# PMI TECHNICAL GUIDANCE FOR FY 2023

PMI | U.S. PRESIDENT'S MALARIA INITIATIVE

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**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.**

***For questions related to technical guidance, please engage with the relevant interagency PMI technical teams.***

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# OVERVIEW AND KEY UPDATES

## Overview of PMI FY 2023 Technical Guidance

As with each version of the U.S. President's Malaria Initiative (PMI) Technical Guidance, the Fiscal Year (FY) 2023 guidance includes revisions throughout each chapter with the latest technical and programmatic information. With recent advances in the malaria vaccine and in other new chemoprevention tools, these sections have been expanded into separate, more detailed chapters. With the October 2021 launch of the PMI 2021-2026 strategy, an expanded chapter on community health and a new chapter on localization have been added. In addition, some existing technical sections have also made explicit links to the three strategic objectives and five focus areas, summarized below for reference. For example:

- The **Elimination** chapter includes criteria for countries that are considered under Strategic Objective 3: To accelerate towards elimination in 10 countries and eliminate in ≥1 country, and a description of key elimination-relevant factors under each of the five strategic focus areas.
- The **Data Integration** chapter includes a table of Malaria Data Integration and Visualization (M-DIVE) tools that may be used in support of or as an example of work in each of the five strategic focus areas, such as new financial dashboards to visualize investments in government-to-government (G2G) and local partners.

Even where links to the strategy are not explicitly described, it should be noted that sections describing core PMI-supported interventions, such as vector control and case management (CM), are relevant across many, if not all, objectives and strategic focus areas. As PMI partner countries work to implement the strategy over the coming year and beyond, the technical guidance will be updated to fill any gaps or needs that are identified.

## New chapters in FY 2023 Technical Guidance

### *Vaccines*

With the October 2021 the World Health Organization (WHO) recommendation and subsequent opening of a Gavi funding window for the RTS,S vaccine, the malaria vaccine section has been expanded into a full chapter. This focus on vaccines is aligned with the tailored deployment of interventions described in PMI Strategic Areas 1: Reach the unreached and 5: Innovate and lead. A consultative approach led by WHO is being developed to determine allocation of the limited initial availability of the vaccine. This will likely include allocation to some PMI-supported countries. Additionally, the pilot implementation countries (Ghana, Kenya, and Malawi) will continue in the Malaria Vaccine

Implementation Program (MVIP) and will likely expand immunization programs into comparison areas. It is not expected that PMI country programs will allocate FY 2023 funding to directly support vaccine implementation, but they should consider whether complementary support might be warranted for those countries selected to receive a portion of the initial limited supply of vaccine. PMI has established a Malaria Vaccine Team that is coordinating closely with colleagues from the USAID Office of Maternal and Child Health and Nutrition, USAID Malaria Vaccine Development Program, and Centers for Disease Control and Prevention's (CDC's) Malaria Branch and Global Immunization Division to provide updates to the field and will provide forthcoming specific guidance on introduction.

### *Other chemoprevention approaches*

With renewed interest in exploring other chemoprevention interventions that may be effective in specific situations or among targeted populations, this section has been expanded to a full chapter covering intermittent preventive treatment for infants (IPTi), intermittent preventive treatment in schoolchildren (IPTsc), mass drug administration (MDA), and ivermectin. This is aligned with the tailored deployment of interventions described in PMI Strategic Areas 1: Reach the unreached and 5: Innovate and lead. For many of these interventions, WHO recommendations and guidelines are in development but are not yet available. Planned or ongoing studies and pilots will be used to inform guidelines. All of these interventions are considered *complementary to* strong vector control, CM, and surveillance programs. The use of any newer chemoprevention intervention should be carefully considered in the context of program goals and resources.

### *Community health (including integrated community case management [iCCM] and digital health)*

Community health has been expanded into a chapter, in support of PMI Strategic Areas 1: Reach the unreached and 2: Strengthen community health systems. The chapter covers both *services* delivered by community health workers (CHWs), and *systems* that are essential in supporting quality delivery of community health services. There are many components of system strengthening that should be considered when supporting CHWs, including selection, scale/saturation, skills, supervision, supplies, salary, and data systems. All of these components are detailed in this new community health section of the technical guidance. In June 2021, PMI officially announced a change in policy regarding use of PMI funds for payment of CHW salaries and stipends, and PMI funds from any fiscal year may now be used to pay CHWs for their work in delivering community-based mCM services.

### *Localization*

The new chapter on localization is in support of PMI Strategic Area 4: Invest locally. In alignment with the USAID Administrator's localization priorities, PMI's localization efforts should reflect both awards to local partners as well as approaches that meaningfully and equitably strengthen the capacity and power of

local actors to inform and lead efforts to combat malaria in their countries. This could include direct and indirect local partnerships, G2G arrangements, private sector engagement, and financial and non-financial collaborations with local entities and communities. PMI's localization efforts should most often be part of an integrated country-level approach and always be coordinated closely with Mission Health Team leadership. PMI is well placed to expand upon its existing partnerships with country governments in order to further shift leadership, ownership, decision-making, and implementation to the people and institutions in our partner countries.

## PMI Strategy 2021–2026: Objectives and Focus Areas

Please see the PMI Strategy 2021–2026: *End Malaria Faster* for additional information.

### *Strategic Objectives*

Building on existing progress, PMI will work with national malaria programs and partners to:

1. Reduce malaria mortality by 33 percent from 2015 levels in high-burden PMI partner countries, achieving a greater than 80 percent reduction from 2000.

2. Reduce malaria morbidity by 40 percent from 2015 levels in PMI partner countries with high and moderate malaria burden.

3. Bring at least 10 PMI partner countries toward national or sub-national elimination and assist at least one country in the Greater Mekong Subregion to eliminate malaria.

### *Strategic Focus Areas*

To achieve these objectives, PMI will take a strategic approach to:

- **Reach the unreached:** Achieve, sustain, and tailor deployment and uptake of high-quality, proven interventions with a focus on hard-to-reach populations.

- **Strengthen community health systems:** Transform and extend community and frontline health systems to end malaria.

- **Keep malaria services resilient:** Adapt malaria services to increase resilience against shocks, including COVID-19 and emerging biological threats, conflict, and climate change.

- **Invest locally:** Partner with countries and communities to lead, implement, and fund malaria programs.

- **Innovate and lead:** Leverage new tools, optimize existing tools, and shape global priorities to end malaria faster.

# VECTOR MONITORING AND CONTROL

***New/Key Messages***

PMI continues to support evidence-informed deployment of traditional and new vector control tools (e.g., new insecticides for indoor residual spraying [IRS] and new types of insecticide-treated mosquito nets [ITNs]) to ensure effective vector control, as well as Operational Research (OR)/Program Evaluations (PEs) for new tools and/or approaches (e.g, larval source management [LSM], topical repellents).

**Vector Control Coverage Goals:** In line with global guidance to pivot away from universal coverage with ITNs and focus on universal coverage with appropriate vector control interventions deployed according to data, PMI recommends coverage with at least one effective vector control tool (ITNs and/or IRS). This may entail sub-national stratification of interventions.

**ITN Procurement:** PMI focus countries should continue to transition to new types of ITNs (e.g., piperonyl butoxide(PBO) synergist or dual insecticide ITNs) where supported by insecticide resistance monitoring data, as funding allows, and in coordination with other donors and national programs. PMI now procures four brands of PBO nets: Olyset Plus, PermaNet 3.0, Duranet Plus, and Veeralin. Note that PMI's procurement policy differs from Global Fund's in that PMI will procure ITNs with a specified pyrethroid whereas Global Fund does not preferentially procure nets with a specific pyrethroid.

**ITN Durability Monitoring (DM)**: PMI has supported development of streamlined DM tools (e.g., protocols, questionnaires, etc.), with an emphasis on new types of nets, for use in countries that already have considerable ITN DM data. Based on feedback, PMI has revised these protocols to account for cost and operational feasibility (see ITN DM section for details).

**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. Two new clothianidin-based products were granted WHO Prequalified (PQ) listings in late 2021: 2GARD (manufactured by Tagros and considered equivalent to Fludora Fusion) and Klypson (manufactured by Tagros and considered equivalent SumiShield). PMI anticipates introducing these new products later in

2022 to assess country-specific performance. When deploying a neonicotinoid for IRS in a given year, products should be used to promote competition and a balanced market per PMI's updated IRS Insecticide Procurement Policy.

**ITN/IRS co-deployment:** Co-deployment of IRS with new types of ITNs is not currently recommended due to limited evidence of additive impact and resource limitations. PMI is supporting ongoing cost-effectiveness studies; however, co-deployment does not seem to be financially justifiable if it inhibits a country's ability to achieve universal coverage with at least one appropriate vector control tool. Note that co-deployment of IRS with pirimiphos-methyl and PBO synergist ITNs is not recommended due to the potential antagonistic effect between the two chemicals.

**LSM implementation in low transmission settings:** PMI funding may be used to support LSM as a supplemental intervention in *elimination settings, in the context of foci investigations.*

**LSM 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 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. LSM may also be appropriate when used as part of an *An. stephensi* control strategy.

***Anopheles stephensi*:** A new malaria vector to the African continent, *An. stephensi*, was first reported from Djibouti in 2012 and has now been reported from Djibouti, Sudan, Somalia, and Ethiopia. As an emerging threat to malaria control and elimination and a vector now established in at least one PMI country, PMI's *An. stephensi* Task Force has generated general guidance for countries at risk of *An. stephensi* invasion.

Two of PMI's main interventions – ITNs and 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 mosquito 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 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 and house screening, may be supported through OR or PE (please see the **Elimination** chapter and below for further guidance).

## Vector Control Coverage Goals

As per the October 2019 WHO Malaria Policy Advisory Committee (MPAC) meeting report,[1] "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 Guidelines for Malaria Vector Control (2019).

[1] WHO, Statement by the Malaria Policy Advisory Committee on reconsidering the formulation of malaria policy guidance, November 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, however 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, 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 due to the potential antagonistic effect between the two chemicals.[2] 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 of vector bionomics to identify key vector mosquito species, seasonality (periods of peak abundance), biting location (indoors vs. outdoors), and biting time is necessary 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).
- Monitoring vector and human behavior in parallel to identifying human-associated biting patterns which may be used to guide selection of vector control interventions.

Please see the **Entomological Monitoring** chapter for more information.

[2] WHO 2017. Conditions for deployment of mosquito nets treated with a pyrethroid and PBO.

## New ITN and IRS Products

The WHO PQ Team leads evaluation of vector control products.[3] 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 CS (organophosphate), SumiShield 50 WG (neonicotinoid), and Fludora Fusion (neonicotinoid + pyrethroid) — and two new types of ITNs — PBO synergist and dual insecticide ITNs (i.e., Interceptor G2 and Royal Guard). In late 2021, WHO PQ granted another IRS recommendation to 2GARD, an equivalent product to Fludora Fusion, and Klypson, an equivalent product to Sumishield, both manufactured by Tagros. PMI has yet to deploy this in countries with IRS programs but will explore adding it to IRS programs in the future. Please see below and the **IRS** and **ITN** chapters for further guidance on where and how to deploy these tools.

## Larval Source Management

LSM, which involves the destruction of larval habitats via draining or filling or through the application of larvicides, has historically been successful in Europe, Brazil, Africa, and Southeast Asia. Modern randomized controlled trials (RCTs) 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."[4] LSM is only indicated when coverage and quality of ITNs or IRS is high, but malaria transmission remains.[5]

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 CM 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

[3] http://www.who.int/pq-vector-control/en/

[4] https://www.who.int/malaria/publications/atoz/interim_position_statement_larviciding_sub_saharan_africa.pdf

[5] https://www.who.int/malaria/publications/atoz/9789241550499/en/

needed to develop more comprehensive guidance on LSM. Any OR/PE that includes a larviciding component should include a quality and effectiveness assessment of the larvicides utilized if they are not WHO PQ-listed products (noting that PMI funds can only procure WHO PQ-listed products), proper environmental documentation, and should also consider an evaluation of social and behavior change (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 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 percent coverage at the household level) is in place, and it is coupled with high quality CM 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 and approved OR or 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., seasonal malaria chemoprevention (SMC), in order to generate the evidence needed to develop more comprehensive guidance on LSM.

3. **Larvicide implementation with entomological monitoring in areas where *An. stephensi* is present** (i.e., Ethiopia presently). As *An. stephensi* uses larval sites, such as water storage containers or other containers, these may be efficiently targeted by LSM. If *An. stephensi* is detected, PMI funding may be used to implement larviciding with entomological monitoring without the need for OR/PE approval using WHO PQ-approved larvicides. Appropriate environmental compliance approvals are required prior to larviciding implementation. See ***An. stephensi*** section below for additional guidance.

Please consult with your PMI HQ Operational and Entomology Leads for guidance on implementation of LSM in any context See the **SBC** chapter 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 widely 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. Note that PMI support for the procurement or deployment of topical repellents is limited to elimination settings and as part of a larger package of interventions for high-risk, and generally mobile populations. These potential tools are being developed by a number of commercial groups as well as the U.S. Departments of Agriculture and Defense. Please see the **Elimination** chapter of the guidance for more information.

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 here and those in development through the Innovative Vector Control Consortium can be found here.

In 2021, WHO provided a conditional recommendation for the use of untreated screening of residential houses for the prevention and control of malaria in children and adults living in areas with ongoing malaria transmission based on low to moderate certainty evidence. However, PMI support for this intervention is currently limited to PE of pilot implementation of house modifications using untreated screening to strengthen the evidence base and determine best practices for scaling up house modifications in specific settings. PMI is currently conducting OR in Uganda to compare the effectiveness and potential to scale up eave tubes and full house screening in a cluster randomized trial. The study will provide key data for guiding PMI policy in light of the recent WHO recommendation, including additional efficacy and cost-effectiveness data, to support any changes to PMI guidance.

**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 to eliminate mosquito breeding sites (e.g., filling ditches, draining surface water) and biocontrol agents (e.g.,

larvivorous fish) (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, i.e., following a natural disaster, 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 CM, has led to dramatic reductions in the malaria burden in Africa with prevalence declining by 50 percent and the incidence of clinical disease by 40 percent. Much of the decline has been attributed to the scale-up of vector control, with ITNs and IRS estimated to account for 68 percent and 10 percent, respectively, of the cases averted.[6] 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, together with our dependence on a limited number of 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 DM).
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

[6] Nature. 2015 Oct 8;526(7572):207-211.

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 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 *An. 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, as well as likely operational impact of any resistance observed.

The concept is simple, though the details can be complex: match insecticides delivered (whether via ITNs 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 PQ for use in adult malaria vector control: organochlorines, organophosphates, pyrethroids, carbamates, pyrroles, neonicotinoids, and insect growth regulators (IGRs).[7] 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 ITN. This product includes both a pyrethroid (alphacypermethrin) and a pyrrole (chlorfenapyr) insecticide. Several products include a pyrethroid and 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 the context of oxidase based resistance,[8] while a more recent study in Uganda indicated a smaller but still significant reduction in prevalence in clusters with PBO ITNs.[9]

For IRS, there are currently five classes of WHO PQ-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 CS) 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.

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[7] https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list

[8] Protopopoff N, Mosha JF, Lukole E, Charlwood JD, Wright A, Mwalimu CD, Manjurano A, Mosha FW, Kisinza W, Kleinschmidt I, Rowland M. 2018. Effectiveness of a long-lasting PBO-treated insecticidal net and IRS interventions, separately and together, against malaria transmitted by pyrethroid-resistant mosquitoes: a cluster, randomized controlled, two-by-two factorial design trial. Lancet 391(10130):1577-1588.

[9] Staedke SG, Gonahasa S, Dorsey G, Kamya MR, Maiteki-Sebuguzi C, Lynd A, Katureebe A, Kyohere M, Mutungi P, Kigozi SP, Opigo J, Hemingway J, Donnelly MJ. 2020. Effect of LLINs with and without PBO on malaria indicators in Uganda (LLINEUP): a pragmatic, cluster-randomized trial embedded in a national LLIN distribution campaign. Lancet 395(10232):1292-1303.

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. An excellent resource for learning more about the modes of action is the Insecticide Resistance Action Committee.

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 currently in use or under consideration for ITNs, IRS, or both should be prioritized; this data can provide immediately actionable information, and a profile of historical insecticide resistance in the vector population. As new insecticides are recommended for IRS or used on 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 CS, SumiShield 50 WG, and Fludora Fusion, notes the recent WHO PQ listing of 2GARD and Klypson, and anticipates WHO PQ approval of two additional products, Sylando and Tenebal. Therefore, PMI currently recommends insecticide susceptibility testing with the active ingredients of these products:

1. Pirimiphos-methyl (organophosphate)
2. Clothianidin (neonicotinoid)
3. Deltamethrin (pyrethroid)
4. Chlorfenapyr (pyrrole)
5. Broflanilide (meta-diamide)

Testing for carbamates (bendiocarb) or DDT are only recommended if these insecticides are currently being used or are under consideration for use. 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 only be done at the diagnostic dose of the pyrethroid. Resistance intensity testing for pyrethroid insecticides should be deprioritized in favor of conducting synergist assays, 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 Monitoring** for additional guidance). If there is a shortage of mosquitoes, insecticides should be prioritized for testing as follows:

1. Susceptibility testing at the diagnostic dose
2. PBO synergist assays at the pyrethroid diagnostic dose
3. Pyrethroid resistance intensity testing (if resistance is detected at the diagnostic dose)

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 two-to-five 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.[10] 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

[10] Note, however, that if sufficient specimens are available, determining the susceptibility of wild-caught, adult mosquitoes may provide additional supplementary information.

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., District Health Information System 2 [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.[11] It is recommended that one (not both) method 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, pyriproxyfen, and broflanilide 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,[12] results from insecticide susceptibility tests conducted using the diagnostic dose should be interpreted as follows:

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

For IRS programs, knockdown or mortality <90 percent at the diagnostic dose (1× 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, data from multiple sites in multiple countries 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

[11] 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.

[12] Test procedures for insecticide resistance monitoring in malaria vector mosquitoes, 2nd ed. Geneva: World Health Organization; 2016.

pyrethroid resistance profiles over time. Please contact your Vector Monitoring and Control Team (VMCT) backstop to discuss details on insecticide resistance testing (e.g., using appropriate resistant mosquitoes with cone bioassays for ITNs).

## *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 culticular thickening. Metabolic resistance can be detected by using CDC bottle assays with synergists. PBO will inhibit mixed function oxidases, s,s,s-tributyl, and 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)[13] and GSTe2 (glutathione-S-transferase)[14] in *An. funestus*, and CYP4J5 (cytochrome oxidase P450) and Coeaed1d (carboxylesterase) in *An. gambiae.*[15]

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 is often done through collaborations established with academic research partners. Focus countries can now support local scientists training in molecular methods for insecticide resistance monitoring through the PMI-supported Enhanced Detection of Insecticide Resistance (PEDIR) program at the CDC. Basic or advanced training, with estimated costs of approximately $15,000 and $25,0000, respectively, should be funded through an appropriate

[13] 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.

[14] 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.

[15] Weetman, et al. (2018) Candidate-gene based GWAS identifies reproducible DNA markers for metabolic pyrethroid resistance from standing genetic variation in East African *An. gambiae*. Sci Rep 8, 2920.

implementing partner. Please contact your **Entomology and Operational Leads** for more information.

Standard operating procedures (SOPs) 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), if there are security or access issues, 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.

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. In some settings, building in-country entomological monitoring expertise is possible through community mosquito collector programs. These programs may occur in entomological monitoring sites or be implemented in ad hoc sites. PMI has implemented community entomological training in several countries and full course materials have been developed and are available upon request from the VMCT.

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 (pit traps, clay pots) resting 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 6pm to 6am, 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 8am) 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 sporozite rates may be critical to determine vector status of new or secondary vectors. Sporozoite-positive mosquitoes are identified by enzyme-linked immunosorbent assay (ELISA), bead assays or PCR. 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.** 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. 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. Estimates of host feeding rates are strongly affected by host availability and sampling strategy and should therefore be interpreted with caution.

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 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.

8. **Human-adjusted biting behavior.** Indoor and outdoor human biting rates by malaria vectors may be largely influenced by the timing and movement patterns of humans indoors and outdoors. For example, a shift from outdoor to indoor biting may occur around the same time the majority of humans go indoors for the evening. To provide more detailed context and estimates on human-adjusted hourly biting rates, a brief questionnaire or observational tool may be used to gather hourly data on: the proportion of humans outdoors, proportion of humans indoors and awake, proportion of humans indoors and asleep, and proportion of humans under ITNs. The hours represented should be the same as those used for mosquito biting rates in the same location (for example, 6pm to 6am or extended depending on local vector behavior). More detailed guidance and standardized protocols for the collection of human and vector data are forthcoming.

For additional information on mosquito collection techniques, see WHO's comprehensive *Manual on Practical Entomology for Malaria Control (part 1 and part 2).* Other WHO entomology training materials include, Training module on malaria control: Entomology and vector control and *Training Manual on Malaria Entomology for Entomology and Vector Control Technicians.* Training videos are also available for a number of mosquito collection methods here.

SOPs 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 entomological and laboratory monitoring plans 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 HLCs. These objections usually stem from an ethical standpoint based on the idea of increased exposure for collectors to malaria and other vector-borne diseases. Research shows that HLC collectors on chemoprophylaxis (as recommended) were at considerably less risk of malaria than the surrounding population.[16] 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 NMCPs. Should evidence emerge that collectors are at increased risk compared to non-collectors, this guidance will be revised.

Alternative trapping methods may be used in place of HLCs depending 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, such as a CDC light trap next to a volunteer sleeping under a bednet or in a tent-like trap can be used. 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., *An. 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 I 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

[16] 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

capacity of the reference laboratory, and the purpose of the molecular identification tests. It is recommended that subsamples analyzed for parity, sporozoite infection, blood meal source or molecular markers of insecticide resistance also be identified to the species level using molecular assays. 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 at least a sample of specimens where changes in species composition have occurred. Similar to parity dissections, programs should maintain a reference collection of different species of mosquitoes, and those identifying mosquitoes should be tested frequently.

An invasive malaria vector, *An. stephensi*, has established populations in the Horn of Africa and the current extent of its current distribution on the African continent is unknown. There are known populations in Ethiopia, so neighboring PMI countries and others at high-risk of *An. stephensi* establishment may encounter *An. stephensi* in entomological collections. This species may be misidentified morphologically as *An. gambiae* s.l. if the correct key is not used. Pinned specimens may be requested from Entomology leads. For additional information, see section on *An. stephensi.*

## 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 (QA) 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 the 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 percent on a given day. However, this requirement may be relaxed for mortality assessments that continue beyond five 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).

SOPs for IRS QA 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 fourth or fifth 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 DM and may also be important in identifying ITN QA 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.

Whereas the previous year's technical guidance recommended bioassay (i.e., cone and/or tunnel) 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, based on recent experience, PMI now recommends only conducting bioassay and chemical content testing of 30 nets (instead of 45 nets) at three timepoints (12, 24, and 36 months; "baseline"/one to six months activities are no longer required). Guidance with respect to pre-distribution testing remains the same as in the current version of the streamlined DM protocol, namely: *20 ITNs per site/brand will be sampled from the central stores to undergo bioassay and chemical residue testing. Ten ITNs from the 20 will be tested first and the second set of 10 nets only tested if preliminary results do not meet manufacturer specifications.* For more details, see revised protocols here.

Measurement of insecticidal content by high performance liquid chromatography (HPLC)/gas chromatography (GC) requires highly specialized equipment that is likely limited or absent in nearly all PMI-supported countries. Therefore, this must be done either at CDC or at a WHO 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 DM 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, if possible, wild mosquitoes. If a resistant colony is not available and collection, rearing, and testing of adequate numbers of wild mosquitoes proves to be infeasible, outsourcing of bioassays to a lab with a resistant colony may be necessary. Similarly, 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 in-country. 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 strengthen 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 (QC)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. Verification of the species using PCR should therefore also be done quarterly and 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*$^{R}$, related to organophosphate and carbamate resistance). Alternative bioassays may be useful for other strains, such as the *CYP6p9a_R* mutation in *An. 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 locally derived pyrethroid-resistant strains of *An.* for testing the efficacy of PBO or dual artemether-lumefantrine (AL) 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.

The PMI VMCT advises that testing of all colonies be conducted quarterly 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 2023 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 a minimum, current susceptibility data should be submitted to PMI ideally at least six 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 VectorLink Collect system, the VMCT has completed an analysis of available mobile data collection systems for entomology and is currently piloting a DHIS-2-based application for smartphones and tablets to directly feed into the VectorLink Collect database. If the pilot is successful, mobile data collection for entomology will be rolled out in those countries utilizing VectorLink Collect. For countries that do not support entomological monitoring through the central mechanism and/or VectorLink Collect is not in use, but there is interest in other databases and/or mobile data collection systems, please consult with your Operational and Entomology Leads.

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 Contracting Officer's Representative (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 QA 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 HQ (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 HQ 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 HQ Entomology and Operational Leads receive all relevant entomological information and are involved with these discussions.

## *An. stephensi,* an invasive malaria vector in Africa

In 2012, *An. stephensi,* a primary malaria vector in south Asia and the Arabian Peninsula, was detected in a seaport in Djibouti. Djibouti approached pre-elimination with <2,000 cases of malaria per year prior to the detection of *An. stephensi;* however, by 2019 cases of malaria increased 30-fold and suspect cases increased from 100,000 to over 200,000 between 2018 and 2019 alone. In 2016, *An. stephensi* was detected in Ethiopia, and then in Sudan and Somalia in 2018 and 2019, respectively.

This mosquito vector can thrive in both urban and rural environments. Where established, the vector is often found in artificial containers, such as wells and water storage structures, as well as smaller containers. By using artificial containers as larval habitats, *An. stephensi* can persist throughout both rainy and dry periods, threatening to alter the malaria landscape and seasonal targeted interventions. Further invasion of this mosquito vector on the African continent may put an additional 126 million people at risk of malaria each year based on modeling estimates (Sinka et al. 2020), therefore, early detection and rapid response strategies are necessary.

Currently, the only PMI country where there is a confirmed presence of *An. stephensi* is Ethiopia, where larval surveillance and control efforts are underway. Neighboring countries, those with high influx of trade traffic through major ports, and those with suitable habitats for population establishment (Sinka et al. 2020) should be considered high risk. Specifically, using data available at this time from the three criteria above, the following PMI countries may be considered high-risk for the introduction and establishment of this vector: **Angola, Benin, Cameroon, Côte d'Ivoire, Ghana, Kenya, Madagascar, Mozambique, Senegal, and Tanzania.** However, other PMI countries in Africa should also be aware of the potential introduction of this vector.

## *PMI action plan to respond to An. stephensi*

A PMI *An. stephensi* Task Force was established with representatives from technical areas including: SBC, OR, elimination, CM, surveillance monitoring and evaluation (SM&E), VMCT, and the PMI Ethiopia country team. The Task Force objectives are: (1) to adapt PMI's existing strategy to address invasive *An. stephensi* with urgency across all technical areas, and (2) to determine the policy changes, strategic documents, and OR necessary to mitigate the impact on malaria transmission. An action plan document is being developed which will provide additional information on specific activities, SOPs, and research needs under three scenarios: where *An. stephensi* is present, where there is high risk of invasion, where there is lower risk of invasion. The action plan will be finalized and shared with the field in early calendar year 2022. Given limited data at this time about the extent of the distribution of *An. stephensi* in Africa, the task force has decided to frame its strategic goal as *An. stephensi* mitigation with enhanced surveillance and monitoring. This strategic goal and document will be revisited periodically as more data are made available.

## *Vector surveillance*

In high-risk countries, *An. stephensi* surveillance through larval surveys should be conducted in and around dry and seaports with connectivity to major transport routes. The most commonly reported *An. stephensi* larval habitats in the Horn of Africa are wells and water storage structures with clean water, and these habitats should be prioritized for surveillance. In Ethiopia, invasive *An. stephensi* populations are often found in the same larval habitats as *Aedes aegypti,* the principal vector of dengue, chikungunya, Zika, and yellow fever viruses. Since larval surveillance is a new activity within PMI for most countries, it will likely require additional investment; thus, coordination with existing vector surveillance programs may be an efficient way to leverage existing infrastructure for *An. stephensi* surveillance. As a first step, it

is recommended that a landscape analysis of all urban vector surveillance programs, specifically for *Aedes* species, be conducted to determine how PMI can potentially coordinate efforts since *An. stephensi* often share habitats with *Aedes aegypti.* This coordination may lead to the early detection and rapid response to *An. stephensi.* The following countries are at high-risk of *An. stephensi* introduction and establishment and are also a part of the West African *Aedes* Surveillance Network (WAASuN): Benin, Cote d'Ivoire, Ghana, and Senegal. The following lower risk countries are also a part of WAASuN: Guinea, Liberia, Mali, Nigeria, Sierra Leone.

Adult *An. stephensi* may be misidentified morphologically as *An. gambiae* s.l. if the correct key is not used. The updated key,[17] which includes *An. stephensi*, should be used for morphological identification to ensure any suspected *An. stephensi* are appropriately identified. Pinned specimens of *An. stephensi* have been prepared at CDC and can be requested by countries for use in morphological identification through Entomology Leads. Larval survey protocols are forthcoming and can be obtained from Entomology Leads.

Community-based *An. stephensi* larval surveillance may be explored to ensure high granularity in community-level data on *An. stephensi* abundance and distribution. This approach is being explored in Ethiopia and may allow for targeted vector control and monitoring.

## *Vector control*

When *An. stephensi* is detected in a new country or region, rapid larval control strategies should be developed and implemented in partnership with NMCPs. The rapid implementation of larval control activities with close monitoring is recommended immediately upon detection. Alternative SBC approaches (see **SBC** section below) may also be required due to the different types of larval habitats the species is often found in. Environmental compliance paperwork should be completed for WHO PQ-approved larvicides as soon as possible. Since *An. stephensi* is a unique vector in Africa, larviciding with close monitoring can be conducted without prior OR/PE approval from the OR Committee as long as appropriate interventions are used and national registration and environmental compliance has been approved. At this time, temephos cannot be supported by PMI due to US Environmental Protection Agency (EPA) registration status. Work with your vector control Operational Lead to ensure that the appropriate environmental compliance approvals are in place for larviciding implementation.

## *Social and Behavioral Change*

A prioritization activity is being led by SBC implementing partners, in collaboration with the PMI SBC and VMCT, to develop SBC guidance for *An. stephensi.* This will include identifying human behaviors currently being promoted or proposed to reduce *An. stephensi* populations, evaluating the existing evidence on the impact of specific behaviors to reduce human contact with this vector through a systematic review of the literature, identifying priority behaviors based on the potential for impact and feasibility, and providing technical specifications for how to specifically define, carry out, and promote

[17] Coetzee, M. 2020. Key to the females of Afrotropical *Anopheles* mosquitoes (Diptera: Culicidae). *Malaria Journal,* 19, 70.

target behaviors within SBC programs working with communities and households  The findings from this activity will be used to help further inform a comprehensive strategy for response to this vector.

## *Surveillance Monitoring and Evaluation*

*An. stephensi* is an efficient vector of both *Plasmodium falciparum* and *P. vivax,* and in both rural and urban areas may be responsible for increases in malaria transmission. In high-risk countries, close monitoring of malaria trends in urban and peri-urban environments is recommended to monitor for potential increases that could be associated with *An. stephensi*. When an unexpected increase in cases, however, this may be defined in-country, is detected, *An. stephensi* should be considered as a potential cause and larval surveillance for *An. stephensi* should be conducted as follow-up. *An. stephensi* may also persist during dry periods when other vectors do not. Monitoring malaria case data for increases in urban areas during dry periods is recommended in high risk countries.

Different approaches in high and low burden settings may be necessary as the impact of *An. stephensi* may not be as apparent in high burden settings. Monitoring health center data in urban and surrounding areas with low malaria burden may reveal increases in malaria due to *An. stephensi*, whereas a combination of epidemiological and larval surveillance may be necessary in high malaria burden settings to identify impacts of *An. stephensi.*

Additional guidance is forthcoming.

# INSECTICIDE-TREATED NETS

## Introduction

ITNs 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.[18] More than 2.4 billion ITNs have been delivered since 2004 in malaria endemic countries.[19] The estimated percentage of the at-risk population sleeping under an ITN rose from 30 percent to 53 percent between 2010 and 2016. During this time, disease incidence and malaria-related deaths have fallen by 21 percent and 29 percent, respectively.[20] Additionally, parasite prevalence in endemic sub-Saharan Africa decreased by 50 percent between 2001 and 2015, with 68 percent of this decline attributed to the use of ITNs.[21]

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 program on immunization (EPI), as well as school-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.[22] See ITN Distribution below.

## PMI ITN Procurement Policy

Current PMI policy requires that ITN products, at minimum, be on the WHO 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.

[18] Pryce J, Richardson M, Lengeler C. ITNs for preventing malaria. Cochrane Database of Systematic Reviews 2018, Issue 11.
[19] https://allianceformalariaprevention.com/working-groups/net-mapping/
[20] World Health Organization. Global Technical Strategy for Malaria 2016–2030. Geneva: World Health Organization, 2016.
[21] 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.
[22] Ibid.

In 2019, WHO released and updated (May 2019) its "Data requirements and protocol for determining non-inferiority of ITN and IRS products within an established WHO policy class." The aim of this protocol is to support the generation of entomological data to inform a decision as to whether a candidate ITN 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 population-level trial data.

PMI ITN procurement policy is consistent with the 2021 WHO Malaria Policy Advisory Group (MPAG) recommendations on non-inferiority evaluations of vector control tools. The October 2021 Meeting Report[23] concluded that non-inferiority studies have value in determining whether second-in-class products should be covered by a WHO recommendation formulated for a first-in-class product and that the approach should be adopted as a general procedure across vector control interventions, not just pyrethroid-PBO nets. It recommended that vector mortality be used as the primary end-point for pyrethroid-PBO nets and for other products whose primary entomological mode of action is the killing of mosquitoes. Blood-feeding can be included as a secondary end-point to assist in informing programmatic and procurement decisions, but there is no requirement for noninferiority analysis. The primary end-point should be calculated based on data for the dominant vector species (or species complex) only. Non-inferiority needs to be demonstrated in at least two trials. If results from one of the two trials are inconclusive or one trial shows inferiority, a third trial is required.

As of November 2021, WHO has provided a list of current PQ long-lasting ITN products:[24]

**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]*
- Life Ideas Textiles: PandaNet 2.0® [*Deltamethrin*]
- Mainpol GmbH: SafeNet® *[Alpha-cypermethrin]*
- *Real Relief Health ApS, Reliefnet Reverte *[Deltamethrin]*
- Shobikaa Impex Private Limited: DuraNet® *[Alpha-cypermethrin]*
- Sumitomo Chemical Co. Ltd.: Olyset® *[Permethrin]*
- Vestergaard Frandsen S.A.: PermaNet 2.0® *[Deltamethrin]*
- *Yorkool: Yorkool® *[Deltamethrin]*
- **NRS Moon Netting FZE: Tsara® [Deltamethrin]*

[23] WHO MPAG Meeting Report (October 2021).
[24] WHO Prequalified Vector Control Products (09 November 2021).

- *NRS Moon Netting FZE: Tsara Soft® *[Deltamethrin]*

**PBO**

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

**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 ITN 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 and all WHO PQ-approved ITNs contain one. Resistance to all four insecticide 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.[25] Because of this threat, resistance monitoring should be an essential part of every PMI focus country's vector control 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 introducing and rotating new types of nets as they become available. Guidance

[25] Implications of insecticide resistance for malaria vector control with long-lasting insecticidal nets (LLINs): trends in pyrethroid resistance during a WHO-coordinated multi-country prospective study. Parasites & Vectors, 2018.

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 PQ Vector Control Products: PBO synergist nets and dual-insecticide nets. Two trials have demonstrated improved efficacy of pyrethroid-PBO treated ITNs[26,27] and one trial demonstrated improved efficacy of a dual-insecticide ITN (pyriproxyfen and permethrin).[28]. Two dual-insecticide ITNs, the Interceptor G2[29] and Royal Guard,[30] have received WHO PQ approval, though neither has yet received a WHO policy recommendation. The UNITAID New Nets Project (NNP) (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).

Insecticide resistance monitoring should guide selection of ITN products. Where pyrethroid resistance has been detected and PBO synergist assays result in >10 percent increase in absolute mortality over pyrethroid only assays, PBO ITNs are recommended. For areas where PBO synergist assays do not result in >10 percent increase in absolute mortality or in areas where mortality is lower than 90 percent after PBO pre-exposure, countries should consider dual AI nets such as the Interceptor G2 (alphacypermethrin and chlorfenapyr) or the Royal Guard (alphacypermethrin and pyriproxyfen). Where costs are a concern and more expensive ITNs would result in a drop in overall coverage and/or where addition of PBO or a second AI adds little to the bioefficacy of ITNs, countries may select ITNs with a specific pyrethroid if resistance bioassays (with or without PBO synergism) indicate clear differences between individual pyrethroids. Countries considering procurement of ITNs with specific pyrethroids should consult with the VMCT and the Supply Chain Team.

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[26] Protopopoff N, Mosha JF, Lukole E, Charlwood JD, Wright A, Mwalimu CD, et al. Effectiveness of a long-lasting PBO-treated insecticidal net and indoor residual spray interventions, separately and together, against malaria transmitted by pyrethroid-resistant mosquitoes: a cluster, randomized controlled, two-by-two factorial design trial. Lancet. 2018;391:1577–88.
[27] Staedke SG, Gonahasa S, Dorsey G, Kamya MR, Maiteki-Sebuguzi C, Lynd A, Katureebe A, Kyohere M, Mutungi P, Kigozi SP, Opigo J, Hemingway J, Donnelly MJ. Effect of LLINs with and without PBO on malaria indicators in Uganda (LLINEUP): a pragmatic, cluster-randomized trial embedded in a national LLIN distribution campaign. Lancet. 2020: 395:1292-1303.
[28] 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-randomized controlled trial. Lancet. 2018.
[29] 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.
[30] Efficacy of Three Novel Bi-treated Long Lasting Insecticidal Nets.

Note that PMI's procurement policy differs from Global Fund's in that PMI will procure ITNs with a specified pyrethroid (if the country's susceptibility testing data show a difference in anopheline mortality between the pyrethroids), whereas Global Fund does not allow for specification of the type of pyrethroid on a pyrethroid-only or a pyrethroid-PBO nets (See Global Fund's Malaria Information Note (July 2019). Global Fund commissioned a Review and Meta-Analysis of the Evidence for Choosing between Specific Pyrethroids for Programmatic Purposes,[31] which concluded that, in areas where pyrethroid resistance exists, different mortality seen between the pyrethroids is not necessarily indicative of an operationally relevant difference in control performance, and there is no reason to rotate between common pyrethroids (i.e., deltamethrin, permethrin, and alpha-cypermethrin) as an insecticide resistance management strategy. That said, PMI recommends selecting ITNs based on resistance data that indicate optimal net, not as a resistance management strategy.

## PBO Synergist ITNs

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.

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.[32] Data from a recently completed trial in Uganda also demonstrated reductions in parasite prevalence among users of PBO

[31] Lissenden, N.; Kont, M.D.; Essandoh, J.; Ismail, H.M.; Churcher, T.S.; Lambert, B.; Lenhart, A.; McCall, P.J.; Moyes, C.L.; Paine, M.J.I.; et al. Review and Meta-Analysis of the Evidence for Choosing between Specific Pyrethroids for Programmatic Purposes. Insects 2021, 12, 826.

[32] Conditions for deployment of mosquito nets treated with a pyrethroid and PBO, September 2017. Geneva: World Health Organization; 2017.

ITNs although WHO has yet to update their recommendations for these products.[33] Meanwhile, as stated by WHO's policy guidance, "all pyrethroid-PBO nets that have a WHO PQ 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.

## 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, 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. A recently published study on dual active (Interceptor G2 and Royal Guard) and PBO (Olyset Plus) ITNs in Tanzania found that after two years, only chlorfenapyr ITNs provided significantly better protection than standard ITNs against malaria in an area of pyrethroid resistance. Added protection provided by PBO lasted only for one year, and may have resulted from low textile and active ingredient durability. No significant effects were observed for any outcomes for the pyriproxyfen ITN.[34]

The NNP was launched in 2018, jointly funded by Unitaid and Global Fund with additional support from the Bill and Melinda Gates Foundation (BMGF) and PMI. NNP, which runs through 2022, has the goal of increasing access to newly developed dual-AI ITNs (i.e., Interceptor G2 and Royal Guard). The

[33] Staedke SG, Gonahasa S, Dorsey G, Kamya MR, Maiteki-Sebuguzi C, Lynd A, Katureebe A, Kyohere M, Mutungi P, Kigozi SP, Opigo J, Hemingway J, Donnelly MJ. Effect of LLINs with and without PBO on malaria indicators in Uganda (LLINEUP): a pragmatic, cluster-randomized trial embedded in a national LLIN distribution campaign. Lancet. 2020: 395:1292-1303.

[34] Mosha, Jacklin Franklin and Kulkarni, Manisha A. and Lukole, Eliud and Matowo, Nancy S. and Pitt, Catherine and Messenger, Louisa and Mallya, Elizabeth and Jummame, Mohammed and Aziz, Tatu and Kaaya, Robert and Shirima, Boniface A. and Isaya, Gladness and Taljaard, Monica and Martin, Jacklin and Hashim, Ramadhan and Thickstun, Charles and Manjurano, Alphaxard and Kleinschmidt, Immo and Mosha, Franklin Weria and Rowland, Mark and Protopopoff, Natacha, Effectiveness and Cost-Effectiveness of Three Types of Dual Active Ingredient Treated Nets Compared to Pyrethroid Long Lasting Insecticidal Nets Against Malaria in an Area With Pyrethroid-Resistant Mosquitoes in Tanzania: A Four Arm, Cluster-Randomized Trial.

Innovative Vector Control Consortium (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 RCTs 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 WHO policy recommendation that would be required for scale-up. In addition, the BMGF, 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 NNP has achieved its targeted price for IG2 nets; therefore, any orders placed outside the project will benefit from this lower pricing. When freight, QA and insurance are included, the landed cost ranges from $3.48 to $3.77 based on the size of the net. **See Commodity Price and Lead Times for more details.**

The Global Fund's Net Transition Initiative (NTI) runs from 2021–2023 and supports transition from the UNITAID-Global Fund NNP to Global Fund internal procurement and financing of dual active ingredient nets, spanning the period when a WHO policy is expected (mid-2022) and immediately after. The Global Fund will continue to provide top-up funding to some of their grants to support deployment of these more expensive tools, as well as continued evidence-gathering. While the NNP structure that allows co-pay to be available to PMI as well as Global Fund continues until the end of Calendar Year (CY) 2022, the NTI, in contrast, is an internal mechanism that only supports Global Fund grants. Thus, there will not be a co-pay for PMI starting in CY 2023.

## 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. 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.

## Cost of ITNs

A link to cost assumptions for FY 2023 ITN procurements is provided in the **Commodity Procurement** chapter. The indicative costs provided there include the purchase price of the net itself, freight, insurance, and QA. These costs are based on historical procurement data for delivery into the central level of the supply chain. If a country is planning for the initial delivery into the country to be further down into the country (e.g., requires splitting one order into many different delivery locations at time of order) then the country should reach out to their supply chain backstop to decide if any additional costs should be factored into the procurement budget.

Procurement costs do not include warehousing and distribution to lower level stock holding points. 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 line in the MOP for "Distribution of ITNs."

Furthermore, there are additional costs related to the type of distribution channel used. For mass distribution campaigns, it is 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 per ITN.

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).[35]

[35] Wisniewski et al. Systematic review and meta-analysis of the cost and cost-effectiveness of distributing ITNs for the prevention of malaria. Acta Tropica February 2020.

# 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 than five years prior, countries can consider including a buffer (e.g., adding 10 percent after the 1.8 ratio has been applied) or using data from previous mass campaigns to justify an alternative total amount.[36]

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[37]
- Mop up campaigns
- Hang up campaigns
- Non-essential data collection (e.g., post-distribution monitoring or "check-ups" sometimes required by other partners)

PMI strengthens capacity in countries to manage and implement ITN mass distribution campaigns. Thus, in PMI focus countries with strong in-country capacity, teams should look first to in-country subject-matter experts and partners to lead implementation of mass campaigns. If technical assistance is

[36] Global Fund, Malaria Information Note, 25 July, 2019.

