAID’s PSE page](#). Additionally, for country-specific PSE needs and opportunities, PMI country teams should contact their PSE point of contact at the Mission. Country teams can also contact PMI HQ to discuss PSE opportunities and approaches.

---

<sup>192</sup> [PMI Announces Emergency Loan Guarantee Facility to Shore Up Private Sector Health Care for Malaria During COVID-19](#)

---

# MALARIA PROGRAMMING IN HUMANITARIAN CONTEXTS

---

## **\*Key Messages\***

Humanitarian situations and displaced populations are common in PMI countries and often require malaria prevention and access to diagnosis and treatment.

When acute humanitarian crises occur, PMI staff can helpfully engage to support NMCPs and the humanitarian community to ensure the continuity of malaria services where appropriate.

PMI has developed detailed guidance to assist PMI teams to appropriately engage in humanitarian situations in support of host government, USAID Bureau for Humanitarian Assistance, and Mission actions.

PMI's exposure to humanitarian crises has been increasing over time: the number of internally displaced people (IDPs) in PMI countries has increased by 12x and the number of refugees in PMI countries has increased by 4x in the past 11 years. As of 2020, there were humanitarian situations in all of 27 PMI countries. To develop a reference guide for PMI teams on the continuity of malaria programs in humanitarian settings, an ad hoc PMI humanitarian crises project team conducted over 32 interviews with PMI HQ technical experts, PMI field teams, external global health response experts and emergency response entities. The purpose of this reference guide is to serve PMI country teams and HQ backstops navigating a humanitarian crisis response by providing guidance for managing relationships prior to and during a humanitarian response to mitigate the impact of the crisis on malaria efforts and promote emergency response readiness. The takeaway message is that PMI teams must remain steadfast in reducing malaria cases and deaths while adapting to humanitarian crises by leveraging in-country expertise/situational awareness and external partnerships to optimize impact to save lives. PMI maintains expanded guidelines for humanitarian crises for more information.