[37] See: Alliance for Malaria Prevention. Use of containers to store ITNs: operational concerns and considerations. https://allianceformalariaprevention.com/wp-content/uploads/2021/06/AMP_Container_Storage_Recommendations_052021_EN.pdf

not available at the country level for campaigns, PMI works with the Roll Back Malaria (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 technical assistance 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.

## *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 here. 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.

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.[38]

### *Routine distribution of ITNs through public-sector ANC and EPI vaccination clinics*

Routine distribution of ITNs through public-sector[39] ANC and EPI vaccination clinics are intended to protect pregnant women and children less than five years of age. There is some evidence that ITNs distributed through ANC and EPI channels can serve as an incentive and increase clinic attendance. In most countries the nets are given free-of-charge, but may also be sold at highly subsidized prices. Distribution of ITNs through these two channels is not sufficient alone to maintain ownership levels achieved through mass distribution campaigns.

[38] Scates et al. Costs of insecticide-treated bed net distribution systems in sub-Saharan Africa. Malaria Journal 2020.

[39] 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.

### ***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 has proven to be a feasible and effective strategy for maintaining consistently high coverage.[40] 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 in-country subject matter experts, 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 subregions. See the School-based distribution and step-by-step guide.

### ***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 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. Note that community-based distribution is appropriate only if there is an established and well-functioning existing community-based organization or network that can oversee community-based activities. If such a network is not in place, other channels (e.g., schools) may be more appropriate for the country context. See the Community-based Distribution of ITNs guide for more information about the strengths and weaknesses of the channel, as well as examples of countries that have implemented it (e.g., Madagascar, Nigeria, and Zanzibar).

### ***Other continuous distribution channels***

Other potential continuous channels include:

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

[40] 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

## ITN Indicators

In 2018, the RBM Monitoring and Evaluation Reference Group (MERG) 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 (Malaria Indicator Survey [MIS], Demographic and Health Survey [DHS], and Multiple Indicator Cluster Survey [MICS]):[41]

- 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[42] 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 ITN.[43,44] 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 here. 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 here.

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[41] MEASURE Evaluation, MEASURE DHS, President's Malaria Initiative, RBM Partnership to End Malaria, UNICEF, World Health Organization. Household survey indicators for malaria control. 2018.

[42] 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

[43] Universal coverage with ITNs-applying the revised indicators for ownership and use to the Nigeria 2010 MIS data. 2013. Kilian A, et al., Malaria Jour, 12:314.

[44] 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.

## Care of ITNs

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 Social and Behavior Change Communication (SBCC) Indicator Reference Guide: Second Edition (2017) 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 CM at the country level. Another standardized tool to measure malaria-related behaviors and associated behavioral factors is the Malaria Behavior Survey (MBS); 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.[45] Results from DM studies show that differences in median survival could be attributed at least in part to household environment and net care behaviors, so targeted SBC activities to encourage net care and retention should be considered.[46]

PMI continues to promote guidance on net care and use (including reference to misuse and outdoor sleeping); see Social and Behavior Change for ITNs (2019) document. PMI has funded an OR 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,[47,48] 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

[45] Impact of a behavior change intervention on long-lasting insecticidal net care and repair behavior and net condition in Nasarawa State, Nigeria and Impact of a behavior change communication program on net durability in eastern Uganda.
[46] Abilio et al. Monitoring the durability of the LLINs MAGNet and Royal Sentry in three ecological zones of Mozambique. Malaria Journal 2020.
[47] 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.
[48] 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.

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 SBCC strategies or other platforms.[49]

Reinforcing ITN care behavior should not be a standalone 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 CHWs 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, standalone 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 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 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

[49] 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.

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.[50]

Two important and potentially hazardous practices are: (1) 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 (2) 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, 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

[50] 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 United States 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.

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.[51,52] 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.[53] Other studies, such as those from lakeside communities in Lake Tanganyika and a refugee camp in the Democratic Republic of Congo (DRC) reinforce the drivers identified in Malawi; ITNs are being sold to generate income to support immediate food needs.[54,55,56] While anecdotal reports of mosquito net fishing are growing, the magnitude of the problem remains unclear.

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 ITNs 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

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

[52] 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

[53] 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.

[54] 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.

[55] 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.

[56] 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

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 Behavior Change Communication Messaging and Actions at the Country Level* to provide 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 household 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 – 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 DM 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 DM measures the effect of normal daily use on: attrition [as measured by the loss of nets for any reason including but not limited 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 DM (upon completion of the 36-month report) are made publicly available via pmi.gov and https://www.durabilitymonitoring.org/. All PMI-funded DM activities should follow the study protocols, questionnaires, and other tools (such as budget template) 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 DM (and large countries with expected differences due to ecological, social, etc.).
- In countries that have implemented DM 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 using the Streamlined DM protocol (see below).

In general, PMI will not support DM of products for which data have already been collected in-country. If a country has carried out multiple rounds of DM 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*

Standard ITN DM 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 percent variation in performance among products over a three-year period, equivalent to approximately plus/minus six to seven months of median net lifespan.

Measurement of insecticidal activity (both bioassays and chemical content testing) at baseline (one to six month), 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 (one to six month), 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*

In countries that have previously conducted DM on pyrethroid-only nets and are deploying new types of nets, PMI does not recommend another round of full DM, but rather monitoring focused on insecticide effectiveness (i.e., bioassays and chemical testing). The cost is driven primarily by bioassay and chemical testing costs, plus the cost of net storage (for analysis in future rounds) and net replacement. Training is targeted and remote, focused on a small core country study team. Fieldwork is quicker and requires fewer personnel. Analysis should be led by in-country teams with remote support, if required. Note that a cohort will still be established to ensure that appropriate nets are sampled.

The activity should include, at a minimum:

- Data collection at two sites.
- Collection of 30 nets per site, per time point (12, 24, and 36 months) for bioassays and chemical testing; 20 nets of each type to be withdrawn at pre-distribution. Unlike standard DM, there is no "baseline" (one to six month) data collection.
- 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.

Please refer to the Streamlined DM Package here for more details. All PMI-funded DM activities should adhere to these protocols.

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 ≥80 percent mortality or ≥95 percent 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 ≥80 percent mortality or ≥90 percent blood-feeding inhibition in the tunnel test. However, the equipment and access to an animal colony 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 ≥50 percent mortality or ≥75 percent knockdown in the cone test. If less than 80 percent of nets are minimally effective at any given time point, the ITN product should be replaced. Note that these alternative criteria are not adequate for novel insecticides such as chlorfenapyr and multilateral partners are developing SOPs that rely on the tunnel test as the primary assay for chlorfenapyr against pyrethroid resistant strains. Therefore, PMI recommends that countries acquire the equipment for the tunnel test and obtain the relevant training on its use for their staff.

Criteria for attrition and physical durability are less established but recent guidelines have been presented by the WHO VCAG and the WHO Malaria Policy Advisory Committee. Nets should be considered in need of replacement if they have at least 1,000cm$^2$ 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

DM results can help PMI identify when an ITN product does not meet acceptable standards for integrity and insecticidal effectiveness. However, DM 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.

## 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); the PEA is routinely updated and the 2017 version is available on 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?**

**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 Malaria Prevention section on **Malaria in Humanitarian Contexts**. 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

## Introduction

IRS involves the spraying of residual insecticide on the inside walls of houses or other structures 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 and maximize protection throughout the transmission season.

Successful IRS depends on the quality of spraying and on the use of an insecticide that kills the local malaria vector(s). 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, due to documented pyrethroid resistance, no PMI-supported IRS programs have used pyrethroids alone for IRS 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 **Table 1**.

**Table 1. Advantages and Disadvantages of IRS-Recommended Chemical Classes**

| Chemical class | Advantages | Disadvantages | Cost/sachet or sachet equivalent |
|---|---|---|---|
| Pyrethroids | • Low toxicity<br>• Low cost<br>• >7 months duration for longer-lasting formulations | • Resistance<br>• Used in majority of ITNs | $2-3 |
| Carbamates (Brand name: Ficam) | • Medium toxicity<br>• Less resistance | • Higher cost<br>• < 4 month duration**** | $11* |
| Organophosphates** (Brand name: Actellic) | • Less resistance<br>• CS formulation >6 months duration**** | • Higher relative toxicity<br>• Higher cost | $16 |
| Organochlorines (DDT)*** | • Low cost<br>• >7 months duration | • Management costs<br>• Resistance<br>• Supply | $4-$6.70 |
| Neonicotinoids** (Brand names: Fludora Fusion, 2Gard, SumiShield, Klypson) | • Less resistance<br>• Residual efficacy up to 10 months | • Higher cost | $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.

While there are multiple insecticides within each of the recommended IRS classes, only specific formulated products are recommended by the WHO PQT and PMI will only procure products that have a PQ listing. Currently, only one product from each of the carbamate and organophosphate classes are listed by PQ [FICAM [bendiocarb] and Actellic [pirimiphos-methyl], respectively. There are no organochlorines that have a PQ listing. The updated PQ list can be found here.

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. EPA 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 is currently under evaluation for use in IRS.

The newest IRS insecticide on the market is Fludora Fusion, a combination insecticide containing clothianidin + deltamethrin. Data from Bayer, the manufacturer of Fludora Fusion, shows 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 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 three to four months, with residual activity of only two to three 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 one to two months residual efficacy for bendiocarb and two to three months for pirimiphos-methyl CS. PMI began rolling out SumiShield 50 WG in 2018 and Fludora Fusion for IRS in 2019. To date, all PMI-supported IRS programs have used a clothianidin insecticide for IRS, and current data indicates a long residual life, generally ranging from six to nine months.

### *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* 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 sub-national 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* 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 two 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, in order to appropriately consider needed monitoring and support.

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.

### *IRS Insecticide Procurement Policy*

With multiple 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 percent [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 FludoraFusion and SumiShield 50 WG is identical, thanks to the agreement negotiated at the end of the UNITAID-funded NgenIRS Project; 2Gard and Klypson just received WHO PQ approval but have not yet been procured by PMI. 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*.

### *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 ITN 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 percent 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 percent 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 and eligible structures 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 may occur in 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.

- 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 OR 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 Health management information system [HMIS], and (3) Ecological (i.e., breeding sites identified by entomological studies). Study results found that ecological targeting was associated with a 13 percent reduction in malaria incidence compared to geographic targeting, while health facility targeting was associated with a 35 percent *increase* in malaria incidence compared to geographic targeting. **Given these results and the further study 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 and sustainable malaria control or 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 three 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 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 the primary vector control intervention in an area, it should continue to be implemented even as transmission drops.

- If IRS is withdrawn, it should be in the context of a malaria elimination plan or as part of a malaria control strategy, where effective ITNs (based on insecticide resistance data) are available to ensure high coverage through mass campaigns and/or routine distribution channels (i.e., community-based, school-based, ANC/EPI, others as appropriate). 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 mCM has been achieved in that area.
- To date, all PMI countries with IRS programs have withdrawn IRS from one area (i.e., district), 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 (i.e., reasons for withdrawal, alternative vector control interventions, and promotion of seeking care if sick), high ITN coverage and use, strengthened malaria case detection and response systems (including with CHWs and at the lowest health level), and closely monitored artemisinin-based combination therapy (ACT) and rapid diagnostic test (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.

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 2020, in the majority of PMI-supported countries, insecticide costs average 30 percent of the IRS budget, depending on the insecticide class used. The three largest cost categories were insecticide (30 percent of all costs), spray operations (28 percent of all costs), spray operations (28 percent of all costs), and local labor (26 percent percent of all costs), constituting an average of 85 percent of all costs. Based on results from

2020 PMI-funded spray campaigns, the average cost per person protected was $7.44 (range from $2.87 to $22.10) and the average cost per structure sprayed was $26.36 (range $11.67 to $79.41). 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 2023 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/HQ 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 6: 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 that are PQ by WHO. Typically, insecticides will arrive in-country with QA documents from the manufacturer. However, to ensure due diligence, PMI requires its IRS partner to conduct independent, pre-shipment QC evaluations. In countries where PMI conducts IRS but the insecticide was not procured by PMI, QA testing must still be undertaken by PMI prior to use. QC testing of insecticide can be conducted at a number of qualified laboratories; please discuss with the PMI HQ 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. Not currently.** In select countries, PMI once supported IRS with DDT starting first in 2006, but the emergence of high levels of DDT resistance limited its use, and no PMI-supported IRS program has used DDT since 2012. Furthermore, there is currently no known supply of high quality-controlled DDT for

mosquito control from USAID-vetted distributors. 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 SEAs 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, 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.

**Q4. Who is responsible for monitoring human and environmental safety measures for PMI-funded 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 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 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 Africa Indoor Residual Spraying (AIRS) project developed several supervisory tools and checklists.

**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 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; information, education, and communication (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 Contexts**).

# MALARIA IN PREGNANCY

***New/Key Messages***

PMI country teams are encouraged to review the status of ANC delivery in their countries to ensure alignment between NMCP and Maternal Health Programs with the 2016 WHO ANC Guidelines and implementation of the recommended number of ANC contacts. Examples of PMI implementation support might include training of ANC providers, ANC registers updated and printed, timely HMIS reporting of eight contacts (plus an additional ANC contact at 13-16 weeks to ensure timely access to the first dose of IPTp-SP).

Intermittent Preventive Treatment in Pregnancy (IPTp)3+ is the primary indicator recommended by the **RBM MERG.** PMI recommends tracking IPTp3+ for MIP programming results. Additionally, PMI recommends collecting ANC4+ so that IPTp "missed opportunities" can be tracked using IPTp3 and ANC4 indicators.

Sulfadoxine-pyrimethamine (SP) resistance monitoring should be included in all PMI-supported Antimalarial Resistance Monitoring in Africa (PARMA) countries with no information on molecular markers of SP resistance in the previous two years. In countries where a therapeutic efficacy study (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.

Community-delivered IPTp by trained CHWs may offer an additional and innovative strategy for reaching pregnant women, especially those with limited access to health services. Several pilot studies in PMI countries on community-IPTp are nearing completion or have been completed and are generating evidence that may be used for considerations for broader implementation and scale-up. More information, including training manuals and implementation guidance on c-IPTp, will be forthcoming in 2022. Countries interested in exploring c-IPTp may discuss this with the PMI MIP Team.

## 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 MIP. 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. 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:

- IPTPp
- ITNs
- Effective CM of malarial illnesses and anemia

PMI supports MIP activities through the ANC 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.[4]

## 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 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 85 percent 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.[57,58] This change was made as a result of research demonstrating that providing IPTp at least three times during the course of pregnancy is more effective at preventing the adverse effects of MIP than providing only two doses of IPTp (absolute risk reduction for low birth weight [LBW] was 33 per 1000 [95 percent CI, 10-52] for women receiving three or more versus two or less than two doses).[59,60,61]

**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 ANC 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.

[57] 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.

[58] https://www.who.int/malaria/iptp_sp_updated_policy_recommendation_en_102012.pdf?ua=

[59] 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.

[60] Kayentao K, et al, 2013. Intermittent preventive therapy for malaria during pregnancy using 2 vs 3 or more doses of SP and risk of low birth weight in Africa: Systematic review and meta-analysis. JAMA 309: 594-604.

[61] 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.

## 2016 WHO ANC Guidelines

**The WHO ANC Guidelines, released in late 2016, call for a minimum of eight 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 four weeks prior, as follows:

**Table 2. Adaptation of WHO Recommended ANC Contact Schedule to Include IPTp**

| Timing of Contact | Dose # |
|---|---|
| 1: Up to 12 weeks | ITN provided |
| **1a: 13-16 weeks** | **IPTp-SP dose 1 (additional contact)** |
| 2: 20 weeks | IPTp-SP dose 2 |
| 3: 26 weeks | IPTp-SP dose 3 |
| 4: 30 weeks | IPTp-SP dose 4 |
| 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 four 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 the second trimester, the **RBM MERG has recommended tracking the percentage of women receiving the third dose (IPTp3).** While PMI has historically tracked the second dose, and will continue to do so in order

to continue monitoring trends over time, PMI will also track the third 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 1,500 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 second 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. PMI does not limit our procurements to the one WHO PQ supplier due to market constraints and pricing. Therefore, PMI also procures high quality SP from additional sources through USAID-approved wholesalers. 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 percent batch testing before release. In a drug quality survey conducted by WHO, 33 out of 127 (26 percent) 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 percent 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, including monitoring potential African manufacturers projected to become WHO PQ in coming years. 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. 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 SP and QA/QC subsections within the **Commodity Procurement** and **Supply Chain Management** chapters for more information. Additionally, please see these sections for information on dispersible SP, and please reach out to the MIP team and your Supply Chain team backstop if interested in this product.

As of the end of 2021, there are two WHO PQ-approved dispersible SP suppliers although PMI has yet to procure these products. For more information on dispersible SP and IPTi, please refer to the **Other Prevention Interventions** section.

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 supported a study to further assess IPTp with DP in Malawi, which has been completed and publication pending. In addition, a multi-country study (Tanzania, Kenya, Malawi) funded by the European and Developing Countries Clinical Trials Partnership has been completed with results expected in 2022 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

Community-delivered IPTp by trained CHWs may offer an additional and innovative strategy for reaching pregnant women, especially those with limited access to health services. Although 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." [62] Consultation with NMCP, reproductive health, and community health programs are required prior to implementing delivery at community level; please notify the PMI MIP team about any c-IPTp plans. Moreover, countries should carefully consider gender aspects and whether male CHWs have the same access to discussions with women regarding their pregnancy as their female counterparts.

Community MIP interventions appear to work best if CHWs/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.[63] A second study in Malawi was recently completed and the results are pending publication. Also, UNITAID is supporting a four-country study to pilot community-delivery of IPTp with SP in DRC, Nigeria, Madagascar, and Mozambique. These studies are generating evidence on c-IPTp. More information, including training manuals and implementation guidance on c-IPTp will be forthcoming in 2022 based on these studies' best practices and lessons learned. Countries interested in exploring c-IPTp may discuss this with the PMI HQ 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

Use of ITNs during pregnancy is a key component of PMI's MIP 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 IRS are the only interventions that protect women during the first

[62] WHO Regional Office for Africa: A Strategic Framework for Malaria Prevention and Control During Pregnancy in the African Region (2004).

[63] Gutman JR, Stephens DK, Tiendrebeogo J, Badolo O, Dodo M, Burke D, Williamson J, Vibbert K, Youll SJ, Savadogo Y, Brieger WR. A cluster randomized trial of delivery of intermittent preventive treatment of malaria in pregnancy at the community level in Burkina Faso. Malar J. 2020 Aug 5;19(1):282. doi: 10.1186/s12936-020-03356-9. PMID: 32758233; PMCID: PMC7409482.

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 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 MIP 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 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 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); ACTs should be used for treating uncomplicated first trimester malaria infections if no other efficacious antimalarial treatments are immediately 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 MIP, parenteral antimalarials should be given without delay; maternal mortality in severe malaria is approximately 50 percent, 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 3. Treatment of Malaria in Pregnancy**

| | 1st trimester | 2nd or 3rd 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 AL, 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, in order 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.

CM of MIP 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 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 stockouts 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 and track their progress.
- 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.) and recommended eight ANC contacts (plus one between 13-16 weeks).
- 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 engage CHWs in promoting MIP and uptake of IPTp, 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 local partners, private sector, and other donors and partners, such as the U.S. Peace Corps (PC), to help facilitate MIP activities, including IPTp. For example, Peace Corps Volunteers (PCVs) can assist facility based health workers and CHWs 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, holding focus group discussions, etc. PCVs 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

- Roll Back Malaria MIP Working Group website: https://endmalaria.org/our-work-working-groups/malaria-pregnancy
- 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.
- 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 (updated January 2014): https://apps.who.int/iris/bitstream/handle/10665/338350/WHO-HTM-GMP-2014.4-eng.pdf?sequence=2&isAllowed=y
- The report from the Expert Review Group meeting: http://www.who.int/malaria/mpac/mpac_sep13_erg_ipt_malaria_pregnancy_report.pdf
- *The epidemiology of MIP* (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) and is also available on compact disk. Updated ANC guidance: 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.** While some recent studies present mixed findings on the efficacy of IPTp with SP, 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.[64,65] 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.[66,67] Studies in areas with lower levels of SP resistance (West Africa) have found that IPTp with SP remains effective.[68] 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

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[64] 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.

[65] Feng G, et al: Decreasing burden of MIP in Malawian women and its relationship to use of intermittent preventive therapy or bed nets. *PLoS ONE* 2010, 5:e12012.

[66] Menendez, C., A. Bardaji, et al. (2010). "Malaria Prevention with IPTp during Pregnancy Reduces Neonatal Mortality." PLoS ONE **5**(2): e9438;

[67] Roh ME, Kuile FOT, Rerolle F, Glymour MM, Shiboski S, Gosling R, Gutman J, Kakuru A, Desai M, Kajubi R, L'lanziva A, Kamya MR, Dorsey G, Chico RM. Overall, anti-malarial, and non-malarial effect of intermittent preventive treatment during pregnancy with sulfadoxine-pyrimethamine on birthweight: a mediation analysis. Lancet Glob Health. 2020 Jul;8(7):e942-e953. doi: 10.1016/S2214-109X(20)30119-4.

[68] 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

resistance strata. Consequently, 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. The updated WHO policy recommendations are based on the recent evidence and seek to reinforce the importance and appropriateness of SP for IPTp. PMI also 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$^{th}$ 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 second trimester, although an unskilled provider may not be able to palpate the fundus 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 second trimester, it is preferred that other methods be used to determine gestational age/ whether the woman is in the second trimester.

# SEASONAL MALARIA CHEMOPREVENTION

***New/Key Messages***

SMC has been shown to be an **effective strategy** in reducing malaria morbidity in eligible countries of the Sahel and to be feasible to implement using a country's existing community-based health platforms.

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

The WHO-GMP (Global Malaria Programme) has clarified its support of a less restrictive approach to SMC implementation, especially regarding the addition of a fifth round of SMC where epidemiologically appropriate.

Studies to assess the preventive efficacy of SMC in countries outside of the Sahel that have highly seasonal transmission are ongoing. Some of these areas have not traditionally been targeted for SMC due to concerns about SP resistance. Results of these trials will be used to inform guidance, including monitoring for SP resistance.

Please see the **Vaccines** chapter for information on joint administration of the RTS,S vaccine and SMC in areas of seasonal malaria transmission.

## Introduction

WHO issued a recommendation for the implementation of SMC in March, 2012. SMC, 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 season of peak transmission. The current WHO recommendations consist of distribution of a treatment dose of sulfadoxine-pyrimethamine plus amodiaquine (SPAQ) to children between 3 and 59 months of age at monthly intervals during the period of peak malaria transmission. While historically implemented over a

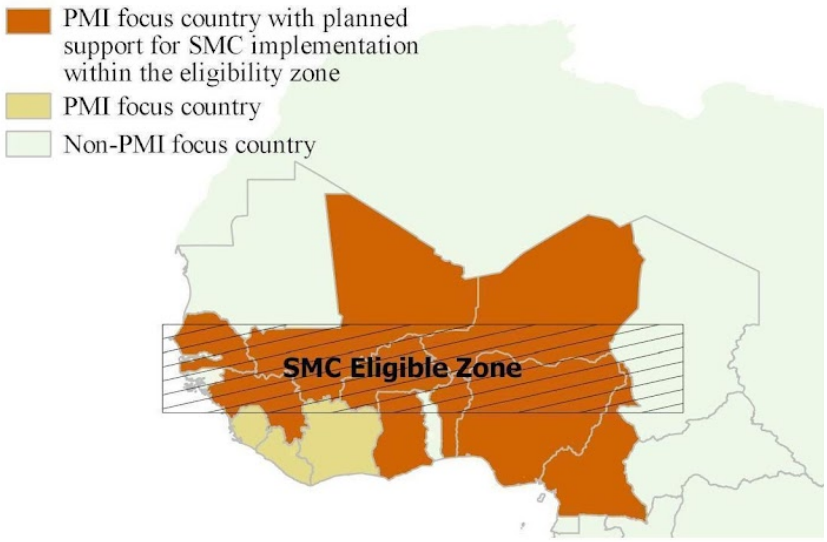
period of three to four months, recent models showing the benefit of additional coverage in certain settings have led a few countries to plan for a fifth round of SMC in targeted areas.

SMC is only recommended for geographic regions in which 60 percent of malaria cases occur within a period of about four months each year. It is not currently 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. WHO recommends that countries implementing SMC should not concurrently implement IPTi, which is the administration of a full treatment dose of SP to infants less than one year of age (see **Other Chemoprevention Approaches** for more information) in the same areas.

PMI currently supports SMC activities in Benin, Burkina Faso, Cameroon, Ghana, Guinea, Mali, Niger, Nigeria, and Senegal. SMC with SPAQ is not currently being used in the seasonal 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. However, studies to determine the feasibility and efficacy of SMC are underway or planned for this area.

SMC programs require a community-based structure to deliver this intervention. Many successful programs are built on existing CHW or iCCM programs, where available. CHWs 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 high transmission season. Results from the PMI-funded pilot implementation and evaluation of SMC in Mali and Senegal, linked here, showed a 66 percent drop in parasite prevalence and a 50 percent drop in cases of uncomplicated malaria among children <5 following four rounds (months) 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 HQ SMC points of contact to determine whether and how to support country-level SMC strategies.

**Figure 1. Map of SMC Eligible Countries with and without PMI support**




## Considerations

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

### *Implementation issues*

The 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 CHWs, and the doses for the second and third day are left with the child's caregiver, along with instructions for administration. In other countries, eligible children receive SMC at a central fixed-point in the village and caregivers take the additional doses for home administration. There may also be community- or household- level "mop-up" to reach children not seen during the core campaign days. 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. Standard protocols exclude sick children and those who have recently received an ACT from receiving SMC. 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, one study documented that door-to-door distribution achieved higher coverage levels. Some countries, such as Senegal, are addressing concerns about adherence to day 2 and day 3 of SMC drug regimens by providing 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 consider supporting local institutions to strengthen their capacity for planning, promoting, implementing, and monitoring SMC campaigns where feasible. Country teams are also encouraged to reach out to the Resident Advisors and NMCP staff in other countries implementing SMC to better understand best practices.

### *Geographic scope*

As mentioned above, SMC has been limited to areas of seasonal malaria transmission in the Sahel, thus far, but expansion to additional geographies is possible according to WHO's current guidance. Research studies are underway in Mozambique and Uganda to explore the feasibility and effectiveness of SMC in areas with seasonal malaria transmission outside of the Sahel (See **Other Chemoprevention Approaches**).

### *Number of cycles*

WHO recommendations specify that SMC 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 number of rounds for drug distribution 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 in areas with longer transmission seasons. Additional data from countries or regions implementing a fifth round (such as coverage and adherence in round five, adverse drug reactions, etc.) are needed to better inform policy. Country teams wishing to use PMI funds to expand the number of cycles of SMC are requested to clearly specify proposed changes in the MOP (or reprogramming memo, with an email notification to the SMC team) and in the gap analysis tables.

### *Age groups*

The current WHO recommendation is for SMC to target children 3 to 59 months of age. 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 in Mali. WHO has not yet published an evidence review or made a recommendation regarding this age group; however, a systematic review of SMC is currently being conducted and results will be considered when recommendations are updated. 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 preventive, 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 of 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 SP and AQ. 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 SP and AQ. WHO is developing a standard protocol for measuring protective efficacy of chemoprevention interventions, recognizing that molecular markers of drug resistance do not necessarily correspond with drug efficacy for malaria prevention. This protocol is currently being piloted as a part of the SMC geographic expansion research in Mozambique and Uganda. Note that therapeutic efficacy monitoring of SP and AQ is not supported by PMI as it would be unethical to use either of these drugs as monotherapy for treatment of clinical malaria in a standard TES protocol. Country teams interested in supporting resistance monitoring or protective efficacy activities should consult with the CM team for guidance.

### *Commodities*

One significant issue for implementing an SMC program is having the necessary quantities of quality-assured SPAQ available in advance of the malaria transmission season. A second WHO PQ manufacturer of the dispersible co-blister presentation of SPAQ became available in 2021. However, due to limited registration of this new supplier, the supply base remains a constraining factor for PMI and other donors so PMI continues to use a pre-positioning strategy to ensure supplies are available to meet demand across the SMC community. The supplier acknowledges that registration is an important factor for PMI and is working to increase its registration profile. Countries are encouraged to work with their local regulatory authorities to advocate for registration where possible. The PMI Supply Chain Team recommends working with your supply chain partner in-country. For more information on your specific country context, reach out to your supply chain backstop. 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 HQ 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, countries must plan accordingly to account for the fact that older children require two blister packs per treatment.

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 HQ 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.

The use of AS-AQ as a first-line malaria treatment is not recommended in areas where SMC with SPAQ is being implemented. Thus, countries implementing SMC with SPAQ 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.

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

### *Surveillance, monitoring, and evaluation*

As a geographically targeted program, SMC presents some unique challenges for SM&E. The first challenge is enumerating the target population of children 3 to 59 months of age. 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 CHWs 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, the WHO SM&E reference manual includes only one standard indicator on SMC programs:

**Proportion of children 3 to 59 months of age (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. Ideally, coverage would mean each child has received all three daily doses of medication each month, over the three, four or five months of the transmission season. In reality, the routine data generally just reflect the children who received the first dose through DOT 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 DOT dose, there was a high likelihood of receiving the additional doses at home.[69] The number of rounds of administration can vary by country and even by sub-national zone depending on a range of epidemiologic and planning factors. Thus, countries should also report on the target number of rounds (3, 4 or 5) and calculate coverage for each round. 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, including those who refused, or presented with malaria. Due to the measurement challenges outlined above and the range of approaches used by countries to report on SMC coverage and adherence, the RBM SMC Alliance worked to standardize metrics. Please see the SMC Alliance Monitoring and Evaluation (M&E) performance framework for the latest guidance on SMC indicators (link below in resources).

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 or recommended, low-cost rapid surveys are one tool that could be used to validate the administrative data on coverage and adherence. Examples of these monitoring tools are available through the SMC Alliance M&E toolkit or through implementing partners (see the M&E performance framework in the link below for more details). 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 Alliance, an official workstream of the RBM

[69] 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.

Country/Regional Support Partner Committee (CRSPC) has an M&E taskforce which has been working on standardization of metrics and developing an M&E toolkit for SMC countries. The performance framework and several elements of the toolkit are linked below.

## 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
- This field guide for SMC implementation, issued in 2013, from WHO could be useful for planning: WHO Guidelines for malaria – 13 July 2021 (magicapp.org) https://www.who.int/publications/i/item/9789241504737
- An additional toolkit from MMV is available at: https://www.mmv.org/access/tool-kits/seasonal-malaria-chemoprevention-tool-kit
- PMI Chemoprevention Briefers https://docs.google.com/presentation/d/1sUc5bXC20AOjAz96L4QunR3uBGL6B4aC/edit?pli=1#slide=id.gf04c60d9d8_0_141
- RBM SMC Alliance SMC M&E toolkit performance framework in French and English: https://www.smc-alliance.org/resources/seasonal-malaria-chemoprevention-monitoring-evaluation-toolkit
- RBM SMC Alliance SMC M&E toolkit (multiple documents in French and English): https://www.smc-alliance.org/resources/seasonal-malaria-chemoprevention-monitoring-evaluation-toolkit

# VACCINES

***New/Key Messages***

On October 6, 2021, WHO announced a recommendation for widespread use of the RTS,S/AS01 (RTS,S) malaria vaccine among children in sub-Saharan Africa and in other regions with moderate to high *P. falciparum* malaria transmission as a new complementary tool within a comprehensive malaria control program. The recommendation is based on an evaluation from the WHO Strategic Advisory Group of Experts on Immunization (SAGE) and WHO Malaria Policy Advisory Group (MPAG, previously the Malaria Policy Advisory Committee (MPAC)) of the results from the ongoing Malaria Vaccine Implementation Program (MVIP). The MVIP is a large-scale pilot implementation program of RTS,S/AS01 in Ghana, Kenya, and Malawi that was initiated in 2019 and had reached more than 800,000 children by September 2021.

In December 2021, Gavi, The Vaccine Alliance, opened a funding window to support vaccine procurement, delivery, and deployment of malaria vaccine(s). There is expected to be a consultative approach led by WHO to determine allocation of the limited initial availability of the vaccine. This will likely include allocation to some PMI-supported countries.

It is not expected that PMI country programs will allocate FY 2023 funding to directly support vaccine implementation as this will be financed by Gavi, see the announcement here, but they should consider whether complementary support might be warranted for those countries selected by Gavi to receive a portion of the initial limited supply of vaccine.

PMI has established a Malaria Vaccine Team that is coordinating closely with colleagues from the USAID Office of Maternal and Child Health and Nutrition, USAID Malaria Vaccine Development Program, and CDC to provide updates to the field and will provide forthcoming guidance.

## Introduction

Important progress has been made against malaria since the start of PMI using the tools described in other chapters of this guidance, but this progress has stalled. While continued utilization and strengthening of existing interventions remains paramount, new tools may have a critical role. This chapter will focus on one of the new complementary tools, the malaria vaccine. The introduction of the RTS,S/AS01 vaccine, the first malaria vaccine, in combination with other proven malaria interventions, could dramatically reduce clinical malaria cases, life-threatening severe disease, and deaths in the target population of children first vaccinated at 5–17 months of age living in malaria-endemic areas.

# Malaria Vaccine

## *RTS,S/AS01 clinical study results*

Research and development towards an effective malaria vaccine has been ongoing for decades. The RTS,S/AS01 malaria vaccine (developed by GlaxoSmithKline with input and funding from many public and private partners) was tested in a Phase III trial in 11 sites across seven African countries with different transmission intensities. The vaccine was tested in two age-categories: children first vaccinated at 5 to 7 months of age, and young infants first vaccinated at 6 to 12 weeks of age. Two different dosing regimens were used: three primary doses of the vaccine administered monthly with no booster dose or three monthly primary doses plus a booster dose about a year after the last priming dose (total of four doses). After approximately four years of follow-up, vaccine efficacy when administered with and without the booster dose (fourth dose) against clinical malaria in children 5 to 17 months of age was 36 percent (95 percent CI 31.8–40.5) and 28 percent (23.3–32.9), respectively, and against severe malaria was 32 percent (13.7–46.9) and 1.1 percent (−23.0–20.5), respectively. In young infants, the vaccine efficacy against clinical malaria was lower at 26 percent (95 percent CI 19.9–31.5) with the booster dose and 18 percent (11.7–24.4) without; no efficacy against severe malaria was observed. Despite moderate to low efficacy, the impact of the vaccine over the four years of the Phase III study was measured and the 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 dose, respectively. The Phase III trial demonstrated an increased risk of febrile convulsions within seven days of vaccination that was deemed causally related to the vaccine. Additional important safety signals were noted but no causal links to the vaccine were established. These signals were: (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.

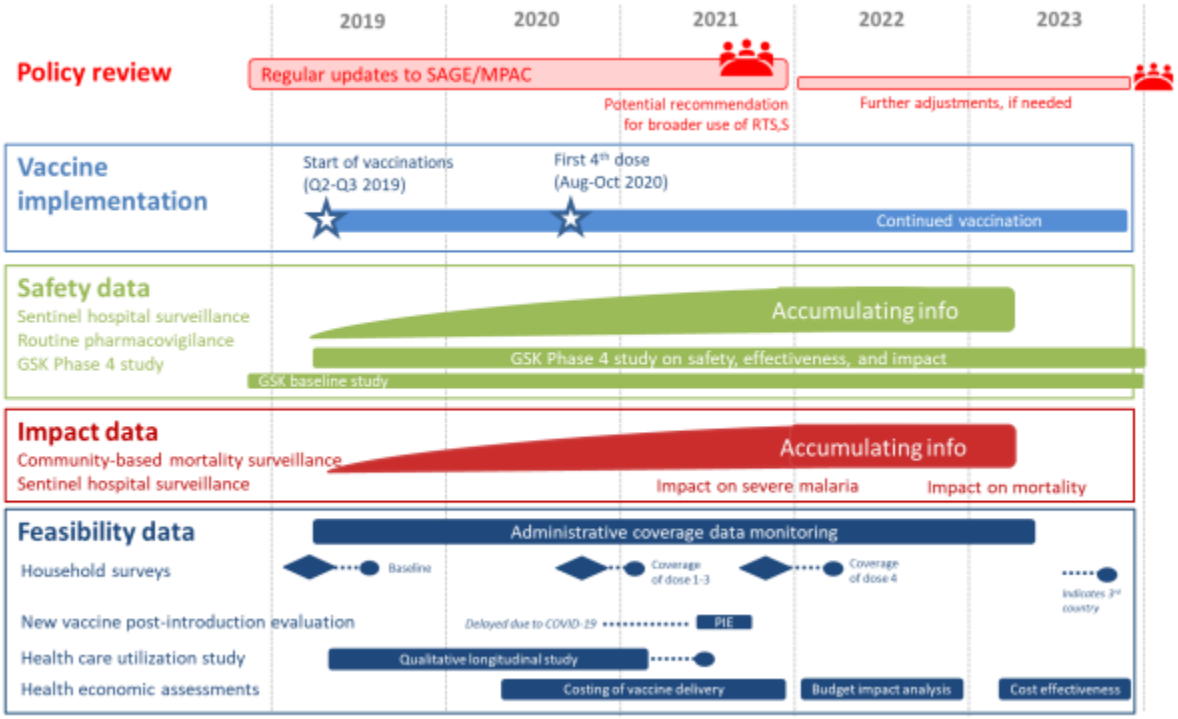
## *Malaria Vaccine Implementation Program*

After reviewing data from the Phase III clinical study, the European Medicines Agency issued a positive scientific opinion on RTS,S/AS01 in July 2015. Subsequently, a joint meeting of the WHO's SAGE and MPAC recommended to WHO that, due to a number of unanswered questions, a large-scale pilot implementation project should be carried out with RTS,S/AS01 vaccination delivered in the context of a routine immunization program in several countries in Africa. The objectives of this pilot program would be to assess the feasibility of implementation of four doses of the vaccine in children 5 to 17 months of age, to evaluate the vaccine's impact on mortality, and to further assess the safety signals identified in Phase III trials, particularly of meningitis and cerebral malaria. WHO secured funding to support this

initial MVIP with support from the Global Fund, Gavi, and UNITAID. Ghana, Kenya, and Malawi were selected as the three pilot countries.

In March 2019, before the pilots were launched, SAGE and MPAC developed a framework for policy decision on RTS,S/AS01, outlining the required MVIP evidence and the timing for the consideration of a broader use recommendation, using a step-wise approach: (1) A WHO policy recommendation for RTS,S/AS01 use beyond the pilot countries could be made ~24 months after the vaccine introduction, if concerns about safety were sufficiently resolved and impact on severe malaria were consistent with beneficial trend; and (2) Refinement of the policy would be carried out at the end of the pilot (~50 months after vaccine introduction, mid-2023), with focus on the value of the fourth dose.

**Figure 2. MVIP implementation and evaluation timeline**[70]




As shown in the figure above, pilot implementation began in Ghana and Malawi in April 2019 and in Kenya in September 2019. During pilot implementation, NMCPs are responsible for ensuring continued wide-scale deployment of existing malaria tools. Although PMI is not providing direct financial support for the implementation of these pilots, PMI supports coverage of vector control and CM interventions in the areas targeted by these pilots. PMI Resident Advisors in the targeted countries have participated in country-level discussions to ensure coordination of these programs with PMI's implementation activities. The four doses of RTS,S/AS01 were integrated into national EPI schedules with Ghana and Kenya giving

[70] Figure copied from Background document for Session 6 Malaria Policy Advisory Group Meeting.

the schedule of doses at 6, 7, 8, and 24 months of age and Malawi using a 5, 6, 7, and 22 month of age. Introduction of the vaccine was aligned with the standard in-country activities for new vaccine introduction, including development of training materials for health care workers; development of SBC materials; adaptation, printing, and distribution of the routing monitoring and reporting tools for use in health facilities; distribution of the vaccines and injection supplies; and implementation of cascade training and SBC activities.

The evaluation of MVIP utilized a cluster-randomized design with approximately 60 clusters per country, which were evenly divided between intervention and comparison districts or sub-counties. The evaluation includes safety data from sentinel hospital surveillance, routine pharmacovigilance and a GlaxoSmithKline Phase 4 study, impact data from community-based mortality surveillance and sentinel hospital surveillance and feasibility data collected through household surveys, an evaluation, health care utilization study, and health economic assessments.

Despite human resource and supply challenges due to COVID-19, between April 2019 and August 2021 more than 2.3 million vaccine doses had been administered, reaching over 800,000 children with at least one dose. In April 2021, WHO confirmed that the MVIP had sufficient safety-related data to sufficiently power the safety analysis to inform the potential recommendation for broader implementation.

### *WHO recommendation for broader use of RTS,S/AS01*

On October 6, 2021, during a joint meeting of WHO SAGE, and MPAG, the RTS,S SAGE/MPAG Working Group met to review the existing data and make a potential recommendation related to the use of RTS,S/AS01. During the meeting, the Working Group confirmed that sufficient data were collected to state that the safety signals of concern that had been noted during the Phase 3 trial were not causally related; furthermore, the pooled results demonstrated that vaccine introduction was associated with a significant reduction in severe malaria, and impact on mortality was consistent with a beneficial trend.

Based on these data, WHO concluded that "in the context of comprehensive malaria control the RTS,S/AS01 malaria vaccine be used for the prevention of *P. falciparum* malaria in children living in regions with moderate to high transmission as defined by WHO. RTS,S/AS01 malaria vaccine should be provided in a schedule of four doses in children from five months of age for the reduction of malaria disease and burden."[71]

[71] WHO. 2021. WHO Malaria Policy Advisory Group (MPAG) meeting- Meeting Report.

## *Deployment of RTS,S/AS01 vaccine in areas with highly seasonal malaria.*

In areas with highly seasonal malaria or perennial malaria transmission with seasonal peaks, WHO further concluded that, "drawing from a growing body of evidence, countries may consider providing the RTS,S/ AS01 vaccine seasonally, with a five-dose strategy (i.e., a primary course of three monthly doses, followed by two annual seasonal doses) in areas with highly seasonal malaria or in areas with perennial malaria transmission with seasonal peaks. When countries choose the seasonal deployment of the RTS,S/AS01 vaccine, they are strongly encouraged to document their experience, including the vaccine's effectiveness and feasibility, and occurrence of any adverse events, in order to inform future guidance updates… Seasonal deployment of the RTS,S/AS01 vaccine constitutes an off-label use of the vaccine."[72] This recommendation for potential seasonal deployment is based on evidence from a study[73] in areas of Mali and Burkina Faso with seasonal malaria transmission that showed that administration of RTS,S/AS01 alone was non-inferior to SMC in preventing uncomplicated malaria. Moreover, the combination of these interventions resulted in a substantially lower incidence of uncomplicated malaria, severe malaria, and death from malaria than either intervention alone. When compared to either the vaccine-alone or SMC-alone, the combination of vaccine plus SMC showed an additional ~60 percent reduction in clinical malaria and >70 percent reduction in hospitalizations and child deaths.

## *RTS,S/AS01 Vaccine Introduction*

At this time, it is not expected that PMI country programs will allocate FY 2023 funding to directly support vaccine implementation as this will be financed by Gavi,[74] but they should consider whether complementary support might be warranted for those countries selected by Gavi to receive a portion of the initial limited vaccine supply. For example, it is important that malaria SBC activities continue to promote the uptake, maintenance, and use of proven malaria interventions throughout malaria vaccine implementation. Additionally, vaccine rollout, HMIS, and LMIS data should be closely monitored with appropriate support from the NMCP, PMI, and its partners. Malaria vaccine introduction is expected to be led by national immunization programs with close coordination and complementary support from NMCP. PMI is coordinating closely with colleagues from the USAID Office of Maternal and Child Health and Nutrition, USAID Malaria Vaccine Development Program, and CDC's Malaria Branch and Global Immunization Division. This interagency group will continue to provide updates to the field and will provide forthcoming specific guidance on malaria vaccine introduction.

## *Next-generation vaccines*

This first malaria vaccine is proof that a vaccine to combat the world's oldest and longest running pandemic is possible. There are two other advanced malaria vaccine candidates in or approaching Phase

[72] WHO. 2021. WHO Malaria Policy Advisory Group (MPAG) meeting- Meeting Report.

[73] Chandramohan, Daniel et al. "Seasonal Malaria Vaccination with or without Seasonal Malaria Chemoprevention." The New England journal of medicine vol. 385,11 (2021): 1005-1017. doi:10.1056/NEJMoa2026330

[74] Gavi. 2021. Gavi Board approves funding to support malaria vaccine roll-out in sub-Saharan Africa.

3 evaluation: R21/Matrix-M from the University of Oxford and PfSPZ from Sanaria. A recent publication of promising Phase 2 field results for the R21/Matrix-M vaccine has garnered much interest but should be interpreted with caution.[75] PMI sent a report to the field about the R21 vaccine in April 2021.

In addition, BioNTech announced in July 2021 that they have a team developing mRNA-based malaria vaccine candidates. This work is in the early stages, but BioNTech has stated a goal of being in early clinical trials at the end of 2022.

USAID does not directly support development of R21/Matrix-M, PfSPZ or BioNTech efforts at this time. However, the USAID Malaria Vaccine Development Program continues to partner with other USG and private entities for the development of highly effective, safe, and durable next-generation malaria vaccines. WHO is tracking 10 additional candidates in Phase 2 evaluation, 12 candidates in Phase 1 evaluation, and over 20 in preclinical development. USAID engages regularly with WHO and others around future malaria vaccine candidates.

[75] Datoo, M.S. et. al. Efficacy of a low-dose candidate malaria vaccine, R21 in adjuvant Matrix-M, with seasonal administration to children in Burkina Faso: a randomized controlled trial.The Lancet. 2021. 397: 1809-1818.

# OTHER CHEMOPREVENTION APPROACHES

***New/Key Messages***

There is renewed interest in exploring other chemoprevention interventions that may be effective in specific situations or among targeted populations. All of these interventions are *complementary to* strong vector control, CM, and surveillance programs. The use of any newer chemoprevention intervention should be carefully considered in the context of program goals and resources. For many of these interventions, WHO recommendations and guidelines are not yet available. Planned or ongoing studies and pilots will be used to inform guidelines.

There is ongoing research on the effectiveness and impact of different approaches to implementation of the WHO-approved IPTi intervention.

IPTsc and ivermectin have gained interest as promising new tools, but these are still in the evidence generation phase with no WHO recommendation.

While there is a large body of evidence of short-term impact of mass drug administration (MDA) from several controlled and non-controlled studies, a recent systematic review on MDA limited to controlled studies concluded that findings differed by transmission settings. In moderate-to high-transmission settings, there was a short term impact limited to parasitemia incidence only but no significant effect of MDA on *P. falciparum* parasitaemia prevalence or incidence beyond four months after MDA implementation. In very low- to low-transmission settings, MDA initially reduced *P. falciparum* and *P. vivax* parasitaemia prevalence and incidence for up to three months; there was no significant effect after four months although long-term absolute risks in both intervention and control groups were low.

The cost of introduction of any chemoprevention approach should be weighed against the potential benefit of these interventions as compared to other interventions.

## Introduction

Although much progress has been made with the scale-up of PMI's core interventions, newer tools to complement these core interventions have generated substantial interest for their potential to reduce malaria morbidity and mortality in targeted populations in high transmission settings and additional tools are being evaluated for their potential contribution. While delivery innovations (e.g., community-based IPTp) and the malaria vaccine are described in other chapters, this chapter will describe ancillary

chemoprevention interventions (IPTi, IPTsc, MDA, and ivermectin) for use in non-elimination and non-emergency settings – their intended role, targeted settings, and level of current evidence. Many of these interventions have come up during in-country strategic planning and intervention tailoring exercises. For more information about stratification and tailoring, please refer to the SM&E section.

Any new chemoprevention intervention is intended to complement, not replace, core interventions, including CM, vector control, and surveillance, and should only be considered for PMI support once requirements and scale for these core interventions have been addressed. Introduction of any new intervention requires extensive planning and strategic decision-making. Prior to introduction of any new intervention, it is critical to consider a series of questions related to the motivation and evidence for introduction, the local context and targeting of the intervention, implementation considerations, and how data will be generated and used. Please refer to the chapter appendix for a detailed summary of the questions. As countries begin to consider the introduction of a new chemoprevention intervention, they are encouraged to reach out to the PMI intervention points of contact for assistance in thinking through answers to these questions in their context.

Interventions designed to interrupt malaria transmission in low-transmission settings to accelerate the pathway to elimination or to interrupt transmission (e.g., MDA, Mass Screen And Treat [MSAT]) are being evaluated in various settings. These approaches are also intended as additional targeted activities and are not a substitute for a robust malaria control program based on vector control and strong CM and surveillance practices. Ancillary interventions in low-transmission settings (e.g., MDA, MSAT) are discussed in the **Elimination** chapter of this guidance.

## Overview of new chemoprevention interventions

The technical leads for novel chemoprevention approaches developed the series of briefers on the chemoprevention interventions that are being discussed in new settings or are still being tested. These briefers are included in the appendix of this section. A brief description of the included interventions is in the table below, but teams should review the briefers for more detailed implementation considerations and information and links to ongoing research.

**Table 4. Overview of New Chemoprevention Interventions**

| Intervention | WHO approved | Target population | Trans mission settings | Goal stated in literature | Treatment used | Main distribution channel | Current status |
|---|---|---|---|---|---|---|---|
| **SMC** | Yes | Children < 6 years old, but some interest in older age groups | Sahel with seasonal transmission, but some interest in other settings | Reduce malaria morbidity & mortality | SPAQ with ongoing studies of DP | Community (comm) campaign | Wide-scale implementa-tion in Sahel with ongoing studies outside Sahel. |
| **IPTi** | Yes | Infants < 1 year old | Moderate-to-high transmission settings where resistance to SP is not high | Reduce clinical malaria, severe malaria, anemia | SP | EPI | Limited use at scale. Ongoing studies of other ages and settings. |
| **MDA** | In limited settings | All ages | Elimination settings, Epidemics, Complex emergencies | Reduce morbidity, mortality and transmission | Many, mostly DP | Comm. campaigns; some fixed site | WHO approved for limited settings. Limited use. |
| **Ivermectin** | No rec. | All ages except infants and pregnant women | Settings with high vector control coverage and residual transmission | Reduce malaria incidence | Ivermectin | Comm. campaign | Extensive ongoing data collection. |
| **IPTsc** | No rec. | School-aged children | Across transmission settings | Reduce malaria incidence/ prevalence | Many | Schools | Limited ongoing data collection. |

## Seasonal Malaria Chemoprevention

SMC is the administration of treatment doses of longer-acting antimalarial medications to children, typically amodiaquine plus SPAQ. Medications are administered at monthly intervals in areas of exclusively seasonal transmission. It has been shown to be an effective and feasible complementary

strategy for reducing malaria morbidity in eligible countries of the Sahel (see full **Seasonal Malaria Chemoprevention** section). Currently, studies to evaluate the feasibility and protective efficacy of administering SMC in areas outside of the Sahel region are underway or being planned. Results of these studies will be used to inform SMC policies in these new areas.

## Intermittent Preventive Treatment in Infants

IPTi is the provision of a full therapeutic course of a single or combination antimalarial treatment to infants during routine immunization services, regardless of current malaria infection. It has primarily been implemented using SP with treatment provided at 10 weeks, 14 weeks, and nine months of age, alongside routine vaccines within the EPI.

In 2010, WHO issued a strong recommendation in favor of delivery of IPTi with SP to infants under 12 months of age in areas of Africa with moderate-to-high malaria transmission and where SP is still effective (where parasite resistance to SP is not high, which can be defined as areas that have less than 50 percent prevalence of *pfdhps* 540 mutations associated with resistance in the *P. falciparum* parasite) at the same time as delivery of the second and third rounds of vaccination against diphtheria, tetanus, and pertussis and against measles. The routine EPI scheduling varies by country but usually includes doses at 10 weeks and 14 weeks (with DPT vaccinations), and nine months of age (with measles vaccination). WHO advised that 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.

A systematic review (Esu et al., 2019) included 10 studies on the impact of IPTi with SP and limited data from studies using other drug combinations (dihydroartemisinin-piperaquine, amodiaquine-artesunate, SP-artesunate and amodiaquine). All studies were from areas with moderate to high transmission. It found that IPTi with SP reduced clinical malaria by 22 percent (rate ratio 0.78, CI: 0.69 to 0.88). The review concluded that SP also likely reduced sub-clinical malaria infection, anemia, parasitemia, and hospital admissions, but likely did not affect all-cause mortality. More recent studies showed declining efficacy, potentially due to drug resistance and the most recent study was published in 2014. While there are considerable start-up costs with introducing a new program, the annual costs post-introduction are relatively inexpensive (Manzi et al., 2008).

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. WHO recommends that countries implementing SMC should not also implement IPTi in the same areas.

Several research partners (e.g., UNITAID, BMGF, Malaria Consortium, EDCTP) are planning or undertaking investments to generate evidence to accelerate the adoption and scale-up of IPTi in moderate-high transmission settings, to older age groups (i.e., through two years of age), via different delivery methods, and using different therapeutic agents (e.g., SP in combination with azithromycin). Results of these trials, expected in 2024, will inform future WHO IPTi policies.

While PMI country teams are not currently prioritizing IPTi implementation, it is possible to support IPTi with PMI resources. Any potential implementation of IPTi should be complementary to strong CM, MIP service provision, and vector control and should be accompanied by robust surveillance. Requests for PMI to support IPTi must be discussed with the PMI HQ CM Team and PMI leadership, in consultation with the supply chain team. Please reach out to the HQ POCs if your NMCP is considering support for IPTi or for more information.

## Intermittent Preventive Treatment in School Children

IPT is a standard malaria prevention intervention with pregnant women and infants in selected areas, but recent data on the delivery of IPTsc are limited. Studies of IPTsc have distributed treatment courses of different antimalarial drugs, including SP, SPAQ, SP-artesunate, AL, and dihydroartemisinin-piperaquine (DP). Distribution is often implemented monthly in school settings to school-aged children, generally aged five to 15 years old, for up to six rounds. IPTsc differs from other interventions such as SMC in that it leverages schools as a distribution channel. IPTsc was piloted in diverse settings, but has not been sustained.

IPTsc is still in the evidence-generation phase with no current WHO recommendation. The goal of IPTsc would be to reduce malaria incidence and prevalence among school-aged populations, a group that in some settings have a prevalence greater than 50 percent (Cohee et al., 2020). This population may also serve as a reservoir for infection. PMI does not support the use of IPTsc for malaria prevention outside of potential operations research. Please reach out to the HQ POC if your country is currently discussing IPTsc or if you have any questions

## Mass Drug Administration

MDA of antimalarials is the provision of therapeutic doses of antimalarial drugs to targeted populations, regardless of symptoms and without testing. Please see the Elimination section for information about Mass Screen and Treat. These drugs clear malaria infections (symptomatic or asymptomatic) and prevent reinfection through the effect of post-treatment prophylaxis. MDA is primarily used to support elimination of *P. falciparum* malaria where there is minimal risk of re-introduction as a complement to good access to CM, vector control, and surveillance. It has been used in the greater Mekong Subregion in the context of artemisinin resistance. To support epidemic control or respond to complex emergencies where there is disruption of routine services, WHO has recommended consideration of

time-limited MDA deployment and/or presumptive treatment of fevers with ACTs. While MDA has been piloted for malaria burden reduction in moderate- and high-burden settings, the evidence of impact in these settings is limited. MDA is intended to achieve rapid prevalence reduction, but must be accompanied by broader surveillance, vector control and CM strengthening across settings.

During a large-scale MDA campaign, every person in the targeted population and geographical area is provided treatment at approximately the same time and high coverage should be achieved. Campaigns typically include multiple distribution rounds spaced by approximately one month, starting prior to and timed to coincide with the peak transmission period. The most recent common implementation model is monthly distribution of dihydroartemisinin + piperaquine (DP +/- single, low-dose primaquine) for three months.

WHO does not currently recommend the use of MDA in situations other than for areas approaching elimination, or during epidemics or complex emergencies due to insufficient evidence of efficacy (WHO Guidelines). MDA produced mixed results during eradication efforts of the mid-20th century and as a result was discouraged by WHO. Interest was revived in the context of artemisinin resistance in Southeast Asia, but a 2010 WHO panel determined there was no evidence of long-term benefits of MDA for large population groups. A 2013 systematic review and 2015 review concluded that while MDA can be successful at rapidly reducing parasite prevalence, there is a strong tendency for malaria to return to previous transmission levels once stopped, especially in higher transmission settings. In 2019 the WHO Malaria Policy Advisory Committee concluded that combined with vector control and CM, MDA may rapidly reduce malaria transmission for a short period (one to three months), but these reductions were only sustained in very low- to low-transmission areas and on small islands with moderate transmission. WHO developed Mass drug administration for falciparum malaria: a practical field 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.

Most recently, a 2021 Cochrane review limited to controlled studies concluded that MDA in moderate- to high-transmission areas had little to no effect in the short- or mid-term on parasite prevalence. In very low- to low-transmission areas, MDA reduced parasitemia incidence and prevalence one to three months post-distribution, but the impact on *P. falciparum* declined over time. Studies have demonstrated time-limited impact of MDA when timed to coincide with intensive implementation of CM and vector control interventions. For example, results from southern Zambia showed marked reductions in malaria prevalence and incidence across both control and MDA arms. This impact followed aggressive efforts to achieve universal coverage of long-lasting insecticidal nets, IRS, and effective community CM.[76] In

[76]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.

addition, focal MDA (MDA targeting households or small-scale foci) was not as effective or cost-saving compared to MDA.

Care must be taken when deploying strategies such as MDA 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 percent 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 (included in some MDA implementation models) is contraindicated in pregnancy and lactating women.

MDA may be an appropriate intervention in the setting of complex emergencies such as an Ebola outbreak or natural disaster when routine health systems are disrupted. Temporarily reducing the burden of malaria (including incidence of fever) on the health facilities allows health workers to focus efforts on the emergency response. For additional information on use of MDA during complex emergencies please refer to the Malaria Programming in Humanitarian Contexts section.

PMI is not currently supporting MDA implementation outside of the context of the operations research studies. Please reach out to the HQ POCs if your country is currently discussing MDA implementation or if you have any questions. For guidelines regarding the use of MDA or reactive drug administration (RDA) in low-transmission settings as a tool along with core interventions to advance elimination, see the section on **Elimination**.

## Ivermectin

MDA of ivermectin has been a pillar of neglected tropical disease programs since 1987 for its benefit in reducing helminth burden. When this broad-spectrum endectocide is administered to humans or to livestock it reduces the lifespan of *An.* mosquitoes who bite the person or animal. Ivermectin MDA is now being tested as a malaria prevention tool to be used on top of universal coverage of proven vector control strategies. Ivermectin is being piloted as a standalone intervention with monthly distribution to humans and/or livestock and has been combined with antimalarial MDA and SMC. The WHO has not made a recommendation related to use of ivermectin for malaria control, but has established the criteria for ongoing studies to provide sufficient data to inform a future recommendation.

Ivermectin for malaria is a first-in-class, novel intervention for drug-based malaria prevention. Ivermectin was first shown to kill malaria vectors by interfering with the glutamate-gated chloride channels in 1985. Since then it has been shown to be effective in killing multiple malaria vectors. A study on the use of albendazole + single doses of 150-200 μg/kg ivermectin in Burkina Faso attained low coverage, but found reduced cumulative malaria incidence in the group that received ivermectin relative to the control groups (risk difference 0.49; 95 percent CI: 0.21, 0.79) (Foy et al., 2019). A study in Kenya of single doses of 300 μg/kg and 600 μg/kg ivermectin with DP found the drug was well-tolerated and reduced mosquito survival (Smit et al., 2018). Ongoing studies are using different distribution strategies (stand-alone to humans and / or livestock, alongside SMC, alongside MDA) and treatment regimens.

Ivermectin is still in the evidence-generation phase with no WHO recommendation. PMI will not support the use of ivermectin for malaria prevention outside of future potential operations research.

# CASE MANAGEMENT

***New/Key Messages***

**Case Management section formatting.** With input from field staff, the CM chapter was reformatted in the FY 2022 Guidance for easier use and reference. Each section in the CM chapter 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.

**Guidance document on the management of malaria RDT stock shortages.** PMI, in collaboration with partners, is developing guidance to assist NMCPs in the management of short- to medium-term malaria RDT stock shortages. A brief summary of the guidance is provided below in the sub-section "PMI Priorities Areas of Support for RDTs." The full document will be circulated to PMI teams when finalized.

**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**. In areas where monitoring suggests the presence of *hrp2/hrp3* gene deletions, systematic surveillance of *hrp2/hrp3* gene deletion may be warranted. Samples collected during therapeutic efficacy studies may be screened for the presence of *hrp2/3* deletions.

**Case Management Resources**

PMI country teams may contact the PMI CM technical team for additional resources, including PMI treatment guidelines checklist, generic training and supervision materials, and job aids.

## PMI priority support for a comprehensive malaria case management program

A successful malaria case management (mCM) program consists of several distinct but interrelated activities that should be implemented in concert. The priority areas for PMI support to a case management program include:

- Reviewing policies and guidelines on the management of fever and diagnosis and treatment of malaria, and harmonizing with WHO recommendations 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, RDTs, biohazardous material disposal)
- Supporting the accurate quantification and forecasting, and the consistent provision of antimalarial treatment for uncomplicated (i.e., ACT, chloroquine, primaquine) and severe (e.g., parenteral artesunate, rectal artesunate [RAS]) malaria
- Supporting QA of diagnostic testing programs including quality control of RDTs and their use, malaria microscopy, job aids, on-site training and structured supportive supervision, and external quality assessment (EQA)
- Supporting pre- and in-service training, supervision and mentoring of clinical staff and CHWs in the management of febrile illness, including adherence to diagnostic test results and management of uncomplicated malaria and severe disease (including in pregnant women), and accurately recording and reporting malaria test and treatment results
- Supporting iCCM programs consistent with recommendations from UNICEF and WHO
- Supporting therapeutic efficacy monitoring of antimalarial treatments.

For additional details of PMI priority support, please see the specific "Key Technical and Programmatic" section of interest 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, the signs and symptoms of malaria typically include fever but generally are non-specific. Malaria therefore should be suspected clinically by a healthcare worker (HW) primarily in the presence of fever or report of history of fever.[102] WHO also recommends that malaria should be suspected in children with clinical signs or laboratory 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, resulting in missed opportunities to diagnose and appropriately treat.[77]

[77] Plucinski MM, Guilavogui T, Camara A, Ndiop M, Cisse M, Painter J, Thwing J. 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.

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

The initial management of a suspected malaria patient should also include an assessment of illness severity in order to correctly classify the patient as having uncomplicated or severe disease and guide CM, including appropriate diagnostic testing and prescribing effective treatment. Please see the WHO Guidelines for Malaria, Integrated Management of Childhood Illnesses (IMCI) Chart Booklet, Integrated Management of Adult Illness (IMAI), and Malaria Surveillance, Monitoring and Evaluation: A Reference Manual for guidance.

### *PMI priority support for recognition and management of febrile illness*

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

## 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 confirmatory diagnostic testing, with either RDTs or microscopy, and for treatment decisions to be based on test results.** RDTs and microscopy are both recommended for the diagnosis of malaria in patients with suspected malaria. Each testing modality has characteristics that make it more or less useful in particular clinical situations or settings**.** WHO has published detailed guidance for laboratory 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.[78,79,80] Diagnosis based on clinical signs and symptoms alone should only be used when diagnostic testing is unavailable.

[78] WHO Malaria Diagnosis website.
[79] Universal Access to Malaria Diagnostic Testing: An operational manual (2011).
[80] Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: round 8 (2016-2018).

## *PMI priority support for diagnostics in general*

**Policy and guidelines**

PMI has prioritized scaling up diagnostic testing for malaria with RDTs and microscopy in all partner 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 is 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.

Policies 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 SOPs and job aids 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, or the diagnosis, including the use of RDTs, and treatment of malaria may be expanded in the community by CHWs or health extension workers who have been trained on iCCM standard algorithms and mCM.

**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 healthcare worker 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*

Because quality assured microscopy services are challenging to implement and maintain at scale, RDTs are essential tools in reaching universal diagnostic testing of suspected malaria cases at 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/μL 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 the HRP2-based RDTs ), and they therefore cannot be used to accurately diagnose reinfections or 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 transfer 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 the differing methods and how to use each of the tests.

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 QA, including supportive supervision, is necessary to ensure appropriate use of RDTs and adherence to RDT results. Please see **Behavior Change** and **Case Management** chapters 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 ≥ 10 percent 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 for specific guidance.

### *hrp2/3 gene deletions*

Although the antibodies on the RDT are designed to recognize the HRP2[81] 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 recently have been identified in Sub-Saharan Africa.[82] Although different research groups have reported detection of generally low rates of deletions in Angola, DRC, Ghana, Mali, Rwanda, and Uganda,, the methods used

[81] Please note that the convention is to capitalize when referring to the HRP2 antigen and revert to lowercase italicized formatting when referring to the *hrp2* gene.

[82] Master protocol for surveillance of pfhrp2/3 deletions and biobanking to support future research.

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 Ethiopia.[83,84,85]

Initial alerts suggesting the presence of *hrp2/hrp3* gene deletion include reports of discordant results between microscopy and RDTs. Alternatively, parasites with *hrp2/hrp3* gene deletion might be incidentally detected during analysis of samples collected for another purpose. Finally, geographical proximity to areas with known *hrp2/hrp3* gene deletion may increase the likelihood of *hrp2/hrp3* gene deletions.

In areas where any of the above conditions are met, systematic surveillance of *hrp2/hrp3* gene deletion may be warranted. WHO has developed a standardized guidance for *hrp2/hrp3* gene deletion surveillance. The guiding principle of this surveillance is systematic testing of symptomatic patients with an HRP2-based diagnostic test and at least one non-HRP2-based diagnostic test (e.g., a Pf-LDH RDT or microscopy). Samples from any patients with a discordant result should then be assayed with molecular techniques to confirm *hrp2/hrp3* gene deletions. The final indicator is the proportion of samples with molecularly confirmed *hrp2/hrp3* gene deletions over the total number of samples screened that were positive for *P. falciparum* on any test. Other study designs, for example health facility surveys (HFS), that also systematically test patient samples using an HRP2-based and non-HRP2-based diagnostic to identify discordant samples can also serve to generate data on the prevalence of *hrp2/hrp3* gene deletions.

Non-HRP2-based RDTs are indicated in settings with >5 percent reported *hrp2* gene deletions in those patients presenting with symptomatic malaria. 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),[(See footnote 8)] and were tested against 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) met procurement criteria. 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.

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[83] Berhane A, Anderson KF, Mihreteab S, et al. Major Threat to Malaria Control Programs by Plasmodium falciparum Lacking Histidine-Rich Protein 2, Eritrea. Emerging Infectious Diseases. 2018, 24(3), 462.

[84] Mihreteab S, Anderson K, Pasay C, et al. Epidemiology of mutant Plasmodium falciparum parasites lacking histidine-rich protein 2/3 genes in Eritrea 2 years after switching from HRP2-based RDTs. Sci Rep. 2021 26;11(1):21082.

[85] Feleke SM, Reichert EN, Mohammad H, et al. Plasmodium falciparum is evolving to escape malaria rapid diagnostic tests in Ethiopia. Nat Microbiol. 2021;6(10):1289-1299..

Highly sensitive RDTs may be useful for certain indications in elimination settings. Please see the **Elimination** chapter for more information.

### *PMI priority support for RDTs*

**Policy and guidelines**

Please see **PMI priority support for diagnostics in general** for general guidance.

**Equipment and supplies**

PMI procures WHO PQ RDTs, with exceptions only in times of severe supply shortages. 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 in most regions (see exception above for settings with *hrp2/hrp3* gene deletions). PMI 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.[86] In these countries, PMI may procure *P. falciparum*/*P. vivax* RDTs.

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, non-vivax 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.

[86] WHO Malaria Microscopy: Quality Assurance manual. Version 2 (2016).

- Programmatically, single species RDTs are less costly (i.e., the unit cost of multi-species RDTs is up to 30 percent greater than single-species RDTs) and simpler to interpret (i.e., there is only one test line and one control line).

**PMI therefore does NOT procure Pan/Pf RDTs.** Exceptions to this guidance will be granted if there is credible evidence demonstrating at least 5 percent prevalence of *hrp2* gene deletions amongst those presenting with symptomatic malaria because options for Pf-LDH RDTs are limited.

Quantification of RDTs primarily is based on case data from routine health information systems (RHIS) 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 analysis 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 NMCPs 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 and quality control**

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 should include, at a minimum, regular supervision at least every six months with observation of HWs' 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.

RDTs 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 to check the quality of diagnosis of symptomatic malaria by RDT or microscopy.

**Training and supervision of laboratory staff**

**PMI priority 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/μL 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 support for microscopy*

**Policy and guidelines** on the diagnosis of malaria should be periodically reviewed, revised, and harmonized with WHO recommendations.[See footnotes 78, 79, 98] In most countries, microscopy is only

available at the hospital level and at larger health centers. Microscopy 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 HQ 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. Please refer to the **Supply Chain** chapter for more details on eligible suppliers.

**Quality assurance**

WHO has developed detailed guidelines on quality control of malaria microscopy, 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 (e.g., blinded rechecking). PMI supports the development or purchase of a validated malaria reference slide bank with known species and parasitemia density for use in training and external quality assessment (e.g., panel testing). Purchasing a validated slide bank may be preferable as developing a slide bank is laborious and can take years to complete. The overall cost to purchase a validated slide bank (also known as a National Archive of Malaria Slides, or NAMS) is dependent on several factors, including the cost per slide (i.e., typically ranges from $20-40 per slide), the total number of slides needed, the shipping costs (e.g. $500), and the need for QA upon receipt of the slides. The total number of slides needed will vary based on the number of labs and laboratory technicians in the country and how the NAMS will be used (e.g., training, external QA). As an approximation, a NAMS of 5,000 slides should be sufficient for a medium-sized country in sub-Saharan Africa. The NAMS should undergo QA by a qualified WHO Level 1 microscopist upon arrival to ensure the accuracy of the types of slides requested. Countries with access to a qualified WHO Level 1 microscopist could perform this QA as part of regular activities. Countries without access to a qualified WHO Level 1 microscopist would require this QA step be conducted by an outside consultant, which would likely cost $200-350 per day; the number of days required will vary depending on the number of slides in the NAMS. Recommended good quality suppliers of NAMS include the Kintampo Health Research Center (Ghana), UCAD (Senegal), and AMREF (Kenya). Additionally, the slides will degrade over time due to environmental factors (e.g., humidity) and use (e.g., handling, breakage). Countries conducting proficiency testing will likely see more rapid attrition than those who are only using slides for training. Countries should consider budgeting on average to replace approximately 25 percent of the slides every two years.

**Training and supervision of laboratory staff**

Please see **PMI priority support for diagnostics in general** for general guidance. Additionally, the CDC malaria diagnostics bench aids and SOPs are available on the CDC DPDx website, 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/

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

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

## Case Management

### *Treatment of uncomplicated malaria*

WHO recommends six ACTs as first-line options for the treatment of falciparum malaria:

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)

ACT preparations partner an artemisinin drug (i.e., artesunate, artemether, dihydroartemisinin) with a second antimalarial. Artemisinins rapidly reduce parasite density in the blood and control fever and are rapidly eliminated. The partner drug, such as mefloquine, SP, amodiaquine, lumefantrine, piperaquine, or pyronaridine, is longer acting and clears residual parasites. Side effects are uncommon, and serious or life-threatening adverse drug reactions are exceedingly rare. Find the full WHO Guidelines for Malaria here.

#### ***Antimalarial efficacy and treatment failure***

The efficacy of ACTs in sub-Saharan Africa remains high and a three-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.[87] 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

[87] WHO. Artemisinin resistance and artemisinin-based combination therapy efficacy: status report (2018).

ACT also must be considered. To help address incorrect dosing, poor patient compliance, and poor drug quality, please see **PMI priority support for treatment of uncomplicated P. falciparum** below for additional details on training and supervision of HWs and quality monitoring of drugs.

### *Antimalarial resistance*

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

Southeast Asia is the geographic region in which antimalarial resistance is the most prevalent. Recent studies from Southeast Asia have 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*),[88] 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,[89] India,[90] and Rwanda.[91,92]

[88] Ariey F et al. A molecular marker of artemisinin-resistant Plasmodium falciparum malaria. 2014. Nature. 505(7481):50-5.
[89] 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.
[90] Das S et al. Evidence of Artemisinin-Resistant Plasmodium falciparum Malaria in Eastern India. NEJM. 2018.
[91] Uwimana A, Legrand E, Stokes BH 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).
[92] Uwimana A, Umulisa N, Venkatesan M, et al. Association of Plasmodium falciparum kelch13 R561H genotypes with delayed parasite clearance in Rwanda: an open-label, single-arm, multicentre, therapeutic efficacy study. Lancet Inf Dis. 2021 Aug;21(8):1120-1128.

**Table 5. ACT characteristics comparison**

| | Artemether lumefantrine (AL) | Artesunate-amodiaquine (ASAQ) | SP-artesunate (SP-AS) | Mefloquine-artesunate (MQ-AS) | Dihydro-artemisinin-piperaquine (DP) | Artesunate-pyronaridine (AS-PYR) |
|---|---|---|---|---|---|---|
| **General comment** | 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 clarifying AS-PYR considered safe and efficacious |
| **Formulation** | 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 |
| **Partner drug safety** | Ample evidence from SE Asia, sub-Saharan Africa | Ample evidence from SE Asia, sub-Saharan Africa | Ample evidence from SE Asia, sub-Saharan Africa | Ample evidence from SE Asia, increased risk of neuropsychiatric effects with repeated dosing | Ample evidence from SE Asia, sub-Saharan Africa | Relatively limited evidence; acute, reversible liver enzyme increases |
| **Partner drug half life, post treatment prophylaxis** | 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 |
| Evidence of resistance to partner drug | 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 sub-Saharan Africa | Limited evidence in SE Asia, none in sub-Saharan Africa |
| Partner drug molecular resistance locus[93] | *Pfmdr1* point mutations | *Pfmdr1* point mutations | *Dihydrofolate reductase (DHFR)* and *dihydropteroate synthase (DHPS)* point mutations | *Pfmdr1* copy number | *Plasmepsin 2* and *3* copy number, *Pfcrt* point mutations | Mechanism unknown |

[93] Venkatesan M, Gadalla NB, Stepniewska K, et al. Polymorphisms in *Plasmodium falciparum* Chloroquine Resistance Transporter and Multidrug Resistance 1 Genes: Parasite Risk Factors That Affect Treatment Outcomes for *P. falciparum* Malaria After AL and Artesunate-Amodiaquine. Am J Trop Med Hyg. 2014 Oct;91(4):833-843.

### ***Determination of first line ACTs: program considerations***

All six ACTs are considered efficacious and safe. 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
   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 percent 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.

### ***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.[94,95,96]

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

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

WHO also recommends single, low-dose primaquine to reduce the risk of transmission in addition to an ACT for falciparum malaria in regions with artemisinin resistance. Please see the WHO Guidelines for

[94] Boni MF, Smith DL, Laxminarayan R. Benefits of using multiple first-line therapies against malaria. Proc Natl Acad Sci USA 2008;105: 14216–21.
[95] 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.
[96] Nguyen TD, Olliaro P, Dondorp AM, Baird JK, Lam HM, Farrar J, et al. Optimum population-level use of artemisinin combination therapies: a modeling study. Lancet Glob Health. 2015 Dec;3(12):e758-66.

malaria (2021)/Management of malaria cases in special situations (section 5.7.1) / Artemisinin-resistant falciparum malaria for details.

### ***Treatments in development***

There are several other compounds/formulations in various phases of development, including triple ACT therapy. Given their Research & Development status, none should be considered during FY 2022 MOP planning. For the latest information on products in development, please refer to the Medicine for Malaria Venture (MMV) website.

### ***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. Non-oral artemisinin monotherapy (i.e., intravenous, intramuscular, or rectal) for initial or pre-referral management of severe malaria is the exception; this initial or pre-referral severe malaria treatment then is followed by a full ACT treatment course. (Please see the **Management of Severe Malaria** section below for additional information).

Artequick is an ACT (artemisinin 62.5mg + piperaquine 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 QA of this medication. If teams become aware of Artequick donation offers in their country, they are encouraged to contact the PMI CM HQ team, which has already been in contact with WHO about this issue.

## *PMI priority 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 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 **Service Delivery in the Private Sector** section below for additional information).

PMI HQ 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 currently 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 SBC 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 RHIS or consumption data. Correct quantification has been a significant challenge in most PMI-supported countries, and an internal PMI analysis of MOP gap analysis 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 medicines**

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 QA program. PMI, through its implementing partners, uses tools such as market surveys and mystery

shopper assessments and collects 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 HW staff**

Training curricula for clinicians and CHWs should be periodically revised to align with the country's most updated mCM policies and guidelines, including integrated management of childhood illness guidelines and other integrated guidelines for surveillance of febrile illness. Whenever feasible, clinical training on mCM 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 HQ staff. Please see the **Community Health** chapter for additional guidance on CHWs.

## *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**.[97]

Parasitemia should be monitored at least every 12 hours during the first two to three days of treatment in order to assess the response to treatment. 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 three-day course of an ACT.

[97] Arjen M Dondorp et al. Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomized trial. Lancet. 2010 Nov 13;376(9753):1647-57.

Toolkits and other helpful information about severe malaria are available at: https://www.severemalaria.org/, WHO Guidelines for malaria (2021), 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 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 RAS only for the pre-referral management of severe malaria in children six years of age or less. This guidance was re-emphasized in a subsequent WHO information note as some NMCPs still deviate from this guidance. Children six years of age or less should receive an immediate dosing of the rectal suppository(s) (10 mg/kg body weight) followed by immediate referral. Because severe malaria is a 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.

Challenges to widespread implementation of appropriate severe mCM include underdeveloped or non-existent community-based platforms for delivery and referral systems, inadequate availability of severe malaria medicines throughout the levels of the health system, and the collection of quality metrics specific to the management of severe malaria. 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 HWs 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 counseling by HWs and SBC materials. Groups such as MMV 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. (Please see the **Severe Malaria Treatment and Referral** section of the Community Health technical guidance for additional information.)

## *PMI priority 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 RAS, a country must update their CM 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 RAS 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-PQ 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.

For RAS, PMI will only procure WHO-PQ 100-mg presentations. Countries that wish to procure the non-PQ 50-mg or 200-mg presentations must contact the CM and Supply Chain Management HQ 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 RAS 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 HW staff**

Training curricula for clinicians and CHWs should be periodically revised to align with the country's most updated mCM 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 the WHO Guidelines for malaria (2021) 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 percent 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.[98]

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), 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).

The BinaxNOW® G6PD screening test is the one qualitative product currently marketed for point-of-care use in G6PD deficiency testing. The BinaxNow G6PD test has been approved by the U.S. Food and Drug Administration (FDA) 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

[98] WHO Guidelines for malaria (2021).

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 and Australia's Therapeutic Goods Administration (TGA). PMI currently is supporting the evaluation of this test in Cambodia to support the deployment of primaquine radical cure.

Tafenoquine received approval from the US FDA and the Australian TGA for single-dose radical cure of *P. vivax* infections. Since the approval, there has been a label change and **tafenoquine should be co-administered with chloroquine only** and not other antimalarials (e.g., ACTs). Among the PMI countries, tafenoquine is registered only in Thailand and is undergoing implementation pilot studies in Thailand and Ethiopia. It is a single-dose treatment, which will improve adherence compared to the currently recommended 14 days of primaquine therapy. A recent modeling study from Brazil showed that the use of tafenoquine would improve the mean effective radical cure rate from 42 percent to 62 percent among clinical cases, leading to a predicted 38 percent reduction in transmission, equivalent to over 214,000 cases averted cumulatively over five years of implementation.[99] 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. 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.

## Integrated Community Case Management

Please see the Community Health section for more information about **Integrated Community Case Management**.

## Service Delivery in the Private Sector

In some PMI-supported countries, opportunities to partner with private sector providers and other non-public entities on key service delivery activities have been identified to further promote appropriate supply and use of diagnostics, treatment, and preventive measures. 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

[99] Nekkab N, Lana R, Lacerda M. Estimated impact of tafenoquine for Plasmodium vivax control and elimination in Brazil: A modeling study. PLoS Med. 2021 Apr 23;18(4):e1003535.

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 proportion of malaria services (ranging from less than 10 percent to over 50 percent of care of children with fever according to the DHS among PMI partner countries) at little to no cost to the public system, reducing the burden on the public sector. As private sector service delivery varies between and within countries (including by urban and rural geographies), a good understanding of the localized context for appropriate malaria service delivery (e.g., CM, MIP) in the private sector is critical for expanding mCM services and impacting malaria morbidity and mortality. The WHO has recently established the Country Connector for Private Sector in Health, an online platform designed to connect countries to resources, tools, guidance, and experiences for strengthening the private health sector's contribution to national health priorities.

Many of the challenges with providing comprehensive services in the public sector are amplified in the private sector. Because it remains essential to ensure that only high quality products (e.g. RDTs, ACTs, preventive medicines) are available, training and outreach, provider SBC, 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. One benefit of malaria treatment via the private sector is the often easy availability of treatments for non-malaria fevers (e.g., antibiotics and antipyretics, such as paracetamol), as it has been shown that inappropriate use of malaria treatment can be reduced if appropriate treatments for non-malaria fevers are available.

Like the public sector, any private sector intervention must be accompanied by good training, supervision, appropriate BCC activities for providers and patients, and collection and reporting of diagnostic and treatment data. It should be recognized that appropriate messaging for private sector CM may be more complex. In addition to standard messaging to consumers to seek treatment for fever, those with fever must be encouraged to get tested and, similar to the public sector, take antimalarial 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[100] is available for more information.

[100] Theodoor Visser et al. Introducing malaria RDTs in private medicine retail outlets: A systematic literature review. March 2017 *Plos One*.

## *PMI priority support for Private Sector Service Delivery interventions*

**Policy and guidelines**

PMI encourages all 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 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 HQ CM 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 (e.g., RDTs, 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. 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 CM 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 CM data should be incorporated into regular CM training and supportive supervision activities. Please see the **Surveillance, and Monitoring and Evaluation** chapter for details on RHIS.

## *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 CM 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 2022.

Other sources of data may include periodic HFS that include indicators on the quality of mCM, 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, and Monitoring and Evaluation** chapter for details on the various HFS.

## *Monitoring the efficacy of antimalarial drugs*

Routine, periodic monitoring of the efficacy of antimalarial drugs is recommended for all PMI partner countries using TESs. 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.[101] To help sustain the capacity of national testing teams, NMCPs may conduct such

[101] WHO Methods for Surveillance of Antimalarial Drug Efficacy.

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 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 HQ, 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 leadership have agreed that PMI will assume sole funding and technical responsibilities in PMI-supported African countries where Global Fund currently or formerly funded a TES. This TES funding arrangement will not impact WHO-funded TESs, which are currently implemented in a handful of PMI African countries.

The cost of a TES will vary based on the number of sites, the number of antimalarials studied per site, the expected time needed for recruitment, and potential additional costs, such as further testing in response to results of previous studies (e.g., day 7 blood lumefantrine levels) or molecular testing being done in country; please see Table 6 for details. PMI suggests budgeting $75,000-$150,000 per site (the lower end for one antimalarial, the higher end for two antimalarials), which includes costs for implementation and supplies.

PMI partner countries are encouraged to build on PMI investments in PARMA by supporting past trainees to perform drug resistance testing in-country for a TES. This may include providing support for supplies and person-time to the local institution and/or QA of testing at a partner laboratory.

**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 partner or requested from WHO or directly from the manufacturer. WHO PQ 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 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 complement 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 six-month period. Thus, data results will be shared and programmatic implications discussed with MCPs 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 HQ 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 or a PARMA partner in Africa (a laboratory worker from the TES country learning the techniques and testing samples during an eight-week visit) 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 NMCP 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 HQ (see Table 6).

**Table 6. Items that may be added to a standard TES with budget implications**

| Item | Purpose | Cost implications | Partner Responsible |
|---|---|---|---|
| Lumefantrine level blood testing | If evidence of waning AL efficacy in country, can use to investigate potential issues with drug absorption | Calculated per sample, varies | Typically subcontracted from TES partner to specialized laboratory (for details please reach out to PARMA team)<br><br>Sample collection supplies through CDC and specialized laboratory |
| Increased sample size | If evidence of waning drug efficacy or high uncorrected failure rate, an increased sample size may be warranted | Varies based on implementation cost | TES partner |
| DNA extraction kits | To extract DNA from dried blood spot samples before PARMA training | Varies based on sample size | TES partner |
| Microscopy QC | To perform quality control on microscopy for a sample of TES slides | Varies based on partner and sample size | TES partner (may subcontract with external lab) |
| PARMA training (ATL) | To build country capacity to monitor antimalarial resistance | $12,000 per trainee | TES partner |
| PARMA training (Africa) | To build country capacity to monitor antimalarial resistance | $12,000 per trainee for travel plus cost of sample analysis (discuss with host laboratory) | TES partner |
| Molecular analyses in-country | Countries that have participated in PARMA training and have the equipment & personnel needed to perform analyses in-country | Discuss with in-country laboratory | TES partner |

*Recommended to test all participants in AL arm.

## Behavior Change and Case Management

Communication and behavior change play an important role in encouraging best practices for CM, 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 CM; 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** chapter for more information on PMI-supported approaches for provider behavior change to improve CM 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.

SBC 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., CHWs, 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.

## Health Systems Strengthening and Case Management

Case management activities contribute to strengthening all recognized core health systems strengthening (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** chapter and **Community Health Systems** section for more details.

In support of health financing and efforts to achieve universal health care, PMI encourages all 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.

# COMMUNITY HEALTH

***New/Key Messages***

- The new community health section of the technical guidance covers both *services* delivered by CHWs, and *systems* that are essential in supporting quality delivery of community health services.
- CHWs are often a critical component, but just one part of a broader community health system and CHWs' effectiveness is often integrally related to the level of functioning of the broader system.
- There are many components of system strengthening that should be considered when supporting CHWs, including selection, saturation, skills, supervision, supplies, salary, and data systems. All of these components are detailed in this new community health section of the technical guidance.
- On June 29, 2021, PMI officially announced a change in policy regarding use of PMI funds for payment of CHW salaries and stipends, and PMI funds from any fiscal year may now be used to pay CHWs for their work in delivering community-based mCM services.
- Building off of initial investments in landscaping digital community health across all partner countries, PMI recommends continued, country-specific investments toward digitally-enabled health services, which have the potential to fundamentally improve not only community health, but malaria programming altogether.
- Other major donors, including the Global Fund, PEPFAR, and the Global Financing Facility/World Bank have also elevated their focus on strengthening CHW programs (see the new Global Fund strategy, for example), and there is great importance in creating synergies with these groups.

## Community Health Systems

A community health system is the set of local actors, relationships, and processes that lead to, advocate for, or support the health of communities and households. These include household caregivers, formal, volunteer, and informal community health providers, the organizational intermediaries for which they might work, health and political structures, and other government structures.[102] CHWs are often at the

[102] Helen Schneider & Uta Lehmann (2016) From Community Health Workers to Community Health Systems: Time to Widen the Horizon?, Health Systems & Reform, 2:2, 112-118, DOI: 10.1080/23288604.2016.1166307

intersection of their communities and the formal health system. As such, their effectiveness is often integrally related to the level of functioning of the broader system.

## Community Health Workers

CHWs are lay members of a community who have been trained to provide specific and limited health services in the community(ies) where they work, either as volunteers or for various types of compensation. "CHW" is an umbrella term for these HWs and the cadre may be referred to by different names in different countries (example: community health volunteers, health surveillance assistants, community health assistants, health extension workers, etc.). There is tremendous diversity in CHWs across different settings, some of which is captured in a series of 29 case studies on CHW programs.[103] Countries may also have multiple cadres of HWs who are considered CHWs, but who are trained in different activities or health areas. For the purpose of this guidance, we will use "CHW" as an encompassing term to describe lay HWs who are based in the community and have been trained to provide health services, including iCCM, education, and SBC, along with campaign style interventions (which are primarily covered in other sections of the guidance). It is expected that PMI staff will familiarize themselves with the CHW cadre(s) in their country in order to better understand their potential contribution to malaria services and any policy or implementation challenges.

CHWs play an essential role in the work of PMI, and this notion is woven throughout PMI's 2021–2026 strategy, "End Malaria Faster." Similarly, the World Health Assembly and the WHO in 2019 acknowledged the critical role and contribution of CHWs, encouraging member states to integrate the cadre within their broader health systems and to provide CHWs with the necessary support required in order to deliver safe and high-quality services.[104] These guiding documents acknowledge that CHWs can reach the unreached with the services they deliver, but that this is only possible if there are robust community health systems to support them. In other words, as the 2018 WHO guidelines on optimizing CHW programs and other global studies have documented: the stronger the systems supporting CHW programs, the better their performance, and the greater their impact on malaria and other diseases.[105,106] Since stronger CHW programs help reduce malaria-specific mortality, morbidity and accelerate malaria elimination,[107,108] PMI and NMCPs we support share a strategic interest in strengthening their

[103] Perry, H. (2021). Health for the People: National Community Health Worker Programs from Afghanistan to Zimbabwe.
[104] World Health Assembly. Community health workers delivering primary health care: opportunities and challenges. 2019.
[105] Panjabi, R. et al (2020) Exemplar Community Health Worker Programs. Exemplars in Global Health.
[106] WHO guideline on health policy and system support to optimize CHW programmes. Geneva: World Health Organization; 2018.
[107] Landier, J., et al. (2018). Effect of generalised access to early diagnosis and treatment and targeted MDA on *Plasmodium falciparum* malaria in Eastern Myanmar: an observational study of a regional elimination programme. *The Lancet.* 391(10133).
[108] Landier, J. et al. (2016). The role of early detection and treatment in malaria elimination. Malaria Journal 15(363).

performance to improve access to quality malaria services.[109] Therefore, this new section of the technical guidance covers both the *services* delivered by CHWs (iCCM, malaria community CM [CCM] for all ages, proactive CCM, referral for severe malaria, quality of care for these interventions, SBC, while other community-based interventions, such as SMC,and ITN campaigns, are covered in other sections) as well as the *systems* that support the delivery of these malaria services. These systems are often broader than malaria and include an enabling policy environment. While this section is intended to provide an overview of some of the critical components of community health, particularly as they relate to CHWs, it is not intended to be exhaustive. There is a vast literature base related to CHWs. Teams with particular questions or areas of interest might find helpful the recent journal supplement on CHWs at the Dawn of a New Era[110] and the Exemplars in Global Health platform on Community Health Workers, which uses evidenced-based country case studies to help guide public health decision makers working to improve the performance of national CHW programs. Please also contact the Community Health team leads to request additional information or resources that might be relevant for your country.

## Community Health Services

CHWs are implicated in a great many community-based services, some of which are described at length in other sections of this technical guidance. The following table describes the community health services that are covered in this section of the guidance (and links to the relevant subsection) and provides links to services that are covered elsewhere.

**Table 7. Community Health Services Outlined in this Guidance**

| Community Health Service | Technical Guidance Section |
|---|---|
| Integrated Community Case Management | Community Health |
| Community Case Management for All Ages | Community Health |
| Proactive Community Case Management | Community Health |
| Severe malaria treatment and referral | Community Health |
| SBC activities | Community Health |
| SMC | SMC |

[109] Rozelle JW, Korvah J, Wiah O, et al. Improvements in malaria testing and treatment after a national CHW program in rural Liberia. *Journal of Global Health Reports*. 2021;5:e2021073.
[110] Zulu, J. & Perry, H. (2021). Community Health Workers at the Dawn of a New Era. Health Research Policy and Systems.

| | |
|---|---|
| Community IPTp | MiP |
| Community-based ITN distributions | Vector Control |

## *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, iCCM is an equity-based approach which aims to increase access to care at the community level for the most vulnerable and hardest-to-reach populations. The iCCM approach provides standard algorithms for CHWs on diagnosis and treatment of pneumonia, diarrhea, and malaria (including the use of RDTs and ACTs), and screening for malnutrition. In addition to managing uncomplicated malaria at the household level, iCCM programs provide a platform for facilitating referral of complicated and severe malaria, including use of pre-referral RAS.

A number of studies[111] have demonstrated that malaria diagnosis and treatment can effectively be provided through CHWs as part of an integrated primary health care system, and WHO and UNICEF issued a joint statement recommending implementation of iCCM for sick children 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, how CHWs will be compensated, and what age groups the CHWs will serve. Country policies and guidelines should also clearly articulate the role of CHWs, including in relation to the broader health sector; what is and what is not permissible for diagnosis and treatment at community level; and the qualifications, supervision and training required for CHWs.

PMI supports iCCM services to children less than five years of age, as well as malaria community case management (mCCM) in older age groups where country policies (e.g. Rwanda, Senegal, Ethiopia, Thailand, Cambodia, and others) allow. PMI is currently supporting OR on the expansion of age ranges for mCCM in two countries to understand some of the implications and help inform effective implementation of the expansion of mCCM to all ages. Please see CCM for all ages section below for more information.

PMI funding may be used to support the full iCCM platform, including:

- Integrated training and supervision

[111] Smith Pantain et al. (2014) Community Health Workers and Stand-Alone or Integrated Case Management of Malaria: A Systematic Literature Review. AJTMH 91(3).

- Integrated supply chain systems
- Equipment and supplies (bicycles, flashlights, etc.)
- Reimbursement of travel or other work-related expenses as appropriate
- Procurement of RDTs, treatment for uncomplicated malaria, and medicines for the pre-referral management of severe illness for use at the community level
- Stipends or salaries[112] for CHWs implementing iCCM/mCCM (see details in the systems section of this document and the FAQ document on the recent policy shift on the payment of salaries and stipends)

PMI funding may NOT be used to support:

- Supplies or treatments for non-malaria diseases managed under the iCCM algorithm, including diarrhea, pneumonia, or malnutrition

PMI country teams should work with local partners to support iCCM whenever possible and actively engage with Maternal and Child Health and other relevant streams of funding in the mission and partners in the country to help strengthen iCCM overall, including the provision of the non-malaria commodities. 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.

## *CCM for all ages*

The documented success and acceptance of iCCM for children under five years of age has led to increasing interest in expanding access for mCCM to older unreached individuals in many PMI partner countries. There are ample examples of PMI partner countries that have always implemented mCCM for all ages (and it should be noted that all PMI eliminating countries implement mCCM for all ages – see **Elimination** section for more information). At present there is a paucity of evidence informing the *expansion* of access to treatment to all ages. The primary example of recent expansion of CCM to all ages comes from Rwanda, which officially expanded mCCM to all ages in 2015 and is one of the few countries that have conducted and published an assessment of the impacts of *changing* this policy,

[112] As per the ADS, https://www.usaid.gov/ads/policy/300/119780, PMI may pay for full stipends or salaries but not salary supplements (additional payment on top of existent salary); This language is in reference to the only USAID policy on the issue of direct support to government employees (written in 1988). The policy discourages support of salary supplements for host government (HG) employees or anything beyond base salary compensation for a regular pay period worth of work. (Salary supplementation occurs when payments are made that augment an employee's base salary or premiums, overtime, extra payments, incentive payment and allowances for which the HG employee would qualify under HG rules or practice for the performance of his regular duties or for work performed during his regular office hours.' (para 3(b)).

looking retrospectively at routine data.[113] However, this study was limited to a retrospective analysis of routine data. Two PMI-funded OR studies are currently underway in Madagascar and Malawi to formally assess the resource needs and impacts of expanding access to mCCM all ages in order to inform policies and implementation in other countries. Expected study outputs will document effects on community care-seeking behaviors, malaria prevalence, CHW workloads, and cost effectiveness, among others, which will allow other PMI countries to build on these experiences to best inform how expansion to all ages might be done. Meanwhile, country teams are encouraged to contact the Community Health team POCs to discuss the benefits and potential logistical considerations of such a strategy within the national context if such a policy change is being considered.

### *Proactive 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 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 in zones of seasonal transmission.

The most well-established example of this approach is the PECADOM *(prise en charge à domicile)* Plus program in Senegal. In this program, CHWs are paid to 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.[114] 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 to moderate transmission. Current efforts extend the period of implementation and increase the proportion of communities (both geographic and other pockets of unreached, such as children living in group settings) benefiting from this intervention.

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[113] Uwimana, A. et al. Expanding home-based management of malaria to all age groups in Rwanda: analysis of acceptability and facility-level time-series data. *Transactions of The Royal Society of Tropical Medicine and Hygiene*, Volume 112, Issue 11, November 2018, Pages 513–521.

[114] Linn A, et al. Reduction in symptomatic malaria prevalence through proactive community treatment in rural Senegal. Trop Med International Health 2015.

Results from a study in Madagascar suggested that ProCCM was associated with decreased parasite prevalence among all ages. 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. It can also be viewed as a strategy for community HSS, since it has the potential to help supervision, supply chain, and community care-level care-seeking also become more proactive, More evidence on the feasibility and impact of this approach in different transmission settings and within different community health systems is likely to become available in the next few years. Studies of ProCCM were recently completed in Mali and Uganda (with some PMI funding) with final results expected next year, and another started in Zambia in 2021 (PMI-funded). The ProCCM approach may be most appropriately deployed in areas where core vector control and passive CM interventions have been scaled, where an existing iCCM program is in place, and where further reduction in burden or strengthening of various components of the system is sought.

Any country considering deploying ProCCM should consult with the Community Health team, Pro-CCM POCs. 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, as well as payment of the CHWs for the active sweeps.

### *Severe Malaria Treatment and Referral*

CHWs' role in managing severe malaria consists of recognition of severe disease, administration of pre-referral treatment, and rapid referral to appropriate health facilities for parenteral treatment. 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 for CHWs.

Pre-referral RAS can be administered by CHWs (building off of the iCCM platform) to manage severe malaria in children six years of age or less. (See the **Case Management** section for dosing guidelines.) Timely referral is crucial following initial treatment, as pre-referral treatment alone is not a substitute for management of severe malaria. 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.

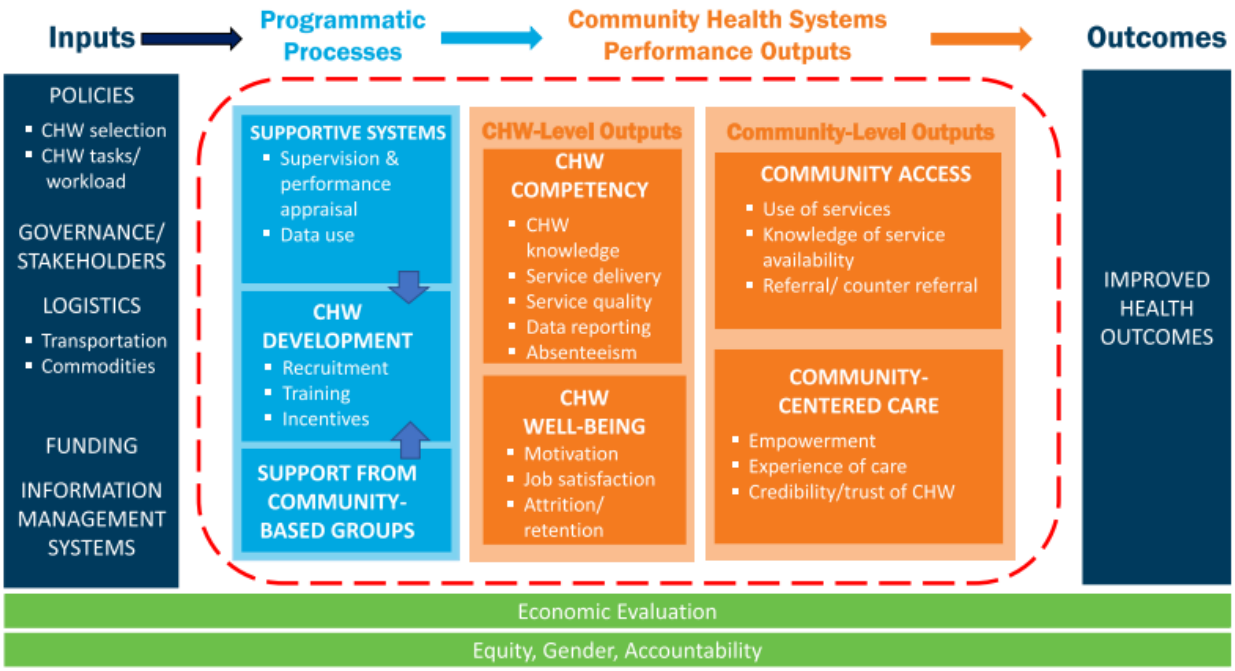
The UNITAID-funded CARAMAL (Community Access to RAS for Malaria) OR study in Nigeria, Uganda, and DRC aimed to inform strategies for RAS implementation and scale-up. Preliminary results

highlighted that the impact of implementing RAS at the community level is highly dependent on the strength of the underlying iCCM platform and community health system, particularly successful referral treatment. The evidence generated will ultimately be used to develop operational guidance for countries looking to scale up this intervention.

## *Quality of Care*

Optimizing the quality of care provided at the community should orient all aspects of a CHW program, including selection and training of CHWs and M&E of their performance. As shown in the figure below and described by Agarwal et al., 2019, quality of care is multifaceted and influenced by various factors, such as a CHW's selection, tasks and development, community support, and access to supportive systems. These in turn influence a CHW's competency (the extent to which a CHW has the knowledge and skills which are necessary to carry out his/her assigned tasks), his or her well-being, community access to CHW services, and the extent to which there is community-centered care. One aspect of CHW competency is his or her adherence to the standards and procedures of his/her tasks.

**Figure 3. Community Health Worker Performance Measurement Framework**




*Source Agarwal et al., 2019*

While there is substantial evidence that CHWs can be very effective and have an impact on malaria morbidity and mortality, these programs often have important gaps and weaknesses, particularly those noted in the "5 Ss" (selection, skills, supervision, supply, salary). For example, the quality of CHW services is strongly influenced by the broader health system, which impacts access of CHWs to

appropriate training, malaria commodities, and supervision. In addition to the influence of the broader system, the quality of an individual CHW's care provision is influenced by individual factors such as knowledge, adherence to guidelines, competencies, attitudes, and motivation. Suggestions on how to address some of these factors, including SBC strategies for provider behavior change are described in other sections of this guidance (see **SBC** chapter, ***SBC in Service Delivery***). Each of these factors should be considered in the M&E of CHWs services.

It is important to monitor the quality of care provided by CHWs in order to identify areas for strengthening. There are diverse ways in which quality of care and broader CHW program performance might be assessed (See Kok et al., 2021), but these assessments should be data-driven and information-generating. One tool for assessing quality of care is through structured supervision, such as outreach training and supportive supervision (OTSS), which includes checklists and collects data on a provider's quality of care, as well as providing coaching and mentorship to improve knowledge, competencies, and adherence to guidelines (See Downey et al., 2021 for an example). An OTSS tool specifically for CHWs is currently under development and will be shared once it is finalized. For more information on effective supervision of CHWs, please refer to the supervision sub-section of this **Community Health** guidance chapter.

In addition to regularly-scheduled structured supervision, CHWs assessments can be implemented as a standalone survey or integrated into HFS and/or as clinical vignette assessments.[115] For example, HFS should, at a minimum, include the collection of core indicators related to the enabling environment for CHW care provision, such as commodity and supervision availability. Quality of care can also be directly assessed through interviews with CHWs and/or their care recipients. Key domains that should be addressed include CHW competency (including CHW knowledge and confidence to perform services) and service quality (correctly identifying malaria, correctly providing treatment, and access to commodities) (Agarwal et al., 2019). For more information on how to incorporate CHW quality of care into planned health facility or community surveys, please reach out to Community Health team POCs.

## *CHWs Implementing SBC Activities*

CHWs are an important communication channel for community-level SBC efforts to promote net use, prompt care-seeking, treatment adherence, ANC attendance, and IPTp acceptance during patient/provider interactions. CHWs typically live in the communities they serve and are trusted by community members to deliver health information and provide health services.

[115] Downey J, McKenna AH, Mendin SF, Waters A, Dunbar N, Tehmeh LG, White EE, Siedner MJ, Panjabi R, Kraemer JD, Kenny A, Ly EJ, Bass J, Huang KN, Khan MS, Uchtmann N, Agarwal A, Hirschhorn LR. Measuring Knowledge of Community Health Workers at the Last Mile in Liberia: Feasibility and Results of Clinical Vignette Assessments. Glob Health Sci Pract. 2021 Mar 15;9(Suppl 1):S111-S121.

As PMI intensifies efforts to strengthen community health platforms, supporting CHWs to deliver effective SBC – either during their routine CM activities with patients or through specific health communication efforts in their communities – should be a priority. Investments to improve CHW delivery of health messaging and behavior uptake will not only extend the reach of such messages by trusted community members, but it will strengthen the capacity of individual CHWs and the community health system of which they are a part. Such support could include CHW training in health communication, procurement and delivery of health communication materials, and logistical support to allow CHWs to travel within their communities. Please refer to the SBC section, *SBC in Service Delivery* for additional details.

There are many SBC approaches CHWs can use to improve malaria behaviors in their communities that are supported by PMI. These may include:

- *Service Communication and Counseling* – Using effective service communication and counseling approaches, CHWs can positively influence health-seeking behaviors throughout the entire continuum of care, including before, during, and after health care services. CHWs may also provide counseling to community members about health topics that coach community members through barriers, listen with respect and empathy to individuals' concerns, and help individuals address those concerns.
- *Community Dialogues* – CHWs may lead or be involved in community dialogues that discuss malaria-related behaviors and factors that facilitate their uptake. During these discussions, CHWs can use this platform to continue to build trust and cooperation with communities and between levels of the health system by addressing specific community norms, concerns, and experiences while identifying strategies to overcome challenges.
- *Home Visits* – Many CHWs make home visits to provide CM or other health services and/or discuss the health of household members. CHWs can use home visits to integrate malaria SBC to: 1) increase general knowledge about malaria, 2) discuss barriers and facilitators to uptake of malaria interventions, 3) address rumors about malaria, and 4) link households to existing resources in the community.

It is critical for CHWs to be adequately trained to effectively deliver SBC in their communities, equipped with the right communication tools, and supported through regular supervision. For example, CHWs need to be trained to use accessible non-technical language, integrate examples and stories, effectively use visuals, and interact with their audience in engaging and non-judgmental ways to encourage trust and two-way communication. Supervisors also need to be trained in these health communication best practices so they can provide effective support.

## *Coordination Between SBC and Service Delivery Partners*

In order to align supply (service provision) and demand (patient/community member demand), coordination between SBC and service delivery partners is essential. The SBC partner should take the lead in supporting CHWs to deliver effective health communications by strengthening their interpersonal communication skills using evidence-based global tools for service communication. This may involve collaboration with service delivery partners to incorporate SBC into CHW training curricula and supportive supervision materials.

Recognizing that CHWs are also a target audience for provider behavior change to ensure quality of care (as described in the preceding section), SBC and service delivery coordination is also important in this domain. Please refer to the SBC section, ***SBC in Service Delivery.***

## *Other Community-based Interventions*

While the community health section of the guidance focuses specifically on CCM and the strengthening of community health systems, many other community-based interventions utilize CHWs, such as SMC, community IPTp, and community-based ITN distributions. Please see the SMC, MIP, and Vector Control sections for guidance on these additional community-based interventions themselves, noting that the various elements of the systems components detailed in this section will be relevant to each intervention.

## *Integrating Malaria Community Health Programs with other Interventions to Strengthen Primary Health Care and Health Security*

Malaria-focused support for CHWs can provide benefits that go beyond malaria care and treatment. Integration offers many opportunities to leverage PMI's resources in this area, both within iCCM services but also in response to other health conditions. CHWs are increasingly being recognized as a critical resource for achieving broader national and global health goals, including the health-related Sustainable Development Goals of Universal Health Coverage; ending preventable child and maternal deaths; and making a major contribution to the control of HIV, tuberculosis, malaria, and noncommunicable diseases.[116] There have been a number of cases in PMI partner countries of initiatives successfully building off of malaria-focused CHW programs.

Leveraging existing CHWs can support national preparedness and response efforts and Global Health Security. In West Africa during 2014, we saw how these HWs were able to rapidly pivot to respond to the Ebola outbreak. CHWs were uniquely positioned to educate communities about healthy behaviors,

[116] Perry, H.B., Chowdhury, M., Were, M. et al. Community health workers at the dawn of a new era: 11. CHWs leading the way to "Health for All." Health Res Policy Sys 19, 111 (2021).

such as safe burial practices and sanitation, to spot symptoms, and to conduct contract tracing and surveillance.[117] In several countries (Liberia, Sierra Leone, DRC) these same CHWs have been used to implement community event-based surveillance for infectious disease threats.

Similarly, in response to the COVID-19 pandemic, investments by PMI and others in CHWs have helped countries fight COVID-19 by identifying people with fevers due to COVID-19 (Liberia, Thailand), tracking their contacts, promoting mask use, and providing education about COVID-19 vaccines (Rwanda). In Madagascar, CHWs were able to help establish a nationwide fever surveillance network. In Rwanda, CHWs were given additional training to support surveillance and provide health education. PMI teams, in deciding how best to support malaria community health programs, should consider how the integration of these workers can contribute to the overall strength of the health system.

## Community Health Systems

USAID's *Vision for Health Systems Strengthening 2030* provides the following definition for community health system: a set of local actors, relationships, and processes engaged in producing, advocating for, and supporting health in communities and households outside, but related to, the formal health system. Health and community systems are dynamic overlapping systems that independently contribute to improving health. This section of the guidance provides details for consideration on a number of these actors, relationships and processes. While many of these considerations are broader than malaria, they have implications for the delivery of malaria services and the systems that support that delivery, and PMI teams should be engaged.

### *Enabling Policy Environment*

Developing an enabling policy environment for a robust community health program is crucial to its success. While iCCM has been largely scaled up in almost all of PMI's partner countries, a common challenge across countries is the lack of institutionalization of CHWs within primary health care systems. The unique context of each country makes it so that there is no one-size-fits-all model for community health that will be effective in every country, and therefore the policies that guide implementation will differ. Acknowledging this, PMI country teams may have opportunities to provide input on the community health policies that will in turn define the implementation of community health services. As a resource, a WHO technical consultation, "Institutionalizing iCCM to end preventable child deaths: a technical consultation and country action planning, July 22-26, 2019, Addis Ababa" provided the following policy recommendations for consideration:

[117] https://www.thinkglobalhealth.org/article/preventing-pandemics-and-ending-malaria-demand-new-investments-community-health

1. iCCM delivered at scale should be part of the primary health care service package for children. It will support progress towards universal health coverage and ensure a continuum of care, from the community to higher-level facilities through a strong, well-functioning referral system.
2. As an extension of integrated management of childhood illness in facilities, iCCM is relevant for hard-to-reach communities with limited access to health services.
3. iCCM should be fully incorporated into national health policies and health sector development plans, and the strategies and plans of programs for malaria, child health, community health, and others should be used as entry points for harmonized, coordinated activities, as appropriate for the context.
4. Implementation of community health service packages should be overseen by the national community health strategy or sector-specific plan, including, as per WHO's guidelines on CHWs: a written contract specifying their roles and responsibilities, working conditions and remuneration; remuneration commensurate with their roles, responsibilities and job requirements; and pre- and in-service training with career development opportunities.
5. The MOH should have full responsibility for planning, implementing, monitoring, and evaluating iCCM by ensuring coordination among community health, child health and malaria control programs, including by creating a designated cross-sectoral unit, as appropriate.
6. Resource allocations for the full package necessary to deliver high-quality iCCM should be included in annual national and sub-national health sector budgets. Domestic and external funding should cover all components of iCCM.
7. The supply chain for the full iCCM package should be fully integrated into the national supply management system, with medicines, diagnostics, and logistics for community services integrated into the health facility supply management and logistics information system.
8. Interventions to improve quality, including supportive supervision and mentoring of CHWs in designated health facilities, are essential to ensure high-quality iCCM and should be budgeted for and included in district plans.
9. Community engagement is essential for institutionalizing iCCM. Community voices and requirements are central to all stages of effective planning and decision-making, selection of CHWs, implementation, oversight, demand, and uptake of iCCM. Targeted outreach should be included from the inception of iCCM program design.
10. iCCM data should be integrated into the health facility information system to allow disaggregated analysis and feedback to CHWs.

Since the community health program generally sits outside of the NMCP, PMI teams are recommended to work alongside their USG and NMCP colleagues to engage with national community health structures, such as directorates of community health and other relevant ministries, such as finance or workforce. This engagement is important for understanding how CHWs are situated within a country, and the different government structures and policies that determine the various components of community HSS as detailed below. Country teams are encouraged to work with these same government entities as well as with other local partners and donors in the country to develop or update the policies.

The governance of community health programs and of CHWs (PMI-supported) is important to consider. The need for country leadership and ownership of iCCM and health system integration is a key challenge.[118] It is crucial that all actors in the system are aligned to ensure that the required and agreed upon policies are implemented as intended and that there are no unintended consequences. There needs to be a clear understanding and agreement of what CHWs can and can not do and appropriate mechanisms to ensure accountability. While the building blocks of CHW programs have already been identified, their design has to be tailor-made to address specific health system infrastructure, workforce structure, task-shifting and other health policies, as well as fiscal space, disease burden, and cultural/social norms in each geography.

Important questions that PMI teams need to consider in relation to CHW program design and implementation include[119] :

1. How and where within political structures are policies made for CHW programmes?
2. Who implements decisions regarding CHW programmes, and at what levels of government?
3. What laws and regulations are needed to support the programme?
4. How should the programme be adapted across different settings or groups within the country or region?

Additionally, PMI teams should consider and actively seek local partners who understand the policy drivers and unique local context when supporting the design, implementation, and or scale-up of community case management programs and efforts to strengthen community health systems.

## The 5 Ss of Community Health System Strengthening

One helpful framework for thinking about the components of community HSS are the 5 Ss: selection

[118] Koya, A. et al. The role of governance in implementing sustainable global health interventions: review of health system integration for iCCM of childhood illnesses.
[119] Lewin, S., Lehmann, U. & Perry, H.B. Community health workers at the dawn of a new era: 3. Programme governance. *Health Res Policy Sys* 19, 129 (2021).

(also related to another S: saturation), skills, supervision, supplies, and salaries.[120] All of these system components are priorities for PMI and should be conducted through the lens of broader health system strengthening to ensure that community health systems are integrated with and an extension of primary health care generally, wherein CHWs should be understood and treated as human resources for health and appropriately supported as such with the other systems components.[121] Considerations for each "S" are detailed below.

### *Selection and Saturation*

The 2018 WHO guideline on health policy and system support to optimizing CHW programs recommends the following criteria be considered for selection of CHWs:

- Minimum educational level that is appropriate to the tasks under consideration
- Membership of and acceptance by the target community
- Gender equity appropriate to the context (considering affirmative action to preferentially select women to empower them and, where culturally relevant, to ensure acceptability of services by the population or target group
- Personal attributes, capacities, values and life and professional experiences

It should be noted that WHO suggests **not** using the criteria of age or marital status for CHW selection.

Selection also has implications for CHW saturation – achieving an appropriate ratio of CHWs per population to allow for the reaching of the unreached. Targets for saturation as stated in community health policies vary widely across PMI partner countries, both in terms of unit for the target (village/health worker/households/population) and intensity (for population-based targets, this ranges from generally between 300 and 2,000 people per CHW). For instance, in remote rural areas, where populations are farther than 5km from the nearest primary healthcare facility, the population density is lower and ensuring geographic coverage may require a higher saturation of CHWs. For example, Liberia increased its CHW density from 1 per 1000 people, which was originally based on a formula for urban areas where people are closer together, to 1 per 350 people – to ensure geographic coverage of the country's hardest-to-reach rural populations. For a cross-country analysis of CHW:population ratios amongst other CHW program design features, see here.

[120] See https://www.exemplars.health/topics/community-health-workers/cross-country-synthesis/recommendations for more information

[121] For more information see another set of 5 S's of health system strengthening and USAID's own HSS vision.

In the aforementioned guideline, WHO suggests using the following criteria in determining a target population size in lieu of suggesting a specific target. These criteria are most useful for policy-level considerations.

- In most settings
  - Expected workload based on epidemiology and anticipated demand for services
  - Frequency of contact required
  - Nature and time commitment of CHWs
  - Expected weekly time commitment of CHWs
  - Local geography (including proximity of households, distance to clinic, and population density)
- In some settings as relevant
  - Weather and climate
  - Transport availability and cost
  - Health worker safety
  - Mobility of population
  - Available human and financial resources

On this last point of the availability of financial resources, it should be noted that modeling to support the question of where would CCM expansion be the most impactful within a given resource envelope is a priority that has emerged out of PMI's OR/modeling prioritization process.

In addition to modeling and point-of-time counts to provide data on CHW saturation, there is growing momentum around the need for the creation of a CHW master list (CHWML) as an essential component of strengthening community health systems. A national georeferenced CHWML is a "single source of truth" that contains essential data elements required to effectively describe, enumerate, and locate all CHWs in a country. A CHWML, as opposed to an enumerated list of CHWs, is routinely updated and is ideally stored in a registry and integrated with national HRH systems. An Implementation Support Guide on the development of a national georeferenced CHWML hosted in a registry has recently been developed by a coalition of partners led by the Community Health Impact Coalition and the Global Fund. PMI teams are encouraged to work with MOH and partners to ensure funding for the development and routine maintenance of the CHWML is secured.

### *Skills*

Ensuring that CHWs have and maintain the needed skills to perform their duties is critical to success in implementation. CHW training and skills acquisition includes pre-service training and continuing education and should be standardized at the national level. The quality of pre-service training strongly influences the effectiveness of CHWs. Determining the content and duration of pre-service training

should be based on the local context and the desired competencies required, according to role the CHW will play within the larger community health system, such as promotive and preventive services, diagnostic and curative services where relevant, data collection and use, and interpersonal and community mobilization skills.

WHO suggests using the following criteria for determining the length of pre-service training for CHWs:

- Scope of work, and anticipated responsibilities and role
- Competencies required to ensure high-quality service delivery
- Pre-existing knowledge and skills (whether acquired through prior training or relevant experience)
- Social, economic, and geographical circumstances of trainees
- Institutional capacity to provide the training

The choice of the best modality to train CHWs is dependent on several factors and needs to be based on the local context. Partnering with local institutions is recommended to develop and implement training that aligns to that local context. WHO recommends a mix of approaches encompassing both theory-based and practice-focused skills. A best practice is to have a competency-based formal certification for CHWs who have successfully completed pre-service training. More detailed recommendations can be found in the WHO guide listed above.

Continuous education is important to ensure skills are maintained. As referenced in the WHO guideline, a systematic review has shown that continuous education is a key enabler to positive community health program outcomes. The CHW Assessment and Improvement Matrix (AIM) indicates that continuous training should consider: (1) frequency of need, (2) formalizing a continuous training plan, (3) being equitable in offering continuous training to all CHWs, and (4) involvement of the government health system/facilities. Additionally, the method of delivering continuous training should be considered, with digital tools being leveraged and incorporating best practices in adult education if appropriate/possible.

**Training of CHWs, whenever possible, should reflect the full package of iCCM and not be limited to mCM.** PMI funding can be used to support skill acquisition by CHWs, which includes training on the full iCCM package; revising and/or printing training manuals, updated guidelines, and job aids; and integrated supervision visits. The "integrated" piece of CCM means not just that the program aims to diagnose and treat three main causes of childhood illness, but that programming should be co-supported and co-funded by maternal and child health or community health partners.

### *Supervision*

Like the other 4Ss, Supervision is a key component of helping to ensure strong community health systems and that high quality care is available at the community level. There is strong evidence that shows that CHW technical competency declines after training, and thus, CHW supervision provides the opportunity to reinforce and refresh core competencies. During supervision visits, supervisors not only provide guidance on best practices and SOPs/treatment guidelines, but these visits may also be used as a time to review data and are often linked to a resupply of commodities. We recognize that all supervisory visits are not equal so it is important to put systems in place to maximize the quality of supervision. Ensuring that supervisors have received appropriate training (in terms of clinical training, in which a supervisor would ideally be clinically trained as a nurse, clinical officer or equivalent but also training on *how* to supervise), having an appropriate supervisor-supervisee ratio, and providing adequate resources to supervisors and CHWs can help ensure that high quality supervisory visits take place.

Approaches to supervision for CHWs vary across countries, with some supervision occurring in the communities where CHWs work and others taking place at the health facility the CHW is associated with. Supervision can occur one-on-one or in group settings, and may be done by a clinical supervisor (such as a nurse) at the corresponding health facility (e.g., Ethiopia) or a dedicated clinical supervisor cadre (e.g., Liberia) which may improve proficiency in malaria testing/treatment; through peer supervision (e.g., Malawi and Rwanda), which may improve community embeddedness and motivation; or through a combination of these methods. There are benefits to all these approaches and there is not strong evidence on which supervision models for CHWs are most effective (Westgate et al, 2021); thus, PMI's OR/modeling prioritization process has identified OR to evaluate approaches to improving CHW supervision as a priority.

However, there are some best practices and CHW supervision in general should:

- Occur frequently (no less than monthly) and on a regular basis
- Be guided by structured checklists and focus on real-time problem-solving
- Include coaching or mentoring (i.e., supportive supervision) to strengthen CHW performance (e.g. percent of correct malaria diagnoses made by a CHW)
- Incorporate data review and resupply, as appropriate
- Be conducted by supervisors who are trained clinically (e.g., nurse or clinical officer),and as supervisors, well-supported, and have dedicated time in their work schedule to supervise CHWs
- Include maintenance of a current roster of CHWs associated under their supervision or associated with the health facility they serve

## *Supplies*

The saying "*No product, no program"* works for all levels of the supply chain, but none more so than at the very end of the supply chain: the community level. For PMI to reach its goals, it requires a strong community level health system which in turn needs a steady supply of quality health products.

The best predictor of health product availability at community level is availability at higher levels – the community level supply chain is dependent on and needs to be considered as part of a national level supply chain system. However, availability at higher levels, while a prerequisite, is not sufficient in and of itself for availability at the community level.

Vertical approaches to community level supply chain strengthening may be appropriate over the short term, but longer term, integration of the community level supply chain with the overall national supply chain is a better approach. That said, the supply chain at the community level needs to be adapted around its unique context, including the needs and characteristics of its clients and the communities it serves as well as those of CHWs.

Some key considerations for community level supply chains include:

- Appreciate that every CHW is a discrete stockholding site, something often overlooked in a system design that is fixed/physical site-oriented. Where there is a stockholding site there should be logistics tools and processes in place that support continued availability of commodities.
- Supply chain systems at community level need to be clearly designed and documented with roles and responsibilities clearly delineated and tools such as stock cards and order forms standardized and available.
- Whether it's focused on maintaining current processes or redesigning the supply chain, PMI investment in community health works best when both service delivery and supply chain partners and support are coordinated and work together, albeit with clearly defined roles and responsibilities. Those precise responsibilities will vary from country to country and program to program but in many cases investments should be made in service delivery partners to support health product availability.
- When developing data systems, including electronic systems, look for ways to incorporate supply chain data as well as simply logistics management functionality. See **Logistics Management Information System (LMIS)** within the Supply Chain section.
- CHWs need to be trained in supply chain management, ideally as part of a preservice training program supplemented by inservice or on the job training. See Capacity Building within the Supply Chain section.

- Quantification of health products needs to explicitly include the needs of the community level. See quantification. This is not just for the quantities of health products but community level may also have unique needs in product attributes. See product selection within the Supply Chain section.
- See Monitoring and Supervision within the Supply Chain Section. 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.

## *Salaries*

WHO's 2018 guideline on health policy and system support to optimizing CHW programmes **strongly recommends** (1) "remunerating practicing CHWs for their work with a financial package commensurate with the job demands, complexity, number of hours, training and roles that they undertake"; and (2) "providing paid CHWs with a written agreement specifying role and responsibilities, working conditions, remuneration and workers' rights."

On June 29, 2021, PMI officially announced a change in policy regarding use of PMI funds for payment of CHW salaries and stipends, and PMI funds from any fiscal year may now be used to pay CHWs for their work in delivering community-based mCM services. Given that this is a new policy, PMI has been and will continue to be working to develop and update a comprehensive FAQ document. This technical guidance provides a summary, and teams are encouraged to refer to the FAQ document for details that will be updated as we learn through the implementation of this policy. Key points on the new policy are listed below:

- This change in PMI policy is consistent with USAID policy and WHO recommendations on salary payments in the ADS, which allows for payment of host country government salaries as part of a longer-term goal to achieve sustainable staffing approaches using non-USG sources. In addition, while PMI funds may not be used for salary supplements (i.e., top-ups), they may be used to support bonuses or incentives for CHWs who meet performance-based criteria that are directly linked to achieving program goals.
- This policy may apply in settings where payment of CHWs is **in line with government policy** and resources are needed to implement the policy.
- What is new in this policy is the **regular** payment (compensation in the form of salaries or stipends) for **routine** CM activities (differentiated from campaign style activities like net distribution and IRS, for which we already pay actors, including CHWs. It was not intended to distinguish payment for CM of malaria from CM of pneumonia and diarrhea. If a cadre implements iCCM, PMI may pay for the entire, regular salary or stipend for the CHW. However, in countries where Maternal Child Health and Nutrition or other streams of funding are available (as applicable to the government-defined package of services for the CHWs), it is expected that this support be shared across funding elements to strengthen the integrated platform.

- The aim of this policy is to be catalytic for the financing of CHW programs – both for other donors in the short term and for host country governments in the longer term. Having a progressive financing plan in place before moving forward with paying CHWs with PMI funds is essential. Understanding that PMI funds are appropriated on an annual basis, PMI encourages country teams to **plan** for a minimum of three years of support. If the PMI team does not have a clear plan for how this investment can be sustained (within the MOP envelope or including other resources) for three years, it should work with USG and MOH partners to define a sustainable strategy to ensure that CHW payments are sustained with non-PMI resources.

For PMI to be successful in supporting CHWs the following pieces need to be in place:

1. An enabling policy environment
2. Coordination and harmonization with other donors in the space
3. A progressive costing and financing plan to ensure sustainability in the long term
4. An implementing partner or mechanism with the ability to provide payments
5. A detailed plan for *how* CHWs will be paid (see detailed list of what this should include in the FAQ document)
6. A plan and mechanism for tracking payment of CHWs
7. A learning agenda to set the guiding questions to be answered as PMI and partners move forward in-country under this new policy

### *Data systems*

Community-level data can contribute to the continuous improvement of outcomes in a community when the data are used to monitor quality and quantity of service delivery and then adjust CM practices, stock levels and management, or density or location of service provision. Such data can also be used to detect outbreaks and spur local response, and to monitor trends to inform public health decision-making at more central levels. CHWs diagnose more than 50 percent of malaria cases in some PMI countries (e.g., Cambodia and Rwanda), underscoring the importance of timely reporting of high-quality community-level data, as well as the role that CHWs play in increasing the detection, testing, and treatment cases and reducing the burden of malaria on health posts/centers. Most PMI partner countries capture CHW-confirmed malaria cases in their HMIS; however, that data is rarely disseminated or used for decision-making and the quality of community data tends to be low compared to heath facility malaria case data.

The 2018 WHO guidelines, while reporting the available data were of very low quality, concluded:

- Involving CHWs in data collection can reduce CHW absenteeism and attrition and improve the service delivery, self-efficacy, and self-esteem of CHWs
- Retention of CHWs may improve if they are supported to analyze their data and use it to adjust their practice and environment

- Mobile/digital data systems may result in improvements in community-level data, as well as CM, and may result in cost savings compared with paper-based systems (see Digital Community Health section below)

Thus, best practices for community data systems include:

- Ensuring integration with national data systems (i.e., HMIS) directly [if digital], at the health facility, or at the most peripheral level possible
- Prioritizing and standardizing a set of community-level indicators, potentially spanning case data, stock data, and workforce-related data
- Building structures and processes to improve data quality
- Ensuring appropriate data use at all levels of the health system, including the dissemination of community case data through malaria bulletins and at Technical Working Groups
- Creating mechanisms for feedback to CHWs

A compilation of resources for strengthening HMIS systems at the community level is provided in the SME section of this guidance. While these best practices apply to both paper-based and digital data systems, they are explored in more detail in the Digital Community Health section below.

PMI can work to support countries to monitor the performance of systems to support CHW selection/saturation, skills, supervision, supplies, and salaries. One example of this from Liberia is the "Implementation Fidelity Initiative" (figure below) which was developed by the Government of Liberia with USAID funding (see here and here for reference) to monitor the saturation of CHWs (called Community Health Assistants or "CHAs") and their supervisors (called Community Health Services Supervisor or "CHSSs"), how proficient their skills are in diagnosing and treating uncomplicated malaria, the quality of their supervision, what percentage of them have stockouts of ACT/RDTs, and what percentage of them are being paid on time. Supporting national community health and malaria control programs to track community health systems performance at a national scale should be a priority for PMI.

**Figure 4. Key Questions Addressed By The Implementation Fidelity Initiative**


Caption: Government of Liberia's Implementation Fidelity Initiative to track the performance of systems to support its National CHA Program, which delivers services for malaria and other diseases. All counties implementing the CHA Program are monitored using the above framework on a quarterly basis. The categories are recruitment, training, supply chain, supervision, incentives, and service delivery.

## *Digital Community Health*

The digitization of information has revolutionized all facets of daily life across the world. Not only is there an ever-increasing number of tools being developed that introduce new functions and capabilities possible with digitization, but there is also increasing access to these tools across many malaria-endemic countries. This creates a unique opportunity to strengthen health services and revolutionize data collection and use through the adoption of digitally-enabled tools. In fact, a recent report from the Lancet and Financial Times Governing Health Futures 2030 Commission highlighted the integration of digital technologies into healthcare as an increasingly important determinant of health. In response to this shifting landscape, PMI is continuing to prioritize efforts to sustainably incorporate the use of digital tools into malaria programming. 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, to improve the collection of data resulting from these activities, and to incorporate

these data in decision-making processes to meaningfully respond to changes in the field in a timely fashion.

## *Digital Community Health Initiative Vision*

PMI launched its Digital Community Health Initiative in 2020 and established the vision below, with which all investments should align. This initiative was integrated into the new Community Health team to ensure it is aligned with PMI's programming and to avoid creating a technology-driven silo. This will ensure digital tools are context-appropriate and can most effectively enable the transformation and extension of community health systems.

**Vision**: Strengthen quality health at the community level[122] in PMI partner countries, by investing in the scale-up of digitally-enabled community health platforms that:

1. Train and equip frontline workers with connected mobile tools to increase the effectiveness of equitable CM (e.g., job aids, diagnostic tools/readers, support in encouraging 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 possible)
3. Encourage 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 overall needs and health goals of each country
5. Integrate and empower CHWs as valued members of the national health system workforce

This vision aligns with those of USAID and many other donors in order to coordinate future investments in digital health 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.

## *Key Investment Guidance*

The initiative began with a Foundational Assessment in each PMI partner country to analyze its digital community health ecosystem and to identify country-specific priorities. It is recommended that the priorities identified in these assessments continue to inform use of MOP funding for incorporation of

[122] 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.

digital tools into community health platforms. While these assessments established a starting point, priorities are sure to evolve as each country's local context changes with advancements in digital infrastructure and capabilities. Therefore, it is important to be acquainted with the up-to-date national digital health landscape and strategy prior to proposing activities for funding.

Listed below are illustrative examples of activities that could be considered as part of this initiative. This is not an exhaustive list, and all examples should be considered in the unique context outlined in the foundational assessments.

- Develop scale-up strategies for existing, proven digital community platforms, including sustainable business models
- Support digitalization (e.g., development of digital applications or the deployment of digital technology) of CHWs for CM and data collection support, and for systems supporting CHWs, including supervision, performance management and supply chain management
- Create a roadmap for systematic building of capacity for eHealth that includes CHWs 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 three to four 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)
- 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 training 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[123] that align with the in-country architecture and NMCP priorities to support community CM and utilization of data
- Define and establish novel partnerships with private-sector digital companies and/or universities to pursue development objectives aimed at improving community CM 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

Where possible, PMI country programs are encouraged to prioritize activities that strengthen in-country digital capabilities and to identify local partners to lead activities. Examples include, but are not limited to, identifying local software development firms to adapt global goods and manage local implementation, building digital leadership and IT capabilities within the MOH, and helping to establish local public-private partnerships to drive financial sustainability of digital tools.

Note that there are no existing funding directives for digital community health activities. 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.

### *Principles to Adhere To*

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 nonintegrable, malaria-specific systems). For malaria this would generally include iCCM, at a minimum.[124]
3. Build and expand upon systems that already exist in-country instead of investing in separate, parallel systems.

[123] 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."

[124] 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 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 Into 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 (e.g., community, district, national), mechanism and technical area (e.g., CM/CCM, SME/strengthening routine surveillance), all activities that include digital technologies should be clearly identified in Table 2. **Specifically, it is requested that each applicable activity that uses digital technology[125] 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" (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 an iCCM digital tool for CHWs), that should be included in the description for the applicable proposed activity (e.g., community-based CM). Cross-cutting digital health activities (e.g., developing an eHealth capacity building plan), should be identified as a separate activity under the SM&E or HSS MOP sections, as appropriate. This request is applicable to annual MOP planning and to Table 2 modifications as part of Reprogramming Memos.

[125] 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.

**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

Country Foundational Landscape Assessments

# 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. We anticipate that the supply chain will continue to be constrained in 2022. 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 parasite lactose dehydrogenase (pLDH) RDTs in areas that have exceeded the WHO threshold for histadine-rich protein 2 (HRP2)[126] deletions (e.g., Ethiopia).

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 and Pf/Pv RDTs may be indicated.

PMI supports the use of global standards, a common approach for identifying, capturing, and sharing vital information about products and locations across the supply chain. The Global Standards Initiative (GS1) standard is the main global standard available for pharmaceutical products and therefore, the most common global standard that PMI supports. PMI implemented a phased approach in coordination with other donors for all vendors to include GS1 barcodes on products it procures. June 2022 is the final phase, when serialization is expected to be included. Country teams should consider supporting countries to incorporate the use of global standards into their supply chain regulations and routine operations, including encouraging countries to seek opportunities to implement scanning of barcodes on products to improve overall supply chain performance. PMI also supports technical assistance to countries interested in implementing GS1.

PMI continues 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

[126] The two most commonly targeted antigens in the parasite are histidine-rich protein **2** (HRP2), which is specific to *Plasmodium falciparu*m, and Plasmodium lactate dehydrogenase (pLDH). The sensitivity of HRP2-based RDTs is seriously threatened by the increasing occurrence of *P. falciparum* with deleted HRP2 and/or HRP3 antigen-coding genes, which limits the sensitivity of these tests resulting in false negatives. WHO recommends using pLDH tests in areas that exceed 5 percent of HRP2 deletions.

term. In FY 2021 GHSC-PSM revised the Stockout Reduction playbook, for use in PMI countries, to examine root causes of stockouts at the community health level and to inform investments to decrease them.

A Supply Chain Tools Cheat Sheet is kept up-to-date with the latest information on the tools to monitor the supply chains and commodity availability in PMI-supported countries.

# COMMODITY PROCUREMENT

## Introduction

Under the PMI 2021–2026 strategy, Strategic Focus Area One includes achieving and maintaining coverage of high quality interventions to reach the highest malaria burden, highest need populations in each country, all of which are predicated on the availability of high quality commodities. Strategic Focus Area Five includes leveraging new tools. There are a number of new malaria control tools available or soon to be available, including new types of ITNs, tafenoquine for malaria treatment, non-HRP2 RDTs, and new glucose-6-phosphate dehydrogenase (G6PD) diagnostics. Careful planning for introduction and monitoring of deployment for new types of ITNs is required. Tafenoquine is now registered in Thailand, and the Standard SD G6PD Biosensor test has received approval from the Australian Therapeutic Goods Administration, a stringent regulatory authority. Following country registration and NMCP adoption, tafenoquine and SD Biosensor's Standard G6PD tests can be procured by PMI. As with the rollout of any new intervention(s), PMI teams should ensure that appropriate monitoring systems are being considered and implemented in-country. 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 QA 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 different planning requirements, if any, for PMI funding of 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 have increased due to COVID-19 related supply chain disruptions.** The lead times, which start with the receipt of a Requisition Order, include, among other steps, order processing, production, QA testing, shipping and customs clearance; the procurement of many malaria commodities may require a lead time of eight months to more than a year. (Refer to **Commodity Procurement and Supply Chain Management 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 SMC), drugs for severe malaria, other malaria pharmaceuticals (e.g., chloroquine and primaquine 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 the **IRS** chapter of this guidance, as this chapter will not address IRS commodities. Commodities eligible for procurement are included in the PMI Restricted Commodity Waiver (RCW) List.

Additionally, most commodities necessary to implement national surveys (e.g., MIS) do not fall within the scope of PMI's malaria commodity procurement partner and alternative arrangements should be made. Please contact the GHSC-PSM Task Order (TO)2 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 planning for national surveys. As with all procurements, lead times are lengthy, so any research or studies that require commodities should plan sufficiently in advance (see **Commodity Procurement and Supply Chain Appendix 2**).

### *Insecticide-treated nets*

Current PMI policy requires that ITN products, at minimum, be on the WHO 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 over 20 PQ-approved ITNs, but not all meet PMI's requirements for demonstrated community effectiveness. This list includes six PBO synergist ITNs (four of which are eligible for PMI procurement), 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 the **ITN** chapter to see the complete list and those that meet PMI's procurement requirements.

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 $2.50 and $2.90 (commodity cost only), around $0.70 more per net than a standard pyrethroid-only net.

Neither the Interceptor G2 nor Royal Guard ITNs currently have a WHO policy recommendation. The **ITN** chapter outlines PMI's policy on deployment of these nets. The price of the IG2 currently is significantly less than it was in 2018. PMI now pays the same as it did through the NNP co-payment mechanism. However, production capacity remains constrained.

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.[127] 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 PMI Supply Chain Team worked to identify opportunities to rationalize ITN procurement to achieve best value. The PMI Supply Chain Team reviewed the ITN market, which included conducting an ITN cost of goods analysis, discussing the market and procurement approaches with other global ITN procurers (Global Fund and UNICEF), and conducting a survey of ITN manufacturers.

The landscape analysis, and subsequent experience, 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 efficiencies and value for money continues to be important in the current funding environment, particularly 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 the ITN package
5. Do not restrict competition based on material
6. Limit additional packaging labeling to the PMI logo, standard language (e.g., not for retail sale), and the GS1 barcode

[127] 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)

Requirements for procurement of ITNs with specific insecticides will be considered when 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 wants to deviate from these standard specifications, they must provide strong supporting evidence for doing so, and acknowledge other risks the country would potentially assume, to the PMI Supply Chain and PMI Vector Control Teams in order to 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 to the PMI Supply Chain and PMI Vector Control Teams in order to be granted an exceptional approval from PMI Agency Leads.

As ITN campaigns involve very large quantities, they require early procurement planning as well as storage and distribution capacity adequate for the volumes required for the duration of the campaign. By contrast, routine net distribution usually involves more consistent volumes of nets, consistent storage and distribution capacity, and orders placed more regularly throughout the year.

**See Commodity Procurement and Supply Chain Appendix 2 for average lead times.**

### *Artemisinin-based combination therapies, other antimalarial medicines, and essential medicines*

While PMI prioritizes the procurement of a country's first-line antimalarial medicine, 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 CM and PMI Supply Chain Teams to talk through the CM 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 Integrated Management of Childhood Illness (IMCI) guidelines under PMI's iCCM rubric), PMI does not procure ACTs without

*either* an approval through a stringent regulatory authority (SRA)[128] (such as the U.S. FDA) or the WHO PQ Program. Stringent regulatory authorities employ a robust drug dossier review to consider the safety, efficacy, and quality of pharmaceuticals intended for human use.[129] 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.[130]

Currently, there are three ACT products approved by a stringent regulatory authority, two of which have been procured with PMI funding: Novartis' Coartem® (AL), Alfasigma's Eurartesim® (DP), and Shin Poong's Pyramax® (pyronaridine/artesunate).[131] 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 AL, artesunate-amodiaquine, and DP (including dispersible formulations) have been approved by WHO PQ and therefore added to the WHO prequalification list over the recent years. PMI can procure these products subjecting them to the same testing requirements as other non-SRA approved pharmaceuticals procured with PMI funds.

There are several different fixed-dose AL oral presentations approved through the WHO PQ: 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.. Like any procured pharmaceutical, please take into consideration the registration status, the potential need for an importation waiver if the product is not registered, and any additional training needs. For more information on the selection of ACTs PMI procures, please refer to the **Case Management** chapter.

PMI policy to procure either SRA-approved or WHO-PQ ACTs is one element of ensuring the 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

[128] 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 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

[129] 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.

[130] 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.

[131] PMI has yet to receive a request from any PMI focus country to procure Pyramax.

primaquine and most SP products from pre-approved wholesalers.[132] These wholesalers are routinely evaluated against internationally accepted QA standards by a USAID-led team, composed of USAID in-house pharmacists, QA and QC implementing partners, and consultants with significant experience in both current good manufacturing practices and US FDA practices. Wholesalers are required to employ strict QA and QC measures with their vendors. Re-evaluation of approved wholesalers with site visits and desk audits is routinely carried out. Product testing is conducted at qualified (either ISO-17025 compliant or WHO PQ) laboratories.

As with all commodities, please see the lead time table in **Commodity Procurement and Supply Chain Appendix 2.**

### *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 hard SP tablets indicated for use in IPTp;[133] as such, PMI sources most SP orders from pre-approved wholesalers.[134] The MMV 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 continues to look into sourcing options to lower lead times, but as country teams quantify national level SP needs during OP for IPTp, consideration must still be given regarding lengthy lead times.

As of the end of 2021, there are two WHO PQ-approved dispersible SP suppliers, although PMI has yet to procure these products. For more information on dispersible SP and IPTi, please refer to the **Other Chemoprevention Approaches** section.

### *AQ+SP for seasonal malaria chemoprevention*

Since the 2012 WHO policy recommendation regarding SMC, PMI countries in the Sahel have been 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 three and 59 months of age at monthly intervals during the period of peak malaria transmission season. While historically implemented over a period of three to four 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

[132] Please see most recent ADS 312 for more information on currently approved wholesalers.
[133] SP is included in co-blistered presentations currently approved through the WHO PQ. However, none of those presentations is indicated for use in IPTp.
[134] Please see most recent ADS 312 for more information on currently approved wholesalers.

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. At the end of 2021, there are two manufacturers producing WHO PQ co-blister presentations of dispersible AQ+SP (i.e., packaged in a blister pack together for ease of use). Historically, the limited production capacity has led to challenges in implementing SMC in PMI-supported countries due to the availability of only one supplier. The inclusion of this second supplier does increase production capacity significantly, but the second option is not registered in many countries, so PMI is unable to take full advantage of this increased capacity. We encourage country teams to do what they can to encourage registration of this second supplier in their countries in order to alleviate the limited supply challenges. If you have questions about registration issues, reach out to your supply chain backstop for more information. For countries implementing SMC, please note that there is a section in the MOP template that includes commodity gap tables for AQ+SP, on which the PMI Supply Chain Team relies heavily 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 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.[135]

**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 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 Supply Chain Team immediately so that every possible action can be taken to try and fulfill needs, despite the current market constraints. PMI also maintains a small buffer stock of AQ+SP to fill emergency needs for any increases in needs identified closer to the time of the campaigns.

### *Severe malaria medicines*

PMI is able to procure any of the three available WHO PQ injectable artesunate presentations (30-, 60- and/or 120-mg formulations). There are three WHO PQ suppliers of 60-mg formulation, the most commonly procured. There are also three different strengths of RAS suppository presentations available

[135] There is a dossier for an additional SP/AQ product currently under review by the WHO PQ Program.

(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 RAS suppositories. For these reasons, **PMI is only procuring the 100-mg formulation** moving forward. Countries that wish to procure the non-PQ 50-mg or 200-mg presentations must contact the PMI CM and Supply Chain Teams to seek an exception and indicate how they are transitioning to the 100-mg presentation. RAS production runs are limited (currently one manufacturer has two production runs per year, while another manufacturer has minimum order quantities to produce). Country teams should place RAS suppository orders in advance, given production limitations. Please see the **Case Management** chapter for additional information. Injectable artemether and injectable quinine are also available for procurement, although neither has approval though 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 **Appendix 3**.

### *Rapid diagnostic tests*

PMI requires WHO PQ for *P. falciparum* and *P. falciparum/P. vivax* RDTs, given there are a number of WHO PQ suppliers of these 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 and Pf/Pv RDTs may be indicated; see the **Case Management** chapter for a more detailed explanation).
2. The product has received WHO PQ.

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. HWs 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 CM team will help countries work through the implications of this policy including supporting the development of training and job aids focused on managing different RDTs rather than a single RDT at both the facility and community level. Please work

with the PMI Supply Chain Team if your country has specific requirements (including registration) 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 5 percent, HRP-2 RDTs may no longer be accurate, and RDTs using non-HRP-2 antigens (e.g., pLDH) 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 on this topic.**

Of the few stringent regulatory agency approved G6PD point of care tests, SD Biosensor's Standard G6PD test, a quantitative test, is the only test currently available for use in field conditions. G6PD testing is not required prior to administration of low-dose primaquine for blocking the infectivity of gametocytes for *P. falciparum*. G6PD testing is only indicated prior to radical cure treatment for *P. vivax*. Therefore, requests for procurement of G6PD tests will be supported only from PMI countries with ongoing *P. vivax* transmission and product registration.

### *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 the **Entomological Monitoring** chapter.

### *Malaria Vaccine*

PMI will not procure the malaria vaccine or deliver it to countries. We expect that in-country the vaccine will be managed as part of the EPI supply/cold chain. As the discussions on possible vaccine introduction evolve in the field, we encourage PMI country teams in coordination with their Maternal and Child Health colleagues, to familiarize themselves with their country EPI program, including the EPI

supply/cold chain, so as to be able to identify any potential challenges and areas where PMI may want to consider future support. Please see the **Vaccine** chapter for more information.

## 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 to or concurrent with shipment (depending on how they were approved and on historical volumes procured) in accordance with PMI SOPs and work instructions (detailed documents developed by PMI's QA and QC partner) by an approved laboratory. For all pharmaceuticals, there is a quality testing strategy, with WHO-PQ 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 QC strategy includes an annual sampling of retained samples for all SRA-approved products, based on volumes procured, which includes compendial testing.

Historically, RDTs have been subjected to 100 percent 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 the source of the products and volumes procured (with related QC compliance).

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 QA partner and with the PMI Supply Chain Team. These may be obtained upon request by PMI country teams. 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 PMI QA/QC team and deemed as passing (i.e., in compliance with industry and internationally accepted 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, commodity availability, and resulting stockouts 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.[136] 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.[137] Countries may access this buffer stock to help mitigate pending AL stockouts; albeit, quantities are relatively limited so large-scale emergency procurements are not possible. PMI also maintains a small stockpile of both AQ+SP presentations. 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 one to two months of stock, countries can accept lower shelf-life products without risk of expiry. For example, if a country is experiencing a stockout and is provided with a two-month supply from the stockpile stock with 50 percent 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.

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[136] 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. The emergency funding account is paid back when a country's funding is obligated to the project.

[137] 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.

## Commodity Loss: Theft, Diversion, Damage, and Expiry

PMI implements stringent processes with the aim of ensuring that all malaria commodities procured arrive to the intended country and, once there, get to the intended end-user.

PMI works to combat and avoid all forms of theft, falsification, and diversion of our malaria commodities. However, malaria commodities, especially ACTs and ITNs, are considered to be of high street value, and these issues can still occur. More rarely, PMI commodities are lost due to physical damage from environmental or mechanical hazards, such as fires, flooding, or vehicle accidents.. If your country is aware of, suspects, or hears of any form of loss of malaria commodities through theft, diversion, or damage it is crucial to immediately report the incident **to the USAID Office of the Inspector General and to USAID/HQ (including the PMI USAID Agency Lead) and the PMI Supply Chain Team** with any information such as photos, lot numbers, location where the loss took place, etc. In addition, it is crucial to understand any potential issues for our programs in-country. Such issues require immediate 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.

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 to the last mile with shorter than preferred shelf life. All methods to avoid or minimize 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 countries that could use the needed commodities. If expiry does occur, country teams should support their host government to plan and safely destroy expired malaria medicines to avoid diversion to the private market and illicit sale by vendors.

## Supply Chain Risk Management

Countries should identify supply chain risks and work to manage them. In FY 2021, the Global Health Bureau Supply Chain Risk Management (GH SCRM) Team developed a Playbook with tools and resources that enable Missions to identify, assess, and mitigate supply chain risks proactively. The GH SCRM working group also supports 19 focus countries (including 16 PMI-supported countries) to review their quarterly risk registers and mitigation plans; it will extend this support to other Missions in the coming years as needed. Countries can seek additional support via the Supply Chain Risk Management Team. Countries should also consider investing in risk mitigation activities, including third party monitoring, and activities to strengthen national regulatory authorities.

PMI contributes to the Global Health Bureau and USAID's Anti-Corruption Task Force (ACTF) effort to implement the National Security Study Memorandum, which established the fight against corruption as a core United States National Security Interest. The ACTF is currently working to identify gaps and opportunities in the Agency's anti-corruption approaches, programming, and safeguards through consultations with Missions, interagency, implementing partners, and other stakeholders. We encourage PMI country teams' participation in these efforts.

As part of their supply chain risk management, countries should identify options to mitigate the risk of loss, including regular inspection of storage facilities, review of inventory records, comparison of logistics and CM data to identify significant discrepancies between reported cases and consumption, and strengthening in-country logistics management information systems or complementary systems such as track and trace.

## 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 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 QA 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.

## 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 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 procurement by local entities. 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 QC measures at the level PMI employs for the procurement of its own commodities. These criteria must be met and require discussion between PMI HQ 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.

## Diversifying the Supply Base and Expanding the Pool of Qualified Local Manufacturers

The impact of COVID-19 on the global supply chain highlights the importance of having a diversified supply base and bringing manufacturing closer to demand. PMI's supply chain team is working to grow its supply base for locally manufactured products that meet internationally recognized quality standards. We are doing so by encouraging our international manufacturers to partner with African manufacturers to

produce locally and by using PMI country funding to support local manufacturers to meet global quality standards.

## 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, and others. 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 speed up handling times, improve data quality, and reduce costs when shipping and receiving products in warehouses and health facilities both at the global and in-country levels. 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 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 Plan–Do–Study–Act (PDSA) method to develop a plan that looks towards building an enabling environment for future implementation. The PMI Supply Chain Team can facilitate support to help countries learn more about GS1 standards, introducing a supportive policy environment, tools, and implementing track-and-trace systems.

# 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, 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 products with shorter shelf lives, complex dosing requirements, and varied demand due to the seasonality and dynamic epidemiology of malaria.[138] 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 improvements. Malaria-only supply chain technical assistance investments should 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; Population and Reproductive Health; Maternal, Child Health and Nutrition, etc.) and where other health elements are relying on government systems, PMI investments must be coordinated with other USG health supply chain investments. 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 investments.

## PMI's Stockout Reduction Initiative

To achieve consistent and meaningful change in malaria commodity availability, PMI is continuing its approach to optimizing PMI's supply chain investments. Starting in CY 2020, PMI operationalized a Stockout Reduction Initiative to guide PMI country investments towards achieving a clear, time-bound target for improved commodity availability at service delivery points. Working with our implementing

[138] Guidelines for Managing the Malaria Supply Chain.

partner and coordinating with the Global Fund, PMI established the target to be used across PMI countries (less than 10 percent stockouts) and developed a playbook, which provides 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 the FY 2022 work plans for PMI countries with a supply chain implementing partner. The exercises laid out in the playbook will also inform development of PMI FY 2023 MOPs and prior year reprogramming. PMI country teams are requested to keep this initiative in mind when allocating funding across all PMI interventions during the development of the FY 2023 MOPs to ensure that PMI investments will address each country's most critical issue(s) impacting commodity availability.

## Logistics Management Information Systems

Improving data visibility along the entire supply chain is critical to improving overall supply chain performance, including forecasting accuracy, optimizing inventory levels, and improving supply chain accountability. An effective LMIS is critical for obtaining and exchanging these data. Country teams should prioritize strengthening LMIS and related supply chain information systems 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 and resupply 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. 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 rollout, expansions, adaptation, consistent use, and improvement of an LMIS. Given that LMIS systems are usually integrated (in the sense that they manage products from different programs, for example HIV, malaria, family planning, and other essential medicines), multiple stakeholders are involved in these efforts, and PMI should coordinate support and participate in discussions with these other stakeholders. PMI country teams should, generally speaking, avoid supporting the creation of vertical malaria-only systems. The complexity of healthcare supply chains, often managing thousands of items,

means electronic LMIS (eLMIS) are increasingly not just desirable but necessary. eLMIS systems have been established in most PMI-supported countries. In addition, countries that are implementing digital health technologies at community level are looking to include functionality for stock management and reporting[139] (please see the **Digital Community Health** section for further information). The time and budget required to implement, or extend, an eLMIS is, in part, 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 eLMIS, including the introduction of new systems or extending the functionality or deployment of existing systems to ensure all key issues are taken into consideration.[140] 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, in 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, including down to the community level (see more details below). 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.

A number of countries (including Benin, Malawi, and the Mekong) are currently implementing eLMIS at the community level and reporting commodity data. A number of others are scaling more comprehensive community-level eHMIS with plans to include logistics modules in the near future (Ethiopia and Liberia, for example). When considering LMIS – both paper and electronic systems – at the community level there are a few specific considerations:

- Community level LMIS – paper or electronic – should be part of the overall system-wide LMIS. Electronic systems should be interoperable across levels.
- CHWs are required to both manage products and provide services to clients. This means that where possible, LMIS and HMIS should be integrated, as expecting CHWs to manage multiple systems is unrealistic.
- Many countries have begun pilots or limited implementation of electronic HMIS at the community level; these systems can be adapted to include basic logistics functionality.
- Paper and electronic systems should be as simple and easy to use, by busy CHWs, as possible; in most cases a simple stock card (electronic or paper) and perhaps a reorder form are the only

[139] PMI Digital Community Health Initiative Cross-Country Landscape Report
[140] eLMIS Selection Guide: Electronically Managing Supply Chain Information.

logistics tools required. Complexity may come at the cost of usability and impede uptake and sustainability of the system.

- Paper LMIS forms should be adapted for the community level, and then standardized, preprinted, and supplied to CHWs.
- In most cases, the absence of consistent infrastructure (for example, electricity) means that for electronic systems, mobile technology is the best option. Fortunately the relatively limited number of products managed by CHWs lend themselves to mobile technology, and CHWs are already familiar with using mobile tools.
- While in many countries, most CHWs may already own mobile phones (sometimes smartphones), it may not be realistic to expect CHWs to use their own personal phones in an eLMIS.
- Many paper LMIS aggregate community level logistics data at a higher level (health facility or in some cases district), which means there is no visibility beyond that level of availability of health products at the community level. If this is the case, stakeholders should consider alternatives (surveys, spot checks, etc.) to ensure there is some visibility of product availability at this level, not for operational decision-making (for example, resupply) but for strategic level decision-making (for example, to quickly identify chronic stockout problems).

## 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 HWs 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. PMI and other health elements have supported the development of a new tool called Quantification Analytics Tool (QAT) for forecasting and supply planning, which replaces the Quantimed (for forecasting) and Pipeline (for supply planning) applications. The supply planning component has been completed, and the forecasting component should be available in CY 2022.

Three types of data can be used for forecasting: consumption data, services data, and demographic data. PMI supports the 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 may require adjustments due to stockouts and misuse. 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 ideally be done nationally (even where different funders take responsibility for different geographical areas) and should include a range of stakeholders including other funders (for example, Global Fund).**

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 at least annual commodity forecasts, with at least quarterly updates of the supply plans. Supply plans should be updated whenever new data are available. These forecasting exercises are also part of the Global Fund concept note preparation. Most countries either have an established Supply Chain Technical Working Group or a Logistics Management Unit[141] 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 and, as such, when PMI is providing support towards quantification, the commodities detailed in the gap analysis tables should ideally be included in the quantification. Please see PMI's MOP guidance for updated instructions for compiling the information presented in the gap analysis tables.

## Warehousing, Storage, and Distribution

[141] Logistics Management Units: What, Why, and How of the Central Coordination of Supply Chain Management.

The purpose of a storage and distribution system is to ensure physical integrity and safety of products 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.

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 vary greatly across countries based on country context and 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 government-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. If you have questions about budgeting for warehousing and distribution fees, contact your supply chain backstop.

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 significantly increased costs of supporting 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; instead, governments are outsourcing these services to private logistics providers. **PMI encourages countries' 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 in the MOP from commodity or supply chain and pharmaceutical management technical assistance costs. Tracking these MOP investments helps to understand PMI's support to local supply chain partners, as well as costs associated with the physical movement of commodities in the supply chain.

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. Warehousing infrastructure is increasing in many of PMI's countries as is countries' ability to appropriately manage temporary storage of campaign nets. Country teams are encouraged to work with their supply chain implementing partners to assess country capacity, weigh the risk of country-managed warehousing (e.g., ability to safely secure the nets), and determine how to mitigate that 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 sustainability. 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 WHO PQ ITN supplier recommends storing their nets in containers after their delivery to procurement-defined destinations. For more details, see: Use of containers to store ITNs: 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 QA 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 Office of Inspector General, for example). Moreover, there is a limited number of partners whose relevant scopes of work can accommodate these activities.

Some countries choose to implement their own post-shipment QC. PMI will liaise with these countries on a case-by-case basis if issues or discrepancies arise from the country's QC testing. Many PMI-procured products require a specific testing procedure that, if not used, can produce false out-of-specification results. PMI is currently collecting information on which countries require their own post-shipment QC.

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.[142] 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 CM and Supply Chain Teams so that pharmacovigilance efforts may be coordinated with other donors and existing country systems and infrastructure.

## Monitoring and Supervision

[142] 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."

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 Logistics Management Unit (LMU) is a good venue to facilitate M&E 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. For a complete list and more details on our common supply chain tools, please refer to the Supply Chain Tools Cheat Sheet. A few common tools include:

- **The Procurement Planning and Monitoring Report for malaria (PPMRm)** provides data on stock availability for critical malaria commodities (ACTs, SP, injectable artesunate, and RDTs), at the central, intermediary, and/or service delivery point levels. The report describes stock status of anti-malarial products on a country-by-country basis and is produced 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 and overstocks both in the near and far term. The PPMRm can be accessed at 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 one to two times a year. Depending on how the sample is taken, nationally representative estimates are possible. The estimates produced by the EUV Tool are meant to give a general picture of malaria commodity availability 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 implementing partner to discuss the best sampling approach, while also keeping in mind costs. Please consult with PMI HQ 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 and countries 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 TOM table produced biweekly 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 their 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),[143] 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). When developing a scope of work for an SC assessment, the community level – if part of the country's health sector – should be included as a distinct level for the purposes of assessment including as part of a sample for quantitative data collection.

## Capacity Building and Supply Chain Workforce Development

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 develop pre-service training content and to update in-service training content for pharmacy personnel and health workers. PMI also provides technical assistance to build capacity of health facilities and CHWs 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.

As for other levels, the specific capacity-building requirements of CHWs need to be taken into account. Pre-service training programs for CHWs should include supply chain management, and training should include not just the theory of supply chain management but also training on specific competencies (e.g., maintaining a stock card). Supportive supervision visits should include how CHWs are managing their supplies and providing on-the-job training to reinforce skills. If in-service training is provided then opportunities to include logistics training should be considered.

[143] For more information on the NSCA visit:
https://www.ghsupplychain.org/key-initiatives/national-supply-chain-assessment-nsca-toolkit

## 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

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.

The current WHO recommendation is to give parenteral antimalarial drugs for the treatment of severe malaria for a minimum of 24 hours once started (irrespective of the patient's ability to tolerate oral medication earlier) or until the patient can tolerate oral medication. For parenteral artesunate during those first 24 hours, treatment should be given three times at 0, 12, and 24 hours. After the third dose at 24 hours, parenteral artesunate treatment may continue as a single daily dose until the patient is able to tolerate oral medication or for a maximum of seven days (or a maximum of nine total doses). Intravenous artesunate solutions should be prepared freshly for each administration and should not be stored for later use. For parenteral artesunate, the general rule of thumb for number of 60 mg vials needed per dose is:

- <25 kg: 1 vial per dose
- 26 - 50 kg: 2 vials per dose
- 51 - 75 kg: 3 vials per dose
- 76 - 100 kg: 4 vials per dose

Average weights for healthy toddlers, children, young adults, and adults can be found at both the WHO website and the CDC website. With the case of parenteral artesunate as an example, one would need four vials of parenteral 60-mg artesunate for an average man weighing 170 pounds, or about 77 kg (where 1 kg = 2.2 pounds) as an **initial loading dose**. 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.[144] This assumes that the patient is able to swallow ACT tablets after these three doses. If a patient is still unable to swallow ACT tablets after these doses, parenteral artesunate should continue to be given. When assuming an average number of vials, the country team should round up to the next closest vial.

The quantity of intravenous artesunate vials needs to account for the vial strength (i.e., 30mg, 60mg, 120mg), the proportional breakdown of treatments by age/weight, and the average estimated treatment course, which is a minimum of three doses and a maximum of nine doses.

For RAS 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 two months up to three years and two suppositories for children from three years up to five years of age. Available preparations include 50-, 100- and 200-mg capsule suppositories; however, WHO and PMI recommend 100 mg capsules. As a reminder, RAS is indicated in children less than six 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 the 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 Supply Chain Team (which includes a clinical pharmacist) can be available for consultation to help prepare accurate requests (based on available data).

[144] Injectable artesunate has two administration routes: intravenous (as a bolus) or intramuscular. Also of note: although there are three WHO-PQ 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.

# 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 three specific malaria behaviors for which they think more SBC investment or attention is needed in order to have significant impact. That focus should be further refined by geography and target population and should support the National Malaria SBC Strategy and National Malaria Strategic Plan.

**CHWs and SBC:** With PMI's increased emphasis on CHWs and community health services, PMI programming should support CHWs to expand the reach of SBC in their communities and be the recipient of targeted SBC for provider behavior change activities.

**Malaria Vaccine:** At this time, it is not expected that PMI will allocate FY 2023 funding to directly support vaccine implementation but country teams should consider whether complementary support might be warranted for those countries selected to receive a portion of the initial limited supply of vaccine. It is, however, important that malaria SBC activities continue to promote the uptake, maintenance, and use of proven malaria interventions throughout malaria vaccine implementation.

**National Malaria SBC Strategy Development for Low Transmission Settings:** To support strategy development, additional guidance has been developed for SBC in low-to-moderate transmission zones. This can be found as an Annex in the malaria strategy guidance.

**Malaria SBC Site Visit Monitoring Checklist:** The SBC team has developed an adaptable tool to support PMI teams conducting site visits to monitor implementing partners' SBC activities. Data collected is solely for the in-country team's programmatic use and does not need to be shared with the HQ-based SBC Team.

**Zero Malaria Starts With Me (ZMSWM):** A new resource is available, Guidance for Implementing Social and Behavior Change and Zero Malaria Starts with Me, to highlight the complementary roles of SBC and advocacy activities like ZMSWM, provide recommendations for their concurrent implementation, and highlight a case study of successful concurrent implementation.

## Introduction

Achieving and maintaining PMI and 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, 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) M&E.

### *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 MOH 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 MOH staff in regional meetings and technical organizations such as the RBM Social and Behavior Change Working Group.[145] PMI also strongly encourages engagement in online collaboration fora, such as the Springboard for Health Communication Professionals.

- **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

[145] 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.

harmonization, implementation, and M&E 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 M&E 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 MOH staff at the national and sub-national 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, MOHs, other relevant ministries, local civil society organizations, and implementing partners that contribute to SBC activities. Technical assistance is typically focused on planning, development, and M&E of SBC activities, including the selection of appropriate M&E 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, 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. 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.
- RBM SBC Working Group Guidance for National SBC Strategy Development. This guidance, which accompanies the template above, outlines the key elements and considerations for the development of a National Malaria SBC Strategy. In August 2021, this document was updated with an Annex that includes information for developing SBC strategies in low to moderate

malaria transmission zones. The Annex also provides sample SBC strategy content that illustrates how to involve sub-national groups in the development of localized SBC plans to address SBC issues that arise in countries with pockets of lower transmission.

- National Malaria SBC Strategy Development Package. 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. If country teams have questions about SBC strategy and SBC mechanism designs, please contact the SBC Team and we can provide additional resources and guidance, as needed.

### *Invest Locally*

Through capacity strengthening efforts identified above, PMI will continue to help countries – and especially district staff – strengthen their skills in leading and managing malaria SBC programs, and partner more closely with local stakeholders to ensure that effective interventions are implemented by those closest to the people we serve. This means more strategic investment in and support to local governments, local partners, and local research institutions wherever possible.

PMI-supported SBC efforts should be designed and implemented to reinforce the capacity of NMCPs, local government officials, civil society networks, local leadership structures, traditional leaders, and community groups. This is accomplished by identifying and addressing the individual and social determinants of desired malaria prevention and treatment behaviors, implementing SBC approaches that build on existing systems and evidence, and strengthening stakeholder coordination, but it also does this through collaborations with local groups and partners. Thus, these stakeholders should be actively engaged in all phases of SBC design, implementation, and M&E to sustain key results and consider transitioning efforts to local partners over time. This would include country teams identifying opportunities to provide small grants to local organizations to implement SBC activities.

## *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. Please refer to the Malaria SBC Evidence Database for additional information on specific interventions that improve outcomes of primary behaviors of interest.

Primary behaviors of interest include:

- Correct and consistent net use
- Early and frequent ANC attendance
- Acceptance of IPTp
- Prompt care-seeking for fever
- 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).

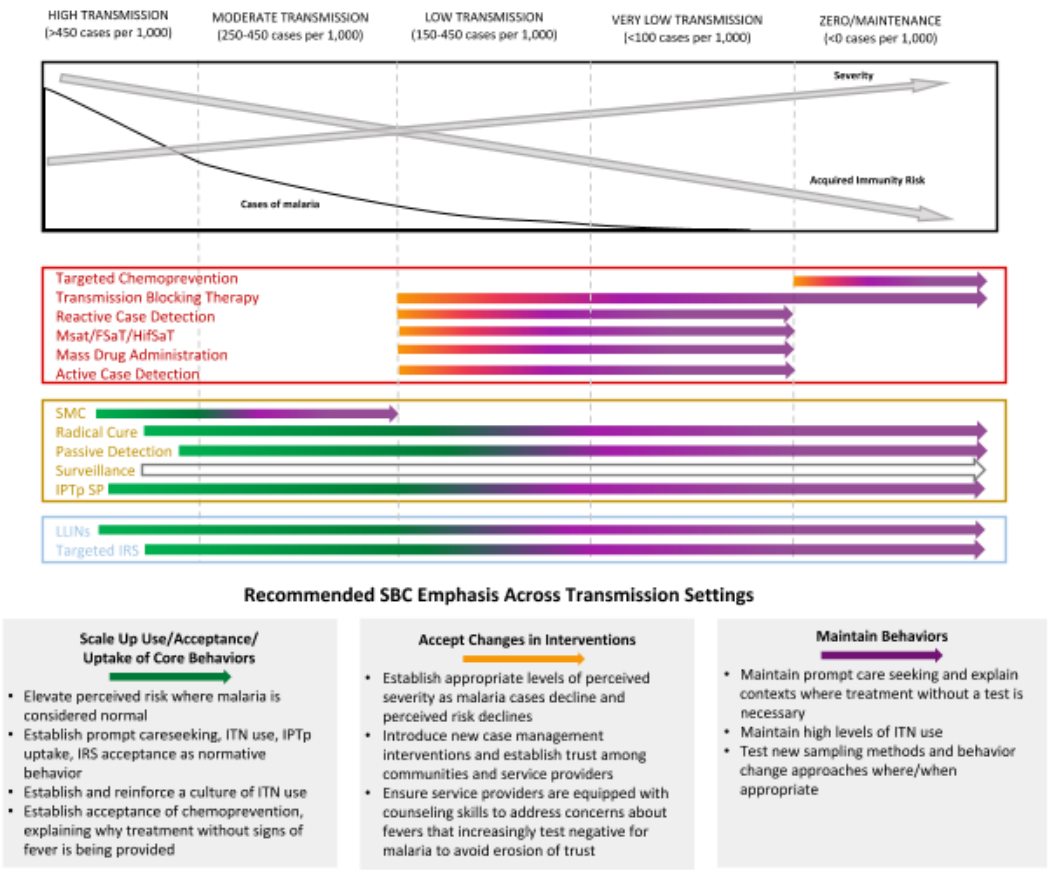
☐ By triangulating data on behavioral outcomes with data on behavioral determinants and demographic information, country teams can make strategic decisions about the appropriate focus of malaria SBC activities. PMI recommends that country teams ***prioritize no more than three specific malaria behaviors for which they think continued or additional SBC investment or attention is needed in order to move the needle.*** As an illustrative example, if prompt care-seeking for fever is low, it's important to understand why. A core intervention like proper testing and treatment is only effective if individuals know when to seek care, are willing to seek care, and have access to care. Thus, country teams should work with implementing partners to ensure all of these conditions are met, requiring investment and coordination with supply chain (to ensure commodity availability), service delivery (to ensure proper quality of care), and SBC (to foster trust in health services available). This prioritization 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.[146] Data sources for such an exercise can be quite varied and are outlined in more detail in the section on M&E.

[146] 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.

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 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.

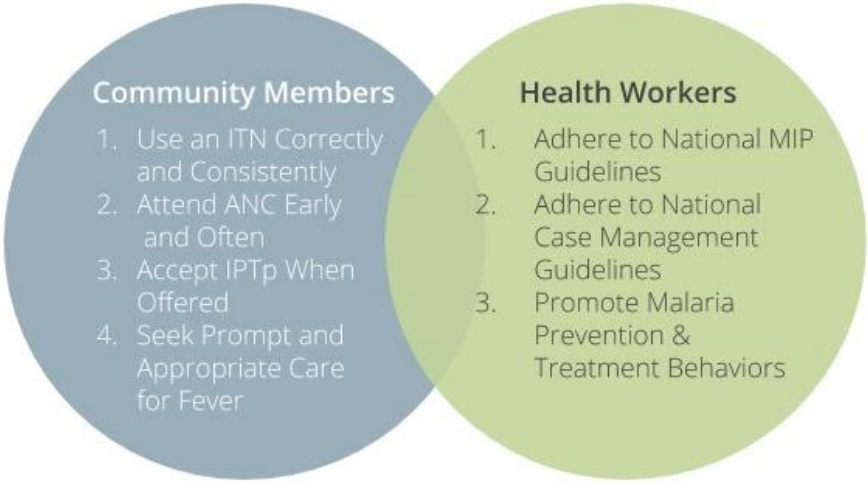
Country teams are also encouraged to consider where their country falls on the transmission continuum and the implications for the appropriate behavioral focus for their country. The figure below provides an overview of such considerations, which are described in Health Communication Capacity Collaborative's (HC3's) report titled SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low, and Zero Malaria Transmission.

**Figure 5. Malaria Transmission Intensity and SBC Focus**




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 no more than three specific behaviors, as well as corresponding target geographic areas and populations, around which to focus PMI's SBC investments.**

**Figure 6. Common Focus Behaviors Associated with PMI-Supported Interventions**[147]




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, 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
- Well-timed, programmatically useful M&E

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.

[147] The SBC Team, in collaboration with the Vaccine Taskforce, will provide future guidance to country teams on malaria vaccine-seeking behavior.

### ***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. Having a better grasp of specific barriers and facilitators to intervention maintenance and uptake further helps to identify the unreached. SBC activities that resonate with target 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 MBS, DHS, MIS, and the MICS, as well as other relevant data sources, such as HFS; 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 M&E 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. 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 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. Audience segmentation involves identifying subgroups within a larger target population to deliver messages that are tailored to those subgroups to ensure the best possible connection to the audience. Audience analysis provides a systematic method for incorporating context-specific factors that prevent or support desired 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. In alignment with PMI Focus Area 1, teams should carefully consider what populations are not being reached by current malaria SBC interventions. Another question to consider is how new or modified SBC measures might be needed to help improve access to or uptake of vector or biomedical interventions among unreached populations.

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.

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 HWs 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.

### ***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, community mobilization, and 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.

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 interpersonal communication 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 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 and by reviewing the Malaria SBC Evidence Database.

**Table 8. Communication Channels**

| Approach | Description | Channels |
|---|---|---|
| Mass Media | • One-way communication<br>• Best for messages intended for large audiences, such as for raising awareness about goods, services, and events<br>• Useful for reinforcing interpersonal communication, community-based, and ICT activities<br>• Can help promote supportive social norms<br>• Allows for dissemination to diverse and hard-to-reach audiences, depending on media access | • Broadcast media (e.g., radio, television, video, serial dramas, game shows)<br>• Print media (e.g.,magazines, newspapers, pamphlets, and posters)<br>• Outdoor media (e.g., billboards) |
| Interpersonal Communication | • Face-to-face interaction<br>• Effective at converting knowledge to action and targeting behaviors that are more problematic or engrained that require more sensitive communication<br>• Facilitates and encourages appropriate action, especially among marginalized populations, and helps people to discuss beliefs and feelings about their ability to take appropriate action<br>• Useful for targeting behaviors for which multiple family members are a part of the decision-making process<br>• Reinforces mass media, community-based, and ICT activities | • CHWs<br>• Home visits<br>• Counseling<br>• School demonstrations<br>• Peer education<br>• Hotlines<br>• Provider (service communication) |

| | | |
|---|---|---|
| Community Mobilization | • Process through which a community's individuals, groups, or organizations plan, carry out, and evaluate activities on a participatory and sustained basis to improve their health and other needs, either on their own initiative or simulated by others | • CHWs<br>• Community dialogue<br>• Community drama |
| ICT | • Use a variety of electronic digital communication and information technology, such as web-based and mobile technologies and software applications, that enable users to engage in dialogue and share information<br>• Electronic digital communication and information technology that is intended to directly improve the effectiveness and efficiency of project interventions | • Mobile phone apps<br>• SMS<br>• Online platforms<br>• Social media<br>• Interactive voice response |

### ***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.

Evidence suggests that the inclusion of specific actionable steps that lead to improved outcomes is also a critical component of SBC messaging. 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 provides a step-by-step guide to the message development and pre-testing process, while How to Conduct a Pre-Test 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 M&E plans, the selection of appropriate indicators, and the measurement and tracking of those indicators. Given the importance of such activities, the role of M&E 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.

### ***Engaging community and faith leaders***

Countries should engage leaders of community and faith organizations as appropriate because they are trusted messengers who can tailor messages to their respective audiences. In addition, their organizations have strengths, community connections, and resources that they can leverage to help influence communities' knowledge, attitudes, beliefs, and social norms to help people adopt key behaviors to prevent and treat malaria. The PMI-funded Malaria SBC Toolkit for Community and Faith Leaders can be shared with organizations as a resource and guide for incorporating malaria activities into their work.

## *SBC in Service Delivery*

A growing area of focus for PMI's SBC efforts relates to healthcare provider behavior, service communication, and collaboration with service delivery stakeholders for MIP and CM 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. Providers themselves are also an important communication channel for complementing community-level SBC efforts to promote net use, prompt care-seeking, treatment adherence, ANC attendance, and IPTp acceptance during 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). With PMI's increased emphasis on CHWs and community health services, there is a valuable opportunity to support CHWs to expand the reach of SBC in their communities. These concepts are explored in more detail below.

### ***Provider behavior change***

Provider behavior change efforts focus on providers – whether health facility-based or community-based – 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 may influence 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 quality service delivery interventions for CM 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)
- Failure to refer a patient receiving pre-referral treatment for severe malaria to a higher-level health facility
- Providing ACTs to patients with negative test results
- Misreporting, whether intentional or unintentional, 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 to fill knowledge gaps, including use of supervision tools and HFS. In these data collection efforts, it is essential to triangulate data sources to assess and characterize whether provider performance is related to access (e.g., commodity availability) or behavioral factors (or both) in order to identify appropriate interventions.

Activities to address these particular provider behaviors may benefit from coordination across SBC, service delivery, and SM&E 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. Further, provider training should include components of SBC for provider behavior change, where applicable. Developed by Impact Malaria and Breakthrough ACTION, the Blueprint for Applying Behavioral Insights to Malaria Service Delivery 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 M&E.

Another promising approach is the application of behavioral economics (BE) methodologies. BE is an approach that focuses on the relationship between individuals' thought processes and the environments in which they are making decisions to understand drivers of behavior. Such a process can offer crucial

insights into the factors that influence provider behavior, including values, professional norms, structural/procedural constraints, and relationships. These insights can then be used to design, pilot, and scale up interventions targeting the identified behaviors. For example, Breakthrough ACTION Nigeria used a BE approach to identify behavioral barriers that prevented providers from following national malaria testing and treatment guidelines. Through a pilot activity, various approaches were designed and tested, including revised patient flow for pre-consult testing, use of performance tracking posters, and consultation tools to assist providers to explore non-malaria diagnosis. (Click here to learn more about Breakthrough ACTION's BE work in Nigeria.)

***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 support 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.

As PMI intensifies efforts to strengthen community health platforms, supporting CHWs to deliver effective SBC – either during their routine CM activities with patients or through specific health communication efforts in their communities – should be a priority. Investments to improve CHW delivery of health messaging and behavior uptake will not only extend the reach of such messages by trusted community members, but it will strengthen the capacity of individual CHWs and the community health system that they are a part of. Such support could include CHW training in health communication, procurement, and delivery of health communication materials, and logistical support to allow CHWs to travel within their communities. Please refer to the **Community Health** section, *CHWs Implementing SBC activities*.

Both service delivery and SBC actors play a role in service communication. Service delivery partners are often working directly at facility and community points of care, and SBC partners may have more technical expertise to support service communication implementation. 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 for service communication.

### ***Coordination***

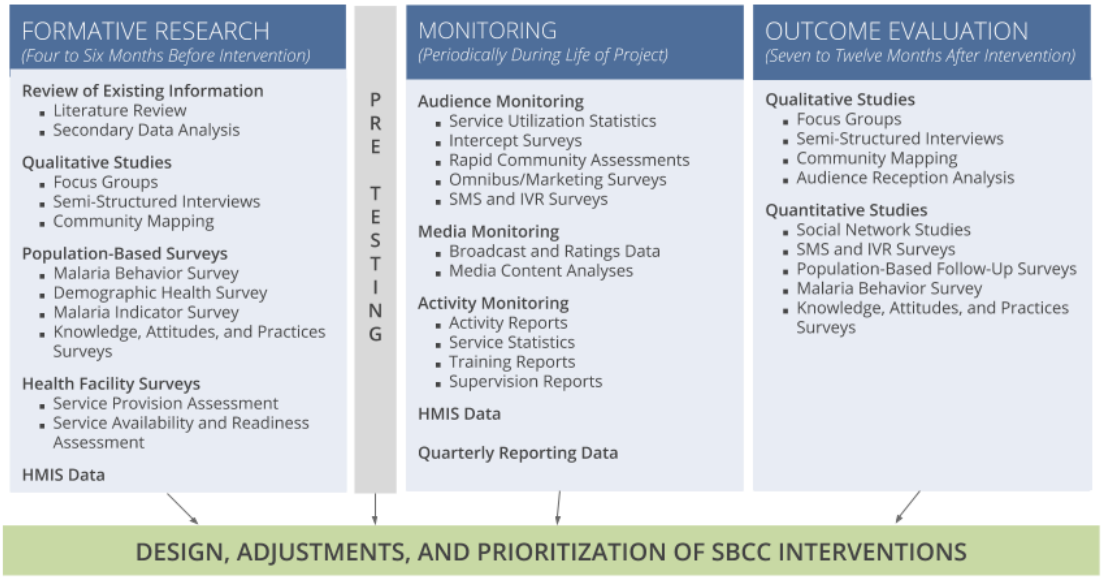
Coordination between SBC and service delivery actors is essential to align supply (service provision) and demand (patient demand) efforts and can provide critical data to both sets of actors that they might not otherwise be able to access. These data can be used to target providers, including CHWs, for SBC support, and for monitoring success of interventions, including provider training. For example, SBC programs can use service statistics to understand if their demand creation efforts are producing an effect, and service delivery partners can 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*

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 M&E of SBC activities. This can be achieved through the development of a comprehensive and systematic M&E plan that draws on previously identified logic models and behavioral and communication objectives for the selected SBC approach. M&E plans should use a practical framework (see Figure 7) to illustrate activities for formative assessments, baseline evaluation and indicator development, process and audience monitoring, and endline (outcome) evaluation.

**Figure 7. Framework for SBC Monitoring and Evaluation**




Partner M&E 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)
- 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 M&E 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.

Monitoring of partner activities is also essential for ensuring SBC activities are effectively reaching their target audience and having measurable effects on behavioral outcomes. To support ongoing monitoring of SBC activities, the SBC Technical Team developed a Malaria SBC Site Visit Monitoring Checklist. The checklist, which was developed in collaboration with representatives from the field, can be used by in-country teams when conducting malaria SBC-related site visits and can be adapted to meet the needs of specific countries. Use of the tool is optional. Data collected is solely for the in-country team's programmatic use and does not need to be shared with the HQ-based SBC Team. The tool is also

intended to complement USAID's Monitoring and Evaluation Toolkit by highlighting unique malaria SBC considerations that should be considered when planning, conducting, and reporting findings from SBC-focused site visits.

### ***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), HFS, 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 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***. Teams should budget at least $350,000 for implementation; however, the final budget should be determined by geographic scope and standard costs for conducting data collection in a given country. Please contact the SBC Team for more information. 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 18 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.
    - **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 worked with Breakthrough ACTION to develop a questionnaire and implementation guidance tailored to low-transmission settings. The adapted questionnaire, 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 was piloted in Zanzibar in CY 2021 and will be ready for use in late CY 2022.

- **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 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. To complement the module, the RBM SBC Working Group and DHS Program released guidance in English and French on how to interpret and use results from the module to inform SBC programming. Data from the module can be used to determine which populations to target with SBC activities, how to frame SBC messages, and the most appropriate channel.

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 an M&E plan for an SBC activity. For example, the DHS and MIS may not provide the sub-national 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 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 HFS 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 healthcare provider behaviors (e.g., development of standardized questions to assess provider behavior in HFS 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 DM 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 M&E 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 M&E 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 and Breakthrough ACTION's SBC Monitoring Guidance.

### *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 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 M&E 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 two to five 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

### *Malaria Vaccine*

At this time, it is not expected that PMI Missions will allocate FY 2023 funding to directly support vaccine implementation, as this is expected to be financed by Gavi, but they should consider whether complementary support might be warranted. However, it is important that malaria SBC activities continue to promote the uptake, maintenance, and use of proven malaria interventions throughout malaria vaccine implementation. Information will be shared with country teams as more information and malaria SBC guidance is developed. Please refer to the **Vaccine** chapter for additional information.

### *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 LSM 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.

However, LSM for *An. stephensi* is an exception. Several efforts are underway to adapt PMI's existing strategy to address invasive *An. stephensi* with urgency across all technical areas, and to determine the policy changes, strategic documents, and OR necessary to mitigate the impact on malaria transmission. A prioritization activity is being led by SBC implementing partners, in collaboration with the PMI SBC and Vector Control Team, to develop SBC guidance for *An. stephensi* that will be available in CY 2022. Please refer to the **Vector Control** chapter for additional information on PMI's planned approach to address *An. stephensi*.

## *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 7** 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.

## *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 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 interpersonal communication 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 interpersonal communication 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 interpersonal communication 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 interpersonal communication activities. As with the COVID-19 pandemic, international organizations, such as the WHO Global Malaria Programme and the 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.

### *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. Through the SBC Team's active engagement with the RBM SBC Working Group, and in consultation with the RBM Strategic Communications Partnership Committee (SCPC), Guidance for Implementing Social and Behavior Change and Zero Malaria Starts with Me was released in June 2021. The purpose of this guidance is to highlight the complementary roles of SBC and advocacy activities, provide recommendations for their concurrent implementation, and highlight a case study of successful concurrent implementation.

## *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*** OR and are an expected and desired aspect of SBC programming. However, as PMI country teams confront SBC-related OR 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 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 OR 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 PC is available in the **Health Systems Strengthening** chapter. However, as it relates to SBC activities, PC and PCVs are a potentially great resource. It is recommended that PMI country teams ensure that PC's 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, PC and PCVs 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 USAID Contracting Officer's Representatives or USAID Agreement Officer's Representatives (A/COR) of a bilateral SBC mechanism or bilateral mechanism with an 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 or not. The Mission-based Activity Manager will work with the HQ-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 sub-national 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 care-seeking should be linked with service delivery projects working to improve the quality of mCM. 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/HQ 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.[148] Similarly, to facilitate communication with PMI/HQ, country teams are asked to identify a single SBC point of contact (POC). The SBC POC will be the primary contact for the SBC Technical Team regarding SBC in-country. The SBC Technical Team at PMI/HQ 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.

[148] For the name of the SBC backstop for your country, please contact any member of the SBC Technical Team at PMI/HQ.

**Table 9. SBC Appendix 1 – Additional Resources**

| Category | Resource | Description |
|---|---|---|
| **General** | RBM Partnership to End Malaria's Strategic Framework for Malaria SBCC | Framework for malaria SBC that outlines a technical and advocacy agenda for the field. |
| | Springboard for Health Communication Professionals | Online platform for exchanging knowledge, experiences, and resources about SBC. |
| | Health Communication Capacity Collaborative Online Learning Center | Rich repository of information on SBC, including webinars, online trainings, and toolkits. |
| | Accelerator Behaviors | Tool that identifies accelerator behaviors and proposes possible program strategies. |
| **Strategy Development** | National Malaria SBC Strategy Template | Standardized malaria SBC strategy template that reflects global best practices. |
| | National Malaria SBC Strategy Development Guidance | Guidance, which accompanies the template above, and outlines key considerations. |
| | National Malaria SBC Strategy Development Package | Step-by-step guide to completing the National Malaria SBC Template in a small working group. |
| | Repository of National Malaria SBCC Strategies | Curated repository of national malaria SBCC strategies. |
| **Design and Implementation** | SBCC Implementation Kits | Collection of in-depth implementation guides on various topics related to malaria SBC. |
| | Health Compass How to Guides | Short guides that provide step-by-step instructions on how to perform core SBC tasks. |
| | SBCC Quality Assurance Tool | Easy-to-use tool to assess and assure the quality of SBCC activities. |
| **Monitoring and Evaluation** | Developing Monitoring and Evaluation Plans for Malaria Social and Behavior Change Programs: Step-by-Step Guide | Resource that introduces the elements of a monitoring and evaluation plan for malaria SBC programs. |

| | | |
|---|---|---|
| | SBCC Indicator Reference Guide | A streamlined, standardized set of priority indicators for malaria SBC activities. |
| | SBC Monitoring Guidance | Technical notes on monitoring methods that may be used for SBC programs. |
| | Malaria SBC Site Visit Monitoring Checklist | Adaptable tool to support PMI teams conducting site visits to monitor implementing partner's SBC activities. |
| | Malaria SBC Evidence Database | Searchable database of literature documenting the impact of malaria SBC. |
| | Priority Research Areas and Approaches for Malaria SBC Programs | Report outlining priority research areas and approaches that need to be explored and utilized as malaria interventions scale-up. |
| | Breakthrough Research SBC Research and Learning Agenda | Research and learning agendas for provider behavior and the integration of multiple health issues within a single SBC program. |
| | Checklist for Reporting on Malaria SBC Program Evaluations | Checklist aimed at improving the evidence base for malaria SBC by outlining standard elements for PE reporting. |
| | Malaria Behavior Survey Website | Comprehensive website that includes standard questionnaires, implementation guidelines, and results from completed surveys. |
| | Standardized Malaria SBC Module for the MIS & DHS | Access to the questionnaire, interviewer instructions, and analysis plan for the standardized malaria SBC module. |
| | ITN Use and Access Report | Provides an estimate of the proportion of the population using nets among those that have access to one within their household. |
| | SBC for ITNs | Comprehensive guide on SBC activities for all types of net behaviors, including acquisition, use, and care. |
| | Guidance for Implementing Social and Behavior Change and Zero Malaria Starts with Me | Guide to highlight the complementary roles of SBC and advocacy activities, provide recommendations for their concurrent implementation, and highlight a case study of successful concurrent implementation. |

| | | |
|---|---|---|
| **Specific Technical Areas** | Monitoring And Evaluation For SBCC - Malaria Case Management | How-to guide on monitoring and evaluating SBC components of mCM interventions. |
| | SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low and Zero Malaria Transmission | Guide to scaling up and maintaining coverage of proven interventions in countries as transmission patterns change. |
| | SBCC for Malaria in Pregnancy: Strategy Development Guidance | Resource on the design of interventions for MIP, especially those interventions that target HWs. |
| | Malaria SBC Toolkit for Community and Faith Leaders | Guide for faith and community organizations aimed at building capacity for the promotion of malaria prevention and treatment behaviors. |
| | Blueprint for Applying Behavioral Insights to Malaria Service Delivery | Framework for understanding provider behavior that can be used when developing strategies for provider behavior change. |
| | Malaria SBC Program Guidance in the Context of COVID-19 Pandemic | Behavioral considerations and programmatic recommendations for the implementation of malaria SBC activities in the context of COVID. |
| **Online Trainings** | Evidence-Based Malaria Social and Behavior Change Communication | Introduction to malaria SBC theory, formative assessments, implementation, and M&E. |
| | Health Communication for Managers | Course aimed at increasing learners' understanding of the basic principles of health communication. |
| | Health Behavior Change at the Individual, Household and Community Levels | Provides introduction to conceptual tools needed to analyze health-related behaviors and the context in which they occur. |
| | Introduction to Human-Centered Design | Introduction to the human-centered design process, which involves creating innovative solutions to real-world challenges. |

# SURVEILLANCE, MONITORING, AND EVALUATION

***New/Key Messages***

**Health management information systems are a key investment area for PMI.** Although a single partner may not be responsible for everything that needs to be done to strengthen RHIS, a checklist of PMI-recommended activities can be used to identify gaps across partners and prioritize support for activities (**Table 10**). 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.

**Surveillance Assessments (Data Quality Assessment)**

WHO, RBM SMERG, and partners have developed a standardized data quality assessment toolkit that has been piloted in Burkina Faso, Cameroon, and DRC, with additional assessments planned in Benin and Ghana. The toolkit contains options for both rapid, targeted assessments, and comprehensive assessments, with an aim to provide baseline measurements for measuring progress over time, as well as identification of areas requiring immediate improvements. Country teams should consider planning and allocating funds for these assessments in their country budgets for HMIS support and the Global Fund will also make funding available for these assessments through their grants.

**Strengthening community-based information systems**

As CHW cadres in the country grow and expand, country teams should remember to incorporate strengthening activities for community-based information systems and improving their use. A list of best practices and resources is included both in this section, with further details in the **Community Health** section of this guidance. Teams investing in community-level HMIS strengthening should consider adding a separate line in the MOP Table 2 to track investments in this element of PMI's strategic focus on strengthening community health systems.

**Five Focus Areas: Measuring unreached populations**

The SM&E team will be working with the pending outputs from the Strategy Implementation Group country roadmap process to contribute to the development of metrics for Strategic Focus Areas (SFA), as warranted. Of particular importance is reaching unreached populations and how to measure progress towards this SFA.

**Stratification and tailoring exercises**

WHO is currently developing a manual for implementation of stratification and sub-national tailoring of interventions which will be circulated to field teams when it is finalized in mid-CY 2022. PMI

participation in stratification and sub-national tailoring exercises is highly encouraged. If you have questions about stratification, how to be engaged and what to look for or your country is beginning the process, please reach out to the SM&E team. Please read more details in the stratification section of this guidance.

**Nationally Representative Surveys: Recommended Frequency and Biomarkers**

**Household surveys will continue to be a key surveillance SM&E activity:**

- In moderate- to high-prevalence areas, household surveys are recommended every two to three years.
- PMI recommends that in countries where national parasite prevalence in children under five years of age is below 3 percent 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 five years of age at or below 3 percent 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 three to five years to continue to assess intervention coverage.
- In lower burden countries (<5 percent national parasitemia) where specific regions and/or districts are targeted for key interventions, a sub-national MIS on obtaining intervention coverage estimates to guide decision-making can be considered based on funding availability and program needs. Please contact your SM&E POC to discuss this option.

**Health facility surveys** 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 three 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). For more information, **please refer to the HFS section** of this guidance document.

**Elimination:**

The new PMI Strategy 2021–2026 again includes an elimination-focused objective: To accelerate toward elimination in 10 countries and eliminate in ≥1 country. Elimination as a sub-national or national goal requires that malaria control and elimination activities must increasingly be tailored and geographically localized 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 quality HMIS/malaria surveillance information. Please refer to the **Elimination** technical guidance chapter for additional information and resources.

*For guidance on entomological monitoring, ITN DM, and therapeutic efficacy monitoring, please refer to the **IRS**, **ITN**, and **Case Management** chapters, respectively. These activities and corresponding budgets should also be included in their respective sections, not the SM&E sections of the MOP.*

# Introduction

PMI's new strategy 2021–2026 focuses on a world free from malaria. The three strategy objectives will continue to be focused on mortality reduction, morbidity reduction, and moving countries toward elimination, but the targets and supporting focus areas have been adjusted.

The goal of PMI's updated strategy for 2021–2026 involves working with NMCPs and partners to accomplish the following objectives by 2026:

1. Reduce malaria mortality by 33 percent from 2015 levels in high-burden PMI partner countries
2. Reduce malaria morbidity by 40 percent from 2015 levels in PMI partner countries with high and moderate malaria burden
3. Bring at least 10 PMI partner countries toward national or sub-national elimination and assist at least one country in the Greater Mekong Subregion to eliminate malaria

These objectives will be accomplished by emphasizing five focus areas : (1) reach the unreached, (2) strengthen community health systems, (3) keep malaria services resilient, (4) invest locally, and (5) innovate and lead.

# 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 Global Fund, World Bank, WHO, UNICEF, and others. SM&E 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.

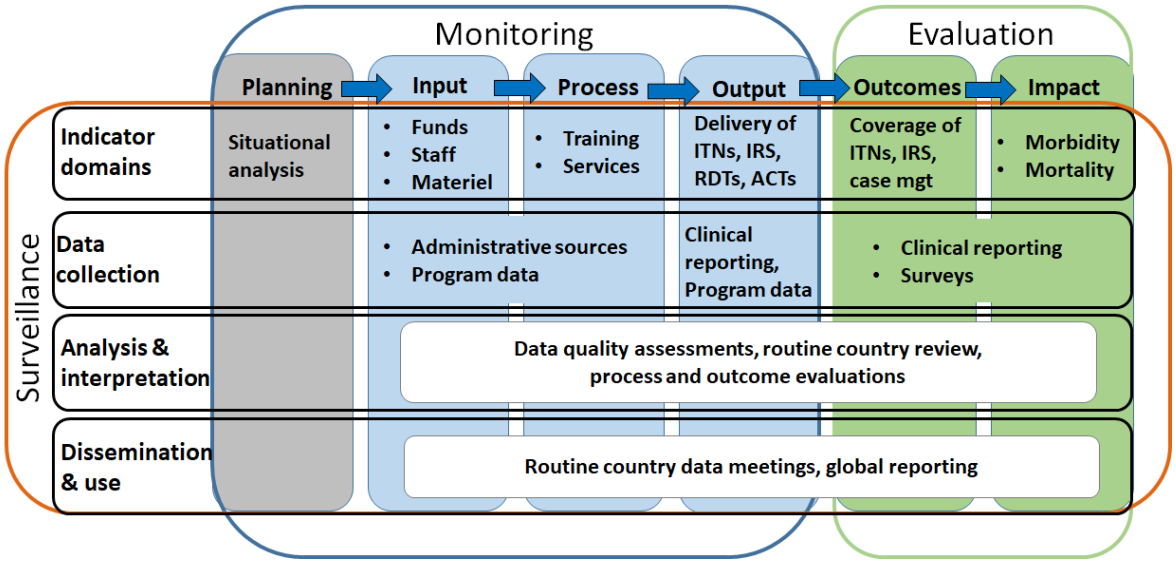
### *Cost-effective, sustainable solutions*

The PMI HQ 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. SM&E 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 standalone 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 in **Figure 8** in organizing its activities. The figure illustrates key indicator domains, potential data sources, and highlights the importance of data analysis, reporting of results, and use as a part of all SM&E activities from input to impact. The areas in the first four columns (blue) are the monitoring domains and the areas in the last two columns (green: outcomes and impact) are the evaluation domains. PMI's three objectives are addressed under the Evaluation/Impact column.

**Figure 8. Malaria Surveillance, Monitoring and Evaluation Framework**




## Measuring PMI Objectives

Determining progress towards the three new strategic objectives requires estimating malaria morbidity and mortality in each PMI focus country. For countries nearing elimination, sub-national 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 malaria mortality by 33 percent from 2015 levels in high-burden PMI partner 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 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 malaria morbidity by 40 percent from 2015 levels in PMI partner countries with high and moderate malaria burden*

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 NMCPs and donors in such settings.

To date, weaknesses in most RHIS 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 RHIS; 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 partner countries, RHIS data (increasingly captured via DHIS-2 platform) is the main data source for suspected and confirmed malaria cases (data availability and quality may vary depending on country surveillance indicators and the frequency of testing), 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.**

A critical component of strengthening RHIS data systems is ensuring that malaria services provided by CHWs are captured and incorporated (ideally in a disaggregated format) as part of the regular DHIS platform. This is of greater importance as part of the new PMI Strategy and Focus Area 2 – Strengthening Community Health Systems.

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 RHIS and population-based surveys is in the **Guidance on SM&E Approaches and Tools** section below.

### *Objective 3 – Assist at least 10 PMI partner countries to achieve national or sub-national elimination*

PMI continues to use a threshold of TPR ≤5 percent to monitor both sub-national and national elimination areas. Countries or sub-national areas approaching elimination must have a highly functioning RHIS that includes reporting of cases diagnosed from all sectors, including public, private, NGOs, military, etc. Use of digital tools may facilitate collecting and reporting data in this way (see **Digital Community Health section** for more information). Preferred impact indicators in settings moving towards elimination include test positivity rates and incidence estimates based on the catchment population of the health facility.

Elimination activities related to case investigation and response such as 1-3-7 (e.g., report, investigate, respond) surveillance and reactive case detection strategies, etc. should be noted and these activities

should be included in the MOP budget table under SM&E for elimination. A more detailed discussion on SM&E and surveillance system requirements in the elimination setting can be found in the **Elimination** chapter.

## Five Focus Areas

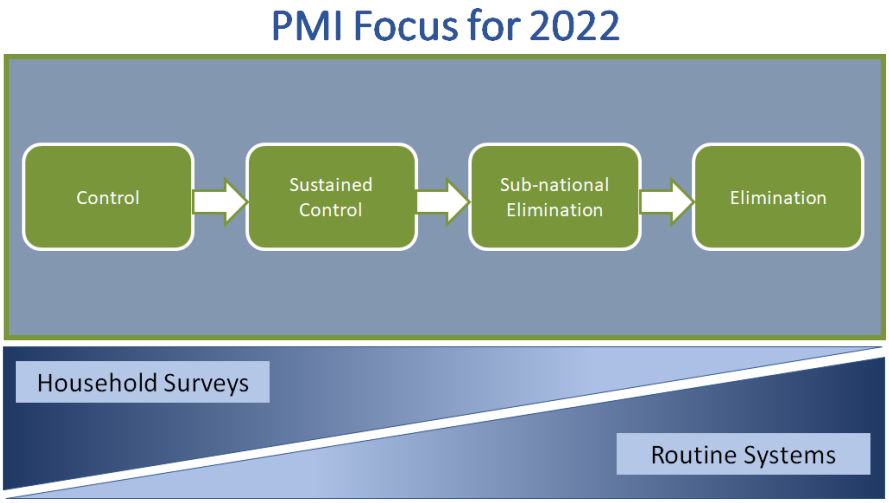
The *PMI 2021–2026 Strategy* has five focus areas that support PMI's three objectives. Focus areas need to be monitored to assess progress that will ultimately have an impact on PMI's objectives. At the time of updating this guidance, the Strategy Implementation Group is collecting information from country teams; information that will help PMI establish metrics to assist countries and PMI to monitor progress in activities across the five focus areas in support of PMI's objectives. For example, the SM&E team plans to contribute to the development of useful metrics for Strategic Focus Area 1 – Reach the unreached: Achieve, sustain, and tailor deployment and uptake of high quality interventions with a focus on hard-to-reach populations.

## SM&E for the PMI Strategy, 2021–2026

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 (see **Figure 9**). 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.

**Figure 9. Changing SM&E in the Context of Progressive Phases from Malaria Control to Elimination**




## Guidance on SM&E Approaches and Tools

### *Malaria disease surveillance*

Malaria disease surveillance plays an important role in the M&E 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, see the WHO guidance on malaria surveillance for control areas. For countries moving towards elimination, please contact the PMI HQ 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.

### ***Routine health information systems***

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 partner 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 as resources are limited, and supporting multiple systems with issues of comparability may be problematic. In low-endemic settings, malaria data may be needed more frequently than monthly in order to permit detection of foci of transmission that require immediate response (see chapter on **Elimination**).

Some countries have epidemic surveillance detection included in their National Strategic Plans. Countries should note that epidemic detection systems are meant for **LOW** burden areas (less than about 100 cases/1,000 per 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 ongoing 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). Please see the **Elimination** chapter for more information on data systems requirements for countries in low burden settings.

Support for models to predict epidemics is not recommended with PMI country funding. There are currently global efforts to develop improved models.

Twenty-six of PMI's 27 partner 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.[149] While issues of completeness and accuracy remain, this should not keep countries from using this information

[149] 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.

for tracking trends to inform programmatic decision-making while still checking data quality and completeness. Frequent use and visualization of routine data should be supported and encouraged not only for decision-making, but also to regularly identify data quality issues and help improve its quality. In addition to country-level use and visualization of malaria data, PMI collects HMIS malaria data by admin 2 level (e.g. district, sub-counties, zones) and month and some programmatic data on a quarterly basis from each country for PMI use. Housed on the M-DIVE platform, the data collection permits PMI to analyze global trends and combine financial, climate and epidemiologic data for improved understanding and tracking of investments (See **Data Integration** chapter).

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.

### *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, paired with efforts to strengthen malaria reporting via RHIS (outside of elimination settings), and made in consultation with the PMI HQ 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 HQ SM&E Team.

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.

### ***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 CM 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 **Table 10**. 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. Country teams should discuss the checklist to strategically identify data priorities and needs to guide activity planning.

**Table 10. SM&E activities recommended and supported by PMI at different administrative levels** *(this can be used as an internal checklist)*

| **Central Level** | |
|---|---|
| Registers | ☐ |
| Checklists, regular data quality activities | ☐ |
| Tools (e.g., indicator glossary), job-aids (design, indicators, definition of data elements, system support) | ☐ |
| Creation of a data dictionary to link specific RHIS elements with frequently used indicators and QR requests. | ☐ |
| Data quality assessments (separate from supervision – funding for travel to lower levels)<br>Program monitoring and technical assistance (funding for travel to lower levels) | ☐ |
| 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) | ☐ |
| Human resources (secondment of person in NMCP or central M&E unit for SM&E) | ☐ |
| Data use (analysis, interpretation, visualization (dashboards, bulletins), dissemination/feedback to lower levels, decision-making) | ☐ |
| Policy guidelines and coordination (updating policies, guidelines, supporting sub-committee meetings, supporting participation in sub-committee meetings) | ☐ |
| External relations/communications/outreach (support travel to international meetings and publications) | ☐ |
| Support to annual operational plans for national malaria program | ☐ |
| Desk review to catch "logic errors" in the system (provide technical assistance to catch logic errors) | ☐ |
| **Admin1 (regional-equivalent)** | |
| Registers for facilities and CHWs (warehousing, printing, distribution) and data collection tools | ☐ |
| Data quality assessments (separate from supervision – funding for travel to lower levels) | ☐ |
| Program monitoring and technical assistance (funding for travel to lower levels) | ☐ |
| 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) | ☐ |
| Human resources (secondment of person for malaria SM&E, office/team for SM&E) | ☐ |

| | |
|---|---|
| Data use (analysis, interpretation, visualization (dashboards, bulletins), dissemination/feedback to lower levels, decision-making) | ☐ |
| Adaptation of national policy guidelines and coordination (adapting policies, guidelines, supporting sub-committee meetings, supporting participation in sub-committee meetings) | ☐ |
| Adaptation of checklists and job-aids | ☐ |
| Participation in national meetings (support for travel costs) | ☐ |
| Support to annual operational plans for admin 1 malaria program | ☐ |
| **Admin2** | |
| Data entry, summary, and transmission (training, re-training, computers, internet, tools)<br>Supervision (training, traveling, supervision tools/checklists, create/design system for organized/methodical supervision) | ☐ |
| Data validation (data validation activities before monthly data submission – organize health facilities) | ☐ |
| Monthly/quarterly data quality review meetings (venue, meeting support) | ☐ |
| Data use (analysis, interpretation, visualization (dashboards), dissemination/feedback to facilities, decision-making) | ☐ |
| Human resources (secondment of person for malaria SM&E, office/team for SM&E)<br>Annual planning with admin 2 (support travel) | ☐ |
| **Facilities** | |
| Data collection/entry, summary, and transmission (training, re-training, computers, internet, tools) | ☐ |
| Digital tools for both job-aids and data collection and transmission (see Digital Community Health section) | ☐ |
| Supervision of CHWs (training, traveling, administering supervision tools/checklists of CHWs) | ☐ |
| Data use (analysis, interpretation, visualization (dashboards), dissemination/feedback to CHWs, decision-making) | ☐ |
| Monthly/quarterly data quality review meetings (support for travel) | ☐ |
| **Communities** | |
| Data collection/entry and transmission (training, re-training, tools) | ☐ |
| Digital tools for both job aids and data collection and transmission (see Community Health section) | ☐ |
| Data use (analysis, interpretation, decision-making) | ☐ |
| Monthly/quarterly data quality review meetings (support for travel) | ☐ |

Data in a fully functional RHIS will move along a continuum: recording, reporting, processing, analysis, presentation, interpretation, use (actions), and feedback. These activities also occur at different levels of the healthcare system. Thus, the 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 percent 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 are 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. With resources available, the scale-up to all facilities (public and private) and communities 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."[150] 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

[150] http://www.who.int/immunization/monitoring_surveillance/burden/vpd/surveillance_type/sentinel/en/

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 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., CM and SM&E) almost always makes sense. In the country MOP, activities that support strengthening diagnostics should be included under the CM 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 CHW 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 the **Elimination** chapter for details on individual case-level surveillance activities such as reactive surveillance.)

### ***Strengthening Community-Level Data Systems***

Community-level data is needed to monitor the quality and quantity of community-based service delivery. The capacity to monitor and use community-level mCM and stock data for decision-making enables programs to target resources and saturation efforts, adjust CM practices, optimize stock management, and ultimately improve outcomes. In some PMI partner countries, CHWs diagnose more than 50 percent of malaria cases, thus underscoring the importance of timely reporting of high-quality community-level data. The majority of PMI partner countries have the capacity to capture CHW-confirmed malaria cases in their RHIS; however, the quality, use and integration of community data is low compared to health facility data in RHIS.

2018 WHO guidelines recommend that CHWs document the services they provide and that CHW data be collected, collated, and used employing recommended practices, which include:

- Ensuring integration with data systems at the health facility and HMIS

- Prioritizing and standardizing a set of community-level indicators, potentially spanning case data, stock data, and workforce-related data
- Building structures and processes to improve data quality
- Ensuring appropriate data use at all levels of the health system including the dissemination of community case data through malaria bulletins and at technical working groups
- Creating mechanisms for feedback to CHWs

These best practices apply to both paper-based and digital data systems. They are explored further in Data Systems and Digital Community Health within the Community Health section of this guidance. In addition, the following resources may be helpful in thinking through the data systems components of community health system strengthening:

- *Model of a Community-Based Information System: Essential Components and Functions*: Measure Evaluation created a model for community-based information systems (BIS) to help countries assess and strengthen their CBIS, by providing them with a reference for what should be included and how a CBIS should function.
- Scale to Track the Stages of Development of Community-Based Health Information Systems: Measure Evaluation created this tool to help governments and/or organizations determine at what stage their CBIS is and what should be in place to get it to the next stage.
- *DHIS-2 Community Health Information System Guidelines: This guidance is a practical guide for national and local decision-makers involved in the design, planning, deployment, governance, and scale-up of successful DHIS-2 based community health information systems.*

In order to assist efforts to strengthen CBIS, PMI is currently supporting work to understand where and how these guidelines for strengthening community-level data have been implemented and to uncover any gaps in the existing guidance that should be filled in order to further support countries in this work.

### ***Supporting data systems for malaria elimination***

Countries approaching the elimination phase, either sub-nationally or nationally, may require a malaria-specific, case-level supplementary surveillance system that builds on the HMIS/IDSR platform and reports directly to national or sub-national malaria control authorities with greater frequency (within day(s) of diagnosis). Such systems should allow reports to be seen and used at all levels to facilitate timely investigations of individual cases or foci. 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, which is operational in all elimination districts in Zimbabwe.

In situations where a country has transitioned into the elimination phase, a malaria-specific surveillance system may become necessary because individual case-level data is required to facilitate case investigations. Ideally, such systems would facilitate access to near real-time, high-quality community data

that flows directly into country HMIS at the most peripheral level possible. Please see the **Elimination** chapter for more information.

## *Surveillance Assessments (Data Quality Assessment)*

WHO, RBM SMERG and partners have developed a standardized surveillance assessment toolkit that has been piloted in Burkina Faso, Cameroon, and DRC, with additional assessments planned in Benin and Ghana. The toolkit is modular and contains options for both rapid, targeted assessments, and comprehensive assessments. The objective is to provide baseline measurements for measuring progress in surveillance systems over time, as well as identification of areas requiring immediate improvements. More information on the WHO Malaria Surveillance Assessment Toolkit is available here: https://www.who.int/docs/default-source/malaria/mpac-documentation/mpac-december2020-session1-surveillance-toolkit-update.pdf?sfvrsn=f3091836_9. The hope is that the standardized outputs can improve both global and national metrics and interpretation of routine malaria data. Additionally, country, donor and partner coordination and investment prioritization in surveillance activities may be facilitated. Country teams should consider planning and allocating funds for these assessments in their country budgets for HMIS support and the Global Fund will also make funding available for these assessments through their grants. Please contact the SM&E team with any questions.

## *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.[151,152] PMI is supporting OR 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.

Any countries considering implementing ANC surveillance for malaria parasitemia or malaria intervention coverage monitoring are encouraged to reach out to the SM&E team.

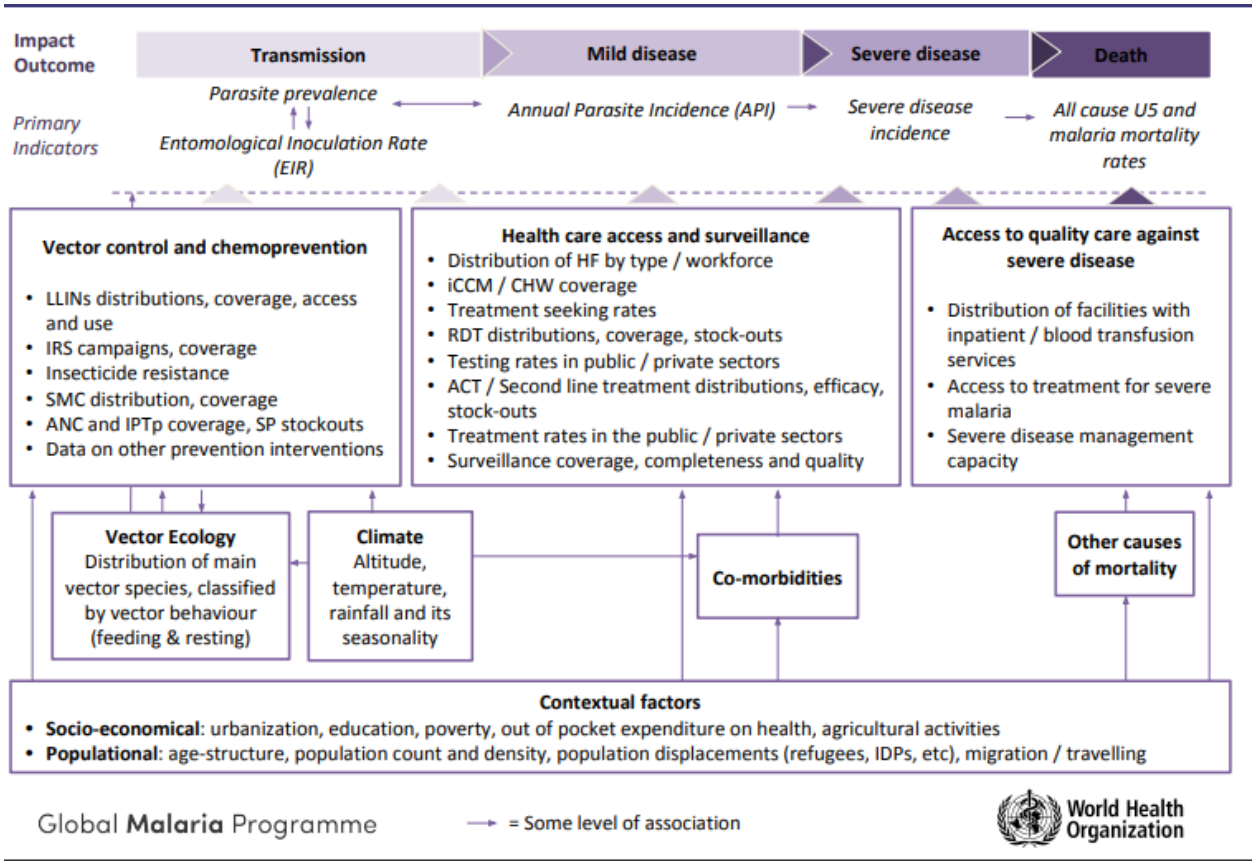
## *Malaria stratification mapping*

Within most PMI partner countries, transmission intensity is diverse. There is growing global, regional, and NMCP emphasis on characterizing this diversity through stratification exercises and tailoring deployment of interventions based off of that stratification. These stratification activities use data to

[151] 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).
[152] ASTMH 2018, Aaron M. Samuels: "Antenatal clinic surveillance for malaria accurately reflects community malaria infection prevalence in a high transmission setting in western Kenya."

answer specific question(s) or help make a decision. A broad set of data can be leveraged to inform this stratification, as noted below in the WHO malaria framework for stratification.

**Figure 10.** [The WHO malaria framework for stratification]




For example, stratification may be done to define different transmission strata and then use approaches such as modeling of the data shown in the WHO malaria framework to identify and target the most effective mix of interventions and optimize the impact of existing resources.

Most countries can now assess annual malaria incidence sub-nationally using data from HMIS. Data quality (completeness, accuracy) should be monitored and strengthened where needed, 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 date, due to quality concerns of HMIS data, many country stratification exercises have used a hybrid approach of using both HMIS data and survey prevalence data. 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 per 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 partner countries.

Although malaria transmission intensity (e.g., incidence) should form the foundation of stratification, as transmission decreases, tailoring should incorporate ecological, entomological, and SBC data in order to determine the appropriate package of malaria interventions and tailor malaria prevention activities to specific settings.

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, seasonality of transmission, and entomological data, 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: Burkina Faso, Cameroon, DRC, Ghana, India, Mali, Mozambique, Niger, Nigeria, Tanzania, and Uganda. 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 are 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 assumptions and scenario inputs and, in turn, the usefulness of the stratification outputs. Note that some PMI partner 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. WHO is currently developing a manual for implementation of stratification and tailoring of interventions which will be circulated to field teams when it is finalized in early CY 2022. If you have questions about stratification, how to be engaged, what to look for or your country is beginning the process, please reach out to the SM&E team.

### *Population-based surveys*

As mentioned above and depicted in **Figure 10**, countries are facing a wide spectrum of data needs, data collection methods, and the frequency with which data are collected and reported based on underlying malaria epidemiology and maturity of health systems. Planning and funding data collection activities should be based on how the data will be used, by whom, and with what frequency. While the previous section focuses on data needs in the RHIS space, many countries still rely heavily on data from population-based surveys. Important considerations for SME investments in surveys are outlined below.

### ***National-level household surveys***

For PMI SM&E needs, conducting a national-level household survey within established survey timelines set by the MOH 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, see the Global Health eLearning course that is available online.

In moderate- to high-transmission areas, a survey every two to three years might be appropriate; in low-prevalence areas, an interval of three to five 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 an 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, to better understand progress, drive better decision-making and demonstrate impact. 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 subregions or population sub-groups (e.g., school-age children or people over 15 years of age). Per RBM 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 three to five zones per country). To obtain reasonable estimates for subregions or for sub-populations outside of RBM SMERG-recommended ones, sample sizes and survey complexity and cost will increase. These concerns, in addition to ongoing 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 HQ 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 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 six to 59 months of age in countries with a national prevalence estimate of >3 percent. 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 to 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 to 49 years of age) 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. Parasite prevalence should be based on the results of a high quality RDT where *P. falciparum* accounts for nearly all infections (≥ 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 to 59 months, PMI will support the survey (provided it has been approved by the PMI HQ SM&E Team), but will not fund the testing in the additional age groups.

As countries enter the 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 five 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 percent in other regions or districts.

Additionally, in lower burden countries where the national parasitemia estimate is below 5 percent and have specific regions and/or districts targeted for key interventions, a sub-national MIS can be considered to obtain intervention coverage estimates in those targeted areas. Please contact your SM&E POC to discuss this option.

### *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 HQ SM&E Team to help negotiate with other stakeholders to ensure that PMI needs will be met, including reviewing the combined survey statistical design and sampling strategy, an agreement such as a memorandum of understanding (MOU) 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.[153] 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 HQ 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

[153] 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.

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 OR; and in such cases, there should be coordination with the PMI HQ OR Committee.

### *Health facility-based surveys*

Nationally-representative 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. HFS are useful in situations where routine information systems and household surveys do not provide all of the necessary information on CM 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. HFS should not be used as replacements for the routine HMIS. 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 HFS. For example, discrepancies between actual CM practices and HMIS reporting are best investigated through smaller-scale investigations than through a nationally representative HFS.**

**Methodology:** HFS typically captures cross-sectional data from health facilities on several aspects of the health system, including availability of commodities, appropriateness/quality of CM, 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. An 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 two to three 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 HFS can be very comprehensive and include many other health delivery systems, PMI should strive to work with other health sectors in the mission and other donor partners to fund HFS.

**Integration:** Children under five years of age with fever are evaluated in health facilities using integrated CM protocols. When an HFS includes an observation or re-examination module, CM of children should be observed and cases re-examined using an integrated protocol. Commodities, HW 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 HFS 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 CM data become increasingly non-actionable if there are significant delays between the survey and the sharing of results.

***Service provision assessment***

Note: At the time of updating this guidance document, a process to revise the SPA and develop a standardized and improved Quality of Care survey is underway through the DHS-8 Program. The goal is to field the new tool in 2022 with standardized indicators and questions across the health sector.

Service provision assessment surveys examine the supply side of healthcare and the strengths and weaknesses of a country's public and private services. An 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 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 HSS. While the SARA is not malaria-specific, it is possible to include a patient exit interview module to assess mCM 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 here.

***Integrated management of childhood illness health facility surveys***

IMCI HFS 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 here.

***End-Use verification tool***

The EUV is a commodity assessment tool, rather than an HFS. Guidance on its use can be found in the **Supply Chain Management** chapter.

## 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 Field Epidemiology Training Program (FETP) national level training efforts. In 2016, CDC reconfigured their FETP program to a three-tiered pyramid model consisting of frontline (short-term three-month training), intermediate (9–12 months of training), and advanced two-year training. PMI support can be directed through the CDC IAA for 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 on malaria program efforts following completion of training.

In addition to advanced two-year FETP program support, PMI also can support trainees in the intermediate and frontline FETP programs **through an appropriate PMI partner operating at the district (or district equivalent) level in collaboration with the CDC intermediate or frontline program team** (see below for additional details). Frontline FETPs are basic level field epidemiology trainings, typically three months long with 12 days of didactic training/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.

Intermediate FETPs are mid-level training programs, targeting either regional level or national program staff. The training duration is typically nine to 12 months long with at least eight weeks of didactic training/workshops and at least 32 weeks of on-the-job training. Unlike the Advanced FETP training (see below), Intermediate participants stay in their home country, maintain their current job and all their field work is related to their actual position. Intermediate FETPs are currently operational in the following PMI partner countries – Benin, Burkina Faso, Cameroon, Côte D'Ivoire, DRC, Guinea, Malawi, Mali, Nigeria, Senegal, Sierra Leone, and Tanzania. Before writing Frontline or Intermediate support into the MOP, the PMI team should consult with the FETP Resident Advisor and MOH leadership in the country regarding their plan and readiness to conduct cohorts during the proposed funding period.

In FETP Advanced training supported by PMI, approximately 20-25 percent of the program time is spent in classroom instruction and 75 percent on field assignments, with field assignments involving malaria

control activities required. The training is competency-based with close supervision, and 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 MOH at the national or sub-national level 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 strengthening component of the USG's Global Health Security Agenda to which PMI aims to contribute. Currently, PMI is supporting FETP advanced program trainees in 12 countries: Burma, Cameroon, Ethiopia, Ghana, Kenya, Mali, Niger, Nigeria, Rwanda, Tanzania, Uganda, and Zambia.

FETP residents/participants may be drawn from NMCP staff or from other applicants nominated by the MOH 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 planned 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 below for further details). 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 Resident Advisors 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 HQ 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 the salary provided by the MOH. 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 Resident Advisors 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) in their FY 2023 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 should not displace 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 allocate 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 teams prioritize support of trainees participating in a frontline/short-course FETP program will not be through the African Field Epidemiology Network (AFENET), but through a PMI implementing partner. The majority of PMI implementing partners work at sub-national 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 continue 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 (percentage) 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

## 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 OR (see **Operational 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 PE 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 PE 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 Five-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. See Malaria programme reviews: a manual for reviewing the performance of malaria control and elimination programmes.

### *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 should be used to ensure consistency and comparability across time and countries. The RMB SMERG framework can be found here. 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 HQ 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.

**Table 11. 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) |
|---|---|---|
| CHW | Test and treat malaria appropriately<br>Document and report all cases<br>Receive supervision and feedback | Test and treat malaria appropriately<br>Document and report all cases<br>Receive supervision and feedback |
| Health Facility | Test and treat malaria appropriately<br>Document malaria cases, diagnostic testing results, and CM in registers<br>Cases are graphed monthly to quarterly to identify trends<br>Aggregated data transmitted monthly to district and higher ideally electronically<br>Receive supervision and feedback | Test and treat malaria appropriately<br>Registers of individual malaria cases, diagnostic testing results, and CM documented<br>Cases are graphed daily to weekly to identify trends that may require focal response<br>Data transmitted weekly to district and higher ideally electronically<br>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<br>Analysis of data<br>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<br>Register of severe cases and deaths maintained and case investigations performed to identify program breakdowns and needs<br>Provide supervision to health facilities and receive feedback |
| National | Monthly to quarterly tabulation of cases and deaths to assess control efforts and prioritize activities<br>Analysis of data<br>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***

The newly launched 2021–2026 PMI Strategy prioritizes expanding the availability and use of malaria data (strategic focus area 5.3) as well as leveraging data for decision-making and monitoring of progress and impact (strategic focus area 1.3)

The **PMI Quarterly Report** (QR) facilitates the monitoring of progress and impact of interventions. Within the report, PMI partner countries are requested to provide **the previous six months of malaria-related** health data disaggregated by month and district on a quarterly basis.

PMI's **M-DIVE platform** 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.

The M-DIVE platform currently includes a number of prototype analytics and tools that can be adapted to the specific needs of HQ and country teams, including: (1) the Global Fund reporting to automate Global Fund reports, (2) the OpenMalaria Visualization tool to run simulations on the impact of interventions on malaria transmission, (3) the Self-Service Analytics and PMI Financial dashboards to geographically map PMI interventions and malaria transmission data, and (4) EPIDEMIA climate-based early warning system to forecast upsurges in malaria cases.

PMI countries in sub-Saharan Africa are strongly encouraged to hire one additional PMI dedicated team member – a **Malaria Data Specialist** – to ensure PMI programs are appropriately staffed and to support data-related priorities. This is not a requirement for the three small, sub-national, 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 HQ 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 USG 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 percent compared with 2015. Perhaps even more concerning than the increases in cases, is the fact that neither countries nor the broader malaria community know whether the plateauing is due to reduced effectiveness and coverage of vector control interventions, increased rainfall, increased case reporting, or more recently the impact of COVID-19 disruptions to care-seeking and service delivery.

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 HQ, 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** have 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 DHIS-2 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 HQ, 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 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 funded from PMI core funding, PMI country programs are no longer required to contribute funding to support the development of the platform. However, PMI country programs wishing to co-develop analytics to facilitate more data-informed resource allocations, in support of NMCPs, can do so via the PMI project named M-DIVE. The M-DIVE project can help PMI

country programs make better use of malaria related data in various ways. The table below outlines some of the ways the M-DIVE project can contribute to the PMI Strategic Focus Areas.

**Table 12. Ways the M-DIVE project can contribute to the PMI Strategic Focus Areas**

| PMI Strategic Focus Areas | Examples of existing M-DIVE Tools |
|---|---|
| 1) **Reach the unreached:** Achieve, sustain, and tailor deployment and uptake of high quality interventions with a focus on hard-to-reach populations | Prototype machine learning-enabled **high resolution satellite imagery** to identify and quantify potentially unreached population settlements and health facilities to better target enumeration and microplanning efforts in support of ITN, SMC, and IRS campaigns. |
| 2) **Strengthen community health systems:** Transform and extend community and frontline health systems to end malaria | PMI's Malaria QR dataset with indicators on **CHWs per district** and malaria cases reported at the community level to help inform scale-up efforts. |
| 3) **Keep malaria services resilient:** Adapt malaria services to increase resilience against shocks – including COVID-19 and emerging biothreats, conflict, and climate change | Prototype OpenMalaria Visualization tool for scenario planning (for **risk mapping** and to run **simulations** on the impact of interventions on malaria transmission using the outputs from OpenMalaria mathematical model). |
| 4) **Invest locally:** Partner with countries and communities to lead, implement, and fund malaria programs | PMI Financial dashboards to map investments in **G2G** and l**ocal organizations** (*from new Table 2). |
| 5) **Innovate and lead:** Leverage new tools and shape global priorities to end malaria faster. | Prototype EPIDEMIA **early warning system** – machine learning enabled predictive analytics integrating climate and malaria surveillance data to forecast upsurges in malaria cases. |

## Data-Specific Staffing on PMI In-Country Teams

To ensure PMI programs are appropriately staffed to support the new data-related priorities, including the new QR, missions in sub-Saharan Africa are strongly encouraged 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 position description. This new position will be 100 percent funded from each country's MOP budget.

## 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 sub-national 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 10 years, USAID and the USG 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 USG 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 USG shall be made freely available in open, machine-readable formats, while appropriately safeguarding privacy, confidentiality, and security.

USAID A/CORs 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:

- Creating and maintaining 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 DDL and M-DIVE.

- As a part of the Monitoring, Evaluation, and Learning Plan, drafting a Data Management Plan 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., DHS, MIS, MBS) 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 MOUs, and all data are publicly available 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 another 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. An expectation of PMI technical and funding support is for host governments to share data on routine indicators disaggregated by district and by month. Bi-directional data-sharing between PMI and partner countries to improve program implementation and strengthen information systems, including systematic sharing of PMI-supported partner program data, is expected.
3. **Access to operational data (e.g., from ITN and IRS campaigns) and data generated from other surveys (e.g., EUVs and HFS), studies (e.g., therapeutic efficacy studies and OR), and other monitoring efforts (e.g., entomological monitoring and DM 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 QR?** PMI has decided to implement a QR 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 USG funds. However, the purpose of the PMI 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 USG funds.
   *1.2. Amplify and build on existing systematic data reporting and analytical efforts.* Many countries are already implementing either monthly or QRs (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 QR will involve an effort to standardize indicators reported by implementing partners for each technical area and benchmarking programmatic results. Because U.S. 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 USG 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 (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 QR 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 DHIS-2, PMI's Data Integration team has assisted nine 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 DHIS-2 connection to transmit PMI QR 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 DHIS-2 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 there is, the better it 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 these 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 datasets and visualizations in the QRs 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).

# ELIMINATION

***New/Key Messages***

**Strategy:** The new PMI Strategy 2021–2026 again includes an elimination-focused objective: to accelerate towards elimination in 10 countries and eliminate in ≥1 country. The 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 percent. Within the PMI portfolio, the countries in the Greater Mekong Subregion are pursuing national elimination efforts, whereas the following countries are working at sub-national levels: Ethiopia, Kenya, Madagascar, Senegal, Tanzania/Zanzibar, Zambia, and Zimbabwe.

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.

Countries/areas that have national strategies for malaria elimination (e.g., Burma, Cambodia, Ethiopia, Kenya, Madagascar, Senegal, Thailand/Regional, Zambia, Zanzibar, and 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 2023 MOPs.

**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, SBC considerations, and environmental characteristics.

**SM&E:** Timely, complete, and accurate recording and reporting of confirmed cases as passively or actively detected in public and private sectors, from both facility- and community-based systems, is the foundation for tracking progress and identifying cases and foci for further investigation and intensified response measures in elimination settings.

**New Tools:** Tafenoquine and SD Biosensor's Standard G6PD quantitative tests are innovative tools for the management of Plasmodium vivax. Please see the **Case Management** section for details, but these products can be procured by PMI in vivax endemic countries with NMCP policy and product registration in place.

Although the use of topical repellents is not currently recommended by WHO for the prevention or control of malaria at the community level, two recent studies in Burma indicated these may be effective in elimination settings among hard-to-reach populations at risk of malaria. Populations where topical repellents are likely to be most beneficial include mobile migrant populations, such as seasonal agricultural workers and forest-goers, as part of a comprehensive package of malaria interventions. Therefore, PMI countries approaching elimination where transmission is largely confined to such populations may procure topical repellents. As there are no topical repellents currently listed by the WHO PQ Unit, procurement is limited to products registered by the U.S. EPA. Note additional environmental requirements may need to be met to procure and distribute topical repellents.

The role of new elimination-relevant tools and approaches, such as mass drug administration or highly-sensitive diagnostic tests, remains unclear and, therefore, they are not recommended for routine implementation. Countries should propose these interventions in the context of OR or PE to help study their appropriate application and feasibility.

## 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 their 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.

The current WHO Global Technical Strategy for Malaria 2016–2030 and the RBM Partnership's Action and Investment to Defeat Malaria 2016–2030 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."

From the last *PMI Strategy 2015–2020,* PMI met its elimination objective: *To assist at least five PMI-supported countries to meet the WHO criteria for national or sub-national pre-elimination by 2020.* The new PMI Strategy 2021–2026 again includes an elimination-focused objective: To accelerate towards elimination in 10 countries and eliminate in $\geq$1 country. The objective aims to target

low-burden countries and bring them toward national or sub-national elimination, with at least one country achieving elimination. The criteria for PMI considering elimination support in a given country is (1) national (or sub-national) parasite prevalence <5 percent, and (2) the national malaria strategy contains specific goals and objectives related to malaria elimination. Within the PMI portfolio, the countries in the Greater Mekong Subregion are pursuing national elimination efforts, whereas the following countries are working at sub-national levels: Ethiopia, Kenya, Madagascar, Senegal, Tanzania/Zanzibar, Zambia, and Zimbabwe.

In order to achieve this objective, the following elimination-relevant factors can be considered under the five strategic focus areas:

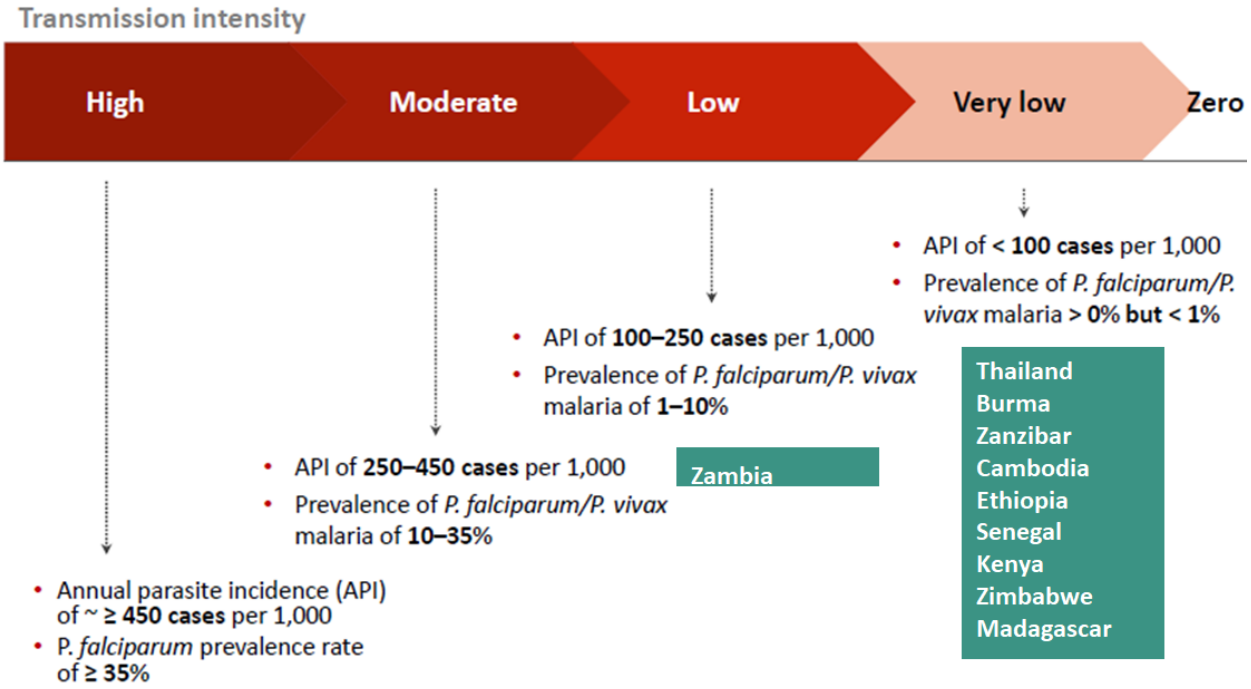
1. *Reach the unreached:* Scale-up of effective interventions and targeting to remaining areas and populations at risk of malaria are fundamental to pursuing malaria elimination. See section below on high-risk populations – but as programs drive down transmission, new demographic risk groups often based on occupational exposure will need to be reached.
2. *Strengthen community health systems:* Access to mCM **for all ages,** often delivered through a network of community health or village malaria workers, has been implemented in all PMI countries pursuing elimination. To best support elimination activities, data reporting needs to shift from aggregated to individual cases, and be timely and high-quality.
3. *Keep malaria services resilient:* Case-based surveillance and response activities (e.g., 1-3-7) fundamental to a malaria elimination surveillance system can be leveraged to support pandemic preparedness or broader notifiable diseases reporting and response activities. In the context of the COVID-19 pandemic, many PMI elimination countries are building stronger case finding, case identification, case detection, and contact tracing. National emergency operations centers/ public health institutes will only get stronger in the coming years due to COVID-19 resources. PMI elimination countries should consider leveraging these growing capabilities to further accelerate malaria elimination and support NMCPs with their elimination goals by taking part in efforts to shape the COVID-19 pandemic and preparedness response funding in a direction that dually strengthens malaria elimination as well as overall pandemic preparedness and response.
4. *Invest locally:* Community mobilization and local, intersectoral coordination are critical to achieving malaria elimination. Many communities form elimination committees with a wide-ranging set of stakeholders/leaders to support and monitor elimination progress. Domestic resource mobilization becomes increasingly critical to maintaining and achieving elimination in the face of decreasing burden and subsequent prioritization.
5. *Lead and innovate:* Recalcitrant foci of transmission despite scale-up of effective indoor vector control and CM services will require new tools and approaches to clear. As illustrative examples, programs in the Mekong are deploying topical repellents for forest-goers and reactive case detection and drug-based approaches are being tested or implemented.

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 CM for all ages. 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 HMIS/malaria surveillance information.

The WHO *Global Technical Strategy for Malaria 2016–2030* and the 2017 *WHO Framework for Malaria Elimination* emphasize that the progression towards malaria-free status is a continuous process. WHO recognizes that countries, sub-national 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. 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 11**). This reorientation emphasizes that all countries, regardless of where they lie on that continuum, should have a long-term vision of malaria elimination. **Figure 11** from WHO spans a wide range of transmission intensities. Most of the PMI eliminating countries fall under the very low transmission category.

**Figure 11. Indicative Categories of Transmission Intensity and Categorization of Relevant PMI Countries/Areas**




Source: WHO *Framework for Malaria Elimination*, 2017; World Malaria Report 2020

Several PMI countries have now set national or sub-national goals of malaria elimination, scaled up control measures, and are improving their routine malaria information systems (see **Figure 12**).

**Figure 12. Tracking Progress and Capacity in Reaching Elimination in PMI-supported Countries/Areas**

| | POLICY | IMPLEMENTATION | | ROUTINE DATA | | | |
|---|---|---|---|---|---|---|---|
| Country/Area | Elimination Strategy | Cases investigated | Foci investigated | API* | Test Positivity Rate* | Case Confirmation Rate* | HF Reporting Rate |
| Thailand | National | National | National | <1 | <5 | 100 | 100 |
| Myanmar/Burma | National | Sub-national | Sub-national | 1-10 | <5 | 100 | 100 |
| Zanzibar | National | National | National | 1-10 | <5 | 100 | 98 |
| Cambodia | National | Sub-national | Not done | 1-10 | 5-50 | 100 | 100 |
| Ethiopia | Sub-national | Not done | Not done | 10-100 | 5-50 | 89 | 97 |
| Senegal | Sub-national | Sub-national | Sub-national | 10-100 | 5-50 | 98 | 98 |
| Kenya | Sub-national | Not done | Not done | 10-100 | >50 ** | 100 | 97 |
| Zimbabwe | Sub-national | Sub-national | Sub-national | 10-100 | 5-50 | 100 | 97 |
| Madagascar | Sub-national | Not done | Not done | 10-100 | 5-50 | 99 | 95 |
| Zambia | National | Sub-national | Sub-national | >100 | >50 | 96 | 92 |

*Limited to the public sector, WMR 2020
**TPR for RDT only

Source: API, TPR, and CCR are from WHO *World Malaria Report* 2020; HFRR are from 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 importation risk for 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 to be collected: number of cases and deaths, Annual Parasite Incidence (API), test positivity rate, case confirmation rate, Annual Blood Examination Rate, case investigation rate*

- Ability to ensure ongoing high-level coverage of vector control and CM interventions
- An SM&E 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 data in HMIS and malaria information system, proportion of cases and foci investigated*
  - *System has capability of moving from monthly/weekly aggregated reporting to case-based reporting from all facilities in the elimination area, 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:
  - *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*
  - *Extensive CHW network of malaria workers who test and treat all age groups at the community level within 24 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 MOH 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 University of California San Francisco's District-level Readiness for Elimination of Malaria Tool (DREAM-IT) 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 their potential adaptation and use in other countries can contact the PMI Elimination Technical Team.

## 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 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 noted earlier, additional support to pilot elimination activities in targeted districts, to further strengthen surveillance systems, digitize community-level data collection, and conduct OR 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 mCM and malaria surveillance, sub-national conditions should inform selection of other malaria-related interventions.

Within most PMI countries, transmission intensity is diverse. WHO's 2017 Malaria Elimination Framework[154] defines malaria transmission strata using 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 per year. Within M-DIVE, 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

[154] A framework for malaria elimination. Geneva: World Health Organization; 2017. License: CC BY-NC-SA 3.0 IGO.

progress and trends in elimination across PMI countries, PMI will use the following categories for district level incidence stratification:

**Table 13. Categories for District Level Incidence Stratification**

| Incidence stratum | # cases / 1,000 population / year |
|---|---|
| High | >450 |
| Moderate | > 250 and ≤ 450 |
| Low | > 100 and ≤ 250 |
| Very Low | > 10 and ≤ 100 |
| Extremely Low | > 1 and ≤ 10 |
| Near Elimination | > 0 and ≤ 1 |
| Zero | 0 |

Although malaria transmission intensity (e.g., incidence) should form the foundation of stratification, as transmission decreases, stratification should incorporate ecological, entomological, and SBC data to determine the appropriate package of malaria interventions. WHO's High Burden High Impact 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 MBS 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) differ 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 MBS).

Ideally, sub-national incidence will be monitored on an ongoing 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.

## *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. As emphasized in PMI's new Strategy, reaching the unreached, high-risk populations is critical to achieving elimination.

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 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 M&E 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 village malaria workers (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 MDA 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 MBS in Low Transmission Settings[155] 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. Given recent evidence from Burma,[156,157] PMI countries may procure topical repellents in elimination settings for mobile, migrant populations, such as seasonal agricultural workers, forest-goers, or others working in remote areas as part of a comprehensive package of malaria interventions. Currently, only countries in the Mekong Subregion are considered to meet these criteria. Note that additional environmental compliance requirements may need to be met.

Direct procurement of other 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 PE. **PMI may provide support for PE or OR 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., insecticide treated clothing, spatial repellents, etc.) to allow them to leverage existing PMI-supported implementation platforms currently being used to distribute other malaria interventions (e.g., LLIHNs in forest packs). In these instances, country teams should consult with the PMI HQ Elimination and/or Supply Chain Teams for additional guidance.**

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[155] The MBS for Low Transmission Settings will be piloted in CY2021 and will be ready for use in CY 2023.

[156] Agius PA, Cutts JC, Han Oo W, Thi A, O'Flaherty K, Zayar Aung K, Kyaw Thu H, Poe Aung P, Mon Thein M, Nyi Zaw N, Yan Min Htay W, Paing Soe A, Razook Z, Barry AE, Htike W, Devine A, Simpson JA, Crabb BS, Beeson JG, Pasricha N, Fowkes FJI. 2020. Evaluation of the effectiveness of topical repellent distributed by village health volunteer networks against Plasmodium spp. infection in Myanmar: A stepped-wedge cluster randomized trial. PLoS Med 17(8):e1003177. doi: 10.1371/journal.pmed.1003177.

[157] Mon Win K, Aye Myint A, Myint Tun K, Lin K, Than Win K, Hawley WA, Hwang J, Gimnig JE, Wiegand R. Impact of mosquito topical repellents and extended standard interventions on malaria control and elimination in Myanmar. PMI OR Study, Unpublished.

# Vector Control and Entomological Monitoring

## *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, indoor interventions can still have a significant impact on the population as a whole since indoor and outdoor biting mosquito 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 ITN 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).

Reactive IRS in response to index cases or active foci is implemented in some elimination countries (e.g., Thailand), but there is limited high quality data to support the impact of this intervention. Reactive IRS involves targeting of IRS to houses around an index case rather than presumptive blanket spraying of an area before the primary transmission season and has been considered as a potentially cost-effective tool in elimination settings where transmission is highly heterogeneous. Reactive IRS was evaluated in two elimination settings to assess its efficacy and cost-effectiveness. In Namibia, reactive IRS significantly reduced malaria incidence and prevalence compared to no reactive IRS while in South Africa, reactive IRS was demonstrated to be non-inferior to standard IRS. Furthermore, modeling based on the South Africa study indicated reactive IRS (rIRS) would be considered cost-effective compared to standard IRS when the incidence of malaria was less than 2.0 to 2.7 cases per 1,000 person-years. However, coverage of IRS in the two studies varied substantially and there remain questions around when and where rIRS is appropriate, whether it is the optimal use of scarce resources, and if it is feasible and/or sustainable given the logistics and timelines associated with implementation. WHO's Guidance Development Group is reviewing this evidence and recommendations should be forthcoming. Currently, PMI does not support rIRS, but may consider support for OR or PE of reactive IRS in elimination settings. Please consult with the Elimination Team for further guidance.

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 that 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. A potential emerging challenge to elimination efforts is the detection and spread of *An. stephensi* in Africa. *An stephensi* is an urban vector that could require expanded entomological surveillance and a change in geographic focus for country malaria control and elimination activities, see new guidance section regarding An. stephensi (*link to* ***An. stephensi*** *section*).

### *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) and/or 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 HQ VMCT 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 CM. 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 ANC 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 healthcare-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 MIP 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.

## 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 CM 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. As noted in the new PMI Strategy Focus Area 2 of *Strengthening community health systems,* all PMI countries pursuing elimination are implementing access to mCM **for all ages** often delivered through a network of CHWs or VMWs.

### *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 (see **Surveillance Approaches** section). PMI has supported OR 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 ultrasensitive RDT or newer hsRDTs for elimination or MIP will need to be under the context of OR or PE. **Neither WHO nor PMI recommend the use of hsRDTs for surveillance or diagnosis of clinical**

**malaria cases in any setting, and PMI 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., PCR, 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. Please see the PMI priority support for microscopy section for additional information on procuring and maintaining a validated slide bank (also known as NAMS). Standardized protocols for development of these slide banks are included in the 2016 WHO Malaria Microscopy Quality Assurance Manual.

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 districts. PMI should consider prioritizing support to help ensure these uninterrupted supplies, and should also 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, VHWs or CHWs often become the foundation for both mCM 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) have also 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, 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 called integrated drug efficacy surveillance, is being used in some countries (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.**[158]

[158] Policy brief on single-dose primaquine as a gametocytocide in *Plasmodium falciparum* malaria, January 2015.

**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 <six months of age, and breastfeeding women of infants <six months of age)** to reduce transmission. Testing for G6PD deficiency is not currently required for this single-use, low-dose primaquine regimen.

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.

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.[159] 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, and Zimbabwe. Procuring lower-dose tablets for pediatric use remains a challenge for programs. Medicines for Malaria Ventures is working with manufacturers to bring pediatric 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*.

[159] 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 ≤100 and a prevalence of *P. falciparum/P. vivax* of ≤1 percent. It is also reasonable to use a health facility test positivity rate of <5 percent as a threshold.

See the **Case Management** chapter for more information on treatment of *P. vivax*.

### *Mass Drug Administration/Mass Screen and Treat*

Although WHO recommends the use of MDA in the elimination context, chemoprevention approaches, e.g., MDA, will need to be conducted in the context of OR or PE to ensure rigorous implementation and evaluation. PMI countries interested in using MDA should consult with the relevant PMI HQ teams (Elimination, CM, and MIP, OR Management) in the planning phases of such activities. See **MDA** section for more detail on general discussion and guidance.

Mass testing and treatment (MTaT) refers to testing all persons in a population with a malaria diagnostic test and providing treatment to those with a positive test result. Some programs or studies might refer to this activity as "mass screen and test" or "MSaT." 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 CM. At present, the currently available RDTs are not sensitive enough to detect very low density parasitemias, which can comprise up to 50 percent of malaria infections found in a population. Evidence from Burkina Faso and Zambia, and from a PMI-supported study in Kenya, indicate that MTaT with conventional RDTs is insufficient to significantly reduce the human infection reservoir. 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 MTaT activities. Any country teams considering MTaT should consult with the PMI HQ Elimination Technical and Case Management Teams in advance of any consideration of MOP support.

## 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 representative household surveys, every three to five 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.

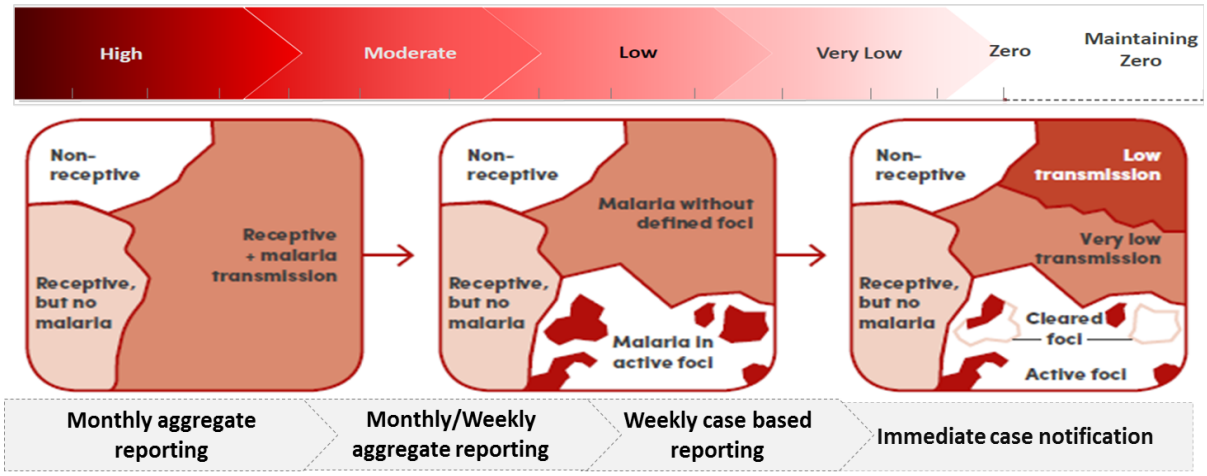
Although population surveys may still be needed in an elimination setting to monitor coverage of interventions, they become less useful for measuring morbidity. PMI has historically used national household surveys (e.g., MIS) to collect data on anemia and parasitemia, and DHS to track all-cause child 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 estimate in children under five years of age is <3 percent, 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 percent 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.** Ultimately, countries pursuing malaria-free certification will need to have a surveillance system of sufficient quality such that all infections would be detected if they were to occur and that the response would be timely and of sufficient quality to stop ongoing transmission.

Other survey methodologies (e.g., respondent-driven sampling to estimate malaria intervention coverage, as well as malaria burden) in populations lacking a sampling frame (e.g., mobile and migrant populations) have been adapted from methods used for monitoring persons with HIV. Piloted in Thailand and Cambodia among migrant workers, these methods, though, have been difficult to implement and appear to be less applicable in the malaria setting where social networks are less well-defined and established.

### *Disease surveillance*

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, RHIS, 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).

**Figure 13. 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, NGOs, military, etc. Use of digital tools may facilitate collecting and reporting data in this way (see **Digital Community Health** section of the Community Health guidance and **Strengthening Community-Level Data Systems** section of SME guidance for more information)

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-travelers, 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 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.

- Surveillance system structures have different attributes and functionalities that impact their utility for guiding elimination activities. Health facility-based routine information systems (HMIS, IDSR – for a more general description of these systems see **SM&E** chapter): HMIS typically report aggregate health-facility level data on a monthly basis, which is insufficient for targeted elimination efforts (e.g., case listing or detection of transmission foci). 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 more timely manner. Some countries have additional malaria surveillance systems with more frequent reporting (e.g., weekly) than routine HMIS systems. Such systems should 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. Any considerations of support for parallel systems should be discussed with the PMI HQ SM&E and Elimination Teams.

- 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 an NMCP may not have timely access to malaria data collected through HMIS or IDSR. In countries that are moving towards but have not yet reached the elimination phase, weekly IDSR reporting may be an adequate platform and the MOH must coordinate appropriate data access for the NMCPs.

- Countries approaching the elimination phase may require a malaria-specific, case-level supplementary surveillance system that builds on the HMIS/IDSR platform and reports directly to national or sub-national malaria control authorities with greater frequency (within day[s] of diagnosis). Such systems should allow reports to be seen and used at all levels to facilitate timely investigations of individual cases or foci. 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 which is operational in all elimination districts in Zimbabwe.

### ***Hardware/software***

There are no specific requirements regarding hardware and software for an effective 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. Additionally, USAID's Digital Health Vision and its four key priorities (building country digital capacity, advancing national digital health strategies, strengthening national digital health architectures, and leveraging global goods) may be referenced for guidance and alignment. 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 CHWs 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 smartphone-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 BMGF and is available here.

An additional resource is the PMI-supported digital community health assessment, which was published in 2021 for all 27 supported countries. The summary report provides recommendations on the use of digital tools to support community health programming, including elimination-related efforts.

### ***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, community-level, and other relevant sectors e.g., military data. Passive surveillance does not generally capture cases and deaths that occur outside of a healthcare 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**: As stated in the **SM&E** chapter, 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 CHWs or HWs 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. Border screening, which is most often used by programs in the prevention of reintroduction phase, is a topic of WHO Guidance Development Group and WHO guidance is forthcoming.

  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 RDA are being evaluated as a strategy to reduce and interrupt transmission. In addition, it is strongly advised that if RDA activities are being considered, this should be done in

consultation with the PMI Elimination Technical Team; it will generally be required to first be piloted as an OR study unless the country is implementing these strategies based on local evidence of effectiveness

- **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. The decision to initiate RCD activities depends on multiple factors but in general are not initiated in higher burden areas (e.g., API>5/1,000). Case notification, investigation, and response efforts, such as China's "1-3-7"[160] 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.

- **Reactive drug administration**: RDA is defined as treating those living with/near an index case with a full course of antimalarials, without testing or screening for symptoms. RDA is typically initiated from a passively-detected index case but may be initiated from an actively-detected index case. A systematic review of RDA noted that acceptability was generally high though it probably results in little to no reduction of parasitemia incidence and may result in little to no reduction of parasitemia prevalence. Although not statistically significant, when compared to RCD, RDA was favored. PMI is currently supporting a study comparing RCD and RDA in

[160] 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

elimination areas of Ethiopia. Introduction of RDA strategies will need to occur in the context of OR/PE, except in countries such as Senegal that have adopted and scaled up RDA approaches based on local evidence of effectiveness.

### *Draft PMI Elimination Indicators*

In order to track progress towards elimination, the following indicators are recommended for countries embarking on elimination:

- Annual Parasite Index
- Test Positivity Rate (annual and monthly)
- Proportion of patients with suspected malaria who received a parasitological test
- 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
- Proportion of malaria-endemic villages with access to community-level case management
- Proportion of expected public health facility reports received
- Proportion of expected private 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
- National stratification updated in the past year
- National Strategic Plan and Surveillance, M&E Plan for malaria elimination in place

The indicators noted in black can be tracked through data elements that are currently collected through PMI quarterly reporting.

## Social and Behavior Change

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, maintenance of behaviors will also become more important.

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). **Figure 5** featured in the SBC Section provides an overview of behavioral considerations across the transmission continuum, which 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).

A strong National Malaria SBC Strategy supporting behaviors in low-to-moderate transmission zones is critically important to ensure a deliberate and harmonized approach to malaria SBC in such settings. PMI should work with NMCP to ensure the National Malaria SBC Strategy incorporates behaviors and associated factors are addressed for use in areas where there are sub-national groups that have identified SBC needs that are unique to their low-transmission area(s). The RBM SBC WG has updated the malaria SBC strategy template with guidance for low to moderate malaria transmission zones included in the Annex. This guidance includes sample content that illustrates how to involve sub-national groups in the development of localized SBC plans to address SBC issues that arise in countries with pockets of lower transmission.

### *Vector control*

Two of PMI's main interventions – ITNs and 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.

Countries that implement topical repellents will need to adopt SBC messages specific to this mode of personal protection. Like LLINs, topical repellents are only effective when used. However, while LLIN use is generally aligned with sleeping behaviors, topical repellents should be encouraged when people are in malaria risk areas (e.g., forests), particularly during hours when they are awake and active. Furthermore, users need to understand that topical repellents need frequent reapplication to provide continuous protection. Last, it is important to emphasize that repellents are for the prevention of malaria while in remote areas where other vector control interventions are not feasible. The use of repellents for prevention of nuisance biting and/or in stable communities where deployment of LLINs is feasible would represent an inefficient use of PMI resources.

### *Case management*

A key component of SBC for mCM is increasing treatment-seeking behaviors, especially through the public sector. In all transmission settings, SBC for CM 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 CM 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 mCM.

### *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[161] 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 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

[161] RBM Partnership to End Malaria. 2017. Malaria Social and Behavior Change Communication Indicator Reference Guide: Second Edition. Venier, Switzerland: RBM.

coordinated efforts between the SBC and Elimination Technical Teams. The adapted tool will be piloted in CY 2021 and will be ready for use in CY 2023. Please see the **SBC** chapter for more detailed information.

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 Subregion 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 Subregion. Please see your HQ 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, Re-establishment, and Elimination Certification

## *Prevention of Reintroduction and Re-establishment*

As malaria cases decline to zero in a particular area or country, activities that prevent the reintroduction and re-establishment of the disease become critical.

Based on WHO[162] guidance, reintroduction 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 three or more indigenous cases of malaria of the same species per year in the same focus for three consecutive years. Countries that are approaching 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, treatment, and notification of all malaria cases; (2) determination of the probable causes and routes of the reintroduction 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; in addition to implementation of activities as appropriate to reduce receptivity and vulnerability (defined below).

It is essential for a country to have a comprehensive, robust, and responsive national surveillance system throughout the country (and at this point generally this system should be integrated with reporting for other infectious diseases) to detect, notify, and report all malaria cases promptly. All malaria cases (including the private sector) must be investigated in a timely manner and information compiled in a national register of malaria foci. Diagnostic capacity and quality of laboratory services

[162] Regional Framework for Prevention of Malaria Reintroduction and Certification of Malaria Elimination (2014-2020), Regional Office for Europe.

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 *An.* mosquitoes are still present and conditions for spread are favorable. Thus, receptivity and vulnerability will be key concepts to monitor and evaluate. Receptivity generally depends on the 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 are 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 has developed an operational manual on Preparing for Certification of Malaria Elimination, 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 sub-national levels. WHO does not provide specific guidance for sub-national 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.

Preparation for certification of elimination needs to start before a country has reached zero cases. Documentation that is required for certification should cover about five years before applying for certification. As such, quality systems should be in place to collect, analyze, and store this data before actual submission for certification of elimination, and countries targeting elimination should plan accordingly.

# OPERATIONAL RESEARCH AND PROGRAM EVALUATION

***New/Key Messages***

**Central OR Mechanism:** PMI Insights is a central OR and PE mechanism with the objectives of implementing OR and PE activities in collaboration with PMI-supported country research institutions, supporting an annual OR prioritization process, and tracking and disseminating findings to inform programs and policies. This mechanism will be the default mechanism for core-funded OR/PE and can support MOP-funded activities spanning full implementation to targeted technical assistance, e.g., study design, protocol development, modeling, and statistical and laboratory support.

**PMI OR/PE Portfolio:** Most PMI-funded completed and ongoing OR studies are searchable through an external website hosted by MesaTrack.

**Investing Locally:** PMI country programs should partner with in-country research institutions whenever possible to lead the design, development, and execution of studies. OR/PE should draw on in-country knowledge and insights to test approaches in the local context and identify locally adapted solutions that can inform broad-reaching applications. PMI will track and aim to increase overall study implementation resources allocated to local partners to ≥50 percent across the PMI OR portfolio. Each core-funded study will engage in-country research institutions early and develop an institution-specific activity development plan. Upon completion of all PMI-funded studies, investigators will be requested to complete a study completion form detailing the level of NMCP and in-country research institution involvement and potential policy or programmatic impact of the study results.

**Updated OR Prioritization Process:** For FY 2022 core-funded priorities and beyond, PMI OR/PE investment decisions will incorporate the following inputs: country-driven Global OR Prioritization Agenda developed and periodically refreshed by PMI Insights, annual MOP submissions, annual interagency technical team priorities, and donor consultations with BMGF and the Global Fund.

**MOP-funded OR/PE:** All proposed OR and PE topics should be captured under the OR/PE heading in both the MOP narrative and Table 2 and at minimum include a clear question, proposed study design, study implications, allocated budget and mechanism. Although countries should consider the PMI Strategic Focus Areas and the final Global OR Prioritization Agenda, MOP-funded PE and OR proposals should be based on country-specific priorities and thus will

fall outside the core-funded OR/PE prioritization process. Requests for concept note submission will be sent out semi-annually (Quarter (Q) 2 and Q4). An annual timeline of relevant OR activities has been added for quick reference. 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 the PMI Front Office. MOP-funded OR studies will require protocol review by the OR Committee prior to submission to relevant ethical review boards.

**Distinguishing activities that do not require OR Committee Review:** PMI undertakes many M&E activities which include standardized surveillance and M&E/PE approaches that are repeated across countries and are routine (e.g., TES, MIS, DHS, entomological assessment tools, LLIN DM, MBS, EUV Surveys, HFS, project midline and end-line evaluations, etc.). These do not require OR committee review unless study components are added that would shift them towards research. For the purposes of determining if the proposal requires OR Committee review, please consider if the investigators will direct the allocation of intervention(s) (e.g., through randomization) and whether additional data collection (e.g., through cross-sectional surveys with or without blood sample collection) are included. As an illustrative example, plans to conduct routine entomological monitoring and evaluate RMIS data only to evaluate the impact of NMCP's distribution of PBO nets would not require OR Committee review. Please consult the OR Management Team if there are any doubts on whether a study should be considered OR.

**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 OR and 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 Figure 14 in the Distinguishing OR and PE section 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 utilizing both core- and MOP-funded resources.

The guidance below focuses on objectives and priorities, guiding principles, and processes for proposing MOP- or core-funded OR/ PE for PMI country teams and HQ interagency technical teams.

## PMI Strategic Plan and OR and PE Objectives

PMI-supported OR/PE will support all strategic focus areas of the new PMI Strategic Plan 2021–2026 but in particular, the focus area to lead and innovate. The Focus Area of Investing Locally will guide how OR/PE is supported with PMI resources such that PMI country programs should partner with local research institutions whenever possible to lead the design, development, and execution of studies. OR/PE should draw on in-country knowledge and insights to test approaches in the local context and identify locally adapted solutions that can inform broad-reaching applications. PMI will also track and aim to increase overall study implementation resources allocated to local partners to ≥50 percent across the PMI OR portfolio.

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

## Funding Sources and Channels/Mechanisms for PMI OR and PE

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 to 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.

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. The choice of the selected mechanism(s) depend(s) 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 with engagement of local research institutions
2. USAID country bilateral and central implementing partner mechanisms, including USAID mechanisms that provide direct funding to local research institutions through subcontracts
3. Research collaboration involving CDC and/or USAID HQ technical staff and a USAID country bilateral or central implementing partner mechanism
4. Use of the CDC IAA to support OR/PE activities conducted by CDC staff (see important restrictions against third party transfers below)

For option (1) above, please reach out to PMI Insights AOR with questions regarding project scope and timeline. PMI Insights will be the default mechanism for all **core-funded** OR/PE unless a strong rationale exists for an alternative mechanism. PMI Insights can also accept field support for MOP-funded OR/PE.

The CDC 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 Insights), the OR Management team does not anticipate exception requests for third-party transfers under option four during the PMI Insights 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's "CDC IAA" 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, including when relevant, the leveraging of non-PMI capacities at CDC.

## Co-funding of OR Activities

PMI co-funding of OR/PE activities with MOP and core resources and other donor organization funding occur and are highly encouraged. Co-funding opportunities will be explored proactively with BMGF and the Global Fund based on a signed MOU as part of the 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/project. 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.

## PMI OR Priority Setting Process

Beginning in FY 2018, the U.S. Global Malaria Coordinator announced a new process for setting OR/PE priorities for core-funded OR/PE. The OR/PE priority setting process aims to generate a strategically narrow, focused set of scientific and OR/PE priority questions each year to support the PMI Strategy 2021–2026. In 2020, PMI Insights began to design and implement a consultative process with malaria

stakeholders to identify the most pressing knowledge gaps in malaria control and elimination policy, strategy, and implementation guidance, and define a priority OR and PE agenda to address and close these gaps. This new Global OR Prioritization Agenda builds upon and aligns with other malaria research prioritization-setting processes that countries, regional initiatives, and global-level organizations have recently undertaken. The overarching goal is to foster greater alignment of OR and PE priority areas of national malaria programs with donors, informing a more coordinated and complementary approach to investments in the country-identified priority areas.

For FY 2022 core-funded priorities and beyond, this process will incorporate the following inputs: NMCP priorities, country-driven Global OR Prioritization Agenda, annual MOP submissions, annual interagency technical team priorities, and donor consultations with BMGF, Global Fund, and other relevant organizations in the future.

The outcomes of this process along with the recommendations from the OR Management team will be reviewed with the PMI Front Office. Ultimately, the U.S. Global Malaria Coordinator will approve the core-funded priorities and identify an overall funding envelope for the year.

The annual OR/PE prioritization process applies to all core-funded OR and PE proposals. Although countries should consider the PMI Strategic Focus Areas and the Global OR Prioritization Agenda, country-specific, MOP-funded PE and OR proposals should be based on country priorities and may fall outside the core-funded OR/PE 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 the Table 2 of the MOP Funding Tables . Approval of the MOP that includes OR/PE funding does not necessarily constitute approval of the MOP-funded OR or PE proposal as these concept notes and protocols (if OR) need to be submitted for technical review by the OR Committee during the semiannual requests for MOP-funded OR/PE concept notes (Q2 and Q4).

## *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 with a justification on the broader applicability of anticipated study results. Please reach out to the OR Management to explore opportunities to leverage core-funded activities as well as multi-country coordination.

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 total budget. When proposing a mechanism, please consider the overall timeline from study conception to dissemination to ensure continuity of a study given contract/agreement end dates.

***Guiding principles for core-funded research***

Core-funded study ideas will 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

General considerations for MOP- and core-funded OR/PE priority submissions include:

- Is the idea strategically important to PMI (i.e., does it support PMI Strategy objectives and focus areas)?
- Does it have broad relevance with many countries struggling with similar 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)?
- What is the overall funding and global priority of the topic? Has this been funded by PMI in the past? Are there other groups already doing this research? What research are other donors funding on this topic and how does it relate with the scope?
- What is the estimated time from study conception to likely time of intervention implementation, result dissemination, and/or policy change.

A list of all PMI-funded OR/PE projects can be found in the MESATrack database.

# Study Review and Approval Process

## *MOP-Funded OR/PE*

### ***Review of MOP-fundedOR/PE concept note***

The OR Management team will solicit concept notes for MOP-funded OR or PE ideas (OR/PE Concept Note template provided in **OR Appendix 1**) approved in the MOP review or reprogramming process from country teams semiannually (Q2 and Q4). **Concept notes are required for both MOP-funded OR and PE studies.** In addition, MOP-funded OR studies require protocol review. For **new** MOP-funded OR/PE proposals to be funded with reprogrammed funds, country teams must obtain reprogrammed request approval prior to concept note submission.

Concept notes will be reviewed by the OR Committee and appropriate technical team staff designee(s), as needed, during two review periods (Q2 and Q4) 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 semi-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 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. It should be noted that there may be times where the OR Committee may only have clarifying questions or questions for consideration by the study team; in these instances, responses are still required before the concept note can be considered approved. Status of concept notes, protocols and budgets allocated to each study will be reviewed quarterly with the PMI Front Office.

**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 the PMI Front Office, and can move forward as appropriate 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*

### ***Concept Note Review of Core-funded OR/PE***

Relevant HQ interagency technical teams and country teams along with PMI Insights (if applicable) will co-develop concept notes for core-funded OR/PE priorities approved by the PMI Front Office.

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 note 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.

***Protocol review of Core-funded OR/PE studies***

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 with the PMI Front Office.

## 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 PE (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,[163] 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." OR 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 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 M&E activities, which include standardized surveillance and M&E/PE approaches that are repeated across countries and are routine (e.g., TES, MIS, DHS, entomological assessment tools, LLIN DM, MBS, HFS, EUV surveys, project midline and end-line evaluations, etc.). These do not require OR committee review unless study components are added that would shift them towards research. For the purposes of determining if the M&E proposal requires OR Committee review, please consider if the investigators will direct the allocation of intervention(s) (e.g., through randomization) and whether additional data collection (e.g., through cross-sectional surveys with or without blood sample collection) are included. As an illustrative example, plans to conduct routine entomological monitoring and evaluate

[163] Lantos-Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act, 2008.

RHIS data only to evaluate the impact of NMCP's distribution of PBO nets would not require OR Committee review. CDC staff persons involved in these types of evaluations would need to ensure that it is covered under the approved "blanket" protocol or seek a separate non-research determination.

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 general 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.

**Figure 14. Distinguishing monitoring, evaluation and research**

| | Monitoring | Program Evaluation | Operational Research |
|---|---|---|---|
| **Definition** | 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. |
| **Purpose** | 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. |
| **Research/ Human Subjects Review?** | No* | Yes/No | Yes |
| **CN reviewed by OR Committee?** | No | Yes | Yes |
| **Protocol reviewed by OR Committee?** | No | Core funded PE: Yes<br>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 CDC

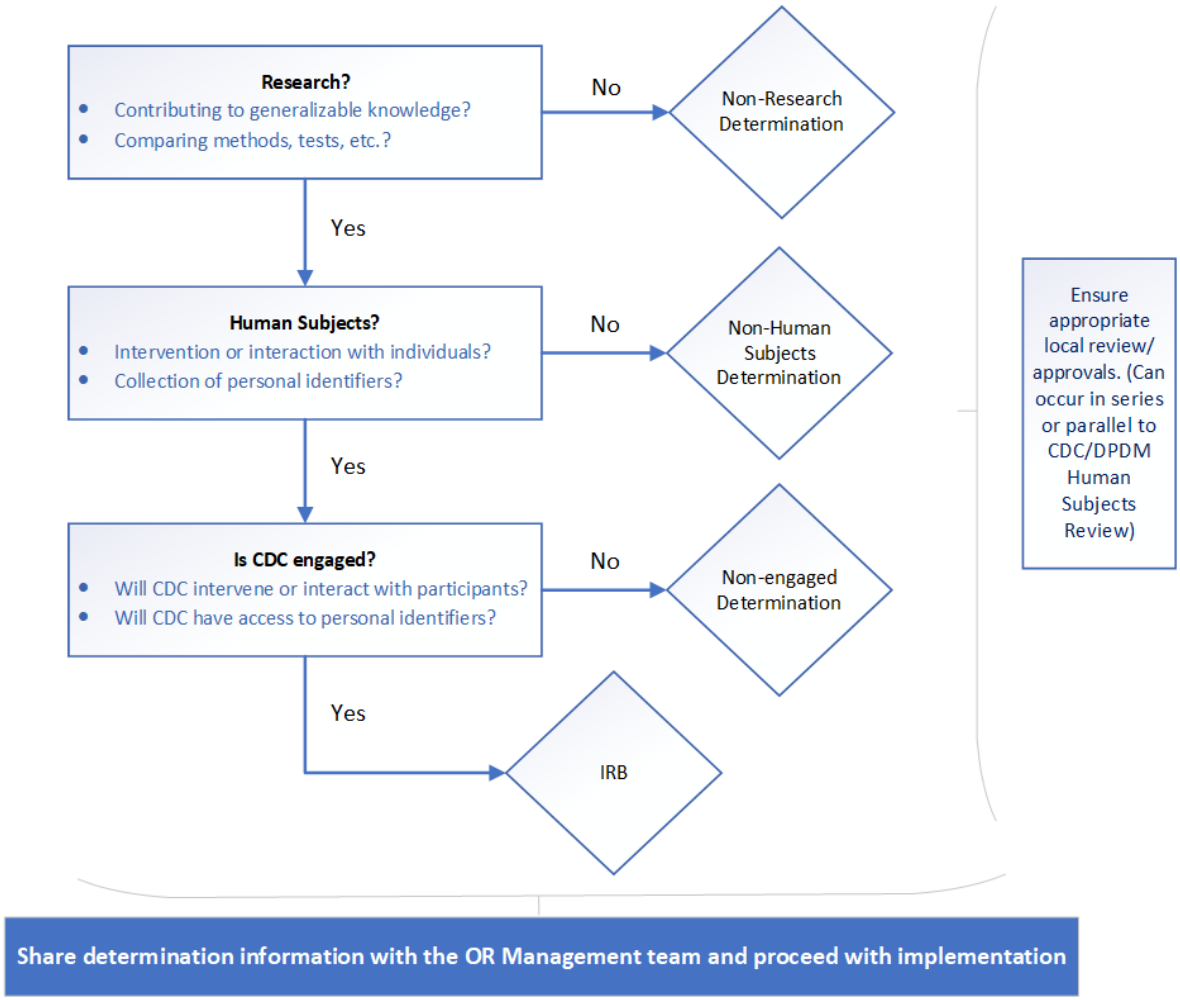
DPDM Human Subjects and the OR Management Team to ensure all needed prior review is appropriately sought.

## 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 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.[164] 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. **Figure 15** 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 that are determined to be researched 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.

[164] Please refer to ADS chapter 200 "Protection of Human Subjects in Research Supported by USAID" for more information.

**Figure 15. Guiding questions for CDC's Human Subjects Review**




## 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 percent between the original concept note budget and final protocol budget. If a protocol budget is greater than 10 percent 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 percent) of **approved protocols/ongoing studies** requires re-submission and re-approval by the PMI Front Office through reprogramming of MOP-funded studies or action memos for core-funded studies.

## Commodities for OR

For OR studies that require commodities (including RDTs, ACTs, ITNs, etc.), it is recommended that orders be 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 the country. Contact can be made directly with the Supply Chain Team or through the OR Management team. **The study budget in the concept note and protocol 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** chapter for procurement lead times and plan accordingly.

## 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 HQ 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 and the Front Office, if appropriate, 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.

## Responsibilities of the OR Management Team and OR Committee

The PMI Front Office Team (U.S. Global Malaria Coordinator, Deputy Coordinator[s], and Agency leads) is responsible for providing overall annual budget guidance and approval of core-funded OR/PE priorities.

Responsibilities of the OR Management team include:

- Coordinate with PMI Front Office Team on OR priorities
- Coordinate with GF and BMGF on Workstream OR
- Manage the PMI Insights OR central mechanism
- Manage OR communications to PMI HQ and Country teams
- Manage concept notes, track proposals/protocols/reports/budgets, track semi-annual study progress reports, update all PMI-funded studies in MESA Track, and report to the PMI Front Office on a quarterly basis
- Develop/update MOP OR guidance and manage MOP reviews annually
- 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:

- Review concept note, protocols, and budgets to support the development of scientifically strong OR/PE studies
- Coordinate with technical teams and OR Management team to develop a prioritized list of OR/PE priority ideas yearly

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 ongoing OR studies are searchable through an external website hosted by MesaTrack. 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 (Q3); a report covering activities September-February will be due in March (Q1). A template to guide preparation of the progress report can be found in **OR Appendix 2**. Funding allocation broken down by mechanism and whether the institution is local or international will be collected. 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).** Please note that submission of abstracts and manuscripts to the OR Management team is not for review but for notification purposes only. Only PMI HQ or country staff can submit a manuscript or abstract for clearance (i.e., manuscripts of PMI-supported partners must be submitted by the PMI HQ 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/PE 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)
- 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)
- 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/).
- 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)
- Reporting guidelines for implementation and OR (http://www.who.int/bulletin/volumes/94/1/15-167585/en/)
- Gather for studies that calculate health estimates (http://gather-statement.org/gather-statement/)

### *Peer-reviewed Publication and Access*

Selecting a journal for submission needs to take into account many factors, including topic focus, audience, impact factor, time to print, etc. Although PMI defers to the co-authors to select the most appropriate journal for submission, we encourage submission to journals that provide open access to all readers. Recognizing that publication fees are common, especially to publish in open-access journals, study budgets should incorporate this cost in their dissemination costs. In addition, to facilitate

compliance with USG's Open Data Policy, corresponding authors should include and make available OR/PE data in a machine readable format as part of the publication process.

### *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/Entomology 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."

**Table 14. Annual OR Timeline**

| **Quarter (Q)** | **Q1** | **Q2** | **Q3** | **Q4** |
|---|---|---|---|---|
| **Prioritization** | | | | |
| Interagency technical team priorities | X | | | |
| MOP Submissions | | X | | |
| Global OR Prioritization Agenda Refresh, if planned | | | X | |
| OR Management and Committee Review | | | X | |
| Front Office Review and Approval | | | | X |

| **Implementation** | | | | |
|---|---|---|---|---|
| MOP-funded OR/PE Concept Note Submission | | X | | X |
| Semi-annual OR updates | X | | X | |

**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**

# 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.** In fact, most, if not all, PMI-supported activities – whether intervention-specific or cross-cutting – contribute to HSS. PMI investments in systems that deliver health services at facility and community level, that ensure stable supplies of quality assured commodities, and that enable M&E of progress and impact of interventions are critically necessary to foster resilience and maintain continued progress in malaria control. As described in Strategic Focus Area 3, PMI investments in strengthening surveillance and laboratory systems also contribute to enhanced global health security, as systems built for malaria are leveraged to detect and track other febrile illnesses. Therefore, PMI will continue to invest in strengthening priority areas of health systems across PMI's country programs including: (1) health information and surveillance systems, (2) supply chain systems, and (3) community health systems that improve access to services for the most rural and high-risk populations. 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) Integrated health programs; (2) Training and Capacity Strengthening Building for NMCPs and local government staff; and (3) PC.** Please note that guidance for the Field Epidemiology Training Program has been moved to the SME 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. Investing locally and strengthening health systems are core areas of focus in the PMI Strategy 2021–2026. Therefore, it is part of PMI's mandate to strengthen capacity to enable countries and communities to lead, manage, and 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 2030**. The agency's Health Systems Vision emphasizes health systems outcomes, including desired intermediate outcomes of equity, quality and resource optimization that lead to positive health outcomes in the countries we partner with.

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).[165] However, although PMI does not support hiring of public sector staff as mentioned above, PMI can support technical and management capacity strengthening approaches at national level and/or regional/provincial/zonal levels in the form of technical experts seconded to the NMCP or MOH Management Teams to work as integral members of these teams transferring knowledge and skills and strengthening 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 looks for opportunities to integrate malaria activities with other USG-supported health and development programs in-country. The *PMI Strategy 2021–2026* clearly articulates the importance of integration: "Integration with USG global health investments: Where beneficial, integrate malaria activities with maternal and child health, HIV/AIDS, tuberculosis, neglected tropical diseases, and Global Health Security 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 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 mosquito vectors with resistance

[165] For detailed guidance on how PMI may support paying CHWs, please see the community health section of the guidance. Please note that PMI's payment of CHWs is not equivalent to hiring public sector staff.

to insecticides used for vector control. They may also contribute to strengthening community health systems and routine health information or disease-reporting systems. PMI teams are encouraged to liaise with GHS colleagues in the country and engage regularly on topics with the potential for shared benefit, including surveillance and laboratory strengthening. Designation of a PMI activity manager to lead this engagement is a best practice.

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 member(s) 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 agencies 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.

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.

## 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 NGOs, community-based organizations, and faith-based organizations, and private and public sector entities, including academic institutions. NGOs 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.

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

Capacity strengthening activities with NMCPs 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 CM section). Training activities for NMCP and other government staff that do not appear within the technical intervention sections of the MOP, including FETP, should be described in the "Capacity Strengthening" section of the MOP.

As a part of efforts to strengthen national level to local capacity in malaria control, PMI supports short-term training of permanent government staff in areas that directly benefit the country's malaria program. Training may cover technical aspects of malaria in addition to management and leadership skills to oversee and implement malaria programs. Since other donors and international organizations (e.g., Global Fund, World Bank, WHO, BMGF, 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 another region or the United States be considered and only when justification for this training is provided. As mentioned earlier, PMI also supports technical, leadership, and management capacity strengthening approaches at national level and/or regional/provincial/district levels in the form of technical experts seconded to the NMCP or MOH Management Teams to work as integral members of these teams transferring knowledge and skills, and strengthening 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 G2G support to NMCPs and local government entities is also a critical way in which PMI can help to strengthen the capacity of the countries with whom we partner. See the **Localization** chapter for more information.

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 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 activities designed to strengthen NMCP capacity, and/or within interventions related to a specific technical area. MOPs 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.

## Peace Corps

### *Background*

On March 15, 2020 PC temporarily suspended all PC operations globally and evacuated all PCVs, returning them to their homes in the United States due to the COVID-19 pandemic. Prior to this suspension, the PC had over 3,400 total PCVs in Africa, and over 2,400 PCVs in PMI countries in Africa across sectors (health, education, agriculture, environment, youth, community economic development), and was thus well-positioned to assist in the collective efforts of the USG to reduce the burden of malaria in sub-Saharan Africa. As of July 2021, PC was planning to reopen programs, with El Salvador announced as the first country to be reopened. Once the PC is able to reopen programs in Africa, the guidance below will continue to guide PMI's targeted investments with the PC.

The PC 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 (details can be found here). In 2011, PMI teamed up with PC to harness its reach and capacity in the fight against malaria in countries in sub-Saharan Africa where PMI and PC have a common presence. Funding for this is provided via a USAID Small Project Assistance (SPA) program, which supplements the PC' own appropriations.

In countries where there is PC-PMI collaboration, the expectation is that activities will be part of 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 were underway in 15 countries prior to the onset of Covid-19.

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 one to three PC MVs should budget approximately $10,000 per malaria volunteer per year. There are two potential mechanisms to support PC MVs: (a) the USAID-PC IAA (SPA Agreement) managed by USAID/Washington, or (b) through a 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 PCV malaria community projects (i.e., malaria prevention mural on market wall, or school based malaria messages) through a small grants process, budgeting maximum of $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, CHW, district health worker, etc.) or be linked directly to a 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-PC IAA managed by USAID/Washington. PCVs can access small grants via their country's PC office/the USAID Mission SPA award process. 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 teams are encouraged to 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 PC 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*

PC 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 has 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.

PC 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 IRS 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. PCV 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*

PC historically conducted a comprehensive 10-day Malaria "Boot Camp" training in Senegal, funded by PC (not PMI), that provides 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, PC transitioned to a new model, which prioritizes in-country training as well as virtual, online training. 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*

PC 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 an 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.

# PRIVATE SECTOR ENGAGEMENT

***New/Key Messages***

**Resources for Private Sector Engagement (PSE):** One of the primary outputs of PMI's investment in stronger PSE is a toolkit that enables MOHs, NMCPs, PMI country staff, implementing partners and stakeholders to continuously and proactively identify opportunities to engage with the private sector and co-create activities linked to malaria programming.

**Monitoring and Evaluation:** As of FY 2021, the Standardized Program Structure and Definitions (SPSD) has a new cross-cutting indicator area on Private Sector Engagement with three new standard PSE indicators for reporting via the Performance Plan Report (PPR) to gain an understanding of what engagements have been successful across Operating Units (OUs), how PSE has been integrated into OU's program cycle, and the lessons learned from these efforts. Guidance for these indicators will be provided via the PPR process, so please consult with your Mission teams to ensure alignment.

## Introduction

A written statement of Administrator Samantha Power in May 2021, stated "The Agency needs to adapt its systems, processes, and procedures to support full engagement with the private sector. In particular, we must upgrade our hiring, data, relationship management, professional development and procurement systems to engage the private sector at scale."

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. 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 or a social enterprise)."** Note: per the PSE policy, the definition of private sector includes commercial foundations, but not family foundations, for example the BMGF.

Engaging with the private health sector to strengthen malaria services is a PMI priority, as seen in the ***Service Delivery in the Private Sector*** section of this guidance. This section complements that effort, largely focusing on PMI's approach to catalyze other private-sector entities to utilize their assets and capabilities to drive local action, leadership, and investment to end malaria faster in PMI partner countries. This approach includes the private health sector, but expands to the broader definition above. Examples of other segments include ICT, mining and extraction, banking and financial services, education, agriculture and many others. Further, strategic partnerships, inclusive of the private sector, are an operating principle in PMI's 2021–2026 strategy with the goal to reach a shared vision towards a malaria-free future. PSE can be an enabler for achieving impact across all five of the strategic focus areas, depending on the specific activity and the partnership need. **Country teams interested in engaging with the private sector can reach out to the PMI Private and Community Partnerships team (formerly External Affairs) if consultation would be helpful and/or to understand if there are learnings or similar activities from other countries. Communication should be directed to the PSC POC.**

## Key Areas of PMI's Engagement with the Private Sector

PMI's engagement with the private sector can include a broad range of activities and focus areas. A recent landscape of the private sector across four PMI partner countries has identified the following opportunity areas that are likely applicable in all PMI partner countries (also specified in the PSE toolkit):

1. **Protect large at-risk workforces and their communities:** Activities aiming to provide funding/technical assistance or implementing malaria workforce protection programs benefiting employees, their families, and their surrounding communities.
2. **Innovation support and resources, knowledge-/skills-sharing between private and public sectors:** Monetary and non-monetary contributions by the private sector (commodities, drugs, capital equipment, internet services, transportation, etc.) and skills/knowledge transfer.
3. **Promote local manufacturing of health products:** Activities aiming to increase the number of locally-produced products.
4. **Employ innovative/blended finance for malaria funding:** Activities aiming to close funding gaps for malaria by actively pursuing private sector opportunities for co-investments.
5. **Engage private sector providers for effective malaria service delivery:** Activities supporting private providers to obtain training, improve quality or access subsidized malaria drugs and commodities. Please see the **Case Management** chapter for more details on private sector service delivery.

6. **Engage private providers to contribute their data into national health information systems:** Activities funded or implemented by/with private actors and aiming to improve the quantity and quality of healthcare data flowing into MoH databases. Please see the *SM&E* chapter for details on RHIS.
7. **Extend reach of national messaging campaigns:** Activities or funding to engage a popular social media platform, messaging service, or telecommunications company to spread public malaria messaging widely and cost-effectively.
8. **Engage private sector to build targeted communication campaigns:** Activities that use private sector communication, advertising, marketing or brand capabilities to build targeted campaigns that engage children and adults in behavior change for malaria prevention.
9. **Engage private sector to support community mobilization initiatives for malaria:** Activities such as "edutainment" dramas and music to facilitate community engagement in malaria control and trust building.

These areas may not be all encompassing, but serve as a strong starting point for considering opportunities. All PMI partner countries are encouraged to think creatively about how they can engage the private sector on these opportunity areas to improve overall malaria outcomes as well as leverage private sector resources to expand funding for malaria in countries. Examples for several of the opportunity areas are shown below.

**Example of #1: Protect Large At Risk Workforces and Their Communities**

FILTISAC, a leading textile manufacturing company in Cote d'Ivoire, commanded a study in 2010 that showed that malaria was the first cause of absenteeism in the company, translating to a revenue loss of 7.5 million CFA in that year in addition to several millions in healthcare costs. To address the issue, the company and its partners started implementing malaria activities: provision of nets to staff and their families, community sensitization on prevention measures, and training for the medical staff in their clinics and the social workers on malaria prevention and treatment. As a result of these activities, morbidity related to malaria among FILTISAC staff and their families decreased by 20 percent between 2010 and 2013 and absenteeism linked to malaria fell from 24.24 percent in 2011 to 17.53 percent in 2014. The company has raised a total of 165 million CFA from partners and employees for the intervention and would benefit from technical assistance and better collaboration with the NMCP.

**Example of #4: Innovative/Blended Finance for Malaria Funding**

PMI, with support from USAID's Center for Innovation & Impact, partnered with the Development Finance Corporation and the Health Finance Coalition to mobilize a $20 million loan guarantee to

unlock up to $35.5 million from the Medical Credit Fund 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 and treatment. These loans will be paired with digital training resources from SafeCare on COVID-19 and malaria.[166]

**Example of #7: Extend reach of national messaging campaigns**

Airtel Uganda Ltd. conducts quarterly medical camps in selected districts to offer comprehensive health services and information to communities including malaria services, sexual reproductive health services, and safe motherhood services. On average over 3,000 people are served during each of these two-day camps.

Note: Examples #1 and #7 were not completed in partnership with PMI. Therefore, the technical soundness of the activities is unknown. However, any PSE activities completed in partnership with PMI should align with applicable PMI guidance.

## PMI's New PSE Toolkit

Utilizing learnings from recent private sector landscape assessments, and building on previous PMI work and existing resources, PMI has invested in the development of a PSE toolkit. This toolkit will enable NMCPs, PMI country staff, implementing partners and stakeholders to continuously and proactively identify opportunities to engage with the private sector and co-create activities. Any questions on associated tools and their use can be directed to the Private Sector and Community Partnerships team.

## Global Private-Sector Partnerships

PMI has several global level partnerships that partner countries can benefit from. These are described below. Interested country teams should reach out to the identified points of contact.

### *Novartis*

As a way to leverage the technical expertise of the private sector, PMI is engaged in a strategic partnership with Novartis. PMI partner countries can develop formal scopes of work in which Novartis volunteers may bring unique technical skills. Illustrative examples include leadership development, laboratory capacity, research and innovation. The volunteer(s) can be mutually selected by PMI, the NMCP and other stakeholders, as desired, based on professional background, regional location and other criteria established by in-country stakeholders. Country teams are invited to utilize this strategic

[166] PMI Announces Emergency Loan Guarantee Facility to Shore Up Private Sector Health Care for Malaria During COVID-19.

NMCP and other stakeholders, as desired, based on professional background, regional location and other criteria established by in-country stakeholders. Country teams are invited to utilize this strategic partnership to support NMCP priorities and capacity strengthening. Introductory information about this partnership opportunity can be found here. If interested, please reach out to the Private Sector and Community Partnerships leads for more information.

### *Power Africa*

PMI sees the potential of electricity as an enabler for reaching the unreached and strengthening health systems to detect, prevent, treat, track and report infectious diseases.

Power Africa (a sister USG interagency initiative led by USAID) has already leveraged nearly $25 billion in contributions to Africa's energy sector to expand access to cleaner, more reliable electricity generation. Power Africa has invested $9 million in providing electricity to approximately 2,000 health facilities across sub-Saharan Africa. Moving forward, Power Africa has committed to mobilizing $30 million over the next five years to provide electricity to 10,000 healthcare facilities in sub-Saharan Africa. This will be accomplished through a large-scale public/private alliance for health facility electrification (HFE) and PMI has an opportunity to help shape this effort.

PMI country teams can pursue both funded and unfunded partnership opportunities with Power Africa. In an unfunded role, PMI country teams can work with Power Africa to identify and prioritize unreached health facilities where electrification could significantly improve or expand malaria services. Alternatively or additionally, PMI countries may choose to contribute MOP funds to the Global Development Alliance (GDA) that Power Africa is implementing to electrify health facilities. PMI countries interested in pursuing this approach should consider:

- Multi-office Contributions: As HFE is cross-cutting, PMI funds should not be the only resources dedicated to HFE in-country. Ideally, at least one other health or other sector element (or Power Africa) would contribute funds, in partnership with PMI.
- Geographic Priorities: Ensure that with the financial contribution, PMI will have a voice in prioritizing which facilities are electrified in alignment with local malaria programming needs and priorities. Power Africa is developing maps of known or expected clinics without power access in certain countries, but Mission teams should guide where electrification will help strengthen existing program investments.
- Resident Legal Officer (RLO) Clearance: Use of PMI funds for HFE has been cleared with USAID General Counsel. However, it is recommended that this be cleared with the Mission RLO prior to buying into the GDA since this is a new way of using PMI funds.

- Clarifying the Leverage and Number of Facilities: Leverage is the ratio of private sector to USAID contributions under the GDA. The leverage for the GDA may differ across countries. Therefore, it is important to confirm the leverage from the private sector and the number of facilities that can be electrified during initial discussions as an input into the decision to use PMI funds for HFE.

### *Rotary*

PMI has an opportunity to engage with local private sector business leaders through a partnership with Malaria Partners International (MPI), a non-for-profit organization run by Rotarians. Rotary is a non-political, secular service organization that organizes its 1.2 million global members through a vertical structure starting at the global-level and ending at the local club level. Local Rotary Clubs, which exist throughout many PMI countries, have autonomy to make grassroots decisions and may already be well-connected to leaders in the business community. MPI's focus is on advocacy, education, partnerships, and small-and-large grants programs in the regions where malaria is most prevalent. For example, in Zambia, MPI was a key actor in facilitating a $6 million investment to train, equip, and deploy 2,500 CHWs. PMI country teams can expand engagement with this well-networked organization by connecting with local Rotary clubs or Rotary's District Governors to learn more. PMI has developed resources in partnership with MPI to support these connections. Contact the Private Sector and Community Partnerships Leads if you are interested in learning more or would like help with facilitating connections to local Rotary clubs.

## Additional Resources

### *Internal to USAID*

USAID's PSE Pages inclusive of the PSE Toolbox (Resources) and USAID's Public-Private Partnerships Dashboard is the agency-wide one-stop-shop for private sector resources.

The PSE Prerequisite training course is now required for all new USAID staff. Registration can be found at USAID University.

### *External to USAID*

USAID has created a resource hub, called Work With USAID, intended for new, current, and future local and international partners, inclusive of the private sector, to navigate how to work with USAID. The Partner Directory houses a dynamic list of small businesses, corporations, and other organizations engaged with USAID's development work.

The WHO has guidance on *Engaging the private health service delivery sector through governance in mixed health systems* and, additionally, has created a newly released Country Connector on Private

Sector in Health, which includes six key activities for engaging the private sector as a way to foster better global coordination and accountability given the private sector's involvement in combating COVID-19. Many of these PSE resources can also be applied to malaria.

## *Policies*

USAID Private-Sector Engagement Policy is the leading guidance document for PSE.

- Global Health Private Sector Engagement Plan is the Bureau-wide plan to extend engagement with the private sector even more

## *Metrics, Evaluation, and Evidence-Base*

Private Sector Engagement Evidence and Learning Plan serves as a guide to set the direction for key activities that will strengthen and improve the use of evidence in decision-making on PSE approaches.

Standard Agency PSE Indicators and Harmonizing Indicator Tool updated FY 2021 SPSD includes a new PSE cross cutting area and three new sector-agnostic PSE indicators aimed at measuring the breadth of PSE across the Agency.

Private Sector Engagement Evidence Gap Map is a visual representation of existing evidence, using a matrix of USAID's conceptualization of PSE means and value propositions that both the private sector and development actors offer.

## *Contacts*

USAID PSE Points of Contact at the mission – Consider if it would be beneficial for these POCs to participate in any parts of the MOP process for awareness-raising and/or to share possible ideas and opportunities for PSE.

PMI's Private Sector and Community Partnerships team at HQ.

# LOCALIZATION

***New/Key Messages***

**Key Messages:**

PMI aims to move more resources closer to the people and communities we serve. This means finding ways to bring malaria prevention and treatment services nearer to communities, making sure services are accessible, reliably available, and provided in a manner that promotes local leadership, ownership, and dignity. In many cases, local governments, local partners and local organizations possess the capabilities, connectedness, and credibility to help PMI and MOHs ensure cost-effective, life-saving malaria interventions achieve malaria goals.

In alignment with the USAID Administrator's localization priorities, PMI's localization efforts should reflect both awards to local partners as well as approaches that meaningfully and equitably strengthen the capacity and power of local actors to inform and lead efforts to combat malaria in their countries. This could include direct and indirect local partnerships, G2G arrangements, private sector engagement, and financial and non-financial collaborations with local entities and communities.

PMI's localization efforts should most often be part of an integrated country-level approach and always be coordinated closely with Mission Health Team leadership. To this end, PMI is not establishing its own specific localization targets, but PMI country teams are encouraged to set targets that are well-aligned with other health and Mission targets.

PMI is well placed to expand upon its existing partnerships with country governments in order to further shift leadership, ownership, decision-making, and implementation to the people and institutions in our partner countries.

Localization will require PMI to shift how we perceive local actors and the roles they play: valuing their knowledge, respecting their commitment and integrity, and engaging them as partners rather than primarily as beneficiaries. It will also require continued evolution of our assessment tools, programming models, award types, funding arrangements, staffing patterns, performance incentives, budget allocations, and the way that PMI defines results so that PMI can better support local actors in responding to local challenges. These shifts are critical for strengthening capacity for regional, national, and sub-national responses to malaria and are critical to sustaining core malaria programs over time.

**Important Resources:**

- **Administrator Power on a New Vision for Global Development**
- **Internal Agency Locally Led Development website**, offers resources for working with local partners
- **Draft Agency Local Capacity Development Policy**, lays out key aspects and principles of the Agency's localization approach
- **PMI Strategy 2021-2026: End Malaria Faster**
- **PMI Guide to Partnering with Community Led Organizations (CLOs)**, offers recommendations for country teams to expand engagement with CLOs
- **PMI's Commitment to Investing Locally**, PMI's response to a letter in Nature Medicine
- **Workwithusaid.org**, is the Agency's resource hub for new, current, and future partners

## Background

On November 4, 2021 Administrator Power outlined her priorities for USAID. She committed the Agency to: a target of 25 percent of USAID's assistance going directly to local partners within four years and 50 percent of USAID's programming placing local communities in the lead to either co-design a project, set priorities, drive implementation, or evaluate the impact of USAID programs within the decade. As an initiative that is led by USAID, PMI intends to support the Agency in reaching these targets.

USAID's new Local Capacity Development Policy establishes a common set of principles to guide USAID's approach to strengthening local capacity and reinforces the Agency's commitments to diversity, equity, and inclusion. Once it is released (anticipated in 2022), the Global Health Bureau's Locally Led Development Implementation Guide will help to translate this policy into action by supporting Mission and Washington health teams to consider locally led development in the design and implementation of our programs.

Over the past 16 years, PMI has seen that malaria control and prevention activities have been most successful when partner countries and affected communities lead these efforts. For this reason, PMI has worked closely with local actors, particularly partner country governments, to ensure its investments are strategically aligned with country malaria control plans. PMI has also historically engaged with local actors through consultations during the MOP process, as prime and subaward implementing partners, through capacity strengthening activities, through small grants to community led organizations, through awareness-raising activities, organically through routine meetings in countries, as well as through other avenues.

Local partnerships are invaluable to PMI's work. For example, when possible, PMI supports the use of local in-country warehousing and distribution systems for malaria commodities. For CM, PMI partners with local NGOs and research institutions to monitor and analyze drug resistance and support health workers at facilities and in the community. PMI also partners with local research institutions to implement critical entomological monitoring activities that form the backbone of our vector control programs. PMI's OR approach has included partnerships with more than 30 local research institutions to design and conduct research to address important country-driven challenges. Through PMI's SBC work, PMI partners work closely with communities to identify and overcome community-specific factors that prevent or support malaria-related behaviors.

With the release of PMI's new strategy, USAID's Local Capacity Development Policy, and the soon-to-be released Global Health Bureau's Locally Led Development Implementation Guide, PMI has an opportunity to expand and improve the way it pursues locally led development in our partner countries.

## PMI's Localization Vision

Achieving PMI's 2021–2026 strategic goals of preventing malaria cases and reducing malaria deaths will require a whole of society approach that leverages a broad and diverse set of actors to ensure that malaria care meets people's needs. PMI's vision for investing locally is outlined in Focus Area 4 of PMI's 2021–2026 Strategy: *Invest Locally: partner with countries and communities to lead, implement, and fund malaria programs*. Through this effort, PMI seeks to promote local ownership, equitable and dignified partnerships, flexible and responsive programming, and sustainable investments. This means more strategic investment in and support to local governments, local communities, and local institutions wherever possible.

To this end, PMI believes that partner country governments and communities should be directly involved in addressing the problems that affect their communities. Local institutions, such as universities, NGOs, businesses, and civil society, are uniquely positioned to help their members/communities solve complex local problems such as malaria. PMI countries should strategically expand PMI's investment in local partners as well as create and promote systems and opportunities for local entities to drive malaria programming and implementation.

## Key Definitions

PMI's definition of local partners is in line with USAID's definition of local entities in ADS 303:

> ***Local Entity****: An individual or organization that: (1) Is legally organized under the laws of a country that is receiving assistance from USAID; (2) Has as its principal place of business or operations in a country that is receiving assistance from USAID; (3) Is majority-owned by individuals who are citizens or lawful permanent residents of a country that is receiving assistance from USAID; and, (4) is managed by a governing body, the majority of whom are citizens or lawful permanent residents of the country that is receiving assistance from USAID.*

Partner government ministries (e.g., MOH), subunits of government ministries, and parastatal organizations are considered local partners as part of this definition. A parastatal organization may be fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations. *Thus, local partners include both local organizations (community-based and for-profit) and country governments.*

It should be noted that local partners (also called local entities) are not the same as locally established partners, which ADS 303 defines as:

> ***Locally Established Partner (LEP):*** *A U.S. or international organization that works through locally led operations and programming models.*

LEPs must have maintained continuous operations in-country for at least five years and materially demonstrate a long-term presence in a country and must have demonstrated links to the local community. Despite many of PMI's traditional implementing partners meeting the definition of locally established partners, PMI's intention is to move toward working with more local partners. Thus, this guidance focuses largely on local partners, not LEPs.

Additionally, PMI is using the below definitions related to investing locally. Wherever possible, PMI has tried to align its definitions with those being used by USAID's Localization Working Group. These definitions may be refined as the Agency releases additional guidance around localization.

Community-Based Organization are not-for-profit organizations aimed at making desired improvements in the community they serve. The priorities of the organization may or may not be defined by the community they serve.

Community-Led Organizations are one sub-set of local actors with whom PMI seeks to partner, both financially and non-financially. CLOs are led by the people they serve and are primarily accountable to them. CLOs may include faith based organizations, local civic groups, private sector associations, colleges and universities, cooperatives, and foundations. They may be based at and serve national, provincial, district, or village-level populations. They may have national, regional or global networks that extend beyond their local context.

Local Actors are defined as individuals, communities, networks, organizations, private entities, and village/district/provincial/national levels of government within a country.

Local Capacity Strengthening (development) is an investment in local actors – individuals, organizations, and networks – to jointly improve the performance of a system in producing valued development outcomes. Effective local capacity strengthening strategically and intentionally supports an actor's ability to achieve its own mission, to take action to design and implement solutions to local development challenges, to learn and adapt from that action, and innovate and transform over time. In doing so, it strengthens local actors' contributions to the performance of their local system.

Localization –is the process by which USAID and PMI move toward a more locally led development approach.

Locally Led Development is defined by USAID as the process in which local actors set their own agendas, develop solutions, and bring the capacity, leadership, and resources to make those solutions a reality.

Partner is a relationship based on mutual commitment and complementary purpose with values that are often supported by shared resources that result in positive change, which, in the case of PMI, ends malaria faster.

Whole of Society Approach **–** adapted from USAID's Vision for Health System Strengthening 2030, a whole of society approach means society as a whole plays a role in ensuring that the health care provided meets people's needs. This means that communities, civil society, faith based organizations, and the private sector are engaged with the government as partners in the management and oversight of health care systems.

## Key Investment Guidance

Investing locally means that PMI is committed to positioning PMI countries and communities (local entities) to lead, implement, and fund malaria programs through our approaches and investments. This should include: (1) supporting partner country governments to lead, manage, and execute malaria programs successfully; (2) investing in people and partners closest to those we serve; and (3) encouraging country commitment (government, private sector and other local stakeholders) to end malaria.

To this end, each PMI country team is expected to continuously evaluate opportunities to invest in PMI partner country governments, locally based private sector, and CLOs, including integrating those opportunities into existing programs, where relevant. Country teams should consider what type of local investment is most appropriate in their country and identify the best mechanism and approach based on the country's previous experience working with local partners. Regardless of country context, PMI's disposition should be to build equitable and dignified partnerships in the countries where we work.

Below are illustrative examples of appropriate investments that PMI can make to further PMI's vision of localization, both indirectly and directly. These are not exhaustive lists and PMI country teams should discuss the appropriateness of a particular investment for their country's context.

### *Illustrative Examples of Appropriate INDIRECT Investments*

Investing locally is about more than directly funding local partners; it is about ensuring that PMI country stakeholders, particularly at the community level, have opportunities to influence malaria intervention decision-making and implementation throughout the lifecycle of our programs. Illustrative examples of ways that PMI can do this include:

- Adjust the solicitation, evaluation, and structure of traditional contracts, grants, and cooperative agreements to create stronger incentives and accountability for prime awardees to work with and fund their sub-awardees and local actors in PMI countries in ways that advance local determination and implementation.
- Fund a market landscaping assessment to identify potential local partners working on malaria or related health issues. This could potentially be done through an existing partner.
- Incorporate increasing degrees of community participation in PMI's decision-making process, such as by actively inviting feedback from CLOs during MOP stakeholder discussions as well as by including local organizations/leaders on Selection Committees for new awards. The PMI Guide to Partnering with Community Led Organizations offers suggestions for how to do this.
- Promote domestic resource mobilization by including community and private sector partners in malaria stakeholder discussions.
- Directly funding local partners to conduct malaria activities takes additional staff expertise and time. PMI countries may want to consider building their own staff capacity to manage awards to local partners. This could include:
    - Hiring additional staff (including from the MOP budget)
        - As is consistent with PMI Policy Staffing Guidance, additional staff can be budgeted in the staffing section of the MOP, including for Program staff that would be supporting localization efforts.
    - Allowing time for staff to be trained on how to work with local partners

### *Illustrative Examples of Appropriate DIRECT Investments*

Below are illustrative examples of ways that PMI countries can fund local capacity strengthening. This is not an exhaustive list and PMI country teams should discuss the appropriateness of a particular investment for their country's context.

- G2G agreements – In countries where the context allows, G2G agreements can allow PMI to gradually strengthen the capacity of local and national governments. Please consult this factsheet on the G2G process and reach out to PMI's representative on the Global Health Bureau's G2G working group, with any specific questions.
- The Global Health Bureau's Locally Led Development Implementation Guide (forthcoming in 2022) will include models for strengthening the capacity of local organizations to directly implement USAID programs. These models can include both technical and management (financial, governance, administration, human resources) capacity strengthening. In particular, PMI countries may want to consider:
    - Transition awards to local partners to build malaria or management expertise
    - Fixed Amount Awards to local partners, including government
    - Embedding advisors in local organizations
- Support for the development of community health policies that enable the provision of compensation for CHWs for a package of services inclusive of mCM, and support to national and/or local governments to set-up processes for sound implementation of CHW payment policies.
- Support to local manufacturers and distributors to help them to meet global quality standards to increase the supply of high quality locally produced malaria commodities and to be eligible for USG procurement.
- Support national, regional, and district government staff in partner countries to strengthen skills in leadership, management, and implementation of malaria programs.
- Support local investigators to conduct entomological monitoring and surveillance of drug and insecticide resistance. Funding could include support for institutional growth and capacity-strengthening for local institutions so that they can grow to meet their own capacity objectives.
- Support local research institutions to lead the design, development, and execution of OR studies. Draw on in-country knowledge and insights to test approaches in the local context and identify locally adapted solutions for broad-reaching application.
- Support surveillance officers at all levels of the health system to regularly gather and analyze data from RHIS and other sources.

- Support local training programs, such as the field epidemiology training program, that contribute to public health system strengthening and build skills and provide mentorship for future public health leaders.
- Support local government authorities, district health officers, communities, and civil society to use local data to prioritize activities, to actively participate in priority setting, to budget based on prioritized needs, and to implement activities that address their core needs.
- Support the development and implementation of local malaria action plans/community action cycles by community health committees to increase adoption of prioritized prevention and treatment behaviors.

## *Government-to-Government*

Direct G2G agreements can be a cost-effective, although technically and staff resource-intensive, means to implement malaria programs while simultaneously strengthening national and/or sub-national government management and financial systems. PMI's G2G investments are usually part of broader, cross-Mission efforts and often involve other health areas as well as Democracy and Governance colleagues and financial management specialists. In many, if not most, cases, Missions will pursue integrated G2G agreements. Support to NMCPs and local government entities must be in accordance with USAID G2G policy and regulations and procurement guidelines on grants to governments. USAID issued updated guidance that addresses eligibility for G2G funding, which includes risk mitigation strategies, and 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 MOH, NMCPs, or other local government entities may include support for financial management and tracking of the funds provided. G2G can be used as a lever for driving broader reforms for the health workforce, including CHW payments and strengthening supply chain systems. Technical assistance and support to the MOH, NMCPs, or other local government entities to strengthen 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 is currently supporting G2G in six countries: Benin, Ghana, Liberia, Mozambique, Senegal, and Zambia.

Reach out to PMI's representative on USAID's G2G working group with any G2G-specific questions.

## *Principles to Adhere To*

When identifying activities for investment, countries should adhere to the following principles: country ownership, equity, local leadership, strategic partnerships, efficiency, flexibility/responsiveness/ adaptability, multisectoral approaches, and integration with USG global health investments. These

principles are further elaborated in PMI's Strategy as well as in the Guide to Partnering with Community Led Organizations.

## Incorporation of Investments in Local Partners into Table 2

A column has been added to Table 2 of the MOP where PMI country teams are asked to indicate whether a mechanism will be implemented by a local partner or local sub-partners. This column is not intended to be used for official reporting purposes, but will help PMI track its investments in local partners in order to help PMI meet its strategic objectives.

## Important Resources Coming in 2022:

- **USAID's Localization Agenda/Vision**
- **Finalized Agency Policy on Local Capacity Development**
- **GH Localization Framework**
- **GH Bureau's LLD Implementation Guide**, will include capacity strengthening recommendations along the program cycle
- Agency-wide **definitions** for "local organization/partner" and "localization"
- **Metrics** for the Administrator's two localization targets

### *Questions?*

PMI HQ staff are available to answer questions and discuss potential activities and projects with country teams during MOP planning and as they make funding decisions.

# MALARIA PROGRAMMING IN HUMANITARIAN CONTEXTS

***New/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 the 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